MINUTES OF 296th MEETING OF CENTRAL LICENSING BOARD HELD ON 2nd APRIL, 2024

296th meeting of the Central Licensing Board (CLB) was held on 2nd April, 2024 the Committee Room, Ground Floor, NCLB, Drug Regulatory Authority of Pakistan (DRAP) National Institute of Health (NIH), Chak Shahzad, 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 (participated through zoom link)	Member
3.	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Government of Khyber Pakhtunkhwa	Member
4.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Baluchistan, Quetta	Member
5.	Mr. Abdul Hafeez Tunio, Chief Inspector of Drugs, Government of Sindh, Karachi	Member
6.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member
7.	Ms. Mahvish Ansari, Additional Director, representative from QALT, DRAP	Member

Mr. Babar Khan Additional Director/Secretary Licensing Board presented the agenda before the Board. Mr. Mubashir Iqbal, Deputy Director (Lic), Mr. Yaqoob Kakar, Assistant Director (Lic), Ms. Zunaira Faryad, Assistant Director (Lic), Mr. Abdullah, Assistant Director (Lic), Mr Muhammad Umer, Deputy Director (QC) and Mr. Hassan Afzal Deputy Director (QA) assisted the Secretary, Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 295th MEETING**

All members of the Central Licensing Board (CLB) formally confirmed the minutes of 295th meeting of the Central Licensing Board (CLB) held on 11th January, 2024 including QC part (2 cases).

ITEM II. WHO GLOBAL BENCHMARKING OF NATIONAL REGULATORY SYSTEM OF PAKISTAN.

First audit May 2023.

The Regulatory System Strengthening team from the World Health Organization (WHO) conducted a benchmarking assessment of Pakistan's National Regulatory System from May 3 to May 12, 2023. This mission included a group of 14 auditors from WHO's headquarters in Geneva, the Eastern Mediterranean Regional Office (EMRO) in Cairo, and the local country office participated in the evaluation using the WHO's computerized Global Benchmarking Tool.

During the assessment, the WHO auditors visited the Drug Regulatory Authority of Pakistan (DRAP), the Central Drug Laboratory in Karachi, and the Directorate of Drugs Control in Punjab to interview Pakistan's regulatory workforce. The auditors aimed to review and evaluate various aspects of Pakistan's regulatory system, including the organizational structure, processes, and procedures.

Licensing is a module within the Global Benchmarking Tool (GBT) that is designed to assess and evaluate various aspects of the licensing functions of a regulatory authority. Two auditors conducted an audit of the licensing functions of the Drug Regulatory Authority of Pakistan (DRAP) using the GBT tool. The first audit aimed to assess the efficiency and effectiveness of DRAP's licensing procedures and identify areas for improvement. Licensing function achieved score of 70% with ML-2.

Following the evaluation of the licensing functions by WHO auditors, the team of experts offered recommendations to enhance the regulatory system in Pakistan. The recommendations focused on strengthening the licensing framework and ensuring compliance with international standards. The WHO team also agreed on a roadmap for future cooperation, outlining key areas of collaboration and the objectives to be achieved.

Virtual Audit March 2024.

World Health Organization (WHO) team conducted another virtual observed audit from March 18th, 2024, to March 19th, 2024. This audit focused on specific areas related to licensing, status of implementation of institutional development plans and aimed to further enhance the performance of the licensing system in Pakistan.

The WHO auditors highlighted the need for ongoing coordination and collaboration among provincial authorities and the DRAP to achieve the Maturity Level 3 (ML-3) in the licensing process. ML-3 refers to the level of maturity achievable in the licensing functions, indicating that best practices are consistently followed and regulatory requirements are effectively implemented.

The provincial licensing authorities play a crucial role in facilitating the achievement of institutional development goals, which ultimately contribute to the overall achievement of the World Health Organization (WHO) certification at the national level. Without active participation of provincial licensing authorities and achievement of these goals, it becomes challenging for the DRAP to attain the Maturity level.

Following are the tasks through IDPs to be performed by the provincial licensing authorities for successful achievement of ML-3.

Sr. No	**Maturity Level**	**Task**
1.	III	Amendments in Punjab regulation to clarify that all changes or variations to the conditions under which the initial license was issued to points of sale (pharmacies, medical stores, and distributors) must be notified to the authority.
2.	II	Job descriptions of all HR involved in licensing activities of all Provincial Governments.
3.	III	SOP for Internal and External Communications to reflect the frequency of meetings and channel of communication between all stakeholders relevant to licensing activities.
4.	III	Development of a communication matrix to outline communication pathways between relevant stakeholders.
5.	III	Evidence of implementation i.e training records of the procedure, minutes of meeting of the process among the stakeholders and the resultant outcomes.
6.	III	Development of a Competency metrics that include qualification, professional Experience, Operational Experience, and training relevant to Licensing activities.
7.	III	Development of operational manual and Operational guidance document of Provincial Quality Control Board and all Boards related to licensing activities.
8.	III	A training plan of staff involved in licensing activities to be developed based on specific training needs.

9.	III	Implementation of a system to maintain records of the training conducted as part of the training plan related to Licensing activities.
10.	III	Establishment of clear criteria and indications for the harmonization of assessment of applications related to licensing activities.
11.	III	Procedures for the assessment of applications related to licensing activities by all provincial Governments **except Punjab**.
12.	III	Establish a mechanism to ensure GSDP inspections are conducted at the provincial government before points of sales become operational **except Punjab.**
13.	III	Perform a risk evaluation to identify essential modifications of a licensed facility which will require the conduction of a regulatory inspection for their approval.
14.	III	Development and implementation of standard procedures for conducting inspections before granting or re-granting a license or approval of a substantial modification.
15.	III	SOP for inspection processes and inspection Plan for Licensing establishments by all provincial Governments.
16.	III	Develop procedures for the assessment of applications with clear timelines by all provincial Governments.
17.	III	Provide SOPs for assessment of application with clear timelines by all provincial Governments **except Punjab.**
18.	III	Amendments of the regulation to apply same criteria for licensing governmental facilities throughout the supply chain, and independently from the activity of sale.

Decision of the Central Licensing Board in 296th meeting:

The members of the Central Licensing Board demonstrated a strong commitment to enhancing coordination towards achieving the WLA ML-3 status. It was discussed that Drug Regulatory Authority of Pakistan (DRAP) should formally request the provincial secretaries to allocate a budget (adequate resources) to establish and operate an effective Quality Management System. Additionally, the provincial Chief Drug Controllers will nominate focal persons responsible for sharing the required information as per the tasks under IDPs provided by the Global Benchmarking Tool (GBT).

Item-III: **GRANT OF NEW DRUG MANUFACTURING LICENSE.**

The respective panel of experts for grant of new Drug Manufacturing Licenses have 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 One Health Pharma, Plot No. N/28-II A, Area S.I.T.E., Kotri Sindh. (New License) *(Evaluator: - Mubashir Iqbal (DD-Lic)*	28-02-2024	Good	1. Mr. Abdul Hafeez Tunio, Chief Drugs Inspector Sindh, Karachi. 2. Abdul Rasool Sh. Additional Director, DRAP, Karachi. 3. Syed Hakim Masood, Area FID, DRAP, Karachi.
	QC In-charge	Mr. Mohsin Ali Rind S/o Muhammad Usman Rind (BS Chemistry) CNIC No.41202-9416904-5.		
	Production In-charge	Mr. Ali Muhammad S/o Muhammad Hashim Kakepoto (Pharm-D) CNIC No.41307-1132673-7.		

Recommendations of the panel: -

Panel inspected the premises of M/s One Health Pharma, S.I.T.E., Kotri in compliance to DRAP, Islamabad F.2-5/2009-Lic (Vol-II) dated 7th February, 2024, for grant of Drug Manufacturing License. Based on production sections, HVAC system, utilities, QA system, QC Laboratory, Technical persons and commitment of the firm/ management for continuous improvement as per DRAP Act 2012, the panel is of the view to **recommend** grant of Drug Manufacturing License (Formulation) to the firm for following sections:

i. Oral Liquid (General) Section Vet
ii. Oral Powder (General) Section Vet.
iii. Aerosol (General) Section Vet
iv. Liquid Injectable (General) Section Vet.
v. Oral Powder/ Granules (General) Section Vet.
vi. Tablet Bolus (General) Section Vet.
vii. Sachet /Granules (General) Section Vet.

Decision of the Central Licensing Board in 296th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s One Health Pharma, Plot No. N/28-II A, Area S.I.T.E., Kotri Sindh on the recommendations of the panel of experts for the following sections subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting;

i. Oral Liquid (General) Section Vet.
ii. Oral Powder (General) Section Vet.
iii. Aerosol (General) Section Vet
iv. Liquid Injectable (General) Section Vet.
v. Oral Powder/ Granules (General) Section Vet.

<table>
<tr><td></td><td colspan="4">vi. Tablet Bolus (General) Section Vet.
vii. Sachet /Granules (General) Section Vet.
viii. Quality Control Laboratory
ix. Microbiology Laboratory
x. R&D Facility</td></tr>
<tr><td>2</td><td>M/s Neophar Healthcare Pakistan (Pvt) Ltd, Plot No.568, Sunder Industrial Estate, Lahore.

(New License)

Evaluator: - Zunaira Faryad (AD-Lic)</td><td>28-02-2024</td><td>Good</td><td>1. Dr. Farzana Chaudhry, Expert Member.
2. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore.
3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td>Production In-charge</td><td colspan="3">Mr. Rashid Mahmood S/o Inayat Ali (Pharm-D) CNIC No.35302-1931810-3.</td></tr>
<tr><td></td><td>QC In-charge</td><td colspan="3">Mr. Muhammad Lutf Ullah S/o Inayat Ullah (M. Phil Chemistry) CNIC No.16502-6169762-5.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel: -</u>
In view of above inspection proceedings and facilities verified such as company profile, building, material management, production, in-process controls, quality control testing, machinery equipment, air handling, water treatment system, personnel and documentation etc. the panel of inspectors is of the opinion to recommend the issuance of Drug Manufacturing License to M/s Neophar Healthcare Pakistan (Pvt) Ltd, Plot No.568, Sunder Industrial Estate, Lahore for the following Sections:
i. Tablet Section (General)
ii. Capsule Section (General)
iii. Sachet Section (General)
iv. Cream/Ointment/Gel Section
v. Lotion Section (Topical)

<u>Decision of the Central Licensing Board in 296th meeting:</u>
The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Neophar Healthcare Pakistan (Pvt.) Ltd, Plot No.568, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the following sections subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting:
i. Tablet Section (General)
ii. Capsule Section (General)
iii. Sachet Section (General)
iv. Cream/Ointment/Gel (General)
v. Lotion Section (General)</td></tr>
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Item- IV: **GRANT OF ADDITIONAL SECTIONS/ REGULARIZATION / 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 Abbott Laboratories Pakistan Limited, Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Karachi. DML No.000001 (Formulation). (Regularization of Sections) *Evaluator: - Mubashir Iqbal (DD-Lic)*	12-12-2023	Very Good	1. Dr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Syed Hakim Masood, Area FID, DRAP, Karachi. 3. Ms. Sanam Kausar, Assistant Director, DRAP, Karachi.

Recommendations of the panel: -

The panel inspected the premises of M/s Abbott Laboratories Pakistan Limited, Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Karachi, in compliance of DRAP, Islamabad Letter No.F.2-6/2003-Lic (Vol-III), Dated 12 May 2023 and recommends as follows:

a) Based on the people met, areas visited and commitment of management for continuous improvement in line with cGMP, the panel is of the view to **recommend** the Regularization of Lay out plans for following sections namely:

i. Effervescent Tablet (G).
ii. Sachet Section (G).
iii. Liquid Injectable Lyophilized (G). *
iv. Liquid Injectable Vial (G). *

*As per record firm has one section Liquid Injectable with lyophilization facility.

Decision of the Central Licensing Board in 296th meeting:

The Board considered and approved the grant regularization of following sections in the name of M/s Abbott Laboratories Pakistan Limited, Opposite Radio Pakistan Transmission Centre,

	Hyderabad Road, Karachi under DML No. 000001 (Formulation) on the recommendations of the panel of experts for following sections subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting: i. Effervescent Tablet (General) (Regularized) ii. Sachet Section (General) (Regularized) iii. Liquid Injectable vial section with Lyophilizer (General) (Regularized) ❖ Regularized means it's not a new or additional section.			
2	M/s. Bosch Pharmaceuticals (Pvt) Ltd., Plot No.221, 222 & 223, Sector 23, Korangi Industrial Area, Karachi. DML No.000350 (Formulation). (Grant of Additional Sections) *Evaluator: - Mubashir Iqbal (DD-Lic)*	14-02-2024	Good	1. Mr. Abdul Hafiz Tunio, Chief Drug Inspector, Karachi. 2. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 3. Miss Hira Bhutto, Assistant Director (I&E), DRAP, Karachi.
	Recommendations of the panel: - M/s. Bosch Pharmaceuticals (Pvt) Ltd., Situated at Plot No.221, 222 and 223, Sector 23, Korangi Industrial Area, Karachiwas inspected in connection with the Grant of additional sections under Drug Manufacturing License No.000350 (Formulation) as per DRAP, Islamabad letter No.F.2-4/91-Lic (Vol-II) dated 03rd January, 2024. Following are the observations: Panel inspected the firm in detail and observed that the Sterile Dry Powder Injection (Penicillin), Quality Control Lab, Research and Development Laboratory are built as per DRAP approved design, wherein appropriate Personnel and Material flow is given. HVAC System is supplied there to maintain the required environmental conditions. Quality Assurance System/QMS and critical documents Processes, SOPs and qualification documents presented during initial meeting were reviewed in detail and found an adequate level of compliance. Water Treatment Plant and Engineering Utilities seen installed and observed operational in the production as well as in Quality sections. Firm has adequate technical persons with relevant qualifications available on site that observed well conversant with the technical knowledge of GMP/cGMP. Based on the people met, documents reviewed and observation made during the inspection, panel unanimously recommends the grant of additional sections of Sterile Powder Injection (Penicillin), QC Lab & R&D Lab under DML No.000350 (Formulation) known for dedicated Penicillin Building. **Decision of the Central Licensing Board in 296th meeting:** The Board considered and approved the grant of following additional and revised sections in the name of M/s. Bosch Pharmaceuticals (Pvt) Ltd., Plot No.221, 222 & 223, Sector 23, Korangi			

Industrial Area, Karachi under DML No. 000350 (Formulation) on the recommendations of the panel of experts for following sections.

i. Sterile Powder Injection (Penicillin) Additional
ii. Quality Control Lab
iii. R&D Facility.

3	M/s Kaizen Pharmaceuticals (Pvt) Ltd. Plot No. E-127 E-128 & E-129, North Westren Zone, Port Qasim Authority, Karachi. DML No.000755 (Formulation) (Grant of Additional Sections) *Evaluator: - Mubashir Iqbal (DD-Lic)*	16-02-2024	Good	1. Mr Hakim Masood Area FID, DRAP, Karachi. 2. Mr Abdul Rasool Sh Additional Director, DRAP, Karachi. 3. Ms. Tehreem Sara, FID, DRAP, Islamabad. 4. Dr. Akhtar Abbas Khan, Director (Licensing), DRAP, Islamabad.

Recommendations of the panel: -

In compliance to DRAP, Islamabad F.2-5/2009-Lic (Vol-II) dated 07th February, 2024, The panel conducted inspection of the premises of M/s Kaizen Pharmaceuticals (Pvt) Ltd. Situated at Plot No. E-127 E-128 & E-129, North Westren Zone, Port Qasim Authority, Karachi, for grant of Additional Section.

The panel evaluated aspects related to Cytotoxic Drugs manufacturing/testing requirements for personnel, environment and product safety in all areas/ sections and found good at the time of inspection process.

Therefore, based on areas inspected, evaluation made and commitment of the firm/ management for continuous improvement as per cGMP, the panel is of the view to **recommend** grant of Additional Section as follows to the firm Ms. Kaizen Pharmaceuticals (Pvt) Ltd. Under DML No.000755 (By way of Formulation).

S. No.	Section	S. No.	Section
Ground Floor			
i.	Tablet Cytotoxic (**New**) Section	ii.	Capsule Cytotoxic (**New**) Section
iii.	Soft Gelatin Capsule Cytotoxic (**New**) Section	iv.	Warehouse for Cytotoxic Area (**New**)
First Floor			
i.	Quality Control Lab (**New**)	ii.	Product Development Department (**New**)

Decision of the Central Licensing Board in 296th meeting:

The Board considered and approved the grant of following additional sections in the name of M/s Kaizen Pharmaceuticals (Pvt) Ltd. Plot No. E-127 E-128 & E-129, North Westren Zone, Port Qasim Authority, Karachi under DML No. 000755 (Formulation) on the recommendations of the panel of experts for following sections subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting:

S. No.	Section	S. No.	Section
Ground Floor			
i.	Tablet Cytotoxic (New) Section	ii.	Capsule Cytotoxic (New) Section
iii.	Soft Gelatin Capsule Cytotoxic (New) Section	iv.	Warehouse for Cytotoxic Area (New)
First Floor			
i.	Quality Control Lab (New)	ii.	Product Development Department (New)

4	M/s. Scilife Pharma (Pvt) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Area, Karachi. DML No.000837 (Formulation). (Grant of Additional Section) *Evaluator: - Mubashir Iqbal (DD-Lic)*	20-02-2024	Good	1. Mr. M. Abdul Hafeez Tunio, Chief Drug Inspector, Karachi. 2. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 3. Ms. Hira Bhutto, Assistant Director, DRAP, Karachi.

Recommendations of the panel: -

M/s. Scilife Pharma (Pvt) Ltd., situated at Plot No. FD-57/58-A2, Korangi Creek Industrial Area, Karachi was visited and inspected in compliance to the directions contained in DRAP Islamabad Letter No.F.2-4/2011-Lic (Vol-I) dated 17th January, 2024 in connection with the grant of addition of Warehouse facility.

Visited area found with adequate man and material flow with more than enough capacity for quarantine, release areas for raw material, primary packaging material, secondary packaging material, cold storage area and rejection areas.

Based on the above stated facts the panel unanimously recommends the grant of Additional Section Warehouse – Additional under DML No.000837.

Decision of the Central Licensing Board in 296th meeting:

The Board considered and approved the grant of following additional sections in the name of M/s. Scilife Pharma (Pvt) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Area, Karachi under

	DML No. 000837 (Formulation) on the recommendations of the panel of experts for following additional facility: i. Warehouse – Additional			
5	M/s. Martin Dow Marker Ltd., 7-Jail Road, Quetta. DML No.000028 (Formulation). (Grant of Additional Section) *Evaluator: - Mubashir Iqbal (DD-Lic)*	25-01-2024	Good	1. Mr. Muhammad Salik Zahid, Chief Drug Inspector / Member CLB. 2. Dr. Kirshan, Area Federal Inspector of Drugs, DRAP, Quetta. 3. Mr. Mubashir Iqbal, Deputy Director (Licensing), DRAP, Islamabad.
	Recommendations of the panel: - The panel inspected the firm in detail including manufacturing section, stores and QC Lab and found the facility as per approved lay out plan and compliant. The facility has been provided with necessary utilities, machineries and equipment as required under the guidelines. Necessary documents related to QC, QA and production and qualification of machines, HVAC and other utilities, the panel recommends the grant of following Additional Section : - i. Psychotropic Injectable (Ampoule) Section **Decision of the Central Licensing Board in 296th meeting:** The Board considered and approved the grant of following additional sections in the name of M/s. Martin Dow Marker Ltd., 7-Jail Road, Quetta under DML No. 000028 (Formulation) on the recommendations of the panel of experts for following sections 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 and verification of necessary testing equipment as per decision of CLB in its 290th meeting: i. Psychotropic Injectable (Ampoule) Section - New			
6.	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhobattian Sikka Street, 8-Km, Raiwind Road Lahore. DML No.000732 (Formulation). (Grant of Additional Section)	24-01-2024	Good	1. Mr. Abdul Rashid Shaikh, Additional Director / Federal Inspector of Drugs, DRAP, Lahore. 2. Mr. Ishtaiq Shafiq Assistant Director, DRAP Lahore.

	Evaluator: - Zunaira Faryad (AD-Lic)			
	Recommendations of the panel: - Keeping in view the manufacturing fallibility, like, building, HVAC system production Machinery, Equipment's in Quality Control and Microbiology Laboratory, Water Treatment Plant, Testing Facilities, Technical Personnel, documentation, the panel of inspectors is of the opinion to **recommend** the grant of additional section i.e, **Liquid Injectable (SVP) Section (General) (Veterinary)** to M/s Fizi Pharmaceutical & Chemical Laboratories, 8-Km, Raiwind Road Lahore. **Decision of the Central Licensing Board in 296th meeting:** The Board considered and approved the grant of following additional sections in the name of M/s Fizi Pharmaceutical & Chemical Laboratories, Bhobattian Sikka Street, 8-Km, Raiwind Road Lahore under DML No. 000732 (Formulation) on the recommendations of the panel of experts for following Section subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting: i. Liquid Injectable SVP-Vet (General)-Additional			
7.	M/s. BF Biosciences Limited, 5-Km Sunder Raiwind Road, Raiwind, Lahore. DML No.000655 (Formulation). (Grant of Additional Section) *Evaluator: - Zunaira Faryad (AD-Lic)*	26-12-2023	Good	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore
	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 grant of additional section i.e., Injection Pre-Filled Syringes (Biotech) Section to M/s. BF Biosciences Limited, 5-km Sunder Raiwind Road, Raiwind, Lahore. **Decision of the Central Licensing Board in 296th meeting:** The Board considered and approved the grant of following additional sections in the name of M/s. BF Biosciences Limited, 5-Km Sunder Raiwind Road, Raiwind, Lahore under DML No. 000655 (Formulation) on the recommendations of the panel of experts for following Section.			

	i. Injection Pre-Filled Syringes (Biotech)-Additional			
8.	M/s. BF Biosciences Limited, 5-Km Sunder Raiwind Road, Raiwind, Lahore. DML No.000655 (Formulation). (Grant of Additional Section) *Evaluator: - Zunaira Faryad (AD-Lic)*	01-03-2024	Good	1. Dr. Akhtar Abbas Khan, Director (Drug Licensing), Islamabad. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore
	<u>Recommendations of the panel: -</u> Keeping in view the manufacturing facilities like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommends** renewal of Drug Manufacturing License, additional and revised section to M/s BF Biosciences Limited, 5-Km Sunder Raiwind Road, Lahore for the following sections: i. Parenteral (Liquid Lyophilized) Biotech Section (Renewal) ii. Injectable (Ampoule/Vial) SVP (Lyophilized/Liquid) (General) Section (Revised) iii. Product Development Section (New) **<u>Decision of the Central Licensing Board in 296th meeting:</u>** The Board considered and approved the grant of following additional sections in the name of M/s. BF Biosciences Limited, 5-Km Sunder Raiwind Road, Raiwind, Lahore under DML No. 000655 (Formulation) on the recommendations of the panel of experts for following Sections. i. Injectable (Ampoule/Vial) SVP (Lyophilized/Liquid) (General) Section (Revised) ii. Product Development Section- Additional			
9.	M/s. Sunshine Pharmaceuticals, Emanabad G.T Road, Gujranwala. DML No.000662 (Formulation). (Grant of Additional Sections)	08.01.2024	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore

	Evaluator: - Abdullah (AD-Lic)			
	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 **recommended** the grant of additional section that is Tablet General-II Section, Capsule General Section, Research and Development Laboratory and Raw Material Store (Revised) M/s Sunshine Pharmaceuticals, Eminabad GT Road, Gujranwala. **Decision of the Central Licensing Board in 296th meeting:** The Board considered and approved the grant of following additional sections in the name of M/s. Sunshine Pharmaceuticals, Emanabad G.T Road, Gujranwala under DML No. 000662 (Formulation) on the recommendations of the panel of experts for following section subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting: i. Tablet General-II Section ii. Capsule General Section iii. Research & Development Laboratory iv. Raw Material Store (Revised)			
10	M/s. Star Laboratories (Pvt) Ltd., 23-Km, Multan Road, Lahore DML No.000130 (Formulation) (Grant of Additional Sections) *Evaluator: - Abdullah (AD-Lic)*	20-02-2024	Good	1. Mr. Muhammad Arif Ch., Additional Director, DRAP, Islamabad. 2. Mr. Abdul Rasheed, FID, Lahore. 3. Assistant Director, DRAP, Lahore.
	Keeping in view manufacturing facilities like building, functional HVAC system installed production machinery in the respective sections & availability of Quality Control equipments, instruments, Technical &experienced personnel's, having adequate documentation, regarding production, QA, quality control, microbiology lab and purified water production and testing facilities as of today, the panel of inspectors recommends the grant of additional section, Dry Powder for Injection (Cephalosporin) Section (Veterinary), of M/s Star Laboratories (Pvt) Ltd., 23-Km Multan Road, **Decision of the Central Licensing Board in 296th meeting:**			

	The Board considered and approved the grant of following additional sections in the name of M/s. Star Laboratories (Pvt) Ltd., 23-Km, Multan Road, Lahore under DML No. 000130 (Formulation) on the recommendations of the panel of experts for following Section: i. Dry Powder for Injection (Cephalosporin-Veterinary)- Additional			
11	The Searle Company Limited, 32-Km Multan Road, Lahore. DML No.000647 (Formulation). (Grant of Additional Sections) *Evaluator: - Abdullah (AD-Lic)*	28-02-2024 & 29-02-2024	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Farooq Aslam, Assistant Director, DRAP Lahore.
	Recommendations of the panel: - Keeping in view the manufacturing facility like building, HVAC system, sanitation, production machinery, equipment in quality control, testing facilities, technical personnel and documentation, the panel of inspectors recommended the grant of the renewal of the following sections as per the already approved layout plan as following: i. Tablet Section (General)-(Block 1) ii. Tablet Section (Antibiotic)-(Block 1) iii. Oral Liquid Section (General)- (Block 1) iv. Capsule Section (General) – (Block 1) v. Tablet Section-I (General) – (Block 2) vi. Oral Liquid Section (General) – (Block 2) and also recommended the Grant of Additional Section of: i. Tablet General Section-II (New) – Block 2) ii. Raw Material Store (New) – (Block 2) **Decision of the Central Licensing Board in 296th meeting:** The Board considered and approved the grant of following additional sections in the name of the Searle Company Limited, 32-Km Multan Road, Lahore under DML No. 000647 (Formulation) on the recommendations of the panel of experts for following Section subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting: i. Tablet General Section-II (New) – (Block 2)- Additional ii. Raw Material Store – (Block 2)- Additional The Board observed that inspection report was forwarded on 25-03-2024 by the then additional director Lahore who was retired on 22nd March 2024. The Board decided to seek clarification by the FID Lahore before communication of decision.			
12	M/s Sayyed Pharmaceutical (Pvt) Ltd,	23-02-2024	Good	1. Mr. Atiq ul Bari FID / Additional Director, DRAP, Peshawar.

	Plot No. 67/2, Phase-3, Industrial Estate, Hattar. DML No.000697 (Formulation) (Grant of Additional Sections) *Evaluator: - Muhammad Yaqoob (AD-Lic)*			2. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Peshawar.
	Keeping in View the above, the panel unanimously recommends the grant of following Additional Section to M/s. Sayyed Pharmaceuticals (Pvt) Ltd, Hattar. i. Liquid Injectable Ampoule (General) **<u>Decision of the Central Licensing Board in 296th meeting:</u>** The Board considered and approved the grant of following additional sections in the name of M/s Sayyed Pharmaceutical (Pvt) Ltd, Plot No. 67/2, Phase-3, Industrial Estate, Hattar under DML No. 000697 (Formulation) on the recommendations of the panel of experts for following Section: i. Liquid Injectable Ampoule (General)-Additional			
13	M/s. A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore. DML No.000685 (Formulation). Grant of Additional & Revised Sections) *Evaluator: - Zunaira Faryad (AD-Lic)*	26.01.2024	Good	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore
	<u>Recommendations of the panel: -</u> Keeping in view the manufacturing facilities like building, functional HVAC system, installed production machinery in the respective sections & availability of Quality Control equipment's, instruments, Technical & experienced personnel's having adequate documentation, regarding production, QA, quality control, microbiology lab and testing facilities of today, the panel **recommends** the grant of revised facility / new section with the following details: i. Warehouse (Revised) ii. Quality Control Department (Revised) iii. Raw Material Store (Revised) iv. Blister Packing Area (Revised) v. Packing Material Store (Relocation)			

	vi. IPQC vii. Syrup (General) Section (New) **<u>Decision of the Central Licensing Board in 296th meeting:</u>** The Board considered and approved the grant of following additional and revised sections in the name of M/s. A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore under DML No. 000685 (Formulation) on the recommendations of the panel of experts for following Section. i. Warehouse (Revised) ii. Quality Control Department (Revised) iii. Raw Material Store (Revised) iv. Blister Packing Area (Revised) v. Packing Material Store (Relocation) vi. In Process Quality Control Laboratory vii. Syrup (General) Section- Additional

Item-V: **GRANT OF RENEWAL / REGULARIZATION OF LOP OF DRUG MANUFACTURING LICENSES.**

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses and regularization. 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 Karachi Pharmaceutical Laboratories, S/54, Hawks Bay Road, Karachi. DML No. 000074 (Formulation). **Period:** Commencing on 30-09-20 ending on 29-09-2025. Evaluator: - Mubashir Iqbal (DD-Lic)	19-12-2023	**Good**	1. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Dr. Shoaib Ahmed, Area FID, DRAP, Karachi. 3. Abdul Waheed, Assistant Director, DRAP, Karachi
	QC In-charge	Syed Hassan Adil Alvi S/o Syed Ali Mahmood Alvi (M-Pharm) CNIC No.42501-1522998-3.		
	Production In-charge	Ms. Amina Mehboob D/o Mehar Ali (B-Pharm) CNIC No.42101-1552682-4.		

Recommendations of the panel:

*"*M/s Karachi Pharmaceutical Laboratories, S/54, Hawks Bay Road, Karachi was visited and inspected in detail on 19-12-2023 in compliance to the directions contained in DRAP, Islamabad letter No.F.2-7/2005-Lic (Vol-II) dated 18th October, 2023.

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 unanimously **recommends** the grant of renewal of Drug Manufacturing License No.000074 by way of formulation, regularization of layout as follows.

S#	Section	S#	Section
Regularization/Renewal of following Section			
i.	Tablet (General)	ii.	Sachet (General)
iii.	Tablet (Psychotropic)	iv.	Liquid External Preparation (General)

v.	Liquid Syrup (General)	vi.	Cream/Ointment (General)
vii.	Dry Powder Suspension (Penicillin)	viii.	Capsule (Penicillin)
ix.	Eye/Ear/Nasal Drops (General)	x.	Liquid Vial Infusion SVP (General)
xi.	Liquid Ampoule SVP (General)	xii.	Capsule (Cephalosporin)
xiii.	Dry Powder Suspension (Cephalosporin)	xiv.	Dry Powder Injection (Cephalosporin)
xv.	Ware House (Penicillin)	xvi.	QC Laboratory
xvii.	Ware House (Cephalosporin)	----------	

Note: The Cephalosporin and Penicillin are on different floors of the same building.

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000074 by way of Formulation in the name of M/s Karachi Pharmaceutical Laboratories, S/54, Hawks Bay Road, Karachi on the recommendations of the panel of experts for the period commencing on 30-09-20 ending on 29-09-2025 for the following sections subject to verification of necessary testing equipment and 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:

S#	Section	S#	Section
Regularization/Renewal of following Section			
i.	Tablet (General)	ii.	Sachet (General)
iii.	Tablet (Psychotropic)	iv.	Liquid External Preparation (General)
v.	Liquid Syrup (General)	vi.	Cream/Ointment (General)
vii.	Eye/Ear/Nasal Drops (General)	viii.	Liquid Vial Infusion SVP (General)
ix.	Liquid Ampoule SVP (General)	x.	Capsule (Cephalosporin)
xi.	Dry Powder Suspension (Cephalosporin)	xii.	Dry Powder Injection (Cephalosporin)
xiii.	Ware House (Cephalosporin)	xiv.	QC Laboratory

The Board discussed the specific operations related to the manufacture, processing, and packing of penicillin, carbapenems, monobactams. During the meeting, it was emphasized that these activities should be performed in facilities segregated from those used for other drug products for human use. This is due to their potential for causing allergic reactions. In particular, regarding sensitizing ingredients and especially penicillin, all GMP studied clearly forbid their production in areas where other classes of drugs are produced, necessitating their manufacture in dedicated and segregated facilities.

Regarding new facilities, it was decided by the Board that penicillin, carbapenems, and monobactams shall only be manufactured, processed, and packed in segregated and dedicated facilities A segregated facility which implies an entire dedicated building. Therefore, the Board

decided to defer the renewal of the penicillin, carbapenem, and monobactam sections that are located in the same building as other manufacturing areas.

Furthermore, the Board decided to issue a notice to the firms responsible for producing penicillin, carbapenems, and monobactams. This notice will inform them of the Board's decision and advise them to shift to a segregated dedicated facility as soon as possible. The firms will be advised to provide the shortest possible timeframe for this shift. An opportunity of personal hearing shall be provided to the firms if desired, so.

i.	Dry Powder Suspension (Penicillin)	ii.	Capsule (Penicillin)
iii.	Ware House (Penicillin)		

2.	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi. DML No. 000327 (Formulation). **Period:** Commencing on 14-01-22 ending on 13-01-2027. *Evaluator: - Mubashir Iqbal (DD-Lic)*	26-12-2023	Good	1. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Sajjad Ahmed Abbasi, Deputy Director CDL, Karachi. 3. Dr. Shoaib Ahmad, FID-III, DRAP, Karachi.
	QC In-charge	Mr. Syed Ibnul Hassan Hashmi (M.Sc)		
	Production In-charge	Mrs. Naeema Khatoon (B-Pharm)		

Recommendations of the panel:

"As per instructions contained in DRAP Islamabad Letter No. F.2-2/92-Lic (Vol-III) dated 24-02-2022, M/s Manhattan Pharma, Plot No.209/3-B, Sector 5, Korangi Industrial Area, Karachi was visited and inspected in detail on 26th December 2023, by the panel comprising of Abdul Rasool Shaikh, Mr. Sajjad Ahmad Abbasi and Dr. Shoaib Ahmad. Following are the observations: -

The firm Manhatta Pharma is famous for manufacturing veterinary products only. The panel inspected all the manufacturing sections, stores and QC Lab and found the facility at par with respect to machines, equipment, documentations and utilities. QA System was reviewed and discussed at length and noted an appropriate level of compliance. The firm has hired experienced and qualified technical persons in each section. Suitable stability testing & training programs were seen in place. HVAC is purposefully supplied to each section and the entire system is timely validated, SOPs for area monitoring and qualification were seen in place. Necessary documents relating to QC, QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and noted an adequate level of compliance.

Based on the above stated facts the panel unanimously **recommends** the grant of renewal of DML No.000327 for the next five years with following approve section and regularizations of their existing lay out plan: -

i.	Oral Liquid Veterinary (General) Section.
ii	Oral Jar Powder Veterinary (General) Section – Regularization
iii.	Sterile Liquid Veterinary Injectable (G) including two separate filling lines for SVP & LVP
iv.	Dedicated Sterile Liquid Injectable Veterinary (Hormone/Steroid)
v.	Dedicated Angara Autogenous Vaccine (Veterinary Section).

Note: The viral and bacterial vaccine is on the same floor with other section.

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of regularization and renewal of DML No. 000327 by way of Formulation in the name of M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 14-01-22 ending on 13-01-2027 for the following sections subject to verification of necessary testing equipment:

i. Oral Liquid Veterinary (General) Section.
ii. Oral Jar Powder Veterinary (General) Section – Regularization
iii. Sterile Liquid Veterinary Injectable (G) including two separate filling lines for SVP & LVP

The Board decided that biological preparations (eg: live microorganisms), Vaccines and hormonal preparations requires segregated and dedicated facility. A segregated facility which implies an entire dedicated building. Therefore, the Board decided to defer the renewal of following sections.

i. Dedicated Sterile Liquid Injectable Veterinary (Hormone/Steroid)
ii. Dedicated Angara Autogenous Vaccine (Veterinary Section).

Furthermore, the Board decided to issue a notice to the firms responsible for producing biological preparations (eg: live microorganisms), Vaccines and hormonal preparations. This notice will inform them of the Board's decision and advise them to shift to a segregated dedicated facility as soon as possible. The firms will be advised to provide the shortest possible timeframe for this shift. An opportunity of personal hearing shall be provided to the firms if desired, so.

3.	M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi.	19-01-2024	Good	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Karachi, Member CLB. 2. Mr. Abdul Rasool Shaikh, Additional Director /Federal Inspector of Drugs, DRAP, Karachi.

	DML No. 000148 (Formulation). **Period:** Commencing on 10-07-2020 ending on 09-07-2025. *Evaluator: - Mubashir Iqbal (DD-Lic)*			3. Mr. Awais Ahmad, Assistant Director, CDL, Karachi
	QC In-charge	Mr. Muhammad Aamir S/o Syed Shamimul Haq (M.Sc Chemistry) CNIC No.42201-0542257-3		
	Production In-charge	Mr. Adnan Saeed S/o Saeed Ahmed (B-Pharm) CNIC No.42201-0683097-7		

Recommendations of the panel:

M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi was visited and inspected in detail on 19-01-2024 in compliance to the directions contained in DRAP, Islamabad letter No.F.2-29/84-Lic (Vol-III) dated 08th September, 2023 regarding grant of renewal of DML. Following are the observations: -

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. It is further to mention that the firm is built on Plot No.70 and 71 whereas only Plot No. 70 is mentioned on their DML. As their last submission to concerned division the firm had submitted their recent drawing clearly mentioning both plots including 71. The firm holds the ownership of both plots hence it was advised to them to go for regularization of the same and approach the concerned division for further guidance.

Based on the people met, documents reviewed and observations made during the inspection, the panel unanimously **recommends** the grant of renewal of Drug Manufacturing License No.000148 by way of formulation due on 10-07-2020 for sections as follows: -

i. Tablet (General)
ii. Capsule (General)
iii. Liquid Syrup/Suspension (General)
iv. Cream/Ointment (General)
v. Capsule (Penicillin)
vi. Dry Powder Suspension (Penicillin)

Note: The Capsule (Penicillin) and Dry Powder Suspension (Penicillin) are on the same floor along with other General Section and facility. Further, as per available record the firm has been granted DML with address/on Plot No.70, Street No.24, Korangi Industrial Area, Karachi. Whereas the firm didn't apply for Plot No.71, Street No.24, Korangi Industrial Area, Karachi in the Division of Licensing, DRAP.

Decision of the Central Licensing Board in 296th meeting

	The Board considered and deferred the renewal of DML No. 000148 by way of Formulation in the name of M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi for confirmation of approval of site on plot No. 71, lay out approval and any construction over the plot. Furthermore, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for penicillin sections. i. Capsule (Penicillin) ii. Dry Powder Suspension (Penicillin)			
4.	M/s W. Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi. DML No. 000042 (Formulation). **Period:** Commencing on 13-02-2021 ending on 12-02-2026. *Evaluator: - Mubashir Iqbal (DD-Lic)*	**20-02-2024**	**Good**	1. Dr. Saif-ur-Rehman Khattak, Additional Director, CDL, DRAP, Karachi. 2. Mr. Abdul Rasool Sheikh, Additional Director (E&M), DRAP, Karachi. 3. Dr. Shoaib Ahmed, FID-III, DRAP, Karachi.
	QC In-charge	Ms. Anjum Basit D/o M.A Basit Siddiqui (Pharm-D) CNIC No.42201-0319698-6.		
	Production In-charge	Syed Kamranuddin Ahmed (B.Pharm)		
	Recommendations of the panel: *"M/s W.Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi was inspected as per DRAP letter No.F.2-36/85-Lic (Vol-V) dated 06th September, 2021 and 06th May 2021 in connection with grant of Renewal of DML & Regularization of layout.* ***Following are the observations**:* *The firm was found built as per layout plan approved by the DRAP authorities Islamabad vide letter No.F.2-36/85-Lic. (Vol-V), No.F.1-65/84-Lic (Vol-III) (M211) on dated 27th July, 18th December 2017 and 30th October 2008. All production, quality control, research and development laboratory, warehouse and storage facilities were observed well maintained and continuous monitoring system were seen in placed. Equipment were found calibrated and qualified, in general. Adequate technical personnel were available at the site and observed well conversant with the requirements of the cGMP standards. An appropriate & adequate HVAC system operating air process according to grades of rea. The facility is segregated, dedicated and fully contained for Cephalosporin products with access control for staff, who have been assigned responsibilities only for Cephalosporin facility. Key staff has required qualification, experience and skill according to the position and job description for employees.*			

	Based on the people met and the documents reviewed and considering the findings of the inspecting Panel M/s W. Woodward Pakistan (Pvt.) Ltd., F-275, S.I.T.E., Karachi is considered to be designed, established and operating at an acceptable level of compliance of GMP requirements. Therefore, the panel unanimously ***recommends*** *the approval for the grant of Renewal of their DML no. 000042 by way of formulation and regularization of old section with reference to the DRAP letter No. F.2-36/85-Lic (Vol-V) dated 6th September 2021 & 6th May 2021.* Following are the sections mentioned in the above referred panel letters; i. Tablet (General-Antibiotic) ii. Capsule (Cephalosporin) iii. Dry Powder Suspension (Cephalosporin) iv. Cream/ Ointment (General-Antibiotic) v. Sachet (General) vi. Oral Liquid Syrup (General) – Regularization vii. Capsule (General) – Regularization viii. Dry Powder Suspension (General) – Regularization **<u>Decision of the Central Licensing Board in 296th meeting</u>** The Board considered and approved the grant of regularization and renewal of DML No. 000042 by way of Formulation in the name of M/s W. Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi on the recommendations of the panel of experts for the period commencing on 13-02-2021 ending on 12-02-2026 for the following sections subject to verification of necessary testing equipment: i. Tablet (General) ii. Capsule (Cephalosporin) iii. Dry Powder Suspension (Cephalosporin) iv. Cream/ Ointment (General) v. Sachet (General) vi. Oral Liquid Syrup (General) – Regularization vii. Capsule (General) – Regularization viii. Dry Powder Suspension (General) – Regularization			
5.	M/s Avensis Pharmaceuticals, Plot No. F-24/1, Eastern Industrial Estate Zone, Port Muhammad Bin Qasim, Karachi. DML No.000894 (Formulation). Period: Commencing on 08.01.2024 & ending on 07.01.2029.	22-03-2024	Good	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector Sindh, Karachi, Member CLB. 2. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 3. Syed Hakim Masood, Area FID, DRAP, Karachi.

Evaluator: - Mubashir Iqbal (DD-Lic)			
Production In-charge	Mr. Zahid Hussain S/o Ali Murad (B-Pharm), CNIC No.41204-8937655-1.		
QC In-charge	Syed Fida Hussain S/o Syed Akbar Hussain (M.Sc Chemistry), CNIC No.42201-1814132-3.		

Recommendations of the panel: -

M/s Avensis Pharmaceuticals, Plot No.F-24/1, Eastern Industrial Estate Zone, Port Muhammad Bin Qasim, Karachi was visited and inspected in detail on 22-03-2024 in compliance to the directions contained in DRAP, Islamabad letter No.F.2-6/2017-Lic dated 11th March, 2024. Following are the observations: -

1. 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 had 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.
2. Based on the people met, documents reviewed, and observations made during the inspection, the panel unanimously recommends the renewal of Drug Manufacturing License No.000894 (by way of formulation) for he sections follows: -

S#	Section	S#	Section
1.	Capsule (General) Section	2.	Sachet (General) Section
3.	Liquid Ampoule & Vial (General) Section	4.	SVP Infusion (General) Section
5.	Dry Powder Injection (Cephalosporin) Section	6.	Dry Powder Suspension (Cephalosporin) Section
7.	Capsule (Cephalosporin) Section	8.	Tablet (General) Section
9.	Injectable (Steroid) Section	----------	

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000894 by way of Formulation in the name of M/s Avensis Pharmaceuticals, Plot No. F-24/1, Eastern Industrial Estate Zone, Port Muhammad Bin Qasim, Karachi on the recommendations of the panel of experts for the period commencing on 08.01.2024 & ending on 07.01.2029 for the following sections:

S#	Section	S#	Section
1.	Capsule (General) Section	2.	Sachet (General) Section
3.	Liquid Ampoule & Vial (General) Section	4.	SVP Infusion (General) Section
5.	Dry Powder Injection (Cephalosporin) Section	6.	Dry Powder Suspension (Cephalosporin) Section

		7.	Capsule (Cephalosporin) Section	8.	Tablet (General) Section
		9.	Injectable (Steroid) Section	----------	

6.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore. DML No.000863 (Formulation). Period: Commencing on 12.06.2022 & ending on 11.06.2027. *Evaluator: - Zunaira Faryad (AD-Lic)*	18-01-2024	Good	1. Muhammad Shamoon Ch. Expert Member. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore
	Production In-charge	Mr. Ghulam Bari S/o Ghulam Mustafa (M.Sc. Chemistry) CNIC No. 35202-7525041-7		
	QC In-charge	Ms. Rehana Kousar D/o Muhammad Yousaf (B. Pharm) CNIC No.33303-9193596-8.		

Recommendations of the panel: -

In view of above inspection proceedings and facilities verified, such as company profile, building, material management, production, in-process controls, Quality Control Testing, machinery/equipment, air handling, water treatment system, personnel and documentation e.t.c the panel is of the opinion to **recommend** the Renewal of Drug Manufacturing License to M/s. Bio-Mark Pharmaceuticals 527- Sunder Industrial Estate, Lahore, by way of formulation for the following sections:

i. Tablet Section I (General)
ii. Tablet Section II (General)
iii. Sachet Section (General)
iv. Capsule Section (General)
v. Oral Liquid Section (General)

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000863 by way of Formulation in the name of M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period commencing on 12.06.2022 & ending on 11.06.2027 for the following sections:

i. Tablet Section I (General)
ii. Tablet Section II (General)
iii. Sachet Section (General)

	iv. Capsule Section (General) v. Oral Liquid Section (General)			
7.	M/s Kanel Pharma, Plot No. 06, Street No. SS-3, RCCI National Industrial Estate, Rawat. DML No.000758 (Formulation). **Period:** Commencing on 04.10.2022 ending on 03.10.2027. *Evaluator: - Zunaira Faryad (AD-Lic)*	21-11-2023	Good	1. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT), Islamabad. 2. Mrs. Tehreem Sara, FID, Islamabad. 3. Mr. Yaqoob Kakar, AD Lic, Islamabad.
	Production In-charge	Mr. Mehmood Ahmad Jan S/o Abdullah Jan (Pharm. D) CNIC No.12201-1877707-1.		
	QC In-charge	Mr. Asad Khan S/o Maqsood Khan (Pharm-D) CNIC No.14301-6509545-9.		

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, UV- Spectrophotometer, viscometer, stability chambers, Karl Fisher, Polarimeter, hot/cold incubators etc., with the qualified technical personnel of required experience, unanimously **recommends** the grant of Renewal of Drug Manufacturing License to M/s Kanel Pharma, Plot No.06, Street No. SS-3, RCCI, Rawat, Islamabad for following sections:

i. Tablet Section (General).
ii. Capsule Section (General).
iii. Cream / Ointment Section (General)
iv. Lotion Section (General)
v. Capsule Section (Cephalosporin)
vi. Dry Powder Suspension (Cephalosporin).
vii. Dry Powder Vial Injection (Cephalosporin)

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000758 by way of Formulation in the name of M/s Kanel Pharma, Plot No. 06, Street No. SS-3, RCCI National Industrial Estate, Rawat on the recommendations of the panel of experts for the period Commencing on 04.10.2022 ending on 03.10.2027 for the following sections subject to verification of necessary testing equipment:

<table>
<tr><td></td><td colspan="4">i. Tablet Section (General).
ii. Capsule Section (General).
iii. Cream / Ointment Section (General)
iv. Lotion Section (General)
v. Capsule Section (Cephalosporin)
vi. Dry Powder Suspension (Cephalosporin).
vii. Dry Powder Vial Injection (Cephalosporin)</td></tr>
<tr><td>8.</td><td>M/s Aptcure (Pvt) Ltd, 30-Km Multan Road, Lahore.

DML No.000648 (Formulation).

Period: Commencing on 24.10.2023 ending on 23.10.2028.

Evaluator: - Zunaira Faryad (AD-Lic)</td><td>27-02-2024</td><td>Good</td><td>1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore.
2. Mr. Muhammad Arif Ch. Additional Director (CD) DRAP, Islamabad.
3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore</td></tr>
<tr><td></td><td>Production In-charge</td><td colspan="3">Mr. Muhammad Asim S/o Muhammad Yousaf (B. Pharm) CNIC No.35201-1284359-3.</td></tr>
<tr><td></td><td>QC In-charge</td><td colspan="3">Mr. Muhammad Yusuf S/o Shaikh Zahoor Ahmed (B.Pharm) CNIC No.33100-6854171-7.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel: -</u>
In view of the above inspection proceedings and facilities verified, such as company profile, building, material management, production, in-process controls, quality control testing, machinery/equipment, air handling, water treatment system, personnel and documentation e.t.c. the panel is of the opinion to recommend the renewal of Drug Manufacturing License to M/s Aptcure (Pvt) Ltd, 08-Pharma City 30-Km, Multan Road, Lahore by way of formulation for the following two sections only:

i. Tablet Section (General).
ii. Capsule Section (General).

<u>Decision of the Central Licensing Board in 296th meeting</u>

The Board considered and approved the grant of renewal of DML No. 000648 by way of Formulation in the name of M/s Aptcure (Pvt) Ltd, 30-Km Multan Road, Lahore on the recommendations of the panel of experts for the period Commencing on 24.10.2023 ending on 23.10.2028 for the following sections subject to verification of necessary testing equipment:
i. Tablet Section (General).
ii. Capsule Section (General).</td></tr>
</table>

9.	M/s Noble Pharma Plot No. B-1, Old Industrial Area, Mirpur, Azad Kashmir. DML No.000652 (Formulation). **Period:** Commencing on 30.01.2019 and ending on 29.01.2024. *Evaluator: - Muhammad Yaqoob (AD-Lic)*	12.01.2024	Good	1. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT), Islamabad. 2. Mr. Fahad Nadeem, Deputy Director (QA), DRAP, Islamabad. 3. Mr. Muhammad Asad Malik, Deputy Director (Pharmacy Services), DRAP, Islamabad
	Production In-charge	Mr. Faisal Nazeef S/o Muhammad Nazeef (M-Pharm)		
	QC In-charge	Mr. Aisha Sharif D/o Mian Muhammad Sharif (Pharm-D)		
	Recommendations of the panel: - The establishment has been inspected by the panel for renewal of DML. During the inspection few observations / shortcomings were pointed out and the establishment has shown compliance by addressing those shortcoming within two weeks. The panel is of the opinion that the establishment has the SOPs, document control, necessary equipment / machinery for production and quality control (such as FTIR, HPLC, Stability Chambers, UV Visible Spectrophotometer) utilities etc and therefore **recommends** the renewal of DML for the following sections: i. Veterinary Oral Powder (General) ii. Veterinary Oral Liquid (General) iii. Veterinary Liquid Vials Injection (General) **Decision of the Central Licensing Board in 296th meeting** The Board considered and approved the grant of renewal of DML No. 000652 by way of Formulation in the name of M/s Noble Pharma Plot No. B-1, Old Industrial Area, Mirpur, Azad Kashmir on the recommendations of the panel of experts for the period commencing on 30.01.2019 and ending on 29.01.2024 for the following sections. i. Veterinary Oral Powder (General) ii. Veterinary Oral Liquid (General) iii. Veterinary Liquid Vials Injection (General)			
10	M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad. DML No.000498 (Formulation).	22-02-2024	Very Good	1. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT), Islamabad. 2. Mr. Malik Muhammad Asad, Deputy Director (Pharmacy Services), DRAP, Islamabad.

Period: Commencing on 22-06-2022 ending on 21-06-2027. *Evaluator: - Muhammad Yaqoob (AD-Lic)*			3. Mr. Muhammad Yaqoob, Assistant Director (Licensing), DRAP, Islamabad	
Production In-charge	Mr. Muhammad Aamir S/o Abdul Sattar CNIC# 36103-2422120-7			
QC In-charge	Mr. Tariq Mehmood S/o Mirza Muhammad Sadiq CNIC# 37301-2340494-5			

Recommendations of the panel: -

The panel based on the available equipment/ machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and the commitment of the management **recommends** the grant of renewal of drug manufacturing license (DML) to M/s Scotmann Pharmaceuticals, located at Plot no.5-D, I-10/3, Islamabad for the following sections:

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Injection Ampoule Section (General)
iv. Dry Suspension Section (General)
v. Liquid Section (General)
vi. Dry Powder Suspension Section (Cephalosporin)
vii. Capsule Section (Cephalosporin) in place of existing Licensed Dry Powder Suspension & Capsule Section Penicillin.

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000498 by way of Formulation in the name of M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad on the recommendations of the panel of experts for the period commencing on 22-06-2022 ending on 21-06-2027 for the following sections:

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Injection Ampoule Section (General)
iv. Dry Suspension Section (General)
v. Liquid Section (General)
vi. Dry Powder Suspension Section (Cephalosporin) in place of licensed Powder Suspension -Penicillin
vii. Capsule Section (Cephalosporin) in place of existing licensed Dry Capsule Section Penicillin.

In addition, the Board decided to notify the Drug Registration Board to take the necessary action in regard to the cancellation of the firm's penicillin products (Powder Suspension Penicillin section, Dry Capsule Penicillin Section).

11	M/s English Pharmaceuticals Industries, Link Kattar Band Road, Thokar Niaz Baig, Lahore. DML No.000339 (Formulation). **Period:** Commencing on 19-07-2024 ending on 18-07-2029. *Evaluator: - Zunaira Faryad (AD-Lic)*	13.03.2024	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Muhammad Arif Ch. Director (Biologicals) DRAP, Islamabad. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore
	Production In-charge	Syeda Anita Marium Mehdi W/o Syed Hassan Mehdi CNIC No. 54400-0446845-2 (Pharm-D)		
	Quality Control In-charge	Mr. Muhammad Asif Chattha S/o Muhammad Sadiq Chattha CNIC No.36501-1821295-9.(M.Sc. Chemistry)		

Recommendations of the panel: -

Keeping in view the manufacturing facilities like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommended** the renewal of DML to M/s English Pharmaceuticals Industries, Link Kattar Band Road, Thokar Niaz Baig Multan Road, Lahore for the following sections:

1. Tablet Section (General Antibiotic)
2. Oral Liquid Section (General)
3. Oral Dry Suspension Section (General)
4. Oral Dry Powder Suspension Section (Cephalosporin)
5. Capsule Section (Cephalosporin)
6. Dry Powder Injection Section (Cephalosporin)
7. Liquid Injectable (Ampoule) Section (General)
8. Liquid Injection SVP (General).
9. Sterile Dry Powder Injection Section (Penicillin)
10. Dry Powder Injection Vial Section (General)
11. Capsule Section (General).

Decision of the Central Licensing Board in 296th meeting

	The Board considered and approved the grant of renewal of DML No. 000339 by way of Formulation in the name of M/s English Pharmaceuticals Industries, Link Kattar Band Road, Thokar Niaz Baig, Lahore on the recommendations of the panel of experts for the period commencing on 19-07-2024 ending on 18-07-2029 for the following sections. i. Tablet Section (General Antibiotic) ii. Oral Liquid Section (General) iii. Oral Dry Suspension Section (General) iv. Oral Dry Powder Suspension Section (Cephalosporin) v. Capsule Section (Cephalosporin) vi. Dry Powder Injection Section (Cephalosporin) vii. Liquid Injectable (Ampoule) Section (General) viii. Liquid Injection SVP (General). ix. Dry Powder Injection Vial Section (General) x. Capsule Section (General). Accordingly, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for penicillin section. 1. Sterile Dry Powder Injection Section (Penicillin)			
12.	M/s. BF Biosciences Limited, 5-Km Sunder Raiwind Road, Raiwind, Lahore. DML No.000655 (Formulation). **Period:** Commencing on 30-01-2024 ending on 29-01-2029. *Evaluator: - Zunaira Faryad (AD-Lic)*	01-03-2024	Good	1. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Dr. Akhtar Abbas Khan, Director (Drug Licensing), Islamabad.
	Production In-charge	Mr. Shams ul Arifeen S/o Fazal Hussain (B. Pharm) CNIC No. 14301-2005601-1.		
	QC In-charge	Mr. Rashid Mansoor S/o Mubarak Ahmed Mirza CNIC No.42301-4935876-7 (B. Pharm).		
	Recommendations of the panel: - Keeping in view the manufacturing facilities like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommends** renewal of Drug Manufacturing License, additional and revised section to M/s BF Biosciences Limited, 5-Km Sunder Raiwind Road, Lahore for the following sections:			

<table>
<tr><td></td><td colspan="4">i. Parenteral (Liquid Lyophilized) Biotech Section (Renewal)
ii. Injectable (Ampoule/Vial) SVP (Lyophilized/Liquid) (General) Section (Revised)
iii. Product Development Section (New)
<u>Decision of the Central Licensing Board in 296th meeting</u>
The Board considered and approved the grant of renewal of DML No. 000655 by way of Formulation in the name of M/s. BF Biosciences Limited, 5-Km Sunder Raiwind Road, Raiwind, Lahore on the recommendations of the panel of experts for the period commencing on 30-01-2024 ending on 29-01-2029 for the following sections.
i. Parenteral (Liquid Lyophilized) Biotech Section (Renewal)
ii. Injectable (Ampoule/Vial) SVP (Lyophilized/Liquid) (General) Section (Revised)
iii. Product Development Section (New)</td></tr>
<tr><td>13.</td><td>M/s Skims Pharmaceuticals, 10-B, Value Addition City, Khurrianwala, Faisalabad.

DML No. 000830 (Formulation).

Period: Commencing on 03-12-2020 ending on 02-12-2025.

Evaluator: - Abdullah (AD-Lic)</td><td>13-12-2023</td><td>Good</td><td>1. Abdul Rashid Sheikh, FID, DRAP, Lahore.
2. Dr. Madiha Khalid, Director (Operation) CDC, Punjab, Lahore.
3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td>QC In-charge</td><td colspan="3">Mr. Waheed Arshad S/o Siddique Arshad (M. Sc Chemistry) CNIC No.33100-0708814-7.</td></tr>
<tr><td></td><td>Production In-charge</td><td colspan="3">Mr. Hafiz Muhammad Yameen S/o Muhammad Younas (Pharm-D) CNIC No.33100-09263348-3</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>
In view of above inspection proceedings and facilities verified, such as company profile, building, material management, production, in-process controls, quality control testing, machinery/equipment, air handling, water treatment system, personnel and documentation e.t.c the panel of inspectors is of the opinion to recommend the Renewal of Drug Manufacturing License to M/s Skims Pharmaceuticals, 10-B, Value Addition City, Khurrianwala, Faisalabad, by way of formulation for the following sections only.
i. Liquid Syrup Section (General)
ii. Tablet Section (General)
iii. Sachet Section (General)
iv. Capsule Section (General)
v. Oral Dry Powder Suspension Section (General)</td></tr>
</table>

	vi. Oral Liquid (Re-Packing) Section **<u>Decision of the Central Licensing Board in 296th meeting</u>** The Board considered and approved the grant of renewal of DML No. 000830 by way of Formulation in the name of M/s Skims Pharmaceuticals, 10-B, Value Addition City, Khurrianwala, Faisalabad on the recommendations of the panel of experts for the period commencing on 03-12-2020 ending on 02-12-2025 for the following sections subject to verification of necessary testing equipment: i. Liquid Syrup Section (General) ii. Tablet Section (General) iii. Sachet Section (General) iv. Capsule Section (General) v. Oral Dry Powder Suspension Section (General) The Oral Liquid (Re-Packing) section was deferred with the direction to firm to submit the applications along with fee for enlistment of repacking items.			
14.	M/s. Hansel Pharmaceuticals (Pvt) Ltd, Plot No.2, Pharma City, 30-Km Multan Road, Lahore. DML No.000581 (Formulation). **Period:** Commencing on 24-06-2020 ending on 23-06-2025. *Evaluator: - Zunaira Faryad (AD-Lic)*	14-03-2024	Good	1. Muhammad Shamoon Ch. Expert Member. 2. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore.
	QC In-charge	Mr. Muhammad Kaleem S/o Muhammad Ramzan (M. Sc Chemistry) CNIC No. 32202-9575316-3.		
	Production In-charge	Mr. Muhammad Ali Prince S/o Safdar Hussain Raza (Pharm-D) CNIC No. 35202-0444845-3.		
	<u>Recommendations of the panel: -</u> Keeping in view the manufacturing facility like building and availability 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 renewal of Drug Manufacturing License to M/s Hansel Pharmaceuticals (Pvt) Ltd, Plot No.2, Pharma City, 30 Km Multan Road, Lahore for the following section: i. Capsule Section (General) ii. Tablet Section (General)			

	iii. Liquid Injectable Section (General) iv. Eye Drops Section (General) v. Cream /Ointment Section (General) vi. Capsule Section (Cephalosporin) vii. Oral Dry Powder for suspension Section (Cephalosporin) viii. Dry Powder for injection Section (Cephalosporin) **ix. Tablet Section (Hormone)** **x. Liquid Injectable Section (Hormone)** Both Hormone sections that is **Tablet Section (Hormone) & Liquid Injectable Section (Hormone)** are located on the same floor with complete separation through physical barrier/wall. **<u>Decision of the Central Licensing Board in 296th meeting</u>** The Board considered and approved the grant of renewal of DML No. 000581 by way of Formulation in the name of M/s. Hansel Pharmaceuticals (Pvt) Ltd, Plot No.2, Pharma City, 30-Km Multan Road, Lahore on the recommendations of the panel of experts for the period commencing on 24-06-2020 ending on 23-06-2025for the following sections subject to verification of necessary testing equipment: i. Capsule Section (General) ii. Tablet Section (General) iii. Liquid Injectable Section (General) iv. Eye Drops Section (General) v. Cream /Ointment Section (General) vi. Capsule Section (Cephalosporin) vii. Oral Dry Powder for suspension Section (Cephalosporin) viii. Dry Powder for injection Section (Cephalosporin) Accordingly, the Board decided to defer the renewal of the following sections and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for hormonal preparations. i. Tablet Section (Hormone) ii. Liquid Injectable Section (Hormone)			
15	The Searle Company Limited, 32-Km Multan Road, Lahore. DML No.000647 (Formulation). **Period:** Commencing on 24-10-2023 ending on 23-10-2028.	28-02-2024 & 29-02-2024	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Farooq Aslam, Assistant Director, DRAP Lahore.

	Evaluator: - Abdullah (AD-Lic)			
	QC In-charge	Ms. Saima Muzaffar D/o Muzaffar Shah (B-Pharm)		
	Production In-charge	Mr. Gulzar Ahmad S/o Shah Muhammad (B-Pharm)		
	Recommendations of the panel: - Keeping in view the manufacturing facility like building, HVAC system, sanitation, production machinery, equipment in quality control, testing facilities, technical personnel and documentation, the panel of inspectors recommended the grant of the renewal of the following sections as per the already approved layout plan as following: i. Tablet Section (General)-(Block 1) ii. Tablet Section (Antibiotic)-(Block 1) iii. Oral Liquid Section (General)- (Block 1) iv. Capsule Section (General) – (Block 1) v. Tablet Section-I (General) – (Block 2) vi. Oral Liquid Section (General) – (Block 2) and also recommended the Grant of Additional Section of: i. Tablet General Section-II (New) – Block 2) ii. Raw Material Store (New) – (Block 2) **Decision of the Central Licensing Board in 296th meeting** The Board considered and approved the grant of renewal of DML No. 000647 by way of Formulation in the name of M/s The Searle Company Limited, 32-Km Multan Road, Lahore on the recommendations of the panel of experts for the period commencing on 24-10-2023 ending on 23-10-2028 for the following sections subject to verification of necessary testing equipment: i. Tablet Section (General)-(Block 1) ii. Tablet Section (Antibiotic)-(Block 1) iii. Oral Liquid Section (General)- (Block 1) iv. Capsule Section (General) – (Block 1) v. Tablet Section-I (General) – (Block 2) vi. Oral Liquid Section (General) – (Block 2) The Board observed that inspection report was forwarded on 25-03-2024 by the then additional director Lahore who was retired on 22nd March 2024. The Board decided to seek clarification by the FID Lahore before communication of decision.			
16	M/s Unisa Pharmaceutical Industries Ltd, Main GT Road, Adamzai Akora Khattak, District Nowshera. DML No.000740 (Formulation).	16-10-2023	Good	1. Mr. Younas Khattak, Chief Drug Inspector, Peshawar 2. Mr. Faisal Shahzad, Additional Director (E&M) /Area FID, DRAP, Peshawar.

	Period: Commencing on 16-08-2022 and ending on 15-08-2027. *Evaluator: - Muhammad Yaqoob (AD-Lic)*			3. Mr. Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
	QC In-charge	Mr. Rab Nawaz S/o Taus Khan (B-Pharm) CNIC No.16102-5160864-9		
	Production In-charge	Mr. Kamran Khan S/o Rashid Ali (B-Pharm) CNIC No.16101-7167329-3		
	<u>Recommendation</u>: Based on documentation reviewed, technical / management people met, personnel/materials/ processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab, distil water system with continuous loop system, and allied facilities including HVAC system, the panel is of the view that the firm has established good facility following GMP guidelines and unanimously recommended renewal of Drug Manufacturing License No.000740 (Formulation)to the firm for following mentioned two sections as per DRAP, Islamabad letter No. 3-3/2009-Lic dated 05th January 2023. 1. Large volume parenteral / IV infusion (General/Antibiotic) 2. Liquid Injectable Ampoules Section- (General) **<u>Decision of the Central Licensing Board in 296th meeting</u>** The Board considered and approved the grant of renewal of DML No. 000740 by way of Formulation in the name of M/s Unisa Pharmaceutical Industries Ltd, Main GT Road, Adamzai Akora Khattak, District Nowshera on the recommendations of the panel of experts for the period commencing on 16-08-2022 and ending on 15-08-2027 for the following sections: 1. Large volume parenteral / IV infusion (General/Antibiotic) 2. Liquid Injectable Ampoules Section- (General)			
17	M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar. DML No. 000610 (Formulation) Period: Commencing on 12-04-2022 and ending on 13-04-2027. *Evaluator: - Muhammad Yaqoob (AD-Lic)*	20-10-2023 & 08-03-2024	Good	1. Dr. M. Khalid Khan (Ex-Member Policy Board / Director, DTL, Peshawar) 2. Mr. Faisal Shahzad Area Federal Inspector of Drugs, DRAP, Peshawar. 3. Muhammad Yaqoob Assistant Director Licensing, DRAP, Islamabad.
	QC In-charge	Mr. Kalim Ullah S/o Muhammad Shafi Babar (M.Sc Chemistry) CNIC No.38403-2085254-5		
	Production In-charge	Mr. Sardar Ahmed S/o Amir Muhammad (B-Pharm) CNIC No.12103-7206958-5		

Recommendation:

Based on documentation reviewed, technical / management people met, personnel/materials/ processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is of the view that the firm has provided necessary facilities for the following mentioned new section in accordance with DRAP, Islamabad letter No. 3-2/2006-Lic (Vol-II) dated 19-04-2023 and unanimously recommended grant of renewal of Drug Manufacturing License No.000610 (Formulation) for following sections namely,

S.No	Name of Section	S.No.	Name of Section
1.	**Tablet (Steroidal Hormone) Section**	2.	General Liquid Injection
3.	General Dry Powder Injection	4.	General Sachet Section
5.	Dry Powder Suspension (General)	6.	Cream / Ointment / Gel (General)
7.	Sachet (Cephalosporin)	8.	Capsule (General)
9.	Capsule (Cephalosporin)	10.	Tablet (General)
11.	Dry Powder Injection (Cephalosporin)	12.	Dry Powder Suspension (Cephalosporin)

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000610 by way of Formulation in the name of M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar on the recommendations of the panel of experts for the period commencing on 13-04-2022 and ending on 12-04-2027 for the following sections subject to verification of necessary testing equipment:

S.No	Name of Section	S.No.	Name of Section
1.	General Liquid Injection	2.	General Sachet Section
3.	General Dry Powder Injection	4.	Cream / Ointment / Gel (General)
5.	Dry Powder Suspension (General)	6.	Capsule (General)
7.	Sachet (Cephalosporin)	8.	Tablet (General)
9.	Capsule (Cephalosporin)	10.	Dry Powder Suspension (Cephalosporin)
11.	Dry Powder Injection (Cephalosporin)		

Accordingly, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for hormonal preparations.

i. Tablet (Steroidal Hormone) Section

18	M/s Liven Pharmaceuticals (Pvt) Ltd, Sray Road, 49-Km, Multan Road, Phool Nagar, District Kasur.	27-02-2024	Good	1. Mr. Muhammad Shamoon Ch. Expert Member. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore.

	DML No.000881 (Formulation). **Period:** Commencing on 11-04-2023 ending on 10-04-2028. *Evaluator: - Zunaira Faryad (AD-Lic)*			3. Mr. Farooq Aslam, Assistant Director, DRAP Lahore.
	Production In-charge	Mr. Atta Ur Rehman S/o Mr. Abdul Razzaq CNIC No.35200-1537666-1		
	QC In-charge	Mr. Muhammad Ali S/o Muhammad Sarwar (M.Sc. Chemistry) CNIC No. 13101-4788986-3		

Recommendations of the panel: -

Keeping in view the manufacturing facility like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation as of today, the panel of inspectors **recommends** the renewal of DML and regularization to M/s Liven Pharmaceutical (Pvt.) Ltd, Sray Road, 49-Km Multan Road, Phool Nagar for the following sections:

i. Tablet (General) Section
ii. Capsule (General) Section
iii. Oral Dry Powder Sachet (General) Section
iv. Liquid Injectable (Ampoule)(General) Section
v. Liquid Injectable-Vial (General) Section
vi. Liquid Injectable (Psychotropic) Section

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000881 by way of Formulation in the name of M/s Liven Pharmaceuticals (Pvt) Ltd, Sray Road, 49-Km, Multan Road, Phool Nagar, District Kasur on the recommendations of the panel of experts for the period commencing on 11-04-2023 ending on 10-04-2028 for the following sections 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.

i. Tablet (General) Section
ii. Capsule (General) Section
iii. Oral Dry Powder Sachet (General) Section
iv. Liquid Injectable (Ampoule)(General) Section
v. Liquid Injectable-Vial (General) Section
vi. Liquid Injectable (Psychotropic) Section

19	M/s Remington Pharmaceutical Industries (Pvt) Ltd, 18-Km Multan Road, Lahore. DML No. 000061 (Formulation). **Period:** Commencing on 19-06-2023 ending on 18-06-2028. *Evaluator: - Abdullah (AD-Lic)*	14-03-2024	Good	1. Azhar Jamal Saleemi (CDC P&SHC), Chief Drug Controller, Government of Punjab. 2. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore.
	Production In-charge	Mr. Adnan Rafi S/o Muhammad Rafi (Pharm-D)		
	QC In-charge	Mr. Sabir Nazeer S/o Malik Nazeer Ahmad (Pharm-D)		

Recommendations of the panel: -

The panel recommends renewal of DML along with regularization of following sections for M/s Remington Pharmaceuticals (Pvt) Ltd, 18-Km Multan Road, Lahore.

1. Tablet Section (General & Antibiotics)
2. Capsule Section (General & Antibiotics)
3. Oral Liquid Section (General) Syrup / Suspension
4. Eye Ointment Section (General & Steroid)
5. Skin Ointment / Cream Section (General & Steroid)
6. Dry Powder Suspension Section (General & Antibiotics)
7. Sachet Section (General)
8. Eye, Ear Nose Drops Section (General & Steroid) Solution / Suspension
9. Ear, Nose & Throat section (General & Steroid) Solution / Suspension (Ear Drops/Nasal Spray)

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000061 by way of Formulation in the name of M/s Remington Pharmaceutical Industries (Pvt) Ltd, 18-Km Multan Road, Lahore on the recommendations of the panel of experts for the period commencing on 19-06-2023 ending on 18-06-2028 for the following sections subject to verification of necessary testing equipment:

1. Tablet Section (General & Antibiotics)
2. Capsule Section (General & Antibiotics)
3. Oral Liquid Section (General) Syrup / Suspension
4. Eye Ointment Section (General & Steroid)
5. Skin Ointment / Cream Section (General & Steroid)
6. Dry Powder Suspension Section (General & Antibiotics)
7. Sachet Section (General)

	8. Eye, Ear Nose Drops Section (General & Steroid) Solution / Suspension 9. Ear, Nose & Throat section (General & Steroid) Solution / Suspension (Ear Drops/Nasal Spray) The Board observed that inspection report was forwarded on 26-03-2024 by the then additional director Lahore who was retired on 22nd March 2024. The Board decided to seek clarification by the FID Lahore before communication of decision.			
20	M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad. DML No.000616 (Formulation). **Period:** Commencing on 12-04-2022 and ending on 11-04-2027 *Evaluator: - Abdullah (AD-Lic)*	13-02-2024 & 14-02-2024	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
	Production In-charge	Mr. Muhammad Mukhtiar S/o. Mr. Ali Sher (B.Pharm)		
	QC In-charge	Mr. Muhammad Ibrahim S/o. Mr. Muhammad Rafique (B.Pharm)		
	<u>Recommendations of the panel: -</u> Keeping in view the manufacturing facility like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors recommends the renewal of DML, and regularization to M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad for the following sections: 1. Dry Powder for Suspension (General) 2. Cream/ Ointment/ Gel/ (Steroidal) Section (Revised) 3. Liquid Injectable – Ampoule Section (General) 4. Dry Powder for Injection Section (Cephalosporin) 5. Capsule Section (Cephalosporin) 6. Dry Powder for Suspension (Cephalosporin) 7. Soft Gel Capsule Section (General) 8. Liquid Injectable – Vial (SVP) Section (General) **9. Tablet Section (Steroidal-Hormone)** 10. Nasal Spray Section (Steroidal) (Regularization) 11. Cream/ Ointment/ Gel Section (General) 12. Tablet II Section (General) (Regularization) 13. Tablet I Section (General) (Regularization) 14. Sachet Section (General) (Regularization) 15. Capsule Section (General) (Regularization) 16. Tablet Section (Psychotropic) (Regularization) 17. Lotion Steroidal Section (Revised)			

	18. Oral Liquid Section (General) (Regularization) 19. QC Laboratory (Regularization) 20. Ware House (Regularization) **<u>Decision of the Central Licensing Board in 296th meeting</u>** The Board considered and approved the grant of regularization and renewal of DML No. 000616 by way of Formulation in the name of M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad on the recommendations of the panel of experts for the period commencing on 12-04-2022 and ending on 11-04-2027 for the following sections subject to verification of necessary testing equipment and 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: . 1. Dry Powder for Suspension (General) 2. Cream/ Ointment/ Gel/ (Steroidal) Section (Revised) 3. Liquid Injectable – Ampoule Section (General) 4. Dry Powder for Injection Section (Cephalosporin) 5. Capsule Section (Cephalosporin) 6. Dry Powder for Suspension (Cephalosporin) 7. Soft Gel Capsule Section (General) 8. Liquid Injectable – Vial (SVP) Section (General) 9. Nasal Spray Section (Steroidal) (Regularization) 10. Cream/ Ointment/ Gel Section (General) 11. Tablet II Section (General) (Regularization) 12. Tablet I Section (General) (Regularization) 13. Sachet Section (General) (Regularization) 14. Capsule Section (General) (Regularization) 15. Tablet Section (Psychotropic) (Regularization) 16. Lotion Steroidal Section (Revised) 17. Oral Liquid Section (General) (Regularization) 18. QC Laboratory (Regularization) 19. Ware House (Regularization) Accordingly, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for hormonal preparations. **1. Tablet Section (Steroidal-Hormone)**			
21	M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, Plot No. 44, Industrial Triangle, Kahuta Road, Islamabad.	19-02-2024 & 21-02-2024	Good	1. Dr Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Ms. Saadia Mehwish, FID-I, DRAP, Islamabad.

Evaluator: - Muhammad Yaqoob (AD-Lic) DML No. 000628 (Formulation) Commencing date 19-06-2023 ending date 18-06-2028			3. Mr. Muhammad Yaqoob, Assistant Director (Lic), DRAP, Islamabad.	
Production In-charge	Sajjad Ahmad S/o Muhammad Roedad Khan (Pharm-D) CNIC: 16202-7816398-3			
Quality Control In-charge	Mr. Zia ur Rehman Zia S/o Khan Sherin (M.Sc Chemistry) CNIC: 42201-4322112-1 **(In process)**			

Recommendation

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 renewal of following sections of M/s. Focus & Rulz Pharmaceuticals (Pvt) Ltd, Plot No. 44, Industrial Triangle, Kahuta Road, Islamabad DML No. 000628.

i. Tablet (General)
ii. Capsules (General)
iii. Dry Suspension (General)
iv. Liquid Section (General)
v. Cream / Ointment (General)
vi. Sachet (General)
vii. Capsules (Cephalosporin)
viii. Dry Suspension (Cephalosporin)

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000628 by way of Formulation in the name of M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, Plot No. 44, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period Commencing date **19-06-2023** ending date **18-06-2028** for the following sections subject to verification of necessary testing equipment:

i. Tablet (General)
ii. Capsules (General)
iii. Dry Suspension (General)
iv. Liquid Section (General)
v. Cream / Ointment (General)
vi. Sachet (General)
vii. Capsules (Cephalosporin)
viii. Dry Suspension (Cephalosporin)

22	M/s Valor Pharmaceuticals, Plot No. 124-A, Industrial Triangle, Kahuta Road, Islamabad. Evaluator: - Muhammad Yaqoob (AD-Lic) DML No. 000496 (Formulation) Commencing date 29-03-2022 ending date 28-03-2027	19-12-2023	Good	1. Dr Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Ms. Saadia Mehwish, FID-I, DRAP, Islamabad. 3. Mr. Hassan Afzal, Deputy Director (QA), DRAP, Islamabad.
	Production In-charge	Mr. Muhammad Ishaq S/o Naimat Ullah Khan (Pharm-D) CNIC: 21508-3885928-1		
	Quality Control In-charge	Mr. Asif Iqbal (B-Pharm)		

Recommendation

The panel for renewal of DML has inspected the Establishment. During the inspection, some observations were made which were reported above in detail. The Establishment has addressed the observations, however, few still require compliance. In view of the inspection, reviewing the documents, intent of the management, the panel recommends the Establishment for renewal Drug Manufacturing License of M/s Valor Pharmaceuticals, 124/A, Triangle Industrial Estate, Kahuta Road, Islamabad. DML #000496, for following Twelve sections:

S.No.	Name of Sections
1.	Tablet (General/Quinolone)Section
2.	Capsule (General) Section
3.	Cream/Ointment/Gel (General) Section
4.	Tablet (Psychotropic) Section
5.	Eye Drop (General) Section
6.	Cream/Ointment/Gel (steroidal) Section
7.	Eye Ointment (General) Section
8.	Soft Gelatin Capsule Section
9.	Dry Oral Suspension (General) Section
10.	Sachet (General) Section

11	Lotion (General) Section
12	Lotion (Steroidal)

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of renewal of DML No. 000496 by way of Formulation in the name of M/s Valor Pharmaceuticals, Plot No. 124-A, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period commencing date **29-03-2022** ending date **28-03-2027** for the following sections subject to verification of necessary testing equipment and 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:

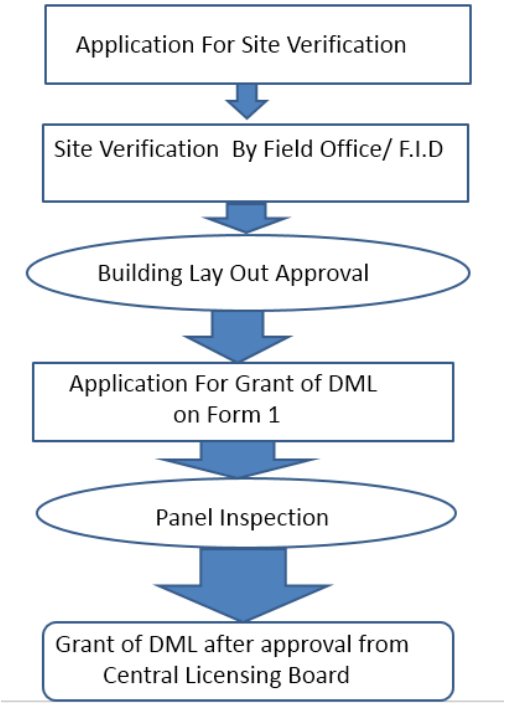
1.	Tablet (General/Quinolone)Section
2.	Capsule (General) Section
3.	Cream/Ointment/Gel (General) Section
4.	Tablet (Psychotropic) Section
5.	Eye Drop (General) Section
6.	Cream/Ointment/Gel (steroidal) Section
7.	Eye Ointment (General) Section
8.	Soft Gelatin Capsule Section
9.	Dry Oral Suspension (General) Section
10.	Sachet (General) Section (Revised)
11	Lotion (General) Section
12	Lotion (Steroidal)

Miscellaneous Cases:

Case No. 1. **REVIEW OF SITE VERIFICATION VALIDITY PERIOD**

Evaluator: - Zunaira Faryad (AD-Lic)

The pharmaceutical sector holds immense potential for growth in Pakistan, and the establishment of pharmaceutical units plays a vital role in meeting the demand and ensuring the availability of quality medicines. However, it is crucial to ensure that approved sites are utilized efficiently and in a timely manner.



In the past, there was no validity period of site verification approval by the Central Licensing Board (CLB). Previous applicants have often come after long periods of time and failed to proceed further with the next steps, leading to delays in the establishment of pharmaceutical units. This has hindered the growth and progress of the sector.

To address these concerns and streamline the process, the CLB took operational decisions in its 294th meeting held on 27th December, 2023. One of the key decisions made was to revise the validity of the site verification for unclassified/agricultural areas/premises down to one year. Similarly, the validity period was increased to two years for sites in industrial zones.

The Licensing division has identified 186 firms in Punjab who obtained approval of sites but have not yet applied for layout plans or the establishment of licenses. It is currently unknown whether these firms are genuinely interested in establishing pharmaceutical units or if they have abandoned their plans. It is crucial to take proactive measures to ensure efficient utilization of approved sites and ensure that all applicants comply with regulatory requirements.

The establishment of pharmaceutical units in Pakistan holds immense potential for economic growth and public health. By implementing stricter regulations and reviewing the validity of the site verification period, the CLB can ensure that all approved sites are utilized for intended purposes and in a timely manner.

Decision of the Central Licensing Board in 296th meeting

Based on the facts on record and a threadbare deliberation, the Board decided to issue a show-cause notice to all companies that have received site approval for a pharmaceutical unit but have not submitted any progress concerning submission of the LOP, building the unit, etc., for more than a year in the light of decision taken by CLB in its 294th meeting.

Case No. 2 CHANGE OF MANAGEMENT OF M/S FAHMIR PHARMA (PVT) LTD, MAIN MANDIANWALA STOP, 26-KM LAHORE JARANWALA ROAD, SHEIKHUPURA UNDER DML NO 000880 (FORMULATION).

Evaluator: - Zunaira Faryad (AD-Lic)

M/s Fahmir Pharma (Pvt) Ltd, Main Mandianwala Stop, 26-Km Lahore Jaranwala Road, Sheikhupura submitted the documents for change in management under DML No.000880 (Formulation). The firm has deposited fee of Rs. 75,000/- for change of management. The detail is as under;

Previous Management as per Form-A	New Management as per Form-A
1. Mr. Roy Zubair Munir S/o Roy Munir Ahmed Khan CNIC No.42201-1403164-5. 2. Mr. Roy Bilal Bin Munir S/o Roy Munir Ahmed Khan CNIC No.42201-2460086-3. 3. Mst. Fahmeeda Munir W/o Roy Munir Ahmed Khan CNIC No.42201-0728295-0. 4. Hafiz Roy Umair S/o Roy Munir Ahmed Khan CNIC No.42201-8565775-7.	1. Mr. Roy Zubair Munir S/o Roy Munir Ahmed Khan CNIC No.42201-1403164-5. 2. Mr. Roy Bilal Bin Munir S/o Roy Munir Ahmed Khan CNIC No.42201-2460086-3. 3. Mst. Fahmeeda Munir W/o Roy Munir Ahmed Khan CNIC No.42201-0728295-0. 4. Hafiz Roy Umair S/o Roy Munir Ahmed Khan CNIC No.42201-8565775-7. **5. Mr. Roy Munir Ahmed Khan S/o Roy Muhammad Ajab Khan CNIC No.42201-7294794-7.**

Decision of the Central Licensing Board in 296th meeting

Based on change of management in SECP, the Board considered and accepted for record the change of management of M/s Fahmir Pharma (Pvt) Ltd, Main Mandianwala Stop, 26-Km Lahore Jaranwala Road, Sheikhupura under DML No. 000880 (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. This approval shall not absolve company from its previous/pending liabilities/obligations of

whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-A	**New Management as per Form-A**
1. Mr. Roy Zubair Munir S/o Roy Munir Ahmed Khan CNIC No.42201-1403164-5. 2. Mr. Roy Bilal Bin Munir S/o Roy Munir Ahmed Khan CNIC No.42201-2460086-3. 3. Mst. Fahmeeda Munir W/o Roy Munir Ahmed Khan CNIC No.42201-0728295-0. 4. Hafiz Roy Umair S/o Roy Munir Ahmed Khan CNIC No.42201-8565775-7.	1. Mr. Roy Zubair Munir S/o Roy Munir Ahmed Khan CNIC No.42201-1403164-5. 2. Mr. Roy Bilal Bin Munir S/o Roy Munir Ahmed Khan CNIC No.42201-2460086-3. 3. Mst. Fahmeeda Munir W/o Roy Munir Ahmed Khan CNIC No.42201-0728295-0. 4. Hafiz Roy Umair S/o Roy Munir Ahmed Khan CNIC No.42201-8565775-7. **5. Mr. Roy Munir Ahmed Khan S/o Roy Muhammad Ajab Khan CNIC No.42201-7294794-7.**

Case No. 3 <u>CHANGE OF TITLE OF M/S ICU PHARMACEUTICALS, KHEWAT NO.13/13, KHATOONI NO.57/66 MOUZA MIRPUR KEHNA, TEHSILE SHARKPUR, DISTRICT SHEIKHUPURA UNDER DML NO 000956 (FORMULATION)</u>

Evaluator: - Zunaira Faryad (AD-Lic)

M/s ICU Pharmaceuticals, Khewat No.13/13, Khatooni No.57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura submitted the documents for change of Title under DML No.000956. The firm has deposited fee of Rs.75000/- for change of title. Detail is as under;

Previous Title	New Title as per Certificate of Incorporation with SECP
M/s ICU Pharmaceuticals, Khewat No.13/13, Khatooni No.57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.	**M/s ICU Pharmaceuticals (SMC-Private) Limited,** Khewat No.13/13, Khatooni No.57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.

<u>Decision of the Central Licensing Board in 296th meeting.</u>

Based on change of management in SECP, the Board considered and accepted for record the change of title of M/s ICU Pharmaceuticals (SMC-Private) Limited, Khewat No.13/13, Khatooni No.57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura. Under

DML No. 000956 (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). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

Case No. 4 <u>CHANGE OF MANAGEMENT OF M/S BF BIOSCIENCES LTD, 5-KM, SUNDER RAIWIND ROAD, RAIWIND, LAHORE UNDER DML NO 000655 (FORMULATION).</u>

Evaluator: - Zunaira Faryad (AD-Lic)

M/s BF Biosciences Ltd, 5-Km Sunder Industrial Estate, Raiwind Road, Raiwind Lahore submitted the documents for change in management under DML No.000655 (Formulation). The firm has deposited fee of Rs. 75,000/- for change of management. The detail is as under;

Previous Management	**Current Management as per Form-29**
1. Mrs. Akhter Khalid Waheed W/o Khalid Waheed CNIC No. 37405-0348706-0.	1. Mrs. Akhter Khalid Waheed W/o Khalid Waheed CNIC No. 37405-0348706-0.
2. Mr. Osman Khalid Waheed S/o Khalid Waheed CNIC No. 37405-0384955-7.	2. Mr. Osman Khalid Waheed S/o Khalid Waheed CNIC No. 37405-0384955-7.
3. Ms. Munize Azhar Peracha W/o Azhar Mehmood Peracha CNIC No. 35202-2778956-0.	3. Ms. Munize Azhar Peracha W/o Azhar Mehmood Peracha CNIC No. 35202-2778956-0.
4. Mr. Rallys Eduardo Pilauzer S/o Rallys Angel Demetrio Pilauzer Passport No. AAF596341.	4. Mr. Sebastian Martin Ferrarassi, Passport No. AAF852264.

<u>Decision of the Central Licensing Board in 296th meeting</u>

1. Based on change of management in SECP, the Board considered and accepted for record the change of management of M/s BF Biosciences Ltd, 5-Km Sunder Industrial Estate, Raiwind Road, Raiwind Lahore under DML No. 000655 (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. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

Previous Management	Current Management as per Form-29
1. Mrs. Akhter Khalid Waheed W/o Khalid Waheed CNIC No. 37405-0348706-0. 2. Mr. Osman Khalid Waheed S/o Khalid Waheed CNIC No. 37405-0384955-7. 3. Ms. Munize Azhar Peracha W/o Azhar Mehmood Peracha CNIC No. 35202-2778956-0. 4. Mr. Rallys Eduardo Pilauzer S/o Rallys Angel Demetrio Pilauzer Passport No. AAF596341.	1. Mrs. Akhter Khalid Waheed W/o Khalid Waheed CNIC No. 37405-0348706-0. 2. Mr. Osman Khalid Waheed S/o Khalid Waheed CNIC No. 37405-0384955-7. 3. Ms. Munize Azhar Peracha W/o Azhar Mehmood Peracha CNIC No. 35202-2778956-0. 4. Mr. Sebastian Martin Ferrarassi, Passport No. AAF852264.

Case No. 5 CHANGE OF TITLE & MANAGEMENT OF M/S DYNATIS PAKISTAN (PVT) LTD, PLOT NO.710, SUNDER INDUSTRIAL ESTATE, LAHORE UNDER DML NO 000891 (FORMULATION)

Evaluator: - Zunaira Faryad (AD-Lic)

M/s Dynatis Pakistan (Pvt) Ltd, Plot No.710, Sunder Industrial Estate, Lahore submitted the documents for change of title & management under DML No.000891. The firm has deposited fee of Rs. 150,000/- for change of title & management. Detail is as under;

i. Change of Title.

Previous Title	New Title
M/s Dynatis Pakistan (Pvt) Ltd, Plot No.710, Sunder Industrial Estate, Lahore.	M/s CCL Pharmaceuticals (Pvt) Ltd, Plot No.710, Sunder Industrial Estate, Lahore.

ii. Change of Management.

Previous Management as per Form-A	New Management as per Form-A & Form-29

1. Mr. Khalid Saeed S/o Saeed Ismail CNIC No.42201-7292832-3. 2. Mr. Zahid Saeed S/o Muhammad Saeed Ismail CNIC No.42201-4791181-1. 3. Mr. Anwar Saeed S/o Saeed Ismail CNIC No.42201-2319109-9.	1. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 2. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 3. Mr. Nadeem Bin Javaid Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3. 4. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 5. Mr. Muhammad Ali Masood S/o Muhammad Masood Ullah Siddiqui CNIC No.42201-7853423-9.

Decision of the Central Licensing Board in 296th meeting

Based on change of management in SECP, the Board considered and accepted for record the change of management and title of M/s Dynatis Pakistan (Pvt) Ltd, Plot No.710, Sunder Industrial Estate, Lahore under DML No. 000891 (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. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

I. **Change of Title.**

Previous Title	**New Title**
M/s Dynatis Pakistan (Pvt) Ltd, Plot No.710, Sunder Industrial Estate, Lahore.	M/s CCL Pharmaceuticals (Pvt) Ltd, Plot No.710, Sunder Industrial Estate, Lahore.

ii. Change of Management.

Previous Management as per Form-A	**New Management as per Form-A & Form-29**

1. Mr. Khalid Saeed S/o Saeed Ismail CNIC No.42201-7292832-3. 2. Mr. Zahid Saeed S/o Muhammad Saeed Ismail CNIC No.42201-4791181-1. 3. Mr. Anwar Saeed S/o Saeed Ismail CNIC No.42201-2319109-9.	1. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 2. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 3. Mr. Nadeem Bin Javaid Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3. 4. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 5. Mr. Muhammad Ali Masood S/o Muhammad Masood Ullah Siddiqui CNIC No.42201-7853423-9.

Case No. 6 **CHANGE OF MANAGEMENT OF M/S ANEEB PHARMACEUTICALS (PVT) LTD, 24-KM, BADIAN ROAD, LAHORE UNDER DML NO 000555 (FORMULATION).**

Evaluator: - Zunaira Faryad (AD-Lic)

M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km Bedian Road, Lahore submitted the documents for change in management under DML No.000555 (Formulation). The detail is as under;

Previous Management as per Form-A	**New Management as per Form-29.**
1. Mr. Shahid Sharif S/o Ch Muhammad Sharif CNIC No.35201-5391544-9. 2. Mr. Atif Sharif S/o Shahid Sharif CNIC No.35201-6971651-5.	1. Mr. Shahid Sharif S/o Ch Muhammad Sharif CNIC No.35201-5391544-9. 2. Mr. Atif Sharif S/o Shahid Sharif CNIC No.35201-6971651-5. 3. Ms. Tahmina Salman Khan W/o Salman Khan CNIC No.35202-9351925-6. 4. Syed Muhammad Taqi S/o Muhammad Pervaiz Haider CNIC No.33100-4520136-3.

Decision of the Central Licensing Board in 296th meeting

Based on change of management in SECP, the Board considered and accepted for record the change of management of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km Bedian Road, Lahore under DML No. 000555 (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. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

Previous Management as per Form-A	New Management as per Form-29.
3. Mr. Shahid Sharif S/o Ch Muhammad Sharif CNIC No.35201-5391544-9. 4. Mr. Atif Sharif S/o Shahid Sharif CNIC No.35201-6971651-5.	5. Mr. Shahid Sharif S/o Ch Muhammad Sharif CNIC No.35201-5391544-9. 6. Mr. Atif Sharif S/o Shahid Sharif CNIC No.35201-6971651-5. 7. Ms. Tahmina Salman Khan W/o Salman Khan CNIC No.35202-9351925-6. 8. Syed Muhammad Taqi S/o Muhammad Pervaiz Haider CNIC No.33100-4520136-3.

Case No. 7 <u>CHANGE OF MANAGEMENT OF M/S HIGHNOON LABORATORIES LIMITED, 17.5-KM, MULTAN ROAD, LAHORE UNDER DML NO 000155 (FORMULATION).</u>

M/s Highnoon Laboratories Limited, 17.5-Km Multan Road, Lahore submitted the documents for change in management under DML No.000155 (Formulation). The firm has deposited fee of Rs.75,000/- for change of management. The detail is as under;

Previous Management	New Management as per Form-29
1. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1. 2. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil Khan CNIC No. 35201-3787935-7. 3. Ms. Nael Najam W/o Syed Najam Rafiq CNIC No. 61101-7901490-4. 4. Mr. Taufiq Ahmed Khan S/o Jawaid Tariq Khan CNIC No. 35201-9273258-3. 5. Ms. Zainab Abbas W/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 6. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 7. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630.	1. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1. 2. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil Khan CNIC No. 35201-3787935-7. 3. Mr. Taufiq Ahmed Khan S/o Jawaid Tariq Khan CNIC No. 35201-9273258-3. 4. Ms. Zainab Abbas W/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 5. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 6. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630. 7. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No.42301-0366936-1.

<u>Decision of the Central Licensing Board in 296th meeting</u>

Based on change of management in SECP, the Board considered and accepted for record the change of management of M/s Highnoon Laboratories Limited, 17.5-Km Multan Road, Lahore under DML No. 000155 (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. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

Previous Management	New Management as per Form-29
8. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1. 9. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil Khan CNIC No. 35201-3787935-7. 10. Ms. Nael Najam W/o Syed Najam Rafiq CNIC No. 61101-7901490-4. 11. Mr. Taufiq Ahmed Khan S/o Jawaid Tariq Khan CNIC No. 35201-9273258-3. 12. Ms. Zainab Abbas W/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 13. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 14. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630.	8. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1. 9. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil Khan CNIC No. 35201-3787935-7. 10. Mr. Taufiq Ahmed Khan S/o Jawaid Tariq Khan CNIC No. 35201-9273258-3. 11. Ms. Zainab Abbas W/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 12. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 13. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630. 14. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No.42301-0366936-1.

Case No. 8 <u>CHANGE OF MANAGEMENT OF M/S DE-MONT RESEARCH LABORATORIES PVT LTD, 30-KM, LAHORE-SHARIKPUR ROAD, SHEIKHUPURA UNDER DML NO 000844 (FORMULATION).</u>

M/s De-Mont Research Laboratories Pvt Ltd, 30-Km, Lahore-Sharikpur Road, Sheikhupura submitted the documents for change in management under DML No.000844 (Formulation). The firm has deposited fee of Rs. 75,000/- for change of management. The detail is as under;

Previous Management as per Form-A	New Management as per Form-A.
1. Mr. Maqsood Ali S/o Muhammad Sharif CNIC No.35201-135699-3.	1. Faysal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No.34101-2601502-3.

2. Mr. Taimoor Mahmood Ahmad CNIC No.35201-4502364-7. 3. Mr. Bilal Ajmal S/o Ajmal Rauf Kahlon CNIC No. 35201-6261490-5. 4. Mr. Ali Sarwar S/o Sheikh Muhammad Sarwar CNIC No.54400-8325570-9. 5. Mr. Muhammad Abbas S/o Muhammad Yousaf CNIC No. 34102-7100357-3.	2. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 3. Mr. Muhammad Ismail S/o Abdul Haq Khan CNIC No. 35202-4728866-3.

Decision of the Central Licensing Board in 296th meeting

Based on change of management in SECP, the Board considered and accepted for record the change of management of M/s De-Mont Research Laboratories Pvt Ltd, 30-Km, Lahore-Sharikpur Road, Sheikhupura under DML No. 000844 (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. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

Previous Management as per Form-A	New Management as per Form-A.
6. Mr. Maqsood Ali S/o Muhammad Sharif CNIC No.35201-135699-3. 7. Mr. Taimoor Mahmood Ahmad CNIC No.35201-4502364-7. 8. Mr. Bilal Ajmal S/o Ajmal Rauf Kahlon CNIC No. 35201-6261490-5. 9. Mr. Ali Sarwar S/o Sheikh Muhammad Sarwar CNIC No.54400-8325570-9. 10. Mr. Muhammad Abbas S/o Muhammad Yousaf CNIC No. 34102-7100357-3.	4. Faysal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No.34101-2601502-3. 5. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 6. Mr. Muhammad Ismail S/o Abdul Haq Khan CNIC No. 35202-4728866-3.

Case No. 9 CHANGE OF TITLE & MANAGEMENT OF M/S GMP PHARMACEUTICALS, 28-KM SHEIKHUPURA ROAD, LAHORE UNDER DML NO 000815 (BY WAY OF FORMULATION)

M/s GMP Pharmaceuticals, 28-Km Sheikhupura Road, Lahore submitted the documents for change of title & management under DML No.000815. The firm has deposited fee of Rs. 150,000/- for change of management and title. Detail is as under;

i. Change of Title.

Previous Title	New Title as per Certificate of Incorporation

M/s GMP Pharmaceuticals, 28-Km Sheikhupura Road, Lahore.	M/s GMP Pharmaceuticals (Pvt) Ltd, 28-Km Sheikhupura Road, Lahore.

ii. Change of Management.

Previous Management	New Management as per Form-29
i. Mr. Khalil Ur Rehman Virk S/o Muhammad Yaqoob Virk CNIC No. 35404-6775556-1. ii. Mr. Zia Ur Rehman Virk S/o Muhammad Yaqoob Virk CNIC No. 35404-9691064-7. iii. Mr. Tahir Zaman Virk S/o Muhammad llyas CNIC No. 35404-5828644-1. iv. Mr. Khurram Shahzad Virk S/o Muhammad llyas CNIC No. 35404-1522502-7. v. Mr. Naeem Ur Rehman Virk S/o Muhammad llyas CNIC No. 35404-1522567-1.	i. Raja Waqar Akbar S/o Raja Muhammad Akbar CNIC No.37401-9598284-1. ii. Syed Khalid Hussain S/o Syed Bunyad Hussain CNIC No.31202-5830578-5. iii. Asher Qureshi S/o Siraj U Din Qureshi CNIC No.33100-8508571-5. iv. Ahmed Naveed S/o Mohammad Pervaiz Naveed CNIC No.35201-7735102-1.

Decision of the Central Licensing Board in 296th meeting

Based on change of management in SECP, the Board considered and accepted for record the change of title and management of M/s GMP Pharmaceuticals, 28-Km Sheikhupura Road, Lahore under DML No. 000815 (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. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

i. Change of Title.

Previous Title	New Title as per Certificate of Incorporation
M/s GMP Pharmaceuticals, 28-Km Sheikhupura Road, Lahore.	M/s GMP Pharmaceuticals (Pvt) Ltd, 28-Km Sheikhupura Road, Lahore.

ii. Change of Management.

Previous Management	New Management as per Form-29

vi. Mr. Khalil Ur Rehman Virk S/o Muhammad Yaqoob Virk CNIC No. 35404-6775556-1. vii. Mr. Zia Ur Rehman Virk S/o Muhammad Yaqoob Virk CNIC No. 35404-9691064-7. viii. Mr. Tahir Zaman Virk S/o Muhammad llyas CNIC No. 35404-5828644-1. ix. Mr. Khurram Shahzad Virk S/o Muhammad llyas CNIC No. 35404-1522502-7. x. Mr. Naeem Ur Rehman Virk S/o Muhammad llyas CNIC No. 35404-1522567-1.	v. Raja Waqar Akbar S/o Raja Muhammad Akbar CNIC No.37401-9598284-1. vi. Syed Khalid Hussain S/o Syed Bunyad Hussain CNIC No.31202-5830578-5. vii. Asher Qureshi S/o Siraj U Din Qureshi CNIC No.33100-8508571-5. viii. Ahmed Naveed S/o Mohammad Pervaiz Naveed CNIC No.35201-7735102-1.

Case No. 10 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HAMAZ PHARMACEUTICALS (PVT) LTD, 13-KM LUTAFABAD BOSAN ROAD, MULTAN UNDER DML NO.000427 (FORMULATION)**

Evaluator: - Zunaira Faryad (AD-Lic)

Case Background:

M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Lutafabad Bosan Road, Multan. DML No. 000427 (Formulation) Period: : Commencing on 01-04-2021 & ending on 31-03-2026.	21-02-2022 & 22-02-2022 & 04-08-2022	Good	1. Mr. Mouqadus-Un-Nisa, Director, Drugs Testing Laboratory, Multan. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and review of the production facilities, building, equipment, quality control and quality Assurance, the panel is of the opinion to recommend the renewal of Drug Manufacturing License No. 000427, by way of formulation to M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Lutafabad Bosan Road, Multan for the following sections:

- Tablet Section (General & Antibiotic).
- Capsule Section (General & Antibiotic).
- Dry Powder Suspension (General and Antibiotic)
- Oral Liquid Section. (General & Antibiotic)
- Liquid Injection (Ampoule & Vials) (General & Antibiotics)
- Sachet Section (General)
- Ointment/ Cream/Gel Section
- Capsule Section (Cephalosporin)
- Dry Powder Suspension (Cephalosporin).
- Dry Powder for Injection (Cephalosporin).
- Dry Powder for Suspension (Penicillin).
- (Oral) Capsule Section (Penicillin).
- Tablet Section (Penicillin).

As per available record of Licensing Division, the detail of sections is as under:

i. Tablet Section (General Antibiotic).
ii. Capsule Section (General Antibiotic).
iii. Dry Powder (General Antibiotic)
iv. Liquid Section. (Antibiotic)
v. Liquid Injection (Ampoule/Vial) (General & General Antibiotics)
vi. Sachet Section (Non Antibiotic)
vii. Ointment/ Cream/Gel Section (General)
viii. Capsule Section (Cephalosporin)
ix. Dry Powder (Cephalosporin).
x. Dry Powder for Injection (Cephalosporin).
xi. Dry Powder (Penicillin).
xii. Capsule Section (Penicillin).
xiii. Tablet Section (Penicillin).

Decision of the Central Licensing Board in 288th meeting

Mr. Azher Jamal Saleemi, Member CLB, informed the Board that M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Lutafabad Bosan Road, Multan, DML No. 000427 (Formulation) has been found involved in manufacturing of Citalem 10mg Tab (Escitalopram) Batch No. 46201 adulterated with other drug i.e., Sildenafil. He also shared a copy of case report. The Board decided to defer the renewal application and referred the case to QA & LT Division for further investigation in the instant matter and to submit the report to the CLB.

A panel comprising of Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore and Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore conducted inspection of M/s Hamaz Pharmaceuticals

(Pvt) Ltd,13-Km Bosan Road, Multan on 18-03-2023. Following were the observations during inspection:

a) Stability data of the Batch No. 46201 revealed that it was out of specifications in assay depicting significant change. Stability data of the previous batches was not available.

b) The method used for testing of finished product was not verified and firm has also not calculated system suitability in accordance with official pharmacopoeia. Firm was testing the previous batch on UV-spectrophotometer.

c) Process validation for the product Citalem 3H 10mg was not performed.

In light of the aforesaid investigation, apparently no evidence of adulteration was found. However, it is proven and also owned by the firm that they had manufactured substandard drug as per their own test reports. So, the firm committed that they engaged in manufacturing of substandard drug (Citalem 3H 10 mg tablet registration number 040726). So, the drug may be cancelled/suspended or any other action as deemed fit may be taken by the competent authorities.

Decision of the Central Licensing Board in 296th meeting

The Board while considering the facts on the record and discussed the case with Mr. Azher Jamal Saleemi, Member CLB. The member informed the Board that the PQCB has granted permission for prosecution in case of Citalem 3H 10mg tablet Regn No. 040726. The Board unanimously approved the grant of renewal of DML No. 000427 by way of Formulation in the name of M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Lutafabad Bosan Road, Multan on the recommendations of the panel of experts for the period commencing on 01-04-2-21 ending on 31-03-2026 for the following sections subject to verification of necessary testing equipment:

i. Tablet Section (General Antibiotic).
ii. Capsule Section (General Antibiotic).
iii. Dry Powder (General Antibiotic)
iv. Liquid Section. (Antibiotic)
v. Liquid Injection (Ampoule/Vial) (General & General Antibiotics)
vi. Sachet Section (Non Antibiotic)
vii. Ointment/ Cream/Gel Section (General)
viii. Capsule Section (Cephalosporin)
ix. Dry Powder (Cephalosporin).
x. Dry Powder for Injection (Cephalosporin).

Accordingly, the Board decided to defer the renewal of the following sections and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for penicillin section.

i. Dry Powder (Penicillin).
ii. Capsule Section (Penicillin).

iii. Tablet Section (Penicillin).

On the recommendation of QA & LT division the Board also referred the case to Registration Board for cancellation / de-registration of Citalem 3H 10mg tablet Regn No. 040726. It was also decided that a penal of inspectors/ experts shall be constituted by the chairman CLB for a follow up inspection of the firm.

Case No. 11 WITHDRAWL/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S A'RAF (PVT) LTD, 23-KM, RAIWIND ROAD, LAHORE UNDER DML NO. 000685 BY WAY OF FORMULATION.

Evaluator: - Zunaira Faryad (AD-Lic)

M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore under DML No. 000685 (Formulation) has submitted request for withdrawal of following licensed section namely:

i. External Preparation Section.

Decision of the Central Licensing Board in 296th meeting

The Board approved the withdrawal of External Preparation Section of M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore under DML No. 000685 and decided to notify the Drug Registration Board to take the necessary action in regard to the cancellation of the firm's external preparations.

Case No. 12 SITE VERIFICATION OF M/S ACE PHARMACEUTICALS, RAWAT, RAWALPINDI.

Evaluator: - Zunaira Faryad (AD-Lic)

M/s Ace Pharmaceuticals, Plot No.23, Street No. SS-2, RCCI, Industrial Estate, Rawat, Rawalpindi applied for site verification of proposed plot. After application was completed by the firm, Dr. Ghazanfar Ali Additional Director (QA&LT) was requested to conduct site inspection of proposed site and submit report regarding suitability of plot for establishment of pharmaceutical unit in response of this office letter No.3-5/2023-FID-II dated 26th December, 2023. The recommendation of the report is as under:

" In 293rd Meeting of CLB held on 20-11-2023, the Board in site verification case of M/s Premier Life Pharmaceutical (Pvt) Ltd, Plot No. 181/1, Road L-9, Industrial Estate, Gadoon Amazai, Swabi decided that in future, green field sites (without any construction for pharmaceutical units will only be considered for approval). In the light of said decision by the CLB, the site is rejected on the basis of existing construction."

The Chairman then constituted a 2-member panel of Mr. Muhammad Arif Chaudhary Additional Director (Controlled Drugs) & Ms. Ume Laila, Deputy Director (Licensing). The site inspection was conducted by panel members and the recommendations are as under: -

1.	**Location**	**:**	The proposed site was located in Rawat Industrial area at Plot No.23, Street No.SS-2, RCCI, Industrial Estate, Rawat, Rawalpindi
2.	**Surrounding**	**:**	At present, the right, the left and the back of the plot is empty. The plot is away from filthy surroundings and is not adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of dust or smoke which may contaminate drugs being manufactured or adversely effect on quality of drugs as laid down in paragraph I of Section–1 (1.2) of Schedule "B". Moreover, the site is located in industrial estate with all basic facilities to establish a state of the art pharmaceutical facility.
3.	**Size**	**:**	The size of the plot is 2400 sq.yds which is equivalent to approximately 4 kanal.
4.	**Construction**	**:**	The subject site is situated in industrial area and there is freshly constructed hall without partition only. Half of the plot is empty with boundary wall. The pictures of the sites are attached.
5.	**Recommendations**	**:**	"The panel visited the site located at Plot No.23, Street No.SS-2, RCCI Industrial Estate, Rawat and found that the site is located into industrial area. The empty site has a hall built as stated above. The panel was informed by the owner of the firm that he filed the application for site verification on 12.07.2023 while the decision made in 293rd meeting of CLB dated 20 November, 2023, while the panel is of the opinion that competent authority may please be decide in light of the above given facts."

Decision of the Central Licensing Board in 296th meeting

The Board considering the facts on the record and after thread bare deliberation decided to approve site located at Plot No.23, Street No. SS-2, RCCI, Industrial Estate, Rawat, Rawalpindi on recommendation of the panel.

Case No. 13 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000613 (FORMULATION) OF M/S GOODMAN LABORATORIES (PVT) LTD, RAWAT.

Evaluator: - Zunaira Faryad (AD-Lic)

Case Background:

M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat is licensed firm having DML No. 000613 by way of Formulation with validity of 20-03-2022. However, it is submitted that as per available record, application for renewal of DML

No. 000613 by way of Formulation for the period 21-03-2022 to 20-03-2027 of M/s Goodman Laboratories (Pvt) Ltd, Rawat has not been received in Licensing Division.

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the License is made after the expiry of the period of the validity of the License, it shall be treated as a fresh application for the grant of a License."

In light of above, DML No. 000613 by way of formulation, M/s Goodman Laboratories (Pvt) Ltd, Rawat is no more valid.

Proceedings and Decision by the Central Licensing Board in 287th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000613(by way of formulation) of M/s Goodman Laboratories (Pvt) Ltd, Rawat may not be declared cancelled by the Central Licensing Board as application for renewal of Drug Manufacturing License is not filed under Rule 5 and Rule 6 of Drug (Licensing, Registering and Advertising) Rule, 1976.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause Notice was issued to M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat on 4thJuly, 2022.

The firm has replied that they have paid DML renewal fee of Rs. 75,000/- within due date on 18-03-2022 and submitted In-Process data through PIRIMS and still waiting for approval.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

No person appeared on behalf of the firm. The Board considering the facts on record and after thread bare deliberation decided to cancel the Drug Manufacturing License No. 000613 (Formulation) of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat as the Drug Manufacturing License No. 000613 (Formulation) is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

DML cancellation letter was issued to the firm on 19th December, 2022. The firm then filed appeal against decision of CLB. The Appellate Board considered the case of M/s Goodman Laboratories (Pvt) Ltd, Islamabad in its 163rd meeting held on 20th December, 2022 and decided as under:

"The Drug Manufacturing License (DML) of the appellant was cancelled by the Central Licensing Board (CLB) in its 288th meeting held on 18.10.2022 due to non-submission of renewal application within prescribed time under the Drugs (Licensing, Registering and Advertising) Rules, 1976. The appellant argued that the prescribed fee along with application (Form 1A) for renewal of DML was submitted timely on 18.03.2022 while the licensing expired on 22.03.2022. However, the DML has been erroneously cancelled by the CLB. It was further submitted that the appellant would be satisfied if the case is remanded back to the CLB for reconsideration after verification of record and the operation of the impugned decision be suspended till that time."

Admin Division of DRAP verified that M/s Goodman Labs. submitted its application of renewal of DML in R&I of DRAP on 18-March-2022.

Licensing Division evaluated the application of the firm received on 27-06-2022 and following shortcomings has been noted:

i. Properly filled, signed and stamped Form-1A along with its all annexures.
ii. Updated nothing due certificate regarding CRF.
iii. Detail of management, if any change, file application for change of management.
iv. Duly attested copies of CNIC of all Directors.
v. Approval letters of Production Incharge & Quality Control Incharge.
vi. Approval letter of sections approved by CLB, if not available, file application for regularization of layout plan.
vii. Latest certified true copy of Form-29 issued by SECP (Original).

Decision of the Central Licensing Board in 296th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 19 , Schedule B under Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000613 (by way of formulation) of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 14 CHANGE OF TITLE OF M/S RELIANCE PHARMA, PLOT NO. 8 STREET NO. S-8 RCCI INDUSTRIAL ESTATE RAWAT UNDER DML NO 000724 (FORMULATION)

Evaluator: - Abdullah (AD-Lic)

M/s Reliance Pharma, Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat. submitted the documents for change of Title under DML No.000724. The firm has deposited fee of Rs.75000/- for change of title. Detail is as under;

Previous Title	New Title as per Registrar of Firms (Form-D)

M/s Reliance Pharma, Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat.	**M/s Global Pharmaceuticals Pakistan,** Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat.

Decision of the Central Licensing Board in 296th meeting

The Board considered and accepted for record the change of title of M/s Global Pharmaceuticals Pakistan under DML No. 000724 (Formulation) as per Form-D 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. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

Previous Title	**New Title as per Registrar of Firms (Form-D)**
M/s Reliance Pharma, Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat.	**M/s Global Pharmaceuticals Pakistan,** Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat.

Case No. 15 CHANGE OF MANAGEMENT OF M/S TITLIS PHARMA (PVT) LTD., 528-A, SUNDER INDUSTRIAL ESTATE, RAIWIND ROAD, LAHORE UNDER DML NO 000799 (FORMULATION).

Evaluator: - Abdullah (AD-Lic)

M/s Titlis Pharma (Pvt) Ltd., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore submitted the documents for change in management under DML No.000799 (Formulation). The firm has deposited fee of Rs. 75,000/- for change of management. The detail is as under;

Previous Management	**Current Management as per Form-29**
1. Syed Faisal Zaman S/o Syed Qamar Zaman Shah CNIC No.35202-7196906-1. **(CEO)** 2. Syed Zain Zaman S/o Syed Faisal Zaman CNIC No.35202-8576066-5. 3. Syed Fahd Zaman S/o Syed Faisal Zaman CNIC No.35202-2513242-1.	1. Mr. Malik Naveed Tariq S/o Malik Tariq Javed CNIC No.35202-7880635-1. **(CEO)** 2. Syed Zain Zaman S/o Syed Faisal Zaman CNIC No.35202-8576066-5. 3. Syed Fahd Zaman S/o Syed Faisal Zaman CNIC No.35202-2513242-1. 4. Syed Faisal Zaman S/o Syed Qamar Zaman Shah CNIC No.35202-7196906-1.

Decision of the Central Licensing Board in 296th meeting

Based on change of management in SECP, the Board considered and accepted for record the change of management of M/s under DML No. 000799 (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. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP.

Previous Management	**Current Management as per Form-29**
1. Syed Faisal Zaman S/o Syed Qamar Zaman Shah CNIC No.35202-7196906-1. **(CEO)**	1. Mr. Malik Naveed Tariq S/o Malik Tariq Javed CNIC No.35202-7880635-1. **(CEO)**
2. Syed Zain Zaman S/o Syed Faisal Zaman CNIC No.35202-8576066-5.	2. Syed Zain Zaman S/o Syed Faisal Zaman CNIC No.35202-8576066-5.
3. Syed Fahd Zaman S/o Syed Faisal Zaman CNIC No.35202-2513242-1.	3. Syed Fahd Zaman S/o Syed Faisal Zaman CNIC No.35202-2513242-1.
	4. Syed Faisal Zaman S/o Syed Qamar Zaman Shah CNIC No.35202-7196906-1.

Case No.16 **ESTABLISHMENT OF PHARMACEUTICAL UNIT – M/S VETERINARY RESEARCH INSTITUTE, PESHAWAR SITUATED AT DIRECTORATE GENERAL (RESEARCH), LIVESTOCK & DAIRY DEVELOPMENT DEPARTMENT, BACHA KHAN CHOWK CHARSADDA ROAD, PESHAWAR, KHYBER PAKHTUNKHWA**

Evaluator: - Abdullah (AD-Lic)

The applicant M/s Veterinary Research Institute, Peshawar submitted application for site verification situated at Directorate General (Research), Livestock & Dairy Development Department, Bacha Khan Chowk Charsadda Road, Peshawar, Khyber Pakhtunkhwa. Additional Director (E&M), DRAP, Peshawar was requested to inspect the site situated Directorate General (Research), Livestock & Dairy Development Department, Bacha Khan Chowk Charsadda Road Peshawar, Khyber Pakhtunkhwa. Federal Inspector of Drugs-DRAP, Peshawar vide letter No. No.F. 10-1/2024-FID(II)-DRAP(P) dated 29/02/2024 submitted site inspection report. The inception report and its recommendations is reproduced as under;

"Please refer to your letter No. F. 3-4/2023-Lic dated 20th November 2023 on the captioned subject.

2. The undersigned inspected the Directorate General (Research), Livestock & Dairy Development Department, Peshawar, Khyber Pakhtunkhwa alongwith Syed Adnan Ali Shah, Assistant Director DRAP Peshawar. Dr. Muhammad Ijaz Ali, Director General (Research), Livestock & Dairy Development Department, Khyber Pakhtunkhwa along with his team accompanied at the time of visit. The said site is proposed site for M/s Veterinary Research Institute, Peshawar.

The management informed that Pakistan did not inherit any research organization or biological production unit at the time of independence so Pakistan developed its first Pakistan Animal Husbandry Research Institute in 1949 under the control of West Pakistan Animal Husbandry Department. In 1970 the Veterinary Research Institute, Peshawar was placed under the administrative control of Government of Khyber Pakhtunkhwa (Formerly N.W.F.P). At that time the site was out of populated area in the Peshawar cantonment. The Institute is arranged in five divisions with an overall establishment of huge numbers of Professional and Para-professional/non-professional/ministerial staff.

The specifications/dimensions of the premises are as under:

Total Area: 16.831 acres (Comprised of already built sections for multiple purposes/activities)
East: Pajagi Road (then commercial area)
West: Peshawar Golf Club Area and Radio Pakistan Peshawar
North: Government Press Offices Area.
South: Charsadda Road Peshawar (Then Traffic Police Line Peshawar)

Environment: The premises is situated near commercial area of Charsadda Road and Pajagi Road Peshawar KhyerPakhtoonkhwa. No Pollution was found in its surrounding at the time of inspection. The institute is involved in the research activities since 1949 and the Total area of the institute is large enough having facilities of electricity, gas, water and sanitation therefore the case may be considered by the competent authority in light of above mentioned site details and national interest.

3. Sketch of premises and its adjoining area is attached as desired."

The above case is included in the agenda of authority, which shall be placed before the DRAP authority in its upcoming meeting for consideration. However, it is pertinent to mention that the Authority, in its meetings, considered cases of a similar nature i.e, VRI-Lahore, VRI-Sinds etc, wherein the Licensing Division was advised to process the case for the grant of a license to M/s Veterinary Research Institute, Lahore. The recommendation/decision of the DRAP authority in its meetings were presented before the CLB in its meeting held and the Board approved the said sites.

Decision of the Central Licensing Board in 296th meeting:

The Board considered the case and approved the proposed site situated at Directorate General (Research), Livestock & Dairy Development Department, Bacha Khan Chowk Charsadda Road, Peshawar, Khyber Pakhtunkhwa of M/s Veterinary Research Institute, Peshawar for establishment of pharmaceutical unit subject to decision of DRAP Authority.

Case No. 17 **ESTABLISHMENT OF PHARMACEUTICAL UNIT – M/S CENTRE FOR ADVANCED STUDIES IN VACCINOLOGY AND BIOTECHNOLOGY (CASVAB), UNIVERSITY OF BALUCHISTAN, QUETTA.**

Evaluator: - Abdullah (AD-Lic)

The applicant M/s. Centre for Advanced Studies in Vaccinology and Biotechnology (CASVAB) submitted application for site verification situated at University of Baluchistan, Quetta. OIC/FID (E&M), DRAP, Quetta was requested to inspect the site situated at) located at University of Baluchistan, Quetta.. OIC/FID (E&M), DRAP, Quetta has submitted site inspection report vide letter No. No.F. 12-03/2024-DRAP(Q) dated 12/03/2024 which is reproduced as under:

> *"I have the honor to refer to DRAP Islamabad letter No. F.4-3/2023-Lie dated 18th December, 2023 on subject above.*
>
> *2. It is to submit that undersigned inspected the premises of Centre for Advanced Studies in Vaccinology and Biotechnology (CASVAB) located at University of Baluchistan, Quetta. Following representatives for CASVAB accompanied during inspection:*
>
> *a) Prof. Dr. M. Zahid Mustafa, Director- CASVAB*
> *b) Dr. Irfan Shehzad Sheikh, Assistant Professor, CASVAB*
>
> *3. The management informed that CASVAB came in existence in 2005, before this, it was working as Veterinary Research Institute under the management of Livestock and Dairy Development Department, Government of Baluchistan and started Vaccine Production Laboratory since 1986. In 2005, it was placed under the administrative control of University of Baluchistan and renamed as Centre for Advanced Studies in Vaccinology and Biotechnology (CASVAB) and they continued to produce vaccines till date.*
>
> *4. A double storied building of CASVA is constructed in the area of approximately 1.74 Acres at proposed site near the department of Livestock and Dairy Development as per statement and documents furnished by the management. Currently CASVAB is producing ten different types of vaccines (List attached) in five different laboratories in above mentioned building with necessary equipment/instruments and also with sufficient technical and management stall.*
> *The specifications and dimensions of premises/building are us under:*
> ***Total Area:** 1.74 Acres (a double storied building is constructed; layout Plan is attached)*

Front side: *A vacant plot of approximately 7.5 Acres*
Back Side: *A small vacant plot and then Animal House situated)*
Right Side: *Directorate of Research and Feed for Livestock*
Left Side: *A small vacant plot for vehicle parking then residential area (houses) for staff of Livestock Department and CASVAB.*
Environment: *The said premises is situated in the vicinity of University of Baluchistan und near Livestock Department and also near residential area of staff of Livestock Department and CASVAB. Neither any pollution/dust generating activities nor sewerage line was found in its surroundings at the time of inspection.*

5. As it is also mentioned earlier that CASVAB is involved in research and production activities since 1986, the total area is large enough having constructed building with necessary facilities of laboratories, utilities (Electricity, Gas, Water and Sanitation) and adequate technical/administrative staff. It is therefore, recommended that the case may be considered by the competent authority for site approval in light of above mentioned site details and in larger public/national interest under the provision of Drugs Act, 1976 and DRAP Act, 2012 and rules made thereunder.

Submitted for your information and further necessary action, please."

The above case is included in the agenda of authority, which shall be placed before the DRAP authority in its upcoming meeting for consideration. However, it is pertinent to mention that the Authority, in its meetings, considered cases of a similar nature i.e, VRI-Lahore, VRI-Sinds etc, wherein the Licensing Division was advised to process the case for the grant of a license to M/s Veterinary Research Institute, Lahore. The recommendation/decision of the DRAP authority in its meetings were presented before the CLB in its meeting held and the Board approved the said sites.

Decision of the Central Licensing Board in 296th meeting:

The Board considered the case and approved the proposed site situated at University of Baluchistan, Quetta of M/s. Centre for Advanced Studies in Vaccinology and Biotechnology (CASVAB) for establishment of pharmaceutical unit subject to decision of DRAP Authority.

Case No. 18 CORRECTION IN DML NO OF M/S SHROOQ PHARMACEUTICALS (PVT.) LTD, 18-KM, FEROZEPUR ROAD, LAHORE UNDER DRUG MANUFACTURING LICENSE NUMBER 000577 (FORMULATION)

The firm M/s Shrooq Pharmaceuticals (Pvt.) Ltd, 18-Km, Ferozepur Road, Lahore under Drug Manufacturing License number 000577 (Formulation) has requested for correction in the DML No. mentioned in the section approval letter.

It is submitted for information that case of additional section of M/s M/S Shrooq pharmaceuticals (Pvt.) Ltd, 18-Km, Ferozepur Road, Lahore was presented before CLB in its 292nd meeting held on 4th October, 2023 and the Board decided as under'

"The Board considered and approved the grant of following section revised in the name of M/S Shrooq Pharmaceuticals (Pvt.) Ltd, 18-Km, Ferozepur Road, Lahore under DML No. 000586 (Formulation) on the recommendations of the panel of experts.

i. Dry Powder Suspension (General) Section (Additional/New)"

However, DML number of M/s Shrooq Pharmaceuticals (Pvt.) Ltd, 18-Km, Ferozepur Road, Lahore was inadvertently mentioned as DML No. 000586 (Formulation) instead of DML No. 000577 in the agenda and minutes of 292nd meeting of CLB. consequently, section approval letter was issued DML No. 000586 (Formulation) instead of DML No. 000577.

Decision of the Central Licensing Board in 296th meeting:

The Board considered the case and approved the correction in DML number from 000586 to 000577.

Case No. 19 CORRECTION IN MINUTES OF 293rd MEETING OF CLB.

The case for renewal of DML of M/s Nextar Pharma (Pvt) Ltd., Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi was presented in 293rd meeting of CLB held on 20-11-2023 and decided as under;

	M/s Nextar Pharma (Pvt) Ltd., Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi. DML No. 000777 (Formulation) Period: Commencing on 15-03-23 ending on 14-03-2028. (Evaluator: Mr Mubashir Iqbal)	12-10-2023	Good	1. Mr. Abdul Rasool Sh. Additional Director, DRAP, Karachi. 2. Mr. Saif-ur-Rehman, Director CDL, Karachi. 3. Area FID, DRAP, Karachi.
	Production In-charge:	Mr. Atif Muhammad Khan S/o Saad Muhammad Khan (B-Pharm) CNIC No.42201-1038326-7.		
	Quality Control In-charge:	Mr. Wajahat Ali S/o Liaquat Ali (M.Sc Chemistry) CNIC No.42401-8742434-1.		
	Recommendations of the panel: *"M/s Nextar Pharma (Pvt) Ltd., was inspected by the panel as per directions contained in DRAP, Islamabad letter no.F.2-4/2004-Lic dated 08th Sep 2023. The following observations were made:*			

	1) *M/s Nextar Pharma (Pvt) Ltd., is pharmaceutical company that has been constructed in accordance with the layout plan approved by the Drug Regulatory Authority of Pakistan (DRAP).* 2) *The company has all of the necessary equipment and machinery for the production, quality control, and storage of registered biopharmaceutical products, as well as a team of relevant technical experts.* 3) *The company has installed the requisite HVAC system in its production, QC, and QA areas, which is managed by a Building Management System and was operational at he time of inspection. The fact that the HVAC system is managed by a BMS also indicated that the company is taking steps to ensure the quality and safety of its products.* 4) *The company's compliance with DRAP requirements and its state-of-the-art facilities and equipment demonstrate its commitment to producing high-quality biopharmaceutical products.* 5) *Overall, M/s Nextar Pharma (Pvt) Ltd., appears to be a well-equipped and well-managed Premises that is capable of producing high-quality biopharmaceutical products.* *Based on the people met, documents reviewed, inspection findings, management's commitment to continuous improvement and compliance with the DRAP Act 2012, and efforts towards exports to various countries, the inspection panel recommends renewal of Drug Manufacturing License No.000777 to M/s Nextar Pharma (Pvt) Ltd., for Pre Filled Syringes and Injectable Ampoule Sections."* Decision of the Central Licensing Board in 293rd meeting: The Board considered and approved the grant of renewal of DML No. 000777 by way of Formulation in the name of M/s Nextar Pharma (Pvt) Ltd., Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi on the recommendations of the panel of experts for the period Commencing on 15-03-23 ending on 14-03-2028 for the following sections subject to verification of testing equipments (M-290th CLB). 1. Pre Filled (General) Syringes 2. Injectable Ampoule (General) Sections

However, the sections mentioned in the panel letters and minutes decision were inadvertantly mentioned as "Prefilled (General) Syringes and Injectable Ampoule (General) Sections instead of "Prefilled (Biological) Syringes and Injectable Ampoule (Biological) Sections.

Decision of the Central Licensing Board in 296th meeting:

The Board considered the case and approved the correction in title of sections as under;

1. Pre Filled Syringes (Biological)
2. Injectable Ampoule (Biological)

Case No. 20 GRANT OF DRUG MANUFACTURING LICENSE TO M/S BLISS INDUSTRIES (PVT) LTD., KARACHI.

Following case regarding grant of Drug Manufacturing License was placed before 289th meeting of Central Licensing Board and is reproduced as under;

<table>
<tr><td>1</td><td>M/s Bliss Industries (Pvt) Ltd., Plot No.G-A-52-A6, National Industrial Park, Karachi.
(Evaluator: Mr Mubashir Iqbal)</td><td>05-01-2023</td><td>Good</td><td>1. Mr. Ghulam Ali Lakho, Senior DI Karachi.
2. Dr. Najam Us Saqib, Additional Director (Licensing), DRAP, Islamabad.
3. Ms. Sanam Kausar, AD, DRAP, Karachi.</td></tr>
<tr><td></td><td colspan="4">Recommendations of the panel:

M/s Bliss Industries (Pvt) Ltd, Plot No. G-A-52-A6, National Industrial Park, Karachi was inspected in connection with the grant of DML (Formulation) as per DRAP letter F.2-2/2022-Lic dated 1st November 2022. Following are observations:
During the inspection, panel observed that the firm has constructed as per approved layout plan approved by the DRAP authorities.
Firm was observed well maintained in general. Necessary Production and quality control machinery/equipment was seen installed and well maintained as required for manufacturing and test/analysis of the pharmaceutical products. HVAC seen installed and operational. Adequate technical personnel also seen available on site that were observed well conservant with the GMP requirements.
“Based on the people met, documents reviewed and considering the finding of the physical inspection, panel recommends the grant of Drug Manufacturing License (Formulation) for the following sections:
<table>
<tr><td>S.No.</td><td>Name of Section</td><td>S.No.</td><td>Name of Section</td></tr>
<tr><td>01</td><td>Tablet (General)</td><td>02</td><td>Capsule (General)</td></tr>
<tr><td>03</td><td>Oral Liquid Section (General)</td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Decision of the Central Licensing Board in 289th meeting

The Board observed that the firm already holds a license at M/s Bliss Industries (Pvt) Ltd. 255/2 Shah Nawaz Bhutto Road Karachi DML No. 000086 (Formulation) in a residential area. The board decided to get the latest status of the court case filed by the firm and place before the CLB in its next meeting.

Accordingly, a letter was issued on 03-03-2023 to Additional Director (E&M), DRAP, Karachi to provide the latest status of the court case filed by the said firm.

Now, Mr. M. Suhail Zafar Bhatti, Advocate vide his letter No. SZB-MS/856 dated 10-04-2023 addressed to the Section Officer – SOL-I, Ministry of Law, Justice & Human Rights Division, Pakistan Secretariat, Government of Pakistan, Islamabad has forwarded updated status of the case. The firm has been called for personal hearing. The firm through legal representative Mr. Muhammad Rafique Bhatti, Advocate High Court vide letter reference No. Suit No. 423 of 2015/MRB dated 27-05-2023 has submitted the following reply;

"Honorable Secretary,

I have been honour to write this letter with reference to your letter No.F.2-2/22-Lic sated 26th May, 2023, regarding personal hearing.

It is very kind to be stated that due to my Client's health problem, he is unable to travel from Karachi to Islamabad and to attend the respective meeting before the Central Licensing Board held on 30th May, 2023 which is pure bonafide on the part of my Client and not deliberate. It is stated that in your letter under reply that you have stated to explain the company's position on the subject case. Nevertheless, under mentioned verdicts are in explanation of the position of my Client, as under: -

Following is/are position on the case:

1. New factory was established as New premises, at G-A-52, A/6, NIP., Karachi.
2. Inspection has been done by DRAP team, in the month of January, 2023.
3. Grant of License is under process for its approval.
4. The company is waiting for issuance of License and transfer of existing product, so operations can be smoothly transferred to new factory.
5. Furthermore, company is willing to withdraw the Suite No. 423/2015 from the Court of Law, if it gets the License and product transfer approval from the DRAP, in order to make smooth operational transfer without any delay in providing quality products to the people of Pakistan.

These are submissions in this regard and it is requested to please go through this letter and to please grant the License to the Bliss Industry and I undertake that after issuance of License in favour of my Client. I will withdraw the matter from the court of Law and obliged.

Thanking you in anticipation,
Muhammad Rafique Bhatti,
Advocate High Court."

Proceedings & Decision of the Central Licensing Board in 291st meeting:

No one on behalf of the firm appeared in person. However, Mr Khalid Ashraf CEO of the firm through telephone confirmed to the Board that if the Board grant them license at new premises they shall withdraw the matter from court of law. The CEO did not clarify whether they shall

withdraw DML from old premised or not. The Board after perusal of record and facts decided to defer the case till decision by the Court.

Court Orders:

Now the firm has submitted the court order dated 22-02-2024 of Civil Suit No.423 of 2015 in the Honorable Court of Senior Civil Judge-III, Karachi East. The order is reproduced as under

"Case called. Learned counsel for plaintiff is present and filed an application under Order XXIII Rule 1 read with section 151 of the C.P.C seeking therein withdrawal of instant civil suit on the ground that the parties have settled their dispute outside the court. He lastly prayed that the application in hand may be allowed in the interest of justice.

Keeping in view the aforesaid application filed by learned counsel for plaintiff, the instant civil suit stands dismissed being withdraw as prayed, with no order as to costs. However, all the pending applications (if any) stand infructuous."

Decision of the Central Licensing Board in 296th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing by way of Formulation in the name of M/s Bliss Industries (Pvt) Ltd., Plot No.G-A-52-A6, National Industrial Park, Karachi on the recommendations of the panel of experts and decision by the Honorable Court as stated above for the following sections subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting. Based on the firm's undertaking dated 02-04-2024, the Board further decided to cancel the Drug Manufacturing License at old premises of M/s Bliss Industries (Pvt.) Ltd. i.e., 255/2 Shah Nawaz Bhutto Road Karachi in the residential area. The same license number 000086 shall be allotted to the firm at new premises "Plot No.G-A-52-A6, National Industrial Park, Karachi". This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature.

S.No.	Name of Section	S.No.	Name of Section
01	Tablet (General)	02	Capsule (General)
03	Oral Liquid Section (General)		

Case No. 21 APPLICATIONS FOR WITHDRAWAL OF APPROVED LICNESED SECTIONS.

(Evaluator: Mr Mubashir Iqbal)

The Division of Licensing, DRAP receives a number of requests from different licensed pharmaceutical manufacturers where they intend to withdraw the already approved and licensed sections and get approval for new additional sections. While the firms are inquired regarding the manufacturing of their registered products which were granted by the Drug Registration Board the firms reply that they will shift those registered products to contract manufacturing under the provisions of the SRO.1347(I)/2021 Dated 15th October, 2021.

In the instant request M/s Maxitech Pharma (Pvt.) Ltd. Karachi has requested for approval of **Ointment/Cream Section** in place of approved **Liquid Syrup (General) Section.** The firm representatives were asked during the discussion of the proposed layout plan that what will be the fate of their registered liquid preparations and they informed that the said medicines have low sales volume and they will shift it to contract manufacturing to some other DML holder under the provisions of Contract Manufacturing as notified vide SRO.1347(I)/2021 Dated 15th October, 2021. Such trend in the pharmaceutical market of Pakistan will bring regulatory challenges. The case was placed before the DRAP Authority and authority referred the case to CLB for consideration. The detail of firms is as under;

Ser.	Name of Firm	DML No.	Name of Section(s)
1.	M/s A.J. Mirza Pharma (Pvt) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.	000234 (Formulation)	Liquid Syrup (General) Section
2.	M/s Maxitech Pharma (Pvt) Ltd., Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi	000851 (Formulation)	Liquid Syrup (General) Section

Decision of the Central Licensing Board in 296th meeting:

The board discussed that some firms frequently change their pharmaceutical lay out / designs to obtain new sections / registrations. These requested designs often do not adhere to the specific requirements for the manufacturing of the new class of drugs. Considerations such as segregation of production areas, provision of airlocks, men and material flow, air handling systems, equipment suitability, and storage conditions may be overlooked.

The board has decided that requests for changes in sections (withdrawal of one section and establishment of another in its place) will not be entertained within four years of the issuance of a new license / renewal of the license or new section (of which a change is proposed).

The firm must submit an application before one year from the due date of renewal of the license, providing proper justification for the proposed change. The change in layout design will be evaluated before inspection for license renewal. If the firm satisfies the requirements for changing sections, it must first surrender the registrations of the previous section. The licensing division shall notify to Registration Board for cancellation of registration of products of section that has been withdrawn.

However, if the firm wishes to improve existing sections with regard to cGMP requirements, addition of airlocks, buffers, improving men and material flow, such requests will be considered at any time. The Board authorized its Chairman to decide on the following applications accordingly.

Ser.	Name of Firm	DML No.	Name of Section(s)
1.	M/s A.J. Mirza Pharma (Pvt) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.	000234 (Formulation)	Liquid Syrup (General) Section
2.	M/s Maxitech Pharma (Pvt) Ltd., Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi	000851 (Formulation)	Liquid Syrup (General) Section

Case No. 22 **SITE VERIFICATION REPORT OF M/S PREMIER LIFE PHARMACEUTICAL ((PVT) LTD, PLOT NO. 181/1, ROAD L.9, INDUSTRIAL ESTATE GADOON AMAZAI, SWABI.**

Site verification report of M/s Premier Life Pharmaceutical ((Pvt) Ltd, Plot No. 181/1, Road L.9, Industrial Estate Gadoon Amazai, Swabi. The inspection was conducted by Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad and Atiq Ul Bari, Federal Inspector of Drugs, Peshawar in response to this office letter No. 3-6/2022-Lic dated 29th May, 2023. The recommendations of the inspection report are as under: -

The undersigned inspected the Plot No. 181/1, Road L-9, Industrial Estate, Gadoon Amazai, Swabi, Khyber Pakhtunkhwa on 22-06-2023. The said plot is proposed site for M/s Premier Life Pharmaceutical (Pvt) Ltd. The plot is situated in the Industrial Estate of Gadoon Amazai, Swabi, KPK having the necessary amenities such as road infrastructure, water and electrical supply. No environmental pollution was found at the time of inspection and a unit of chip board is situated 100 meters away from the back corner of the plot.

The premises have already built halls with partitions / rooms and a double story built block for security guards / admin. The pictures are attached with the report.

Further the Establishment has already submitted an undertaking that they would build a technical floor as per DRAP's requirement. Therefore, the proposed premises is suitable for the construction of the pharmaceutical unit.

Decision of the Central Licensing Board in 292nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm M/s Premier Life Pharmaceutical ((Pvt) Ltd, Plot No. 181/1, Road L.9, Industrial Estate Gadoon Amazai, Swabi before the forth-coming meeting of CLB.
A letter of personal hearing was served on 20th November, 2023 to the said firm for 293rd meeting of Central Licensing Board schedule to be held on 20-11- 2023.
Decision of the Central Licensing Board in 293rd meeting:

Syed Sultan Director of the firm along with Aziz Ahmad, appeared before the Board and contended that the chip board is situated 100 meters away from the proposed site and also played video of the proposed site and chip factory. They requested for re-verification. The Board after discussion in detail decided that the proposed site will be inspected by three-member panel constituted by Chairman of the Board.

It was also observed by the Board that some firms apply for site verification where a multipurpose grey structure is already constructed and it does not qualify for establishment of the pharma units. The Board also decided that in future, green field sites (without any construction) for pharmaceutical units will only be considered for approval. In certain cases, where public interest is involved, applications shall be considered on case to case basis.
In the light of board decision, a panel letter was issued to the firm on 03-01-2024.

In response to the above letter, Dr. Hasan Afzaal, Deputy Director, (QA/LT) DRAP, Islamabad, wherein he has stated as under;-
A panel was constituted to verify the suitability of site for establishment of Pharmaceutical unit i.e. M/s Premier Life Pharmaceutical (Pvt) Ltd. Accordingly, the site verification was conducted by the following panel constituted by the Central Licensing Board in its 293rd meeting on 30-01-2024.

1. Mr. Muhammad Youns Khattak, Member CLB
2. Dr. Hasan Afzaal, Deputy Director, QA&LT, DRAP Islamabad.
3. Mr. Adnan Ali Afridi, Assistant Director, DRAP, Peshawar.

1. Location and Surroundings: -

1.1 Location:

The premises of M/s Premier Life Pharmaceutical ((Pvt) Ltd, Plot No. 181/1, Road L.9, Industrial Estate Gadoon Amazai, Swabi away from residential area at present.

1.2 Surroundings:

Premises are not adjacent to public lavatory, open sewerage and drain which produce fumes or large quantities of soot or dust. In future firm is responsible. Total area of the plot is 1.0 Acre.

2. At present, the adjacent eastern lot is housed by a wood go down for the plywood factory, on the adjacent western plot M/s Reliable Plastic Industry Plot No. 181/2 is situated, on the north

the Road No. L-9 of Indusrial Estate Gadoon is situated and on the south M/s Sakhawat Shah Corporation, Plot No. 306/1 is situated.

3 The plot is situated in the industrial Estate of Gadoon Amazai, Swabi, Khyber Pakhtunkhwa. No pollution was found in the surrounding at the time of inspection however smoke was seen emitting from a chimney of a plywood industry approximately 100 meters from south eastern side of the plot. As reported earlier the firm has submitted an undertaking that they would install their HVAC plant on a GMP compliant technical floor as per DRAP requirement. The location is "suitable" for a pharmaceutical unit as per requirement laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470 (1)/98 dated 15-05-1998) under rules 16 (a) of the Drugs (Licensing, Registration and Advertising) rules 1976at present to the extent mentioned; as there is no evidence of filth in the surroundings at present. As of now, there is no open sewerage, drain, public lavatory nor any factory / installation which produce a disagreeable or obnoxious odor or large quantities of soot.

4 The issue related to saw dust smoke is such that the height of the chimney mentioned above appears to be more than the height of building which is currently build to house M/s Premier Life Pharmaceutical (Pvt) Ltd, supporting the claim of the firm that the smoke emitted by chimneys located on the south eastern side should not affect the quality of the product if the technical floor is developed in such manner that it only intakes air from the western side; however, for ensuring the same the time of grant of Drug Manufacturing License, the firm should be directed to qualify the Air Handling system to demonstrate the desired class of cleanliness is maintained during the manufacturing process.

Conclusion.

In conclusion, the site verification confirms the favorable conditions for pharmaceutical manufacturing at the premises of M/s Premier Life Pharmaceutical (Pvt) Ltd, despite emissions concerns, the firm's proactive approach and commitment, including the installation of a GMP-compliant HVAC system housed in GMP compliant technical floor in order to demonstrate readiness to uphold quality standards at the time of inspection for grant of DML.

Decision of the Central Licensing Board in 296th meeting,

On recommendation of the panel and considering the facts on the record and after thread bare deliberation the Board decided to approve site located at Plot No. 181/1, Road L-9, Industrial Estate, Gadoon Amazai, Swabi, Khyber Pakhtunkhwa on 22-06-2023

Case No. 23 APPROVAL OF MAP OF BSL 3 LAB (INSPECTION OF M/S NATIONAL INSTITUTE OF HEALTH (NIH), PARK ROAD, CHAK SHAHZAD, ISLAMABAD-PAKISTAN, ISLAMABAD

Evaluator: - Muhammad Yaqoob (AD-Lic)

M/s National Institute of Health, Chak Shahzad, Islamabad, is licensed unit and manufacturing various vaccines and sera.

With reference to the letter No. Dy No. 36/2024-Add-Dir(QALT) dated 02/02/2024, Honorable Federal Ombudsman took suo-moto notice on non-availability of anti-rabies vaccine

(ARV) by the National Institute of Health (NIH), Islamabad. Series of meetings were called by the Registrar, Federal Ombudsman in his office during month of January, 2024 to probe the non-availability of ARV and to come up with a way forward to overcome bottlenecks in smooth manufacturing of the vaccine. Both DRAP's and NIH representatives participated in these meetings.

Among the salient features of the meetings mentioned vide above quoted letter, relevant points are reproduced as under:

> "According to the inspection panel, the facility does not comply to Good Manufacturing Practices (GMP) and there were few critical observations related to the testing of vaccine in particular non-compliance of microbiology laboratory. Subsequently, an explanation letter was issued to the NIH management on 24-01-2024 for their non-compliance /non-adherence to the GMP. The management has addressed most of the observations and are preparing Corrective and Preventive Action (CAPA)
>
> During meeting held on 01-02-2024, Registrar Federal Ombudsman, Dr. Muhammad Salman CEO, NIH, Dr. Akhtar Abbass, Director Licensing, DRAP, Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Mrs Tehreem Sara, FID, DRAP participated. NIH management informed that being a public sector organization, it will take time to build a new microbiology laboratory as per DRAP's requirement, however, they have a GMP / GLP compliant BSL-III microbiology laboratory within the premises which can be utilized for microbiology testing after formal inspection / approval by DRAP's team.
>
> DRAP's representative apprised that in case the microbiology laboratory qualifies and formal approval is granted by the Central Licensing Board and additionally other observations pointed out by the panel are addressed then GMP certificate will be issued to the NIH"

The following panel conducted detail inspection on 12/02/2024 of BSL-III microbiology laboratory.

1. Dr, Ghazanfar Ali Khan, Additional Directro (Field office), QA&LT, DRAP, Islamabad
2. Mrs, Tehreem Sara, FID-(IV), DRAP, Islamabad.

The above panel submitted its recommendations vide letter No. 7-3/92-FID-I (Vol-II) dated 12/02/2024. Recommendations of the panel is reproduced as under;

> *"The laboratory is a purpose built facility for diagnostic testing, however, it meets the requirements for interim testing of anti-viral / anti-bacterial vaccines subject to campaign testing after till they establish their own microbiology laboratory. The management should fulfill the qualification criteria after complying de-contamination protocols laid in official compendium and shall meet regulatory requirements of lot release for their registered products. In the light of the foregoing, the panel recommends that the laboratory may be*

permitted for interim testing of anti-viral / antibacterial testing on campaign basis for a reasonable period to be decided by the Competent Authority."

Decision of the Central Licensing Board in 296th meeting

On the recommendations of the panel of inspectors, considering the facts on the record and after thread bare deliberation the Board decided to allow NIH for testing of anti-viral / anti-bacterial vaccines in GMP / GLP compliant BSL-III microbiology laboratory as an interim arrangement subject to campaign testing for a period not more than one year in general larger public interest under the intimation to Honorable Federal Ombudsman. The management should fulfill the qualification criteria after complying de-contamination protocols laid in official compendium and shall meet regulatory requirements of lot release for their registered products. The Board further decided that the NIH should develop GMP compliant microbiology testing laboratory within shortest possible time period.

Case No. 24 INFORMATION REGARDING RENTED / LEASED / SELF-OWNED PREMISES OF MANUFACTURERS / FIRMS OF RAWALPINDI / ISLAMABAD.

Evaluator: - Muhammad Yaqoob (AD-Lic)

The Central Licensing Board in its 294th meeting held on 27th December 2023 decided as under:

"The proposals/applications to establish a pharmaceutical unit on the rented premises shall not be entertained. At least one of the owners of the plot should be part of the management of the firm as a director/partner/owner. "

Meanwhile, Additional Director QA/LT (Field office DRAP Islamabad) has informed regarding rented, leased and self-owned premises of manufacturers/firms of Rawalpindi / Islamabad, which are as under;

Rented Firms	Leased Firms	Owned Firms
08	13	81

Decision of the Central Licensing Board in 296th meeting

The Board deliberated that rented premises involves a degree of uncertainty, dependency, limited expansion options, involves legal disputes and disruption of operations and can jeopardize the continuity of pharmaceutical unit. Furthermore, the Board decided to issue a notice to the firms established on rented or leased premises. This notice will advise them to shift to a place with ownership of firm as soon as possible. The firms will be advised to provide the shortest possible timeframe for this shift. An opportunity of personal hearing shall be provided to the firms if desired, so.

Case No. 25: <u>ADDITIONAL SECTION OF M/S WENOVO PHARMACEUTICALS, PLOT NO.31-32, SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI.</u>

M/s Wenovo Pharmaceuticals, Plot No.31-32, Small Industrial Estate, Taxila, Rawalpindi. DML No.000790 (Formulation). (Grant of Additional Sections) *Evaluator: - Abdullah (AD-Lic)*	01-04-2024	Very Good	1. Dr. Ghazanfar Ali, Additional Director (QA&LT), DRAP, Islamabad. 2. Mr. Hassan Afzal, DD, QALT, DRAP, Islamabad. 3. Mr. Muhammad Yaqoob, Assistant Director, DRAP, Karachi.

<u>Recommendations of the panel: -</u>

The establishment is a DML holder and has the necessary equipment / machinery for production and Quality Control / Quality Assurance of Dry Powder Injection (steroid) such as FTIR, HPLC, UV-Spectrophotometer etc. Taking into consideration the positive attitude and intent of the management, reviewing the documents and inspecting the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the grant of Additional Section of Dry Powder for Injection (steroid).

<u>Decision of the Central Licensing Board in 296th meeting:</u>

The Board considered and approved the grant of following additional and revised sections in the name of M/s Wenovo Pharmaceuticals, Plot No.31-32, Small Industrial Estate, Taxila, Rawalpindi under DML No. 000790 (Formulation) on the recommendations of the panel of experts for following Section subject to verification of necessary testing equipment as per decision of CLB in its 290th meeting:

i. Dry Powder for Injection (steroid)-Additional

<u>Case No. 26 Compliance with Court Orders in Cases Titled State Vs. Others</u>

Licensing division have received a letter dated March 27th, 2024 from the Secretary, Quality Control Board, Gilgit-Baltistan, Drug Control Administration Health Department on 1st April, 2024. The FR pertains to the compliance of court orders in ongoing drug cases. Along with this FR, copies previous letters from the Secretary QC Board GB, dated December 5, 2022, and a

letter from the Section Officer (Regulation) of the Health Secretariat GB, dated December 20, 2022 were also been enclosed.

The Secretary Quality Control Board GB has stated that several drug cases are under trial in Drug Count Gilgit Baltistan since long, in which twelve (12) cases have been returned by Drug Court Gilgit-Baltistan on the plea that despite of issuing repeated summons the above accused are not attending the court. Accordingly, the honorable Drug court Gilgit-Baltistan has directed the Quality Control Board G.B to approach the competent forum e.g., DRAP for cancellation or suspension of license/ registration of concerned related products. This matter was also deliberated during the 35th Meeting of the Quality Control Board Gilgit-Baltistan, where further advice and guidance were sought.

Furthermore, the letter indicates that the Quality Control Board Gilgit-Baltistan has decided to approach the Drug Regulatory Authority of Pakistan (DRAP) to pursue the cancellation or suspension of licenses/registrations for the relevant products (Flag-A) and have formally requested DRAP to take necessary action regarding the license suspension of the manufacturers (Flag-B).

Decision of the Central Licensing Board in 296th meeting:

The board decided to issue notices to the firms advising to comply with the decision of PQCB Gilgit Baltistan.

S#	Name of accused	Name of Manufacturing Firm	Cause of violation	Complain No
1.	Abdul Aleem Eirabi Director	M/s ALBRO Pharma (Pvt) Ltd., 340-S, Industrial Area kot Lakhpat, Lahore 54007.	Manufacture and Sale of substandard drug Tabs. Fenram, Batch#C1247	-
2.	Abdul Razaque Quality Control Incharge Director			
3.	Sajid Ali Jawa Director	M/s Jawa Pharma (Pvt) Ltd., 112/10 Quid-e-Azam Industrial Area kot Lakhpat, Lahore	i) Manufacture & sale of substandard drug Tab. Paracetamol 500mg Batch#7279. ii) Manufacture & sale of substandard drug Susp. Promet Batch#P125	
4.	Saeed Fatima Director			
5.	Muhammad Baqir Director			
6.	Muhammad Raza Jawa Director			
7.	Muhammad Ajmal Production Incharge			
8.	Showkat Hayat Quality Control Incharge			
9.	Sheimkh Muhammad Ahmad managing Partner	M/s ISIS Pharma & Chemical Works, 251/1-3 Sector 12C North Karachi Industrial Area, Karachi	Manufacture & sale of substandard Cap. Vibrdex Batch# 540211	78/2018
10.	Shakeel Ahmad Managing Partner			
11.	Nadeem Ahmad Managing Partner			

12.	Javed Akhtar managing Partner			
13.	Tasneem Akhtar Managing Partner			
14.	Asif Naqi Managing Partner			
15.	Muhammad Saleem Managing Partner			
16.	Muhammad Shoib CEO	M/s Drug Pharma (Pvt) Ltd., 28-KM Sheikhupura Road, Lahore	i) Manufacture & sale of susp. Manomol (Paracetamol) 60mL, Batch#256. ii) Manufacture & sale of Tabs. Folic Acid 5mg iii) Manufacture & sale of Syrup. Metocholopramide Batch# 33. iv) Manufacture & sale of Tabs. Metocholopramide 10mg Batch#19	68/2018
17.	Muhammad Bilal Director			
18.	Kokab Zaman Qureshi Director			71/2018
19.	Tahir Nawaz Hingra Director			68/2018
20.	Syeda Anita Maryam Mehdi Production Incharge			70/2018
21.	Abdul Jabbar Quality Control Incharge			
22.	Akhtar Hussain Bhutta CEO	M/s Naqabsons Labs (Pvt) Ltd 7-A, Friends Colony, Multan Road, Lahore.	Manufacture & sale of Benzyl Benzoate Batch#J-10-122	75/2014
23.	Arjuman Akhtar Production Incharge			
24.	Nadeem Akhtar Quality Control Incharge			
25.	Pervez Iqbal Seddiqui Managing Partner	M/s Venus Pharma (Pvt) Ltd 23-KM Multan Road, Lahore	Manufacture & sale of substandard Inj. Hyosine Batch#H-16513	-
26.	Umair Pervez Saddiqui Director			
27.	Muhammad Akbar Malhi Production Incharge			
28.	Fouzia Anjum Quality Control Incharge			
29.	Ashfaq Ahamad Director	M/s Redex Pharma Industries (Pvt) Ltd. Faisalabad	Manufacture & sale of Counterfeit Susp. Febrisol Batch #002	21/2014
30.	Muhammad Asif Rashif Production Incharge			
31.	Deedar Ali Quality Control Incharge			
32.	Nasiban Khatoon Director	M/s Mediate Pharma (Pvt) Ltd., 150-151, Sector 24, Korangi Industrial Area, Karachi	Manufacture & sale of substandard Caps. Ampicillin 250mg Batch#C-11032	74/2018
33.	Abdul Shakoor Director			
34.	Nasrullah Sheikh Director			
35.	Saira Shakoor Director			
36.	Fehmid Khalid Director			
37.	Muhammad Rashif Quality Control Incharge			
38.	Saif-ur-Rehman director/ Production Incharge	M/s Euro Pharma DP-2 Sector 12-D, North Karachi,	Manufacture & sale of substandard Susp. Paramol Batch# 183	23/2019
39.	Seema Qazi Quality Control Incharge			

		Industrial Area, Karachi		
40.	Mrs. Najma Perveen Director	M/s Standard Drug Company, 530, Mashriq Centre, Opp. National Stadium Karachi	Manufacture & sale of substandard Susp. Staifaminc Batch# SF014	22/2018
41.	Mr. Muhammad Haider Zaidi Quality Control I/c			
42.	Muhammad Haider Zaidi Quality Control Incharge	M/s Ankaz Pharma (Pvt) Ltd. Plot #12-A, North karachi	i) Manufacture & sale of substandard Tabs. Biprim DS Batch # Y-218. ii) Manufacture & sale of substandard Tabs. Rumin 400mg	28/2014 37/2014
43.	Ali Abbas Director			
44.	Naveed Mustafa Production Incharge			
45.	Rukhsana Khan Quality Control Incharge			

QA&LT Division

Case No. I: SHOW CAUSE NOTICE / PERSONAL HEARING OF M/S ROTEX PHARMA, PLOT # 206, 207, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.

BACKGROUND OF THE MATTER

1. The background of the matter is that M/s Rotex Pharma Pvt. Ltd. ('**Rotex Pharma**') has been issued Drug Manufacturing License under Section 5 of the Drugs Act, 1976, read with the Rule 3 of the Drugs (Licensing, Registration and Advertising) Rules, 1976 ('**Rules, 1976**'). Rotex Pharma is a high risk manufacturing facility which has a chequered history of manufacturing without complying with the 'Good Manufacturing Practices' ('**GMP**') *[as defined under Rule 2 (t) of the Rules, 1976]*.

2. A panel of inspectors including the area Federal Inspector of Drug inspected the Rotex Pharma on 01-02-2023 to investigate a complaint received from a consumer related to safety and quality of Rotex Pharma's anticancer product Tab Capex 500mg (Capecitabine). The Panel's Report noted very serious violations of GMP in the manufacturing process of Rotex Pharma. The Panel also recommended creation of a Panel of Experts to undertake a more thorough inspection of the manufacturing facility to ensure compliance with GMP and to avoid any risk to human health. Relevant excerpts are reproduced as under:

"…Based on the areas inspected, people met, the documents reviewed and considering the lack of Dedication of Oncology Section, containment studies, risk assessment based on OEL, appropriate cleaning validation, failure of regulatory compliance in terms of validations, absence of PQS, Quality by design concept and data integrity, absence of an effectively designed & maintained air filtration system as well as non-adherence to guidelines for HVAC mentioned earlier in point no. vii, it is evident that the firm is not only liable to manufacture products with observed quality defects, but also the practices of the firm or lack thereof may cause a serious health hazard to the personnel, product quality as well as the environment. Due to lack of dedication in layout as well as failure of instituting appropriate checks in critical processes/practices, there is also a serious risk of cross-contamination not only within the oncology section but also of Oncology medicine with General Medicines/products & Cephalosporins etc.

[…] It would also be pertinent to note that this inspection was limited to the investigation of subject complaint, it is therefore crucial that a full scale & exhaustive GMP audit of the firm should be carried out by a larger panel to ascertain whether the identified deficiencies exist in the rest of the manufacturing facility as well since the firm is involved in manufacturing of several critical products". *(emphasis has been added)*

2. Previously the inspection of Rotex Pharma was conducted on 11th and 12th of August, 2020 by a Panel of Inspectors, which also noted stark violations of GMP in its manufacturing facility. It was in this context that the Director Quality Assurance and Laboratory Testing constituted the Panel of Experts for inspection of Rotex Pharma in order to ensure its compliance with statutorily imposed GMP, based on the Report of which the instant Show Cause was issued. The 'Central Licensing Board' ('**CLB**') *[created under Section 3 (e) read with Section 5 of the Drugs Act, 1976]* has powers under Rule 8 (17) of the Rules, 1976 to "appoint a panel of experts" to inspect manufacturing units and submit a report to it. CLB has in its 273rd Meeting held on 15-01-2020 by exercising its powers under Rule 8 (10) of the Rules, 1976, delegated, inter alia, its powers to constitute panel for inspection of GMP, issuance of Show Cause to the 'Director Quality Assurance and Laboratory Testing'. The said Director is also a member of the CLB under Rule 8 (1) (b) of the Rules, 1976.

3. Through letter dated 06-02-2023 Rotex Pharma was informed of Panel of Experts who were to undertake GMP Inspection of its manufacturing facility. The inspection was duly planned and informed to the company vide office letter dated 09-02-2023. The same was communicated to Ms. Muavra Bukht, the Director Operations of Rotex Pharma via electronic communication by a member of the Panel. Subsequently, frequent exchange of information between the Director Operations of Rotex Pharma and the Panel took place. The Inspection continued from 20-02-2023 to 22-02-2023.

4. The Inspection Report was finalized by the Panel and forwarded to the Director Quality Assurance and Laboratory Testing through letter dated 03-03-2023. Several shortcomings and GMP non-compliances were noted during the course of inspection from which it was clearly evident that the various quality systems were either non-existent or not in a state of control; the Report very thoroughly highlighted parts of Schedule B which were violated by Rotex Pharma. The Inspection Report, *inter alia*, concluded the following:

"Based on the findings of the inspection, review of documents and records, systems, utilities, physical inspection of areas in the manufacturing facility mentioned above, and interview of personnel, it is concluded that the firm is not operating at an acceptable level of cGMP compliance. 21 Critical, 14 major and 03 other deficiencies were observed related to the product quality, risk of contamination and cross contamination, data integrity, qualification of processes personnel, equipment, and overall facility."

5. The Inspection Report after being prepared in time was then discussed with a team of experts called "Inspection Evaluation Committee", the meeting of which was held on 29th and 30th of March, 2023: the report was thoroughly and critically discussed, analyzed and scrutinized. The Minutes of the Meeting were forwarded to the Director Quality Assurance and Laboratory Testing through letter dated 20-04-2023. This second layer of analysis precluded any arbitrariness from the Inspection Report.

6. This Inspection Report was first challenged by Rotex Pharma before the learned Civil Court, Islamabad in a Suit titled "Rotex Pharma *Vs.* DRAP". The case is still pending, but no interim injunction restraining proceedings of the CLB has been granted. Subsequently, Show Cause Notice dated 28-04-2023 was issued to Rotex Pharma, which was challenged by it along with the Inspection Report before the Honorable Islamabad High Court, Islamabad in Writ Petition No. 1766 of 2023. The Honorable Court through Order dated 28-05-2023 while granting interim relief was pleased to direct Rotex Pharma to file reply to the Show Cause Notice in the following words:

"**C. M. No. 01/2023 Notice.**

Meanwhile, to the extent that an order has been passed to suspend production, such order will stay suspended till the next date of hearing. The respondents may continue with show cause proceedings and the petitioner will appear and file appropriate response."
7. Rotex Pharma was issued reminder of the Show Cause Notice dated 25-05-2023 but it did not file any reply. It was called for hearing in the 291st Meeting of the CLB held on 30th of May, 2023. Rotex Pharma represented by its learned Counsel Mr. Haroon Dugal, instead of filing reply and arguing the matter sought time to appeal against the Inspection Report which was granted in the interests of justice. Relevant excerpts from the Minutes of the Meeting are reproduced as hereunder:

"In compliance to letter dated 28th April 2023, firm's representative i.e. Mr. Haroon Dugal (Legal Advisor), Mr. Umar (CEO), Mrs. Mauvra Khawaja appeared before the Board and presented their stance, in which they submitted that they intend to challenge the inspection report. The firm requested to grant them an adjournment for enabling them to avail the statutory remedy against the inspection under the GMP Inspection Committee (Appeal) Regulations, 2017(S.R.O.1012(I)/2017

DECISION OF 291ST MEETING OF CLB: -
The Board after considering the statement of firm's representative and deliberation on the matter decided to accede the firm's request and adjourned the matter till the decision of GMP inspection committee as per S.R.O.1012(I)/2017."

8. Rotex Pharma appealed against the Inspection Report under Regulation 4 of the GMP Inspection Committee (Appeal) Regulations, 2017 hearing in which was held on 31-07-2023. The learned Counsel for Rotex Pharma Mr. Haroon Dugal again instead of arguing the matter or even arguing for interim relief, simply sought adjournment due to pendency of the instant matter before the Honorable Islamabad High Court, Islamabad. Rotex Pharma in the meantime continued production in violation of GMP.

9. The Honorable Islamabad High Court, Islamabad, through Order dated 08-11-2023 passed in W.P. No. 1766 of 2023 while setting aside directions contained in the Show Cause Notice to stop production was pleased to direct the following:

"The challenge of the petitioner claiming that the impugned show cause notice is corum non judice has not convinced the Court. The DRAP is therefore free to continue its show cause proceeding and pass an order in accordance with provisions of the Drugs Act and the Rules of 1976 after affording the petitioner an opportunity to be heard."
10. Consequent to the above reproduced directions of the Honorable Court, Second Reminder of the Show Cause Notice was issued to Rotex Pharma on 14-11-2023 with approval of the competent authority i.e. Director Quality Assurance and Laboratory Testing. Rotex Pharma was asked to file reply and was warned to definitely argue the matter before meeting of CLB to be held on 20-11-2023 with caution of a decision upon its failure, in the following words:

"7. Therefore, no adjournment on any count will be granted. In case, the matter is not argued by our form i.e. M/s Rotex Pharma, appropriate Order will be passed by the Central Licensing Board after perusal of the record."

11. The Counsel for Rotex Pharma Mr. Haroon Dugal again filed adjournment dated 17-11-2023 on the ground of pendency of other cases before the Honorable Lahore High Court, Lahore. However, on the very date on which the instant Meeting of CLB was to be held i.e. 20-11-2023, the learned Counsel for Rotex Pharma Mr. Haroon Dugal filed W.P. No. 75919 of 2023 before the Honorable Lahore High Court, Lahore on behalf of Rotex Pharma seeking interim relief with the effect of restraining the holding of the instant Meeting of CLB.

12. The Honorable Lahore High Court through Order dated 20-11-2023 dismissed the Petition while noting the malafide attempt of Rotex Pharma to abuse the process of Court to frustrate the instant Show Cause Notice, in the following words:

"[…] Learned counsel for the petitioner questioned that what coercive measures are being taken in pursuance to the Inspection Report. She submits that Show-Cause Notice dated 14.11.2023 has been issued but same is not appended with this petition.

2. Learned counsel for the respondent-DRAP entered appearance and submitted that on same subject-matter the petitioner filed Writ Petition No. 1766 of 2023 before the Islamabad High Court, which was decided on 08.11.2023 and the DRAP was allowed to continue its Show-Cause Notice proceedings, hence, reminder dated 14.11.2023 has been issued. Submits that without disclosing above facts, this petition has been filed at Lahore frustrate the Show-Cause Notice proceedings, which are already upheld by the Islamabad High Court. Submits that the petitioner has intentionally not approached the Islamabad High Court but this Court by not disclosing the correct facts including pendency of Civil Suit, where Inspection Report has been challenged.

3. Learned counsel for the petitioner, when confronted, seeks to withdraw this petition, which is **dismissed** being not pressed."

13. Reply to Show Cause was filed by Rotex Pharma dated 17-11-2023.

PROCEEDINGS OF THE CENTRAL LICENSING BOARD

14. Mr. Waheed Alam, Advocate appeared as proxy counsel for Mr. Haroon Dugal, the counsel for Rotex Pharma, and requested for adjournment. He was given chance to present and argue the case on behalf of Rotex Pharma but he chose not to. On query, he agreed that no Court or appellate authority or committee had granted interim relief restraining the proceedings by CLB. However, he contended that denial of adjournment would deprive Rotex Pharma from the right of hearing and thus would render the instant proceedings in violation of Article 10A of the Constitution of the Islamic Republic of Pakistan, 1973 (the '**Constitution**').

DISCUSSIONS

15. The first issue before CLB is as to whether the matter has to be adjourned on request by Mr. Haroon Dugal, learned Counsel for Rotex Pharma. It was noted that the learned Counsel has repeatedly sought adjournments on one count or another to delay adjudication of the matter; he had earlier been granted adjournment in the 291st Meeting of the CLB held on 30th of May, 2023 on the pretext of being given a change to appeal against the Inspection Report. In the Appellate Committee, the learned Counsel again sought adjournment.

16. Second Reminder of the Show Cause Notice issued to Rotex Pharma on 14-11-2023 gave a specific warning to definitely argue the matter before meeting of CLB to be held on 20-11-2023 with caution of a decision upon its failure, in the following words:
"7. Therefore, no adjournment on any count will be granted. In case, the matter is not argued by our form i.e. M/s Rotex Pharma, appropriate Order will be passed by the Central Licensing Board after perusal of the record."

17. Despite being granted a clear warning, the learned Counsel filed the adjournment for instant hearing which were conducted on 20-11-2023. On the very date he filed W.P. No. 75919 of 2023 before the Honorable Lahore High Court, Lahore, in a bid to frustrate and thwart the instant proceedings by misleading the Honorable Court. The purpose of adjournment seems to be merely an attempt tp buy time to stall the instant proceedings, therefore, this request has been filed with unclean hands and merits no indulgence.

18. The conduct of Rotex Pharma in using adjournment in order to frustrate the instant proceedings by forum shopping before the Honorable Lahore High Court, is spat with malafide and depreciable.

Therefore, on this score alone, the request for adjournment is found to be tainted with malice and is turned down.

19. Even otherwise, hearing by CLB has already been adjourned once on request by Rotex Pharma and therefore, the proceedings cannot be perpetually adjourned on its whim and caprice. As the learned Counsel has willingly absented himself from the right of hearing in a bid to frustrate the instant proceedings, therefore, he has willingly chosen not to avail the opportunity of personal hearing on behalf of Rotex Pharma. In **PLD 2020 Isl. 343** the Honorable Islamabad High Court was confronted with a matter wherein a show caused person sought continuous adjournments from hearing before a departmental authority. The Honorable Court upheld the ex-parte decision by the departmental authority upon the record in the following words:

"27. As regards the contention of the learned counsel for the appellants that Messrs Labbaik had not been provided an adequate opportunity of hearing, the same is contrary to the record. Vide the show cause notice dated 03.12.2019, the licencee/Messrs Labbaik was directed through its Chief Executive Officer ("C.E.O.") to appear for a personal hearing on 10.12.2019. On the said date, the C.E.O. of Messrs Labbaik did not appear before the respondent. However, on the request of Messrs Labbaik's authorized representative, Ms. Naila Noureen, Advocate, the hearing was rescheduled for 16.12.2019, on which date, neither the C.E.O. of Messrs Labbaik, nor his principal counsel appeared before the respondent. Yet another request for an adjournment was made which was not acceded to by the respondent. The respondent or its personal hearing committee is under no obligation to adjourn or reschedule personal hearings simply because the broadcast media or distribution service operator or its principal counsel happens to be preoccupied elsewhere. Enough indulgence had been shown by the respondent to Messrs Labbaik by rescheduling/adjourning the personal hearing on 10.12.2019 to 16.12.2019. In the case of Messrs Evernew Agencies v. Customs, Central Excise and Sales Tax Appellate Tribunal, Lahore (2006 PTD 207), it had been held that a party absenting himself to appear before an Authority could not claim that he was not provided an opportunity of a hearing. Additionally, in the case of Water and Power Development Authority, Lahore v. Messrs Bhatti Ice and Rice Mills, Buchiki (2004 YLR 1263), it had been held that where the petitioner was granted several opportunities to appear and file a reply but failed to do so, he cannot be subsequently allowed to take the plea that the order was passed in violation of the principles of natural justice."

20. A Division Bench of the Honorable Lahore High Court in **2006 PTD 207** also held the same in the following words:
"The appellant who has absented himself to appear cannot claim that he was not provided 'opportunity of hearing."
21. In **2008 MLD 132** similar maxim of law has been held:

"The right of hearing is qualified with attendance, and cannot be made an excuse to perpetuate an illegality […]"
22. The Honorable Supreme Court in **2010 SCMR 1119** also affirmed the trite law in the following words:

"11. The Court cannot force the party to address the arguments. It can at best afford him an opportunity to address it. If the party does not avail of that opportunity it can decide the matter on the basis of material available before the Court."
23. As Rotex Pharma had been issued warning with caution that matter would be decided based upon the available material, therefore, as per the latest judgment of the Honorable Supreme Court in **2023 SCMR 636**, CLB has to honor the warning and decide the matter. Relevant excerpts are reproduced as under:

"Where the Court has passed an order granting the last opportunity, it has not only passed a judicial order but also made a promise to the parties to the lis that no further adjournments will be granted for any reason. The Court must enforce its order and honour its promise. There is absolutely no room or choice to do anything else."

24. Lastly, as Rotex Pharma has been manufacturing life-saving drugs and medicines in non-compliance of the statutorily required GMP, therefore, granting adjournment would expose the people to drugs with compromised safety and quality. It is trite law that pubic interest would trump limited private interests; hence, for this and the above discussed reasons, the request for adjournment by the learned Counsel for Rotex Pharma is turned down and dismissed

25. The Board minutely reviewed the Inspection Report and Reply by Rotex Pharma dated 17-11-2023 and framed the following issues for decision:
i. As to whether the Inspection has been undertaken in accordance with the law?

ii. As to whether CLB can undertake proceedings during pendency of Rotex Pharma's appeal against the Inspection Report under Regulation 4 of the GMP Inspection Committee (Appeal) Regulations, 2017?

iii. As to whether Rotex Pharma has violated the law by manufacturing in non-compliance of GMP? If yes, then has it impacted the safety, quality and efficacy of the manufacturing process and thus endangered public health?

Seriatim findings on the above framed issues is as under:

Issue No. I: As to whether the Inspection has been undertaken in accordance with the law?

27. Rotex Pharma in Para. No. 3 of its Reply has contended that inspection of its manufacturing facility was undertaken on "Risk Based Benchmarking" based on alleged draft rules; that in Para. No. 4 of the Reply it has been argued that it was told that the inspection was only for academic purposes and for training of DRAP officials by the visiting WHO team and hence, the Inspection Report could not be used for any other purpose; that Para. No. 5 (iii) of the Reply emphasizes that GMP compliance inspection cannot be taken in the absence of any Federal Inspector of Drugs. Apart from these, Rotex Pharma has raised no objection regarding constitution or functioning of the Panel for Inspection.

28. It is stated as a way background that Drug Manufacturing License ('**DML**') is issued under Section 5 of the Drugs Act, 1976, read with the Rule 3 of the Rules, 1976. The DML holder has to meet the conditions as provided under Rule 16, 19 and 20 of the Rules, 1976. As a part of the aforementioned conditions, the License Holder has to **mandatorily** abide by GMP as provided under Schedule B of the Rules, 1976.

29. In order to ensure continuous compliance of GMP conditions to ensure safety, quality and efficacy of the drugs and medicines, under Rule 8 (17) of the Rules, 1976, CLB has powers to "appoint a panel of experts" to inspect manufacturing units and submit a report to it. Since the very purpose of inspection is to ensure compliance of manufacturing with the applicable laws/ conditions of license, therefore, the panel has to necessarily undertake GMP Inspection since GMP are a part of the Rules, 1976. Furthermore, as discussed in Para. No. 3 above, the Panel has been constituted strictly in accordance with the law.

30. Since compliance with GMP is a continuous process, therefore, regulator has to also adopt a dynamic process which continuously ensures compliance of pharmaceutical manufacturers with the GMP. International Council for Harmonization1 in its Guideline titled "Quality Risk Management" mandates the process of Risk based Quality Management to ensure a science-based decision making system for adherence to GMP by pharmaceutical manufacturers for ensuring quality of the drug (medicinal) product. This system provides a proactive means and system for DRAP as National Regulator to perform its statutory duty of identifying and controlling potential quality issues and compliance with GMP by the pharmaceutical manufacturers. **Section 7** (c) (ix) of the DRAP Act, 2012 casts statutory duty on DRAP to 'implement' the ICH Guidelines. Therefore, the term 'Risk Based Benchmarking" has been used for which is otherwise in substance a GMP compliance inspection of Rotex Pharma's manufacturing facility in accordance with the Rules, 1976. Rotex Pharma's contention that it arises out of some draft Rules is not based on facts and is fallacious.

31. Rule 8 (17) of the Rules, 1976, uses the term "panel of experts **or** inspectors". The word 'or' is disjunctive in nature and hence, both a panel of experts or inspectors are treated differently and both can freely exercise the powers to undertake GMP Inspection. The powers of Federal Inspector of Drugs under Section 18 do not preclude any Panel of Experts from undertaking GMP compliance inspection. Even powers of Federal Inspector of Drugs under Section 18 (1) of the Drugs Act, 1976, are made subject to rules; as Rules, 1976, expressly grant power to the Panel of Experts to inspect GMP compliance of manufacturers, therefore, this contention of Rotex Pharma also has no basis in law .

32. Lastly, Rotex Pharma has claimed that it was "emphatically told that the risk-based benchmarking is only for academic purposes and for the training of DRAP officials/ inspectors by the visiting WHO team. The Company was assured several times that the aforesaid inspection would not entail any penal consequences and report, if any, would be released for academic purposes only." This is a false and frivolous accusation. The alleged person who gave such undertaking has not been named and no means or time of such purported communication has also been identified. Therefore, this ground being baseless is also dismissed.

33. The instant Issue is decided against Rotex Pharma. The Panel of Inspection was formed in accordance with the law; subsequently, the inspection and its consequent report was also reached strictly in accordance with the law.

Issue No. II: As to whether CLB can undertake proceedings during pendency of Rotex Pharma's appeal against the Inspection Report under Regulation 4 of the GMP Inspection Committee (Appeal) Regulations, 2017?

34. Rotex Pharma in Para. No. 2 of the Reply has argued in brief that its appeal against the Inspection Report under Regulation 4 of the GMP Inspection Committee (Appeal) Regulations, 2017 is currently pending. Therefore, as per the principles of fair trial and the scheme of drug laws when an Inspection Report is under challenge, then no action can be taken by CLB on the basis of the said Report.

35. The said contention is wrong in law as there is no such compulsion for CLB to restrain its proceedings during the pendency of appeal against the Inspection Report. Even otherwise, it is trite law that mere pendency of appeal does not operate as stay of proceedings as held by the Honorable Islamabad High Court, Islamabad in **2016 CLD 2293**. Relevant excerpt is reproduced as under:

"The respondents ought not to have stayed their hands simply because the appellant had filed an appeal before this Court. Mere filing or pendency of an appeal does not operate as a stay of proceedings or as a suspension of the order against which an appeal is filed, unless a specific stay or injunctive order is passed. Reference in this regard may be made to the law laid down in the cases of Shah Wali v. Ghulam Din (PLD 1966 SC 983), Mst. Irshad Begum v. Mst. Gul Farasha (2003 YLR 724), Agro Dairies (Pvt.) Limited v. Agricultural Development Bank of Pakistan (2004 CLD 232) and Naeem Ullah Khalid v. Dr. Hafiz Mushtaq Ahmed (2007 YLR 1418)."

27. As discussed in Para. No. 9 above, Rotex Pharma did not argue the appeal on 31-07-2023 and sought adjournment on account of pendency of the matter before the Honorable Islamabad High Court. Rotex Pharma did not argue even to obtain interim relief knowing well that the authority with the power to grant final relief also has the power to grant interim relief. Since Rotex Pharma itself used adjournment as a strategy to protract the decision of the appeal, therefore, it cannot reap benefit from it to avoid the process of law in the instant matter.

28. In light of the foregoing, this Issue is also decided against Rotex Pharma.

Issue No. III. As to whether Rotex Pharma has violated the law by manufacturing in non-compliance of GMP? If yes, then has it impacted the safety, quality and efficacy of the manufacturing process and thus endangered public health?

29. The jurisprudence is by now settled that drug have to be manufactured mandatorily under conditions and practices required by the GMP regulations to assure that quality is built into the design and manufacturing process at every step. Any small and minor deviation can adversely affect the life of the patients and wreak a public health emergency.

30. The Board has minutely reviewed and discussed the Inspection Report and found it to be exhaustive and its findings to be well reasoned. The Report's findings have disclosed severe violations of GMP which severely impair safety and quality of the manufacturing process. The Report has catalogued the deficiencies and also referenced to the applicable laws which have been violated; for the sake of brevity the complete chart if not reproduced here but is to be read as a part of this Order. The Inspection Report before presentation before CLB was discussed with a team of experts called "Inspection Evaluation Committee", the meeting of which was held on 29th and 30th of March, 2023: the report was thoroughly and critically discussed, analyzed and scrutinized. This second layer of analysis precluded any arbitrariness from the Inspection Report.

31. The Board has reviewed the Reply of Rotex Pharma which apart from raising broad based and bland accusations against the Inspection Report and its findings has not raised any specific objection contradiction the Inspection Report's findings. It has been claimed by Rotex Pharma in Para. No. 5 (iv) of the Reply that "no complaint vis-à-vis the products manufactured by the company has been received so far"; as discussed in Para. No. 2 and 3 above, Rotex Pharma is a high risk manufacturing facility which has a chequered history of manufacturing without complying with GMP.

32. Rotex Pharma has relied upon some old reports to contend that it is GMP Compliant. The said Reports were of inspections carried with the limited purpose of verifying the suitability of granting additional Sections for manufacturing; none of them undertook a comprehensive GMP Compliance Inspection. Even otherwise the last thorough GMP inspection of the company was conducted on 11th and 12th of August, 2020 by a Panel of Inspectors to check compliance to GMP requirements which as discussed in Para. No. 2 above highlighted serious discrepancies in GMP Compliance by Rotex Pharma. The GMP certificate was valid till 11-08-2022, whereafter Rotex Pharma has not been issued a GMP Compliance Certificate. Even otherwise, compliance with GMP is a continuous process; compliance determined at one point in time, does not automatically mean that compliance will be deemed for all time to come. Therefore, Rotex Pharma's contention is false in law and wrong in facts.

33. Any violation of GMP adversely affect the quality, safety and efficacy of drugs, which might not even be reflected in the test reports. Hon'ble Lahore High Court through Order dated 09-09-2016 in W.P. No. 27314 of 2016 emphasized the importance of ensuring compliance with the 'Good Manufacturing Practices' to ensure safety, quality and efficacy of the drugs in accordance with the WHO Guidelines, in the following words:

"11. The WHO Guidelines provide the determinants for ensuring pharmaceutical quality. These guidelines determine the safety, potency and efficacy of the pharmaceutical drugs. The procedures for enforcement of these guidelines have been adopted and have comprehensively and exhaustively been provided for in Schedule B-1 and B-1A of the *Drugs (Licensing, Registering and Advertising) Rules, 1976* (the **Rules**) framed by the Federal Government pursuance to section 43 of the Drugs Act. Schedule B-II of the Rules provides for *"Good Manufacturing Practices (GMPs) for License to manufacture by way of formulation"*. GMP is part of a quality system covering the manufacture and testing of pharmaceutical dosage forms or drugs and active pharmaceutical ingredients, diagnostics, pharmaceutical products and medical devices. Quality Assurance is a wide-ranging concept covering all matters, which individually or collectively influence the quality of a product. GMP is the aspect of quality assurance that ensures that medicinal products are produced, manufactured and controlled to the quality standards appropriate to their intended use and as required by the product specification. GMP defines quality measured for both production and quality control and defines general measures to ensure that processes necessary for

production and testing are clearly defined, validated, reviewed, and documented , and that the personnel, premises and materials are suitable for the production of pharmaceuticals and biologicals including vaccines. GMP also has legal components, covering responsibilities for distribution, contract manufacturing and testing, and responses to product defects and complaints. ”

“13. […] In short, the Rules comprehensively cover and provide for all aspect of quality control appropriate to the manufacture of pharmaceutical products.”
“15. […] The system of drug regulation, is fashioned in a manner in which standards are prescribed, in the shape of Good Manufacturing Practices, WHO Guidelines and also through grant of licenses for manufacture and import of drugs. The task to inspect the, manufacturing facilities also falls on the shoulders of the Federal and Provincial Governments through their inspectors. The various Boards/authorities created under the two enactments are, inter alia, charged with the functions of […] granting licenses for manufacturing and sale of drugs; inspecting the premises of the manufacturer to ensure compliance with regulations and GMPs […] taking action for suspension/ cancellation of licenses …” *(emphasis has been added)*
34. The Honorable Islamabad High Court, Islamabad, through Order dated 22-02-2022 in W.P. No. 3086/ 2021 by relying on the abovementioned **Macter International** Judgment, upheld decision by the CLB to cancel Manufacturing License of an entity which was manufacturing without compliance with GMP.

35. Due to defects in Good Manufacturing Practices, a number of patients died in the Punjab Institute of Cardiology, Lahore. The learned Judicial Commission headed by Hon’ble Mr. J. Ijaz-ul-Ahsan in the Report on Defective Drug in the Punjab Institute of Cardiology, also concluded that the lack of adherence to ‘Good Manufacturing Practices’ resulted in the loss of lives and directed its strong enforcement:

“13.1 (b). During the course of proceedings before the Tribunal it has transpired that a large number of manufacturers engaged in manufacture of pharmaceuticals in Punjab and other provinces may not be in compliance of provisions of Drugs Act, 1976. Further, we have reason to believe that an equal number of manufacturers all over the country are not cGMP compliant. This is an alarming situation for the reason that the only safety net against errors, omissions, defects, contamination etc. of drugs and preventing such drugs from reaching the hospitals, markets and patients is at the stage of manufacturing. Compliance with cGMP requirements minimizes the possibility of defective or injurious drugs reaching the hospital, markets or patients. Once a defective, contaminated or injurious drug comes out of the factory, it is extremely difficult to detect the same and where an exercise of such detection is undertaken, it takes time, effort and resources, which in most instances are not available in Pakistan. This is an all the more reason to stress on strict compliance of cGMP requirements.” *(emphasis has been added)*
36. The Honorable Supreme Court through Order dated 28-07-2020 passed in C.P. No. 70-K of 2019 has held that regulatory action safety and quality of the manufacturing process of drugs and medicines “has direct nexus with the rights of public at large guaranteed under the constitution”. On the one hand Rotex Pharma is vigorously contesting the matter, on the other hand it has submitted a Corrective and Preventive Action as annexure with its Reply in which it while admitting all deficiencies highlighted by the Inspection Report has contended that the same have since been corrected and risks prevented.

37. Corrective and Preventive Action cannot be determined merely from documents; it requires a thorough inspection of the manufacturing facility. Review of the Inspection Report along with tacit admission by Rotex Pharma of the deficiencies by submitting Corrective and Preventive Action as annexure with its Reply, reveals that Rotex Pharma was manufacturing without following the applicable GMP as mandated under the law. The deficiencies are of such a serious nature which severely and adversely affect safety, quality and efficacy of the manufacturing process and thus endangered public health. Therefore, Rotex Pharma has not only violated the terms and conditions of its Drug Manufacturing License but the Rules, 1976 as well by manufacturing drugs and medicines in non-compliance of GMP. This issue is also decided against Rotex Pharma.

DECISION OF 293rd MEETING OF CLB:

For the foregoing reasons and discussions, the Central Licensing Board has decided that it is sufficiently proven that M/s Rotex Pharma Pvt. Ltd. was manufacturing drugs and medicines without following the applicable Good Manufacturing Practices as mandated under the law. The deficiencies are of such a serious nature, which severely and adversely affect safety, quality and efficacy of the manufacturing process and endangers public health. Therefore, M/s Rotex Pharma Pvt. Ltd. has not only violated the terms and conditions of its Drug Manufacturing License but Drugs (Licensing, Registration and Advertising) Rules, 1976 as well by manufacturing drugs and medicines in non-compliance of Good Manufacturing Practices which endangers public health;

Hence, the Drug Manufacturing License of M/s Rotex Pharma Pvt. Ltd. is suspended with immediate effect under Section 41 of the Drugs Act, 1976, read with Rule 8 (16) of the Drugs (Licensing, Registration and Advertising) Rules, 1976. It shall remain suspended till verification by a Panel of Experts that all deficiencies have been removed and M/s Rotex Pharma Pvt. Ltd. which were noted in the Inspection Report and the manufacturing process is in accordance with Good Manufacturing Practices and the applicable law;

The Panel of Experts is constituted as below by exercising powers under Rule 8 (17) of the Drugs (Licensing, Registration and Advertising) Rules, 1976. A comprehensive report in this regard will be placed by it before the Central Licensing Board:

i. Chief Drug Inspector, Punjab.

ii. Additional Director PE&R, DRAP Islamabad.

iii. Additional Director Licensing, DRAP Islamabad.

iv. Area FID, DRAP Islamabad.

Legal Affairs Division of DRAP is requested to place the instant Order before the Honorable High Islamabad High Court, Islamabad in compliance of its Order dated 08-11-2023 passed in W.P. No. 1766 of 2023.

The following comprehensive report has been placed before the board. Additional Director PE&R, DRAP Islamabad did not join the panel for the said inspection.

INSPECTION REPORT

PART A:	
Inspected site(s):	M/s Rotex Pharma, Plot # 206 & 207, Industrial Triangle Kahuta Road, Islamabad
Activities carried out by manufacturer:	1. Manufacture of Finished Medicinal Product 2. Packaging 3. Batch Control and Batch Release
Inspection date(s):	22nd-25th, January, 2024, 30th January 2024, 15th February 2024 & 20th February 2024

Inspector(s):	1. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab 2. Mr. Babar Khan, Additional Director, Licensing Division DRAP, Islamabad 3. Ms. Saadia Mahwish, Federal Inspector of Drugs, DRAP, Islamabad
References:	DML No. 000651 by way of Formulation
Introduction of the Firm:	The pharmaceutical unit comprised of 02 blocks, one for Pharmaceutical production and the other is for animal house. Pharmaceutical production block is triple storey building (ground, first and second floor). The detail of manufacturing sections present on each story is as under. At the time of inspection, the firm possessed 30 approved sections annexed as Annexure III. The unit is shared facility currently manufacturing General, Cephalosporin, Carbapenem, Steroidal, and Oncology products. Following new section have been approved but currently, no Market Authorization has been granted for those sections. 1.Biotech. rDNA Vial 2.Biological Non rDNA Vial 3.Biological Vaccine Ampoule 4.Restructuring /Extension of QC Firm has been granted approval of layout plan of the following dated 28-12-2022.

	Ground Floor **New.** **Prefilled Syringe Section Oncology (Anticancer / Antineoplastic).** **Amendments:** Raw Material Store Restructuring / Extension. **First Floor** **New:** **Sachet section (Cephalosporin)** Biological Non-rDNA (Prefilled syringe section) Biological (Cartridge filling / capping section) Biological r-DNA (Liquid Vial Filling / sealing section SVP) with addition of a **lyophilizer** Liquid Vial Filling / Sealing Section (Steroid) in place of Eye /Ear/Nasal Drop Section (Steroid) **Relocation:** Formulation area (Steroid) Liquid Ampoule Filling / Sealing Section (Steroid) Liquid Ampoule filling /sealing section (Steroid)-II **Expansion** Extension /Restructuring of Biological packing hall / labelling section **Second Floor** **New** Liquid ampoule filling /sealing section –II in place of Psychotropic ampoule section Liquid Vial Filling /sealing (SVP) General /Antibiotic section with addition of a **lyophilizer** in place of Psychotropic vial section Nasal Spray /drops Section in place of solution /external preparation section **Amendment** Extension / Restructuring / Relocation in General sterile area

	Extension /Restructuring / Relocation in Optical, IPQ, packing hall, Terminal Sterilization	
Brief history of inspection activities undertaken:		
Purpose & date of Inspection	**Names of Inspectors**	**Outcome of Inspection/ Recommendation**
For grant of Sections reference letter No. F. 1-53/2003-Lic (Vol-II), dated 04-09-2018. **Date: 19th Sep., 2018**	1. Dr. Obaidullah, Director (PE & R) DRAP, Islamabad 2. Mr. Manzoor Ali Bozdar, Director (Lic.) DRAP, Islamabad. 3. Mr. Babar Khan, (Federal Inspector of Drugs-I) DRAP, Islamabad	Grant of new/additional sections 1. Sterile Dry Powder Vial (Steroid) 2. Sterile Liquid ampoule (Steroid) 3. Topical (Steroid) 4. Ear/Eye/Nasal Drops (Steroid) 5. Warehouse (Steroid) 6. Sterile Liquid Vial (General) 7. Sterile Liquid ampoule, SVP (General) 8. Ear/Eye Drops (General) 9. Oral Liquid (General) 10. Tablet (General) 11. Capsule (General) 12. Sachet (General) 13. Oral Dry Suspension (General) 14. Cream/Ointment (General) 15. Dry Powder Vial, SVP (General) 16. Liquid Vial SVP (X ray contrast media)
For grant of Sections reference letter No. F. 1-53/2003-Lic (Vol-II), dated 23-08-2019. **Date: 28th Jan., 2020**	1. Dr. Noor Us Saba, Director (Bio.) DRAP, Islamabad 2. Mr. Ayyaz Ahmed Add. Dir. (Lic.) DRAP, Islamabad. 3. Mr. Babar Khan, (Federal Inspector of Drugs-I) DRAP, Islamabad	Grant of new/additional sections namely 1. Biotech. rDNA Vial 2. Biological Non rDNA Vial 3. Biological Vaccine Ampoule 4. Restructuring /Extension of QC
For issuance of cGMP certificate for institutional supply (Local) with reference to request vide letter No.ROTEX/No._2018/035, ROTEX/20/158 & 159 dated 11-07-2018 & 23-01-2020. **Date:11th&12thAug., 2020**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I) DRAP, Islamabad 2. Dr. Ishtaiq Shafiq AD, Import & Expert 3. Mr. Babar Khan, (Federal Inspector of Drugs-I) DRAP, Islamabad	Grant of GMP Certificate.

Investigational Inspection regarding patient complaint received by the Email regarding Tab Capex 500mg (Capecitabine) **Date: 1st Feb., 2023**	1. Saadia Mahwish, (Federal Inspector of Drugs-I) DRAP, Islamabad 2. Mehwish Tanveer, AD, Quality Control	Recall of Tab Capex 500mg (Capecitabine) batch# D204006, and Recommendation of full scale & exhaustive GMP audit of the firm
WHO Observed comprehensive GMP inspection for benchmarking of Rotex Pharma **Date: 20th -22nd, February, 2023**	1. Dr. Mahvash Ansari, Lead Auditor 2. Dr. Uzma Barkat, Auditor 3. Dr. Affan Ali, Auditor	Suspension of Drug Manufacturing License with immediate effect under Section 41 of Drugs Act, 1976, read with Rule 8(16) of the Drugs (Licensing, Registration & Advertising) Rules, 1976. by CLB in its 293rd meeting held on 20th November 2023 & communicated vide No.F.4-28/2008-QA dated 2nd January 2024
Scope of Inspection:	The scope of the inspection, in light of decision of CLB in its 293rd meeting held on 20th November 2023 wherein DML of the firm M/s Rotex Pharma was suspended, was verification by a Panel of Experts that all deficiencies have been removed which were noted in the Inspection report and the manufacturing process is in accordance with GMP and applicable law. CLB by exercising powers under Rule 8(17) of the Dugs (LRA) Rules, 1976 constitued the following panel of experts: i. Chief Drug Inspector, Punjab ii. Additional Director, PE&R, DRAP, Islamabad iii. Additional Director Licensing, DRAP, Islamabad iv. Area FID, DRAP, Islamabad Additional Director PE&R could not participate in the inspection due to professional responsibilities.	

Inspected area(s):	1. Raw material store 2. Packaging Material Store 3. Oncology section 4. Dry powder Vial (Cephalosporin) 5. Dry powder suspension (Cephalosporin) 6. Capsule (Cephalosporin) 7. Utilities (HVAC, Water, Compressed air) 8. Quality Control Laboratory 9. Microbiology Laboratory

PART B

S.No.	Observations	Remarks
01	**Organizational Structure** There was no system for defining, controlling and documenting the organizational and structure. There was no procedure for development of organogram. There was no procedure for controlling organogram As per discussion with Director Operations, Manager Microbiology is independent, however the organogram does not have its provision. No SOP for writing job description, The firm do not have JD for Manager Validation and Compliance. There was provision of nomination of deputies in job description. No deputies are nominated. The experience required for Manager microbiology is 2 years whereas in case of production manager it is 10 years. There was no provision of writing microbiology documents provided in the JD of manager microbiology; however, he writes the documents.	SOP for documenting and controlling organizational structure titled "SOP for defining Roles & Responsibilities of Employees in various Departments and Departmental Organogram" HR-G-SOP-001 Rev:00 Effective date 18-12-2023 had been developed and organogram document# HR-F-0001 Rev: 00 effective date 01-01-2024had been prepared accordingly. According to the new organogram Manager Microbiology is reporting to GM Quality Operations. SOP titled Job Description HR-G-SOP-002 Rev:00 Effective date 20-12 2023 had been developed by the firm & JDs have been accordingly developed The designation of deputies was removed and instead designation of Assistant Manager had been included in the organogram and their respective JDs had been prepared. The requirement of 2 years' experience was mentioned in JD for Microbiology Lab Assistant whereas JD for Microbiologist mentions 12 years of experience In the JD of Manager Microbiology, it is mentioned that they will review Microbiology documents but not specifically mentioned in SOP The firm has hired a GM Quality Operations who is reporting directly to CEO. Managers of QA, QC and Microbiology are independently reporting to GM Quality

	There was conflict of interest as Director Operations was owner's spouse and she was responsible for overseeing the QMS as well as technical operations, despite having no relevant qualification and training. There was scarcity of human resource as observed during the course of inspection which was affecting all operations. **Major**	Operations. In the JD for Director Operations HR-JD-001, under the title of Job Objective, implementation of GMP & QA Guidelines is mentioned while under the title of responsibilities no task related to GMP or QA had been assigned. As per organogram GM Production Operations, managers of R&D (Formulation & analytical), manager warehouse, are still reporting to her. In the presence of GM Quality Operations, who is independent, the need for Director Operations to look after GMP and QA becomes redundant. Although, new human resource has been hired but still there is not enough staff in Production Department
2.	**Training system was inadequate as** Training policy and SOP were inconsistent, the training SOP lacked about training schedule, training need assessment, records, trainer's evaluation etc. There was no provision for approval of training material was provided, so no training material was being approved. There was no training was provided to the personnel working in production There was no relevant training record was found for the Director Operations who is also acting as MR and responsible for implementation of quality system and conduct of trainings. The training record comprised of only two forms one was schedule and other was training evaluation which was filled by trainer only. The training provides for storage of punches, states, *apply IPA on punches before storage*. The production manager communicated that they store punches after applying paraffin oil hence there is lack of training or its effectiveness The procedure for analyst qualification was not elaborative for evaluation, as one of the result was OOS, however, the analyst was trained to calculate average of triplicate results. No procedure for rounding off is available, although the analyst has rounded 97.7% to 98%.	The policy for training has been made obsolete and has been replaced by revised SOP for Training Program Doc# QA-G-SOP-003 revision No. 05 effective date 15-12-2024 which replaces SOP# QA-SOP-SE&D-0010 and accordingly training need assessments had been prepared however, evaluation of training plan for the year 2024 QA-F-0012 showed that training of the employees had been planned for relevant SOPs (& SAPs for QC analysts) throughout the year whereas employees were supposed to carry out their duties in accordance with those very same SOPs. Moreover, no consideration had been given to scheduling training of the employees on either International Guidelines or local regulations. Most of the reviewed QA documents were found to be prepared by QA officer Ms Kiran Tauqeer, however, review of her training record showed that she had not been given any training on International Guidelines, writing of SOPs or GMP Principles such as Deviation Handling & Change Management, Cleaning Validation, Rot Cause Analysis, Risk Management etc. instead, she had received training on SOPs that she herself had prepared. Furthermore, SOP on training and SOP for Analyst Qualification QC-G-SOP-009 effective date 31-12-2023 did not define the competency matrix and therefore the level of training required for fresh graduate vs. someone with previous experience. Some of the training records reviewed had proper attendance sheets as well as assessments of the effectiveness of training for the trained employees were also found available. SOP for rounding off data QC-G-SOP-008 effective date 21-12-2023 and SOP for entry and exit PD-GEN-SOP-060 effective date 02-01-2024 had been found prepared and the requisite training record of the relevant employees as well as post training quiz was found available.

	One of the production operator was wearing production uniform and shoes while came for discussion at meeting room outside the production facility, which shows the lack of training regarding general requirements of GMP. **Major**	
03.	**Document Control** Document control system is compromised as • Many documents were found only signed but not dated e.g. Training policy and Job descriptions. • Document retrieval was too slow the firm is found to be under staffed, while some of the documents were printed at the same time during inspection and signed in back dates. • No pictorial demonstration was provided in change room; no SOP or work instructions were provided for change room. • In the change room of Oncology section main entry, the change instructions displayed were those applicable to other sections, and not the oncology specific. **Critical**	The firm has revised most of the SOPs and revamped their documentation to replace the old ones, the documents reviewed by the panel were found to be appropriately signed and dated. The document retrieval time was still found to be very slow and many documents were provided by the firm after multiple reminders sometimes after lapse of several hours to one day. Pictorial demonstrations were found to be displayed in all the change rooms visited by the panel Elaborate entry & exit mechanism had been devised for oncology section, with showers provided at the exit for the workers to de-contaminate at the end of each shift. Secondary and tertiary changeover with PPEs had been provided& pictorial demonstration of each step at each step was found to be displayed.
04	**Record and Review of Data** For quality records, there were two types of log books, one is printed sheets tape bounded and other were log registers There were frequent blank fields, cross outs, omissions, use of correction fluid and even lead pencil in log registers. In encapsulation area, logbook number of RP-PD-GEN-M018, pencil was found to be used while **pages** from 1-7 were found torn. Quality data was not reliable as Critical data (raw data, meta data of	For year 2024 new logbooks had been issued in all the departments which consisted of numbered and controlled sheets held together by tape binding; these included daily temperature/humidity records, daily calibrations, cleaning records of machinery, utilization logbooks etc. Registers were being used for ledgers such as Raw Material etc. The firm has issued controlled, tape bound worksheets to the analysts for the recording raw data and making

	calculations) was being recorded on loose uncontrolled sheets of paper as observed during review of OOS investigation, and also verified during onsite visit of quality control laboratory where dustbins were found to have torn pieces of paper having calculations on those papers.	calculations; each analyst had been issued their own specific logbook identified by its unique number.
	Logbook for analyst worksheets, RP-QC-L001 Version 03, Issued date: 2020 was not specific for analyst. Moreover, no standard format or controlled sheets for calculation was being used.	During the onsite visit, the relevant SOPs, daily verification logbooks etc were found to be placed at the point of use e.g., in RMS, Cephalosporin Section, Steroid Section, Oncology Section etc. the logbooks for the year 2023 were reviewed and were found to be filled by the same individual with the same signatures.
	Neither SOPs, nor log books were found to be placed at point of use such as weighing balances, sampling and dispensing booth, for real time recording of data. Daily verification log book of weighing balance in store was seemed to be filled in one go for multiple entries as consecutive entries were made with same hand writing and flow, and then some other with other hand writing, however, signatures were found to be same for all hand writings. Same was observed in recording of QC data in instrument log book RP-QC-L002 Ver. 02, Issue: Sep 2019, during the verification of conductivity meter, lab attendant recorded the entries along with signature, however previous entries were in different handwriting but with the same signature. One of the employees, office assistant was found filling the logbook of First aid of previous 2 weeks.	The firm had taken measures to ensure adherence to previous SOP RP-QA-SOP-004 & RP-QA-SOP-003 and had also revised SOP for sampling doc# QA-G-SOP-022 Revision 004 effective date 09-01-2024; training had been provided to the relevant officers on the new SOP.
	Recorded data for sampling was inconsistent with the actual practices and many discrepancies were found. Such as “sampled” labels were pasted on 5 boxes despite the fact that only one box was found opened (rest were sealed) for sampling of glass vials whereas, as per SOP they should have opened 6 boxes and should have inspected 500 vials, whereas only 4 vials from one box found sampled.	The firm has attempted to improve the data integrity issue first of all by outlining the parameters as well as Roles & Responsibilities in QA-G-SOP-024 revision 01 effective date 22-12-2023 Temperature and humidity were found to be within defined limits during the onsite visit The firm has revised SOP for review of QC Test Data QC-G-SOP-016 Revision 03 effective date 31-12-2023 according to which after completion of testing all the raw data and calculations are to be reviewed by the Assistant QCM for accuracy and integrity. During the QC visit,

	Moreover, as per QC record the sample quantity was 50 vials which was inconsistent to the actual situation. In a room adjacent to the conference room, a blank calibration label was found on the table of office assistant. It shows that the calibration status of equipment is uncontrolled and not reliable due to data integrity. In blistering area, it was observed that the temperature was exceeding that is 26.2 degrees centigrade at 3:46 PM however the BMR recorded at 3:50 PM as 25 degrees centigrade Similarly, the routine and periodic review, as well as the approval of data was inadequate, specifically in critical data. Although log book for Batch Release, Document ID: RP-QA-L01R showed Personnel responsible for reviewing and checking data, but on many pages' review/check/final approval column was signed despite the fact that analysis was not done yet, QA officer informed that these signature are used to have an indication of a person to whom currently BMR was handed over rather than a reviewing, checking or approval procedure, hence there was no evidence of the review. Final review of BMR is not attributable as the SOP the term QA Team, was written **There was no SOP or utilization record found for the Weighing balance (EQ ID RP-WH-M002), placed in the receiving area, although daily verification of this balance was presented it did not cover the working range of the balance. Working range was not mentioned on any of the weighing balance available in the facility.** **Critical**	analyst logbooks were reviewed and the data was found to be verified and signed by the Assistant QCM. The BMR for Inj. DMX 4mg/ml (Dexamethasone) Batch# F279044 was reviewed and was found to contain signatures of responsible individual at each step; the final review had been done by the Quality Assurance Manager. The firm had revised the equipment ID system and assigned new IDs to all equipment, however, utilization record matching with the assigned equipment ID had been found available in RMS as well as the rest of the facility. Working range of weighing balances had been taped on all weighing balances. The firm was advised to revise the daily calibration log sheets to incorporate working range of all the weighing balances.

05.	**Access and privileges** There was no system in place defining the access and privileges such as data deletion, database amendment or system configuration. Specifically, in computerized systems attached with standalone equipment of quality control, single login access having all the privileges was used and password was being shared among all the users. Such as HPLC, Equipment ID: RP-QC-INS-055, was being used by two analysts and a quality control manager where all users had same login hence sharing password. **Critical**	The firm had developed document titled SOP for Access Control on Audit Trail of Software generated data in QC lab doc# QC-G-SOP-010 rev#00 effective date 19-12-2023 for defining access & privileges in place e.g., unique logins & passwords had been provided for the QCM, Assistant QCM and all the analysts for different equipment such as HPLC. However, privileges were not adequately controlled in accordance with SOP mentioned above; e.g., analysts had the privilege of audit trail review as well as to make changes in method of analyses even those which had already been verified and validated. Similarly, consideration had not been given to restricting the access to delete or amend data base in practice.
06.	**Data Backup and storage** No provision for data backup and restore was available for the computerized systems Business continuity plan was not available. **Major**	Provision for backup of data had been provided in the form of internal backup as well as on external drive and in this regard an SOP doc# IT-G-SOP-001 rev#00 effective date 07-01-2024 had been developed which defined the frequency of backup on local server and external media. SOP for Business continuity plan doc# BD-G-SOP-001 rev#00 effective date 18-12-2023 was found available.
07.	**Change Control and Management** The system for change management and control was not in place. An SOP was available which was not implemented. SOP, RP-QA-SOP-043, Ver. 03 Issue Jan 2021, Review: Jan 2024**,** was reviewed.The scope of the procedure, "to control and record all the changes made to: • QMS documents • Plant facility, layout and premises • Equipment and instruments • Processes and systems • Product and any of its quality or operational parameters." 11 changes were logged in 2022 while 8 forms available in the file of 2021. Change control log of 2021 was not available. Trending and tracking was not being done. No mention of trending or tracking in the SOP. The	Change Control Form record RP-QA-L017 version 02 issued Jan 2022 was reviewed for the year 2023; therein 16 Change Controls had been logged, however, none of the structural changes carried out by the firm such as addition of showers on the exit buffers in Oncology section, building of brick wall instead of glass partition in coating section of Oncology Tablet section etc. Similarly, one of the entry points into RMS of oncology was through non-sterile manufacturing corridor which was closed off by a wall, instead a new entry point had been provided after the secondary changeover but again since Change control was not initiated, no impact analysis was done. Additionally, changes in water treatment system and HVAC had also not been managed through change control. However, shifting of specifications of some products from Manufacturer to official specs had been managed through change control. Revamping of QMS had been done through change control# CC-016-2023 dated 01-12-2023. However, in the change impact evaluation done by QA it was determined that the change will not impact Batch records or SOPs, even though according to the firm, SOPs as well as related forms and documents had undergone a major revision as did the format of BMRs. Introduction

	log book presented had entries forms 08-7-22 to 20-11-2022. The dates were not in sequential order as the last entry was dated “ -02-2022”. This entry was done afterwards in the log book. Change control form was not initiated for changes in the water treatment plant as a real-time activity. On interviewing the DO and QAM, it was noted that the change control was not initiated then, no risk assessment and management was documented and the DO informed that the change control form was filled a week before the inspection although the change had been brought in Feb 2022. The form did not bear any number or date. The DO had filled the Form and signed it in back date of Nov 22 the week before the inspection. Entry 3 had status “closed but the closing date was not mentioned. Following change control forms were reviewed. • CC-009-022 dated 15-10-2022 Title: “Addition of buffers outside ONCO washing area” Risk assessment and impact evaluation by QA had not been done. The change was categorized as Major. Section for Departmental review was left blank. Closeout date given on the form was 06-02-2023. • CC-008-022 dated 14-10-2022, Title: “RMS Oncology” Whereby, the oncology raw material store was expanded. Risk assessment and impact evaluation by QA had not been done. The change was categorized as Major. However, the Final approval was not done by QA. The closeout part was also left blank. **Major**	of personnel buffer dispensing room of oncology RMS as well as a material entry buffer was carried out through change control# CC-014-2023 dated 08-08-2023 however, firstly change category i.e., major/critical had been left blank, secondly, in impact evaluation, it was assumed that there will be no impact on equipment qualification & validation status or purity and quality of the product due to which appropriate measures to mitigate risk had not been taken. This shows that understanding of impact/risk analysis is lacking and is one area where training of the personnel involved from external sources in accordance with International Guidelines should be considered. For the year 2024, SOP for Change Control had been revised, the new SOP doc# QA-G-SOP-004 rev#03 effective date 23-12-2023

08.	**Deviation management** The system for identification, recording and handling of deviations was not in place. SOP was available but not being fully implemented. SOP RP-QA-SOP-016, Ver 03, Issue Sep 2020, Review: Sep 2023, was reviewed. 06 deviations were logged in 2022 (from 19-9-2022 till 22-12-2022), 03 in 2023 (till date). Log of 2021 was not available. Trending and tracking were not being done neither mentioned in the SOP. The RCA and risk assessment system did not exist. It was noted that there was a lack of clear understanding of the concept of deviation by the personnel, the reason and importance of its recording and the impact it may have. Three of the recorded deviations were reviewed. Deviation No. 03/QA/22 Date: 03-10-2022 Volden Forte SR 100mg Batch # A059035 In the first one, "Color variation in tablet color of Volden Forte SR 100mg was observed at coating stage". Reason identified by the company was change of source of coating material from import (ICU-White) to local purchase (Aquashine White). No risk assessment was done. Process validation was not done. Stability studies were not initiated as evident from the records seen. The log books of coating and dispensing for this batch were seen to verify if the deviation had been referenced to. But no such entry/remarks were found. Deviation No. 001/QA/2023 Date: 06-02-2023	9 deviations had been recorded in 2023 on format RP-QA-L015 issue date Jan 2022, it was observed that most of the deviations after the previous panel's audit were pertaining to the observations made by them but, the deviation record did not encompass all of the panel's observations. RCA and risk assessment relating to the WHO observed audit conducted by DRAP was done as a separate exercise by employing fish bone and 5 whys tools; improvement was observed in carrying out RCA however, personnel need training in identifying the root cause so that proposed CAPA is in line with International Guidelines. The firm has revised the SOP for Deviation Handling doc# QA-G-SOP-005 rev# 04 effective date 04-01-2024 and has incorporated RCA, risk assessment, trending & tracking into the routine procedure. However, further improvement is required by the firm to ensure that all deviations that take place during routine manufacturing operations should be duly recorded, investigated and CAPA should be raised against them.

	Vancomed Injection 500mg Batch # E216005 In second, wrong manufacturing and expiry date was printed on the vial labels. Deviation No. 003/QA/2023 Date: 20-02-2023 Icunem Injection 1g Batch # C275007 In the third, some packs of Icunem Injection (Meropenem) were found to be having no water for injection ampoule in them due to an untrained worker. A worker was imparted training as a result. The date on that training form was 07-01-2023 which was prior to the deviation logging date. The BMRs of the above three batches were reviewed. Details are given in later part of the report. **Major**	
09.	**CAPA System** The system for corrective and preventive action was not existing. An SOP **RP-QA-SOP-041, Ver. 02, Issue Sep 2020, Review: Sep 2023,** was available but not being implemented. It was requested to provide CAPA report of the three deviation forms seen but they were not available. Deviations had been closed by the Director Operations without documenting the CAPA. Some CAPAs forms of shortcomings of the previous GMP inspection report were available. They were declared closed but without effective implementation of CAPA as seen during the inspection like no color coding of uniforms, use of GMP non-compliant dispensing scoops. List of dispensing accessories was not available. Moreover, CAPAs for some shortcomings was not done and documented.	The firm has revised the SOP for CAPA doc# QA-G-SOP-012 rev#04 effective date 06-01-2024, however, for the previous year i.e., 2023 three CAPAs were presented which meant that no CAPA had been raised against the 09 deviations mentioned in point# 8 also, the CAPA record against DRAP 2023 audit were presented as separate exercise and was not made part of the routine CAPA record.

	Major	
10	**Management Review** SOP was in place but system was not present. **Other**	QA-G-SOP-021 rev#00 effective date 07-01-2024 titled SOP for Management Review Meeting had been prepared in which frequency was defined as atleast once per year however, Management Review Committee had not been mentioned or nominated in the SOP neither were the roles & responsibilities to conduct MRM been defined. MRM for the year 2024 had not been scheduled yet
11	**Quality Risk Management** System for QRM does not exist. SOP is deficient for identification of possible failure modes, the scale for severity only covers regulatory aspects. Risk assessment mechanism is not defined. **Critical**	The firm has revised the SOP for Quality Risk Management Doc# QA-G-SOP-007 revision 004 effective date 30-12-2023 wherein methods for detection of failure modes had been defined however a comprehensive exercise to identify the probable failure modes associated with each process had not been done. The firm requires to undergo training from external sources in order to grasp the concept & implementation of risk assessment & quality risk management.
12	**Self-Inspection** No record of internal or external quality audit or its report was provided during the course of inspection **Major**	The firm has developed SOP for Self Inspection doc3 QA-G-SOP-009 rev#00 effective date 19-12-2023 and accordingly a schedule of self inspection for QC lab doc# QA-F-0032 issue date 15-12-2023 for the year 2024 had been presented. The schedule of self-inspection for the rest of the facility had not been prepared yet.
13.	**Product Quality Review** SOP Title: Annual Product Review, RP-QA-SOP-002, Version 03, Issue May 2022, Review: May 2025was reviewed. SOP did not mention the minimum number of batches to be taken for the annual product quality review neither did it mention any timeline by which it has to be completed. In the SOP, it was mentioned to consider just the physical and chemical test results of the finished product and in process controls. Review of critical process parameters was not given in the SOP and any evaluation of process capability and performance was not mentioned in the SOP neither it was done. Annual PQR of last two years was asked for. None was available. **Major**	SOP for Annual Product Quality Review was revised by the firm doc# QA-G-SOP-026 rev#003 effective date 08-01-2024 wherein minimum number of batches as well as cutoff period had been mentioned but the timeline for completion was still missing. SOP mentions inclusion of QC, Production & QA data for consideration in APQR however, actual critical process parameters as well process capability and performance were still missing in the document.
14	Actual design as well as dimensions of the building did not correspond to the approved layout plan.	

	Construction of the building against the condition for Grant of License under section 16 of Licensing, Registration and Advertisement Rules, 1976. **Raw Material Store** Design as well as dimensions of the raw material store (receiving, sampling, quarantine) is not as per approved layout plan. The sampling area **as in approved layout plan had two sampling booths** separated with some wall, whereas only one sampling booth was available. Moreover, no change room was provided for sampling area. **Location, design, dimensions as well as and entry exit for liquid material store was not in accordance with the cGMP requirements.** HVAC system was provided in the released raw material storage and dispensing area. **A digital hygrometer (EQ ID R-WH-HG-015) was placed on one of the racks in receiving area and showed a temperature of 21 and humidity of 67% (much more than the firm's defined limits when asked about the informed that this area is not controlled or monitored and the reading from this hygrometer was not being recorded anywhere and when store in charge was asked for how much time the material is placed here prior to sampling, he told that only for 5-10 minutes.** The dispensing log book was available but not maintained. Bad documentation practices were seen. Several lines were left blank. Entry for time of dispensing was missing in	There were two sampling booths which had been separated by a half wall; one for sampling of General materials, the other one was for sampling of steroids however, there were no buffers or change rooms provided before the sampling booths. The firm informed that a major revamp of the Quarantine and sampling area as well as RMS was in the works which will include changeover for sampling area. Since the Liquid RMS was in the same corridor as the buffer for material entry/receiving area in the oncology section which had the potential for causing hazardous cross contamination, therefore, the firm have shifted the Liquid RMS to the front side of the facility (formerly was located on the back side) and considering the size of the liquid containers, the firm arranged for mobile LFH trolley to be placed over the container from which sampling/dispensing is required to be done. The necessary layout changes are in the process of being submitted to Licensing Division. All the thermo-hygrometers in the RMS were showing temperature and humidity within the defined limits i.e., 22±3ºC with RH (relative humidity) NMT 60%, the logbooks of temperature & humidity records were also reviewed and no deviation was found to be recorded. Dispensing logbook for the year 2023 were reviewed, and the same practices of cutting/over writing etc were observed however, the firm has revised the SOP for dispensing of Raw Material WH-RMS-G-SOP-004 rev#004 effective date 08-01-2024 and accordingly, the logbook format has also been changed. The signatures of Warehouse and QA pharmacist were available in the reviewed logbook of 2023 as the firm has hired dedicated warehouse pharmacist.

	some places like for dispensing of Kenatex 40mg/1ml Injection (Batch No. F266012) on 03-02-2023. Cutting and overwriting was seen in the log book. In various entries, signatures of either production pharmacist or QA officer were missing. For example, in the entry of raw material dispensing of Tenamic 250mg Capsule (Batch No. A182008) on 29-9-2022 only signature of Production Pharmacist was there. Signatures of QA officer and raw material store officer were not there. On interviewing the store officer, he confirmed that yes, dispensing may happen in the absence of any of them because of shortage of human resource. This is clear deviation from their SOP and principles of GMP. Similarly, in the dispensing log book of steroid dispensing booth, signatures of production pharmacist were missing on all entries seen and dispensing was done without their presence as confirmed by the store supervisor. The scoops were unlabeled and bore no status label. White powder was seen on one scoop which was in a polybag and kept with the other scoops in the same basket. The store officer informed that the other scoops are clean. Cleaning procedure was not validated. SOP for cleaning of scoops was reviewed. On interviewing the store helper, it was noted that the written procedure was not being followed. The scoops were washed in the QA department area and brought back to the store. There were no controls in place. The operator mentioned that he uses a detergent for washing of these utensils but in the SOP use of detergent for cleaning was not mentioned. The SOP stated that "cleaned" and "not clean" labels will be used but no such label was found during inspection.	The scoops were found to be labeled in accordance with cleanliness status however, the cleaning procedure which was claimed to be validated was not in accordance with GMP principle as detailed in SOP for washing of used tools WH-RMS-G-SOP-008 effective date 06-01-2024, two buckets of RO water were supposed to be carried in the dispensing area and the tools would be washed first in one bucket and then a secondary wash was to be done in the second bucket. The firm was advised to designate an appropriate for washing of sampling and dispensing tools. The sink had been removed, instead in that area an entry buffer with controlled access had been constructed and a material entry hatch had been provided inside the room for oncology RMS. Dispensing tools are going to be washed inside oncology production area. In the current layout of the RMS, there is not enough space to introduce buffers before dispensing area, however, the firm is planning to expand the RMS by including offices of R&D department into the existing RMS. The new layout has been developed by the firm and is in the process of submission to the Licensing Division. Air supply diffusers and return grills were found to be cleaned, the firm was advised to develop a regular schedule for cleaning of the supply and return grills in the dispensing areas. The firm has extended the LFH for all dispensing hoods to provide enough space for placement of personnel and material. Although, magnehelic gauges were provided and found to be operational in the dispensing and sampling hoods, however, action and alert limits had not been displayed and there was no system for daily recording/monitoring of differential pressure. The firm had conducted thermal mapping of the RMS through a third party i.e., M/s MZ Technology; the thermal mapping report of RMS General certificate no. 014761 showed that 7 days study was carried out starting from 12-06-2023 in which 18 data loggers had been placed on the racks; the raw data had been attached with report and on its basis hot and cool points had been

	In the oncology raw material store, a sink was installed in the receiving area for washing of dispensing utensils, a potential source of contamination. Dispensing room for general products and dispensing room was steroidal products was within the store. There was no buffer given between the storage area and dispensing room. Man and material flow was same. Cleaning of air supply diffusers was not satisfactory as dust was seen on them. The dispensing booths for both general and steroidal materials were not qualified regarding placement of material and personnel position. Space constraint was observed in the dispensing booths. The dispensing booth for steroidal materials was so small that drums of materials greater than 10kg could not be placed inside it. The same was confirmed by the store operator that in such cases the raw material container is opened in that room in the area outside the dispensing booth. The manometers installed for measuring differential pressure between storage area and the dispensing areas were out of order. Contamination and cross contamination controls were not given. Data loggers for recording the storage conditions were not provided. Two thermohygrometers were installed in the raw material released area. At the time of inspection, the reading on the thermohygrometer (RP-WH-HG-011) installed near to the dispensing room was 21.6°C and 65%RH. As per the company's SOP condition >25°C and >60%RH was out of limit. One Log book of 2023 for recording storage conditions was available but on it no equipment ID was given. Reading was recorded in the log book on three times i.e. 8-9am, 12-1pm and 3-4pm.	identified. During the inspection, thermo-hygrometers readings were found to be within defined limits. Review of the logbooks for daily temperature & humidity monitoring showed that readings had been noted at the defined intervals and no temperature or humidity excursion had occurred. At the time of inspection, HVAC was found to be working appropriately. Work orders in case of a break down were found available. For off hours monitoring, the firm has designated engineering staff. Segregation/partition of APIs and excipients had been done via hard plastic sheets. Separate racks had been designated for APIs and excipients, however, material traceability is still in rudimentary form. The firm is planning to institute Sap for excipients also. Buffer has been provided at the receiving bay of PMS. Due to paucity of space some of the PVC foils i.e primary packaging material was placed outside the storage area designated for primary packaging. Some of the cartons were still found to be placed very near to the lighting with little space between ceiling and material. Some of the aisles were still a little bit dark due to cramming of packaging material and obstruction of light. Since buffer had been added in the receiving bay, the quarantine area was found better protected from the outside environment. Sampling hood has been provided in the storage area for primary packaging material.

	The inspection team visited the store between 3-5pm. There was no entry in the log book for 12-1pm on that day. There was no recording on Sundays. No temperature/humidity excursion was recorded in that log book. No temperature/humidity mapping protocol or report was available for the store. Hot spots and cold were not identified. The store personnel said that there was a problem in the HVAC system and has been informed to engineering department telephonically. They were asked to provide evidence of a written communication to the concerned department. There was no job order generated for it. It was noted that the air conditioning system was turned off after 5pm and holidays. No monitoring record was available for that time. In the released raw material storage areas, various APIs were stored on same rack without any segregation or physical partitioning posing a risk of mix ups. For inventory management, the company was maintaining computerized bin cards for APIs but not for excipients. **Packaging material store** Packaging material store opens directly to the outside for material receiving no buffer was provided as receiving bay. **The packaging material store was stacked with cartons much more than it could accommodate. There was no space between the stacks of packaging material, including primary packaging material (printed cartons, outer packs,**	The room has been designated for dispensed raw material and the refrigerator has been shifted to the main RMS. The firm was advised to label the room as such.

	leaflets and aluminum foil etc.), and the walls or ceiling of the area. Boxes were touching the tube lights while some even obstructing the whole light further reducing the light in an already inadequate-lit area. Quarantine next to the receiving bay where primary packaging material (aluminum foil) was stacked, was just a few feet away from the door opening to the outside area. **There was a room adjacent to the sampling area that had instructions written on the glass door as "only authorized access", supervisor told that it is a cold storage room, while there was a refrigerator present in the room but also two racks were there and a box containing material (labelled as Aqua Shine Yellow, Dispensed-batch #A361002, 100K TABS) was also present while the staff was unaware of the fact why it was there.** **Critical**	
15	**Production Areas** No material airlock and personnel airlock were provided in tablet and capsule section. The grey structure of walls, was visible in granulation area Moreover a cabinet for documents was available in the processing area. Air supply to Fluidized Bed Dryer was not purified as it passes through a 35% G filter instead of HEPA filter. In process quarantine area in tablet section was too much crowded and it did not have any space for storing material different batches were stacked on one another. The coating solution preparation area in tablet section (General), had floor and wall tiles with grooves, thus it was not GMP compliant. The ceiling of	In the current facility, there is not adequate space for provision of personnel and material lock, the firm is preparing for changes in layout which are to be submitted in Licensing Division. Grey patch had been fixed by the firm and cabinet was found to be removed from the area. HEPA filter of 0.3 micron has been provided in the air supply of Fluidized Bed Dryer Since the DML of firm was suspended, different batches of tablets in various stages of Production had been placed together in drums and cordoned off. Grooves and cracks had been repaired and fresh epoxy coating had been done in all Production areas Fresh epoxy had been carried out in the production areas The over-ride mechanism had been a by-pass switch which had found to be encased in glass casing with written warning "for emergency use only"

	encapsulation area was found with cracks. During Oncology section visit, no production activity was going on however, the dry powder filling area was viewed form the glass window in optical checking room, the operators had access to turn off the interlocking of entry buffer and they did so during the inspection. Magnehelic gauges for Dry Powder Injection (Oncology), were operating at limit beyond the operational range, 60 Pa was the maximum reading on the gauges, however the needle was observed beyond 60 Pa. The differential pressures were not maintained within standard limits. **Critical**	Previous Magnehelic gauges had been replaced with new calibrated gauges having appropriate rangesof upto 500 Pa have been installed.
16	The SOP for employee medical screening (RP-QM-SOP-009) was found deficient for evaluation of test reports, action taken. The record for medical screening was not being reviewed by any medical doctor. No sensitivity testing for cephalosporin was being done for the personnel. There was no system for Occupation Exposure Limit for any of the drug products being manufactured in the unit. No marking/ caution was provided for steps in the quality control area. There was no medical record including eyesight, available for some personnel performing optical checking of Vials/ampoules. Opened wires were found to be present in Granulation Section. **Critical**	The firm has made an agreement with The City Lab for carrying out Blood tests and reports of the employees had been provided which had been conducted in Jan 2024. Sensitivity testing for Cephalosporin had also been carried out. However, screening for communicable diseases had not been done even though SOP for Medical Screening & Examination QA-G-SOP-025 rev#01 effective date 02-01-2024 mentions screening for contagious diseases. SOP for OEL limits doc# QA-G-SOP-023 rev#00 effective date 02-01-2024 had been prepared but was found inadequate, as OELs of the most hazardous material including oncology medicines had not been mentioned, neither was suitable method given for assessment of individuals. The firm was advised to and are in the process of purchasing respirators for employees working in the Oncology section. The firm had carried out eye sight testing of employees who are involved in optical checking. Yellow and black markings had been added on the floor and industrial sockets had been replaced with circuit breakers.
17	**HVAC** No layout for identification of Air handling units and its supply to specific area.	Layout for Identification of AHUs was found available. Cleaning of areas where AHUs were installed had been carried out, however, they are still exposed to sunlight & external environment, the firm has made effort to erect

	HVAC installation area was not maintained, clean and was exposed to sunlight/external environment. Minor leakages were observed on supply duct of Carbapenem air handling unit. Furthermore, Generator operator and HVAC technician was interviewed; they turn off the AHU in off hours as routine practices. Fungal growth and erosion was seen on cladding of supplying ducts of cephalosporin dry powder injection. No record of leakage testing of the ducts since its installation in 2018 and operator informed that they check the leakage manually by exposing hands to the surface of ducts. Washing and drying of filter was done in an uncontrolled area using tap water and compressed air/sun light respectively. SOP was washing of filters was not available. Qualification of HVAC system was not sufficient. Records for qualification of AHUs providing air to sterile sections were reviewed. Records of DOP test were available for year 2022, but Air balancing was inappropriate, despite many changes in design of the facility. Exhausts were not there hence air balancing could not be justified for the 15% air which is provided to the AHUs. **Critical**	metal compartments around sides of AHUs to partially protect against exposure whereas roof shed had already been provided over AHUs. Duct leakage tests had been performed to verify duct integrity. The firm claims that Blowers of AHUs keep running around the clock and engineering staff has been deputed to monitor temperature & humidity in the off hours. Affected cladding was found to replaced and thorough cleaning of AHUs had been undertaken. Duct leakage testing had been conducted by M/s EM enterprises in September 2023. Washing of filter was still in uncontrolled area with tap water, the firm was advised to either provide RO water and controlled environment or to replace the filter if it is choked. The firm has installed magnehelic gauges across the filter compartments of AHUs; they were advised to display action & alert limits prominently and to maintain record of differential pressure monitoring so that frequency for replacement of filters can be determined scientifically. PAO (DOP) test records were available for November 2022 from M/s Biotroll International and for July 2023 form M/s Biogold International, however, some discrepancies were observed in the record such as, even though HEPA filters had not been replaced but their performance seemed to have improved from 2022, therefore the firm carried out repeat PAO testing form a third vendor i.e., M/s EM Enterprises in February 2024. The firm was advised that PAO test should be conducted in the presence of Engineering & QA representative and if possible on the spot printouts should be requested from the vendor. Qualification of AHUs had been carried out in 2022 by M/s Biotroll International and in 2023 by M/s Biogold International, however when the reports were compared with DQ, IQ, OQ & PQ of AHUs of general sterile, cephalosporin, carbapenem& oncology section, it was observed that the total calculated CFM of areas supplied by a particular AHU were exceeding the total CFM of blower as fixed during the IQ. Therefore, a third vendor M/s EM Enterprises were engaged by the firm for air flow/air changes test which was carried out in February 2024. Smoke tests/air flow visualization had also been performed and videos were found available.
18.	**Water System and Steam** There was no documented evidence that the manufacturer has the **design,**	The documents for operational qualification RP/VD/OQR/002 effective date 12-04-2018 and performance qualification RP-VD-PR-006 effective date

	control, maintenance, operation, and monitoring of the water system under control so that pharmaceutical water BHPW and WFI can be consistently produced at the quality required for the intended use. At the time of the visit to the water treatment system, the circulation pump of WFI loop was turned off, when the supervisor was interviewed about the operation, he turned it on and told that they turn off the circulation pump during off hours, Sundays and holidays. When the operator turned the pump and motor on, temperature appearing on the controller was 31degrees centigrade. this water was used for ampoule/vial washing in the general section earlier in the day. The area where the water treatment plant was installed was not clean. There was dirt and fungal growth on the floor. Drains were open. There was stagnant water in multiple places on the floor. The whole water system, including treatment system, storage as well as distribution did not meet the criteria to have integrity such as • There was leakage from the lid of the RO tank. • Water flow direction was not labelled. • The piping was having leaks and rust in some areas. • There were various leakages in the piping supplying water from WFI storage tank to the production areas. • The level monitor glass tube of the WFI storage tank was broken. The operator had wrapped aluminum foil on it to cover the breakage.	28-04-2023 were available. Also SOP for operation and monitoring of Purified water facility doc# ENG-ELC-SOP-001 rev#3 effective date 21-12-2023 had been provided. The firm claimed to be undergoing third phase of water treatment testing after shifting the specification of Purified Water/WFI from BP to USP through change control no. CC-015-2023 dated 28-08-2023 (according to firm change was actually instituted in April 2023 and August date is a typographical error).However, review of records on format RP-VD-WV-002 issue date -3-04-2023 showed that firm had not taken critical parameters of Qualification under consideration as per USP like testing of Calcium, Magnesium & free Chlorine during qualification stage to ensure softening of water and removal of free Chlorine before passage through RO membranes. The firm was therefore advised to perform re-qualification in accordance with guidance provided in USP The area where water treatment system has been installed had been revamped with epoxy coating on the floor, fixing of leakages etc. At the time of inspection, the temperature of WFI loop was found to be 78ºC. overall cleanliness condition was found to be improved. leakage from the lid was found to be fixed water flow directions were found labelled affected piping had been replaced and the rest of the pipes were found cleaned leakages of piping had been fixed and at the time of inspection, no leakages were apparent anywhere. The level monitoring glass of WFI storage tank had been replaced but the firm was advised to install digital monitoring device Spray balls had been installed in WFI & Purified Water Storage tanks Temperature controllers of RO water & WFI were found calibrated As per doc# RP-VD-SP-009 issue date May2023, there were 13 sampling points from bore upto UV light which encompassed Purified water treatment system and were all included in the reports. However, sampling points from distillation plant and WFI storage tank were not included in the protocol; instead, sampling of WFI was being done form user end points only. For chemical testing, the protocol provided for pH, TDS, chloride & sulphate for sampling points pre-RO membrane, whereas starting from RO membrane the chemical tests performed included pH, conductivity, chloride & TDS.

	• Spray balls were not installed in the WFI storage tank for the prevention of biofilm growth. • Temperature controllers for RO water and WFI storage tanks were not calibrated. Sampling was inadequate as it was not being done in accordance with the defined sampling points as there were 26 sampling points from bore to distillation but the record could not be verified for sampling from these points. Furthermore, since the firm has added a new source of natural water as well as new storage tanks for raw water. During the review of the revalidation data, it was noticed that the test values are consistent and recorded without actually performing the test as the data of same could not be verified from the laboratory records. Validation of the sanitization of the system was also not available and the response of the personnel was insufficient and inconsistent there, where no details have been given as to how the validity of the system is to be established in detail. Steam was being used for sanitization of the water system as informed by Manager Engineering but relevant documentation was not available and supervisor was not aware of the defined frequency of sanitization. Moreover, steam was not being tested for its quality. Documents were not available for evidence of system components or qualification including drawings, certificates of conformity for materials of construction, weld/joining records, dead leg calculation, calibration, or records of system pressure test**.** **Critical**	However, since the firm had switched from BP to USP specs and for routine testing of Purified water& WFI, USP recommends only 2 tests i.e., conductivity and TOC, however, neither the criterion of USP for water qualification were considered neither complete monograph testing of water was being carried out by the firm. The firm was therefore advised to carry out re-validation and subsequent routine testing in accordance with USP monograph & general chapters. The firm has revised SOP for Sanitization of Water treatment plant doc# ENG-ELC-SOP-005 rev#03 effective date 22-12-2023 according to which sanitization with steam at 110-115ºC will be carried out once every 2 weeks. Also SOP for passivation ENG-ELC-SOP-006 rev# 03 effective date 22-12-2023 was reviewed in which frequency of passivation was defined at 6 monthly basis; the firm had recently carried out passivation of SS 316L pipes in the water distribution system as well as storage tanks to ensure smoothness and prevention of Biofilm formation. Clean steam validation had not been carried out, only Bacterial Endotoxin test was being performed at user end points. The firm has provided WFI loops for all the sterile areas where previously it was only available for Sterile Section General; furthermore in line with USP the firm has installed online conductivity meters in WFI distribution lines to ensure that bulk WFI complies with USP monograph specs.

19.	**Compressed Air & Gases** Compressed air being used in vial/ampoule washing, bottle blowing, was not being tested for its quality except the microbiological testing. Similarly, nitrogen gas being used for Nitrogen Purging was not tested for its quality and no record was provided. **Critical**	The firm has carried out chemical testing compressed from third party i.e., M/s Corshe in October 2023 test reports reviewed included oil content, water vapor, CO and CO_2. Percentage Purity test for Nitrogen had been conducted by M/s Modern gases in January 2024 Microbial testing of both compressed air and Nitrogen is being carried out on monthly basis in accordance with SOP# MIC-G-SOP-036 rev#01 effective date 05-01-2024 which replaces the previous SOP. Since Nitrogen is being passed through a microbial filter prior to being used in purging, the firm is advised to include PUPSIT at defined intervals in accordance with risk management principle.
20	**Power backup** Total backup 920 KV with 3 generators, switch over was manual, while switch over time was 1-1.5 minutes. **Other**	The firm have 3 backup Generators of 625, 600 & 110 KVA each in addition to UPS supply for sensitive instruments such as HPLC, stability chambers, incubators etc. switch over is still manual.
21	Batch Processing/Manufacturing Records Three BMRs with following details were reviewed. 1. Vancomed Injection 500mg (Vancomycin as HCl), Batch No. E216005 2. Volden Forte SR 100mg Tablet (Diclofenac Sodium), Batch No. A059035 3. Icunem Injection 1g (Meropenem), Batch No. C275007 Gross deficiencies and irregularities in all the BMRs were noted. There was no proper system for BMR issuance and control. There were several discrepancies and ambiguities as elaborated below. Poor documentation practices were observed. It was in the form of loose sheets put in a folder and very	The firm has devised proper system for issuance and control of BMR through an SOP titled Issuance and Submission of BMR doc# QA-G-SOP-27 rev#00 effective date 07-01-2024, in which it is systematically defined that QA shall issue the mater copy of BMR with Controlled stamp on each page to the store department as a complete file so that issues identified during DRAP audit shall not be repeated. In line with SOP, the firm has developed a standard format for BMR issuance which includes checklist of documents to be verified by QA department at the end. The BMR for Inj. DMX 4mg/ml (Dexamethasone) Batch# F279044 was randomly selected for review, and even though said BMR had been issued & completed prior development of the above-mentioned SOP, significant improvements were observed compared to the previous practices of the firm. Protocol for Hold time studies, Process validation plan for the year 2024, while SOP for in process sampling has been updated by the firm and SOP for handling non-conforming products has also been developed by the firm. Issues related to Good Documentation practices have been addressed by revision of the existing SOP. The firm

	difficult to handle. Overwriting was done in many places. The production part of BMR was printed by the Compliance Manager and the Packaging part was printed by the QA manager. The BMR of Volden Forte SR 100mg Tablet seen also had an incorrectly printed page having Volden SR 100mg Tablet printed on it and encircled by someone. It was a raw material issuance sheet, and it was filled and signed by various persons. Later on, another sheet was generated after correction of the product name. There was no practice of writing date with signatures. Pencil was also being used in the BMR for signatures and other entries. BMRs were not reviewed and closed as required in the last step of the BMR. There was no BMR review checklist and no timeline given in the SOP for finished batch release as to who and by when will review the BMR. All operations done in the manufacturing of the batches were not recorded in the BMR. For example, as informed by the QAM, during vial washing, in some vials fibers were observed after washing and before sterilization. The trays from which the samples were taken and in which fibres were observed in washed vials, those vials were rejected and rest of the vials in those trays were rewashed. This step was not documented and neither there was a sampling plan or formula used for picking vial samples representing the washed trays. Random sampling was done by the QA officer as informed by QAM. In the BMR of Icunem Injection 1g (Meropenem) Batch No. C275007 (Batch size: 10948 packs, Final Yield: 9463 packs, Yield: 86%) it was recorded that at the start of filling operation, 10 vials were	has provided training to the employees on the new document QA-G-SOP-016 rev#01 effective date 22-12-2023.

	reconstituted, and 01 white particles was observed. In the in process optical checking (Title: Line clearance and in process for optical check, RP-QA-SOP-034, Version 03, Issue May 2021, Review: May 2024) by QA team, total 10 vials were checked at different times and particles were observed in 2 vials. The PM and QAM informed that the same was informed to Seraph Pharma (contract giver) telephonically. As per the BMR, during optical checking after filling, 438 vials had black/white particles. The company had not done any risk assessment or further investigation regarding these particles in the reconstituted and dry powder filled vials, rather released the batch for market. The team said that they informed Seraph Pharma's owner telephonically about all the observations who told them to optically check the vials and release the rest. None of this was documented. Deviations were not made part of the BMR. There was no written procedure for acceptance criteria of batches based on the sampling and rejection percentage in any stage like optical checking or final yield. The QC record for this material was checked and the team informed that a sample pouch was received along with the bulk material (that was filled) and no solubility issue or any particulate matter was observed during QC testing. For Volden Forte SR 100mg Tablet, as informed by the Production Manager, coating was done in 3 lots due to large batch size. Desired color shade was not achieved in first lot so additional raw material was issued from the store and added to the coating suspension, the first lot of tablets was again coated. There was no mention of any of these additional steps in the BMR or that coating will	

	be done in three lots in the standard process. The coating suspension was kept for so many days. No hold time studies had been done for in process materials. PQR or process validation of none of these products was done. In the BMR of Vancomed Injection 500mg (Vancomycin as HCl) Batch No. E216005, wrong manufacturing and expiry date was printed on the BMR which was later corrected by the Compliance Manager who issues that part. He made corrections with pen in some pages where it was printed. Some of the filled pages still had wrong dates when the BMR was seen during inspection. On interview with the team, they informed that the packaging part of the BMR was printed by the QAM. She was unaware of the wrong printing of the dates on the first part of the BMR and she issued the packaging part of the BMR with those dates and same were printed on the labels when the labelling process started. The problem was later identified after printing 2500 labels and was corrected. But it was noted that the system and controls were still lacking. There was no document for root cause analysis and CAPA. On some pages batch size was written as 9433 vials from 5 kg on some it was written 9433 vials from 4.85 kg. In optical checking 25 vials were recorded to have black/white particles. On material issuance page also both quantities were given. Many columns for entries or signatures in the BMR were blank. Like page 37, 39 and 41 of 64.	

	Page 37: (Transfer of filled vials to labelling area: Entry for total quantity transferred missing, signature of QA officer missing for overprinting on 07-02-2023) Page 39: (Labelling material and filled vials received and labelled reconciliation missing) Page 41: (Batch packaging record Reviewed by QCM signatures missing, received by packing supervisor signatures plus other entries missing) On the page for in process checks for printing unit carton, several rows were left blank in between entries. The batch was transferred to the finished goods store on 08-02-2023 as per the BMR but the BMR had not yet been closed and reviewed.	
	Control of Contamination and Cross Contamination The Controls measures taken and the records provided do not assure complete and comprehensive separation between potent products(steroids) cytotoxic products (anticancer etc.), sterile products and adjacent production areas. For example, the following controls for design, construction, monitoring and personnel flow were not established: • Design and construction of facility • Environmental monitoring data that establishes containment. • Limitations on personnel flow, rather the same personnel are performing the function in all of the otherwise dedicated /segregated and containment areas.	The firm has undertaken extensive measures to control cross-contamination between cytotoxic, cephalosporin/carbapenem and general products which include: ➢ Introduction of showers at the exit buffer of Oncology section ➢ Removal of Liquid material store from the same corridor which also leads to material entry buffer of oncology section ➢ Complete enclosure on oncology AHUs through brick walls and entry of personnel inside after donning appropriate PPEs ➢ Installation of HEPA filters on the return ducts right before entry of air in the AHUs ➢ Provision of magnehelic gauges on terminal HEPA filters in Oncology Production area ➢ Purchase of separate and dedicated particle counters and viable air counters for oncology, cephalosporin, carbapenem and general sterile area ➢ Removal of entry and exit of material in the Cephalosporin area from the General products corridor to admin office area (which will be cordoned off by a wall so that there is no interaction of admin staff) ➢ Relocation of Personnel and material entry and exit of Carbapenem area from second floor General Production area to a separate staircase at the front of the building near admin block

	• Lack of control of contamination of materials • Lack of organizational measures **Critical**	➢ Provision of dedicated staff for critical areas such as Oncology, Cephalosporin, Carbapenem area etc.
22	**Facility and Utilities design, validation, monitoring and controls** **No layout for identification of Air handling units and its supply to specific area, Schematic diagrams for AHUs of General Oral Solid Dosage form sections and General Sterile area was not appropriate.** **No layout for plate exposure was available, although plates were being exposed for environmental monitoring but no rationale provided for the placement of settle plates by the Manager Microbiology or Microbiologist.** Dispensing room for general products and dispensing room for steroidal products was within the store. There was no buffer between the storage area and dispensing room. Man and material flow was same. Cleaning of air supply diffusers was not satisfactory as dust was seen on them. The dispensing booth was not qualified regarding placement of material and personnel position. The manometer installed for measuring differential pressure between storage area and the dispensing area was out of order. The liquid store entry was from an outdoor corridor just opposite the sampling area. The entry/exit of store in outdoor corridor was through a door without any change room. There was a single booth, used for both sampling as well as dispensing but neither the booth was operational/qualified nor the size was	Layout of AHUs accompanied with the areas where they supply was found available. The firm had identified the areas where plates were being exposed in area specific SOPs for viable count monitoring which were based on worst case scenario such as in front of HVAC return grills and in accordance with the results of smoke test/air visualization studies. The firm was advised to include those areas in environmental monitoring consideration in class A under LFH where human intervention was taking place or where first air was being interrupted. In the current layout of the RMS, there is not enough space to introduce buffers before dispensing areas of general & steroidal products, however, the firm is planning to expand the RMS by including offices of R&D department into the existing RMS. The new layout has been developed by the firm and is in the process of submission to the Licensing Division. Air supply diffusers and return grills were found to be cleaned, SOP for cleaning of air diffusers and washing of return grill filters doc# ENG-MEC-SOP-004 rev#00 effective date 28-12-2023 was found available in which frequency of once a month had been defined. The firm was advised to increase the frequency of cleaning of the supply and return grills in the dispensing areas. The firm has extended the LFH for all dispensing hoods to provide enough space for placement of personnel and material. Since the Liquid RMS was in the same corridor as the buffer for material entry/receiving area in the oncology section which had the potential for causing hazardous cross contamination, therefore, the firm have shifted the Liquid RMS to the front side of the facility (formerly was located on the back side) and considering the size of the liquid containers, the firm arranged for mobile LFH trolley to be placed over the container from which sampling/dispensing is required to be done. The

	enough to accommodate the containers of the liquids being dispensed. Cardamol oil used in the vitamin D injection was being dispensed in this area. **After dispensing, the route, a person takes from this area to the production area will be through receiving bay which doesn't have any control measures including protocol for entry.** The QA officer responded that after dispensing oil is autoclaved, as part of firm's strategy of contamination control. Different aluminum foils were stacked on one another, posing risk of mix up. No metal detector was available with the firm. The pallets available in packaging material store were of wood. No sampling booth was provided for sampling of primary packaging material. Same was for its dispensing. **Critical**	necessary layout changes are in the process of being submitted to Licensing Division. They were advised to carry out qualification of the mobile dispensing hood as well as define the mode of transportation of dispensed liquid to the production area with appropriate controls. Efforts had been made by the firm to ensure that sampling procedures encompass all materials, including primary packaging material such as aluminum foil. During visits to the packaging material store, discrepancies in sampling practices were identified and addressed like wrapping the reels of foils in polybags with identification labels to avoid mix-up. Clear instructions, in the form of revised SOP had been provided to personnel regarding the correct sampling method and sample size for primary packaging materials to ensure consistency and accuracy in sampling practices across all materials. The firm had placed order for 3 metal detectors but had yet to reach the facility. Plastic pallets as well as LFH hood had been provided in the primary packaging store which will serve as both sampling & dispensing hood.
23	**Environmental control, validation and monitoring** There was no continuous particle monitoring in any of the sterile/ aseptic processing areas. One of the two double door hot air sterilizers installed in Cephalosporin vial washing area was being used as cabinet for storage of dirty laundry, empty glass vials and a basket was present having dirty, muddy reusable gloves, while other sterilizer had trays filled with dusty dried inverted empty glass vials which were claimed to be there since 1 month for the purpose of validation. The ISO-classified areas had visibly dirty equipment and difficult to clean surfaces. Specifically, chipped walls in entry to cephalosporin section,	The firm did not have system for online non-viable particle count; during production particle count reading is being taken twice, once before the start of operation & once during the operation. However, in order to avoid cross-contamination the firm has purchased additional particle counters which will be dedicated for each sterile area. During the inspection Hot air sterilizers/Dry Heat Sterilizers (DHS) were inspected and found to be clean and operational. Reports of qualification of Cephalosporin and Oncology DHS conducted on 14-01-2023 & 19-01-2023 were reviewed by the panel which had been conducted by M/s MZ Technology. However, the firm was advised for re-qualification of DHS on account of the fact that DHS of Cephalosporin was found in dirty non-operational condition by the previous panel after its supposed qualification. Furthermore, determination of worst case scenario had not been made for thermal mapping of loaded cycle.

	apparent rust on cleaned equipment, and a build-up of residues were observed in and around **cleaned** equipment used for filling different products of Dry powder for suspension vials. A rusted fork lifter was placed in classified area of cephalosporin section. Air balancing was not appropriate, as reviewed for sterile general area, where the AHU produces 2700CFM, whereas only 1845 CFM could be reconciled as per available records. No layout for air distribution and connection with other areas was available. No layout for identification of Air handling units and its supply to specific area, while schematic for AHUs of OSD and Sterile was not appropriate. Similarly, plates exposure plan/ Layout was not available. There was no rationale provided for the placement of settle plates. The magnehelic gauges were maintained against main corridor the magnetic gauges were not working as well magnehelic gauges and sterile general area were not working properly. **Moreover, SOP for environmental monitoring lacked for stepwise procedure, the firm informed that they only perform viable non-viable monitoring before production for rest and during production for operation however when the record was evaluated it was found that since there was no production on 6th February 2023 same was done for both at rest and in operation however no area monitoring for non-viable count was done since then.**	Qualification of AHUs had been carried out in 2022 by M/s Biotroll International and in 2023 by M/s Biogold International, however when the reports were compared with DQ, IQ, OQ & PQ of AHUs of general sterile, cephalosporin, carbapenem& oncology section, it was observed that the total calculated CFM of areas supplied by a particular AHU were exceeding the total CFM of blower as fixed during the IQ. Therefore, a third vendor M/s EM Enterprises were engaged by the firm for air flow/air changes test which was carried out in February 2024. Layout identification of AHU was available. Plate exposure plan had been laid out in the Viable count monitoring SOP which was separate for every section. At the time of inspection, the magnehelic gauges in all sterile areas were found to be functioning appropriately and were found to be calibrated. SOP for environmental monitoring had been revised and divided into Particle count monitoring & viable count monitoring. Separate SOPs for viable count monitoring had been written for all Sterile areas with their respective identification of locations for exposure plates. The facility for continuous particle count monitoring is still not available.

	Critical	
24	**Personnel Hygiene, Training, and Movement** PPEs provided for the areas which need containment were not adequate, particularly in Oncology dry powder section where product Oncophos (cyclophosphamide500mg& 1000mg, a known human carcinogen) is manufactured. Although QA manager informed that masks are dedicated to enter the facility yet only two (02) out of the five (05) masks stored in glass cabinet were seen with the number on them corresponding to the list of 10 persons who occasionally enter in this section, including production manager, sterile section in charge as well as QA officer. Although claimed clean and ready for use by the change room supervisor, one of those dedicated masks had white powder inside it, which might be introduced during the manufacturing. Personnel/ operators were not dedicated to prevent the risk of cross contamination. There was only one RMS supervisor who was responsible for sampling and dispensing work in all 04 raw material stores. The same was the case with plant operators and production in charge. **Critical**	PPEs were found available; in Oncology the firm had arranged for disposable N-95 masks as the Production activities had been suspended. For the employees Gas masks corresponding to number of employees had been provided however, in accordance with International Guidelines, the firm was advised to arrange respirators for routine working of personnel in Oncology department. The firm have SOP for maintenance of PPE in which routine checks by change room supervisor and QA inspector have been included. Dedicated personnel/operators had been provided for Oncology Section in particular. The firm was advised to maintain dedicated personnel particularly in Oncology Section but also in other sections requiring dedication like Cephalosporins and Carbapenems
25	**Control of Materials** The manufacturer does not perform full identity testing on the raw material. Reagent grade Glycerin was being used in manufacture of drug product. Furthermore, despite the directions from DRAP vide letter No. F. 6-30/2022-QA, dated, 13-12-2022, firm did not perform the USP test B that references the "Limit of Diethylene Glycol and Related	The firm has started getting Glycerin & Propylene Glycol from CDL before use. They have also purchased Gas Chromatography but have yet to purchase column and reference standard for testing The glycerin Lot No. 29.3021201, Mfg. by Chem-Lab was purchased in small quantity for use in R&D only and its test report from CDL was available at the time of inspection which had been declared of Standard Quality by CDL. The firm was advised to ensure availability of complete document trail for solvents like Glycerin, Propylene Glycol, Sorbitol, Polyethylene Glycol.

	Compounds." to quantify the amount of DEG, a poison, present and to verify the purity, relied on the certificate of analysis (COA), which too lacked the above test, provided by the supplier of **glycerin, Lot Nr. 29.3021201, Mfg. by Chem-Lab.** The chain of custody or distribution history of the glycerin was also not readily known whether the glycerin may have been sold several times between its manufacture and its use in medicinal syrup or other drug product. Liquid store as described earlier was uncontrolled. Crodomol oil used in vitamin D injection was dispensed in the same uncontrolled area of liquid store. Reagent grade paraffin oil was being used for lubrication of dies and punches Similarly, compressed air was being used in various operations such as bottle blowing and specifically during the vial washing for sterile manufacturing, before the final rinse with WFI, was not tested for its quality except microbiology testing. **Critical**	Since the Liquid RMS was in the same corridor as the buffer for material entry/receiving area in the oncology section which had the potential for causing hazardous cross contamination, therefore, the firm have shifted the Liquid RMS to the front side of the facility (formerly was located on the back side) and considering the size of the liquid containers, the firm arranged for mobile LFH trolley to be placed over the container from which sampling/dispensing is required to be done. The necessary layout changes are in the process of being submitted to Licensing Division. Food grade oil has been arranged for lubrication of punches & dies. The firm has carried out chemical testing compressed from third party i.e., M/s Corshe in October 2023 test reports reviewed included oil content, water vapor, CO and CO_2. They were advised to start PUPSIT for the 0.3µ microbial filter at defined intervals in accordance with risk management principle.
26	**Validation Master Plan** The given document RP-VD-VMP, Version 02 Issue Nov 2020, Review: Nov 2025was just printed before bringing to show the inspection team as confirmed from the company's personnel. The company was asked to provide the plans of years 2022 and 2023. Yearly plans were not available. There was no system for planning and conducting of re/validation and re/qualification activities. **Other**	A process validation plan, analytical test validation plan and cleaning validation plan on Form# QA-F-0069 issue date 15-12-2023 for the year 2024 was available. The firm has hired a new validation manger with more than 15 years of experience to carry out validation activities. Overall improvements have been implemented to ensure the completeness and reliability of the VMP, as well as the planning and execution of validation activities.

27	**Vendor Qualification** Vendor evaluation, qualification and approval system was inadequate and not reliable due to DI issues seen throughout the course of inspection. Several deficiencies and lack of controls were noted. Vendor qualification SOP, RP-PR-SOP-001, Version 01, Issue: March 2019, Review: Mar 2021, was reviewed. The company changed the source of the coating material of Volden Forte SR 100mg Tablet (Diclofenac Sodium) and a deviation was recorded by the company in Batch No. A059035 and the deviation form mentioned that it was due to the change of source of the coating material. The vendor qualification report of the new source was asked for. A two-page document was provided after some time. On further investigation it was found that the qualification document was freshly generated to show to the inspection team and signed by Procurement Executive, Procurement Manager and CEO with back dates of 02-6-2021 and 03-3-2021. The approved vendor list of materials had only three pieces of information. Material name, supplier name and origin. No information regarding the plant address, pack size or type, storage information, etc. was given. In the general released raw material storage area it was seen that some drums of the material "Aceclofenac 450kg (18 containers), Batch No. MIAC F002021P" were placed and they did not bear any label of the principal manufacturer mentioning its name and address. That information was only available on the documents received in the company for that material. On seeing those documents, it was noted that they were of Aarti Drugs, India which has multiple manufacturing plants but the team of	Revision of Vendor Qualification SOP: QA-G-SOP-015 rev#02 effective date 07-01-2024, had been completed by the firm & includes audit performa, quality agreement as well as onsite audit of the supplier & quality questionnaire. The vendor approval process has been improved to ensure the reliability and integrity of approved vendors. Approved vendor lists now include comprehensive information, including material name, supplier name, origin, plant address, pack size, type, storage information, etc. This will ensure transparency and accountability in the vendor approval process. Measures were also found to be implemented to improve oversight and documentation of vendor activities. Store personnel had been trained on the importance of verifying manufacturer information on labels and documents received with materials. The firm was advised to regularly review & update approved vendor lists to reflect changes in vendor status, such as additions or removals based on performance or changes in sourcing strategies. This will ensure that only qualified and reliable vendors are included on approved vendor lists and that materials are sourced from reputable suppliers.

	Rotex did not have information that the material from which plant is approved. Moreover, no mention of the manufacturer on the label on drums was something unusual and not taken into consideration by the store personnel. It was also noted that in the pre-inspection document submission, a newer version of the approved vendor list of APIs was provided to the inspection team (i.e. Version 3 Issue: Feb 2021 Review: Feb 2022) and in that list Aarti Drugs had been removed from the vendors of Aceclofenac. **Major**	
28.	**Equipment Validation** The documentation and qualification record of production as quality control equipment was not available. Equipment qualification SOP (RP-VD-SOP-003) did not had provision for URS, DQ, FAT and SAT. Moreover, the contents and formats for URS, IQ, OQ and PQ. Such as RP-QC-INS-055, Shimadzu HPLC did not include URS and PQ. Only IQ and OQ was documented to be performed by vendor, but for no record for caffeine was available although it was mentioned that caffeine solution was used for OQ. No URS for software of HPLC, Lab Solution were available, the CSV performed was inadequate as it did not challenge the requirements. No protocol for validation was available. Accordingly, IQ, OQ and PQ was not performed. No Transport Validation was performed by the firm. Computer System validation SOP (RP-VD-SOP-013) was inadequate in non-availability for QRM principles, URS, IQ, OQ an PQ, the format of protocols and reports and its content.	The firm has provided qualification record of some of the Production Equipment like Dispensing and sampling hoods, mixers etc. qualification of DHS had been done prior to the previous audit but after identification of issues regarding it re-qualification is required to be done. Revision of SOP for Qualification of equipment was required to incorporate provisions for User Requirement Specifications (URS), Design Qualification (DQ), Factory Acceptance Testing (FAT), and Site Acceptance Testing (SAT). Equipment Qualification plan for the year 2024 included all manufacturing and QC equipment Latest calibration certificate of HPLC also did not include validation through caffeine check; it was assumed by the firm that caffeine check is only required at the time of initial Performance Qualification but not during subsequent re-qualifications. Qualification of autoclaves had been performed on 17-01-2023 i.e., before commencement of previous audit. Re-qualification had not been performed but in the previous report also, Critical Process Parameters had been forgone such as determination of worst case scenario for loaded cycle mapping of autoclave, use of Biological Indicator with its D value & consequent Z value & F^o calculation was not available, therefore Sterility Assurance Level (SAL), half cycle could not be determined, vacuum leak test, steam quality tests which are defined as the measurable physical aspects of steam used for sterilization which include temperature (superheat), dryness (liquid water content), and non-condensable gas content, had not actually been

	IQ and OQ (RP-VDF-QFR-005) protocols of Rotary Compression Machine ZP-17 was reviewed and found deficient for all the tests. Equipment Qualification of Autoclave was reviewed as per PQ protocol (RP-VD-PV-BIO-002) 12 thermocouple probes but only 5 thermocouple probes were used. The PQ activity was outsourced. It was claimed that biological indicators were used during qualification activity but no record was provided. Area Qualification record was not provided. Area recovery study was not performed. No media fill has been done for two years for any of the process. No monitoring for differential pressure for filters at Air Handling Units. **Major**	performed by the firm. Therefore, the firm was advised to perform re-qualification of autoclaves. The firm have provided protocol for area qualification of Oncology Section doc# AQ/R-23-001/01 authorized on 18-12-2023 which includes the area recovery test, the protocols for area qualification of other Sterile areas had been similarly prepared. Protocol for Media fill trials had been prepared but awaits execution since DML has been suspended by DRAP The firm have installed magnehelic gauges on AHUs, display of action/alert limits and regular monitoring and recording of differential pressure was advised. Thermal mapping of transport vehicles had been performed.
29	**Process validations** There was no system for validation of manufacturing processes. The available SOP, RP-VD-SOP-005, Version 02, Issue Apr 2020, Review: Apr 2023**,** was reviewed. It was not in line with the standard guidelines. It did not cover the validation of manufacturing process at development and trial stage or throughout the product lifecycle. Media fill trial record was not available. Although firm claimed that they have archived the older record (more than 2 years) in some place outside the premises and since two years they have not performed media fill trial. There was no list available of the manufacturing processes that had been validated. The team informed that manufacturing process of around ten batches had been validated yet. And 5 were planned in 2023. It was	In response to the critical observations regarding the lack of a system for process validation, outdated SOPs, absence of documentation, and discrepancies in process validation plans, improvements have been implemented to ensure the validation of manufacturing processes and compliance with standard guidelines. A process validation plan on Form# QA-F-0069 issue date 15-12-2023 for the year 2024 was available corresponding to doc# QA-VD-SOP-002. The firm has hired a new validation manger with more than 15 years of experience to carry out validation activities. Re-validation of de-pyrogenation via DHS and sterilization via autoclave still needs to scheduled keeping in view critical process parameters. Protocol for Media fill trials had been prepared but awaits execution since DML has been suspended by DRAP. The firm was advised to carryout media fill trials as well as qualification of DHS and autoclave on priority basis before resumption of manufacturing activity.

	asked to show the list/plan for process validations planned in 2023. However, the plan provided was printed and signed with an older date (01-01-2023) just before presenting to the inspection team as confirmed from the company's team. Process validation plan of 2022 was not available. **Critical**	
30	**Cleaning Validation** There was no system for validation of cleaning procedures. Cleaning procedures were not validated. No plan for performing cleaning validation for the year 2022 and 2023 was available. SOP, RP-VD-SOP-004, Version 02, Issue Feb 2020, Review: Feb 2023 was reviewed. It was outdated and not in line with the standard guidelines. There was no mention of HBEL. Out of all the equipment and the wide range of products being manufactured in the facility, the cleaning procedure of only one equipment and compound (Triamcinolone Liquid Injection) in the steroid section was validated according to the SOP as informed by the company's team but the personnel informed that selection was done based on literature review and difficult to clean approach. Any working on the selection was not documented and not available. **Critical**	Although Cleaning validation plan for the year 2024 was provided however, selection criteria for the products was not available, determination of worst case scenario in each category in accordance with International best practices was also missing. The SOP for cleaning validation also needs to be revised to includes determination of health-based exposure limits (HBEL) where applicable. Documentation of Cleaning. Equipment train for different products being manufactured on same equipment had also not been considered. Cleaning validation protocol for dry powder suspension area doc# CV/R-24/001/01 was presented to the panel however evidence based selection of product to considered for validation was missing.
31	**Calibration** Calibration of equipment being used for area monitoring, manufacturing and quality control of materials both finished products as well as raw material, was inadequate. Verification log of balances did not cover working range such as the verification of (RP-WH-M001) was being done up to 20kg whereas drums	Annual Calibration plan for the year 2024 approved on 07-01-2024 was reviewed which encompasses equipment including Production, QC and utilities. practices. Efforts have been made to expand the calibration range for equipment to cover the entire working range effectively. Working range of weighing balances have been mentioned on them and dead weights have been purchased to encompass the working ranges however, change in Verification logs need to be made for balances, include calibration up to the maximum weight capacity required for handling drums available in the warehouse.

	of more gross weight was available in warehouse. During the inspection of packaging material store, it was observed that Top loading balance was displaced from higher shelf to the lower shelf by a worker without considering its impact on calibration status. Calibration of Quality Control equipment was not adequate such as for HPLC, Equipment ID RP-QC-INSP-028, calibration record, RP-QC-INS-005, indicated it was calibrated for Column oven temperature, flowrate and caffeine checks. Similarly, volumetric glassware of QC laboratory was not calibrated volumetric flask of 50 milliliters were not calibrated while 2 volumetric flasks from the same lot had different marking. **Major**	The firm has revised SOP for daily calibration verification accordingly doc# QA-G-SOP-0014 rev#05 effective 01-01-2024 has now been implemented During the inspection all weighing balances were found to be placed in their designated spaces. Measures have been implemented to prevent displacement of equipment and ensure the maintenance of calibration status. Clear instructions have been provided to personnel regarding the proper handling and placement of equipment to prevent unintended impacts on calibration. Regular inspections are conducted to monitor the status of equipment and ensure compliance with calibration requirements. Calibration records of quality control equipment, such as HPLC include comprehensive calibration checks for all relevant parameters, including column oven temperature, flow rate. However, additional checks for accuracy, such as caffeine checks are still missing. Volumetric glassware in the quality control laboratory has been subjected to calibration to ensure accuracy and consistency in measurements. Volumetric flasks, including those with discrepancies in marking, have been calibrated to verify their accuracy and reliability.
32	**Sampling** Sampling was not adequate, sampling SOP was deficient and did not incorporated the sampling of all materials including primary packing material, such as during visit of packaging material store, pharmacist told that 100g of aluminum foil is taken as sample, whereas, 2 feet was mentioned in log book. Moreover, the SOP, RP-QA-SOP-004, (ver.04, issue: June 2022), Sampling of Packaging Material had no provision for primary packaging material such as aluminum foil and its acceptance criteria. **Major**	The previous Sampling SOP (RP-QA-SOP-004) has been reviewed and revised to address deficiencies and incorporate all necessary sampling procedures. The revised SOP doc# QA-G-SOP-004 rev# 04 effective date 09-01-2024 now includes provisions for the sampling of all materials, including primary packaging materials such as aluminum foil. Clear guidelines and acceptance criteria have been established for the sampling of each material type to ensure consistency and accuracy in sampling practices. The revised SOP has been communicated to all relevant personnel, and training sessions have been conducted to ensure understanding and compliance with the updated procedures.

33	**Drug Product** The firm failed to conduct, for each batch of drug product, laboratory determination of testing/analysis conformance to specifications for the drug product, prior to release hence there was lack of scientific evidence that all drug product conformed to the appropriate quality specifications. Firm did not have the list of chemical and microbial specifications, including test methods, used to analyze drug products for decision regarding release. **Critical**	To address the failure to conduct laboratory determination of drug product conformance to specifications prior to release, measures have been implemented. SOPs has been revised and reinforced to ensure that laboratory testing is conducted for each batch of drug product prior to release. The revised SOP doc# QC-G-SOP-003 rev#04 effective date 31-12-2023 outlines the receiving of samples, assigning of QC no. etc.; whereas individual SAPs of the products delineate the specific testing protocols and analysis methods including chemical and microbial specifications to be followed to confirm conformance to quality specifications to facilitate release decisions. The firm has planned training sessions of QC personnel for the year 2024 to educate personnel on the importance of pre-release testing and ensure compliance with established protocols.
34	**Water** The firm did not establish the adequate laboratory controls and specifications for bulk highly purified water and water for injection being used in the manufacturing of general and sterile products. Although CoAs were generated for the water for injection but for some of the tests recorded in CoA, such as nitrates, required reagent diphenyl amine were not available. For example, Rubidox batch # D318007 was manufactured on 18-02-2023 but neither the sample of WFI, was received in Microbiology laboratory for testing in receiving log, nor the analysis report was found in the record. For same batch, results verified from the quality control laboratory water was tested for TOC but equipment was found to be out of calibration since December 2022. **Raw Material**	The documents for operational qualification RP/VD/OQR/002 effective date 12-04-2018 and performance qualification RP-VD-PR-006 effective date 28-04-2023 were available. Also SOP for operation and monitoring of Purified water facility doc# ENG-ELC-SOP-001 rev#3 effective date 21-12-2023 had been provided. The firm claimed to be undergoing third phase of water treatment testing after shifting the specification of Purified Water/WFI from BP to USP through change control no. CC-015-2023 dated 28-08-2023 (according to firm change was actually instituted in April 2023 and August date is a typographical error).However, review of records on format RP-VD-WV-002 issue date -3-04-2023 showed that firm had not taken critical parameters of Qualification under consideration as per USP like testing of Calcium, Magnesium & free Chlorine during qualification stage to ensure softening of water and removal of free Chlorine before passage through RO membranes. The firm was therefore advised to perform re-qualification in accordance with guidance provided in USP. Furthermore, as per doc# RP-VD-SP-009 issue date May2023, for chemical testing, the protocol provided for pH, TDS, chloride & sulphate for sampling points pre-RO membrane, whereas starting from RO membrane the chemical tests performed included pH, conductivity, chloride & TDS. However, since the firm had switched from BP to USP specs and for routine testing of Purified water& WFI, USP recommends only 2 tests i.e., conductivity and TOC, however, neither the criterion of USP for water qualification were considered neither

	DEG and EG testing was not being performed by the firm. Moreover, the same was also not done by the manufacturer of glycerin. **Critical**	complete monograph testing of water was being carried out by the firm. The firm was therefore advised to carry out re-validation and subsequent routine testing in accordance with USP monograph & general chapters. The firm has implemented procedures to address the absence of testing for diethylene glycol (DEG) and ethylene glycol (EG) in raw materials. Solvents like Glycerin & PG are routinely being sent to CDL for test/analysis. The firm has also purchased GC and are in the process of obtaining column and reference standards for DEG & EG determination.
35	**Reference standards and reagents** Management, handling and labelling of reference standards, reagents, glassware etc. was not adequate. The firm was standardizing working standards but evidence was missing. Such as record for standardization of working standards, cefixime against reference standard was available but the available record does not provide the traceability to the primary reference standard. Similarly, for bisoprolol was standardized against working standard and record for standardization of bisoprolol was not available. No record/log book for consumption of reference or working standard was available. The chemicals were found to be stored without any segregation specifically no segregation on the basis of hazard was observed. The chemical crystal Violet Indicator Batch # C.I 42555, was stored in chemical cabinets but the firm did not have its CoA and it was observed that it was very old chemical without any expiry or date of opening. **Major**	Corrective actions have been implemented to ensure adequate management, handling, and labeling of reference standards, reagents, and other laboratory materials. SOP doc# QC-G-SOP-011 rev# 00 effective date 19-12-2023 has been devised to establish clear guidelines for the proper storage, handling, and labeling of reagents. Training sessions have been conducted to educate personnel on the importance of proper management practices and ensure compliance with established protocols. SOP for Handling of Reference and Secondary/Working standards doc# QC-G-SOP-006 rev#04 effective date 31-12-2023 has been revised & implemented but was however did not elaborate either traceability of the standard provided by the supplier neither does it address the standardization of such working standard. A comprehensive recordkeeping system also needs to be established to track the consumption of reference and working standards accurately. Measures had been taken to improve the storage and segregation of chemicals within the laboratory. Chemicals were found to be stored in accordance with established safety protocols, with proper segregation based on hazard classification & labeled with expiration dates and dates of opening to facilitate proper inventory management and ensure the timely disposal of expired or obsolete chemicals. Certificates of analysis (CoAs) were found available for all chemicals, and records were maintained to track the receipt, usage, and disposal of chemicals in compliance with regulatory requirements. Hazardous chemicals were labeled and stored separately to prevent cross-contamination and ensure the safety of laboratory personnel. However, improvements were required in tracking of expiry date of microbial strains as, COAs of 2 strains showed that they were being utilized upto 5 passages whereas, the supplier had provided the strains at 2nd or 3rd passage. The firm was advised to conduct regular

		inspections to monitor the condition of stored chemicals/microbial strains with expiry dates and ensure compliance with regulations.
36	**Out of Specification Investigations / Out of Trend Investigation** There was no SOP or practice of out of trend recording or analysis. Out of specification investigation was found deficient for formalized approach for batch disposition in case of unassignable cause. **Out of specification (OOS) record for only one previous year 2022 was available, during which 7 OOS were recorded. OOS record form/log, Document ID: RP-QC-L0 Version: 02 issued: 2020, was a loose uncontrolled document. There was no number of OOS on OOS form as listed in the log. The batch number of the product was neither mentioned on log nor on the OS investigation form Document ID: RP-QC-R002. There was no investigation done after the OOS, no RCA was performed and hence no CAPA was initiated, QCM told that QA personnel initiate the CAPA, hence he has no information on that. Such as DMX-T, Eye Drops batch #, Nil, was reported as OOS regarding assay of the dexamethasone which was found to be 51%. There were no further actions regarding this OOS. Furthermore, he replied that this problem in assay quantity might arose due to the absence of continuous mixing of formulation during the filling of Drops as Dexamethasone which is suspended in formulation, tends to settle in the bottom of mixer.** **Critical**	In the year 2023, 09 OOS results had been logged by the firm, SOP for Investigation of OOS had been revised. New SOP doc# QA-G-SOP-019 rev# 02 effective date 31-12-2023 has been implemented and accordingly OOS investigation forms for chemical/microbiology & packaging material have been developed and implemented for the recording and analysis of out of trend data. The SOP outlines the protocols for conducting OOS investigation in a systematic manner. Training sessions have been conducted to familiarize relevant personnel with the SOP, ensuring consistent adherence across all operations. However, the firm requires to devise SOP for identifying, documenting, and analyzing out of trends results in product quality parameters as well as in utilities. Furthermore, corrective measures need to be taken to address deficiencies in the out of specification investigation process, particularly concerning the formalized approach for batch disposition in case of unassignable cause. A procedure needs to be established by the firm, which delineates clear steps for investigating out of specification results and determining appropriate batch disposition based on root cause analysis (RCA). Moreover, RCA needs to be incorporated into the SOP to facilitate systematic identification of the underlying causes of OOS results, so that appropriate corrective action preventive actions (CAPAs) are initiated to address root causes and prevent recurrence.
37	**Stability Studies**	Regarding the absence of a policy or plan for stability testing, a comprehensive stability testing protocol has

	There was no policy or plan or protocol (interval, analytical methods etc.), described for the stability testing of products. Two different Log Form having same versions; RP-R&D-L003 VERSION 01 ISSUE 2018, REVIEW 2025 & RP-R&D-L003 VERSION 01 ISSUE 2020, REVIEW 2025, were in form of loose sheets. There were 457 products placed in the stability chamber as per list provided for which they have started testing the product randomly. Complete testing is not performed and reduced testing is done without defining the parameters based on criticality, such as Stability study data provided for product Kenatex Injection, B # E266004, on time point of 12 months showed that Assay, average weight and pH were performed while test for both Bacterial Endotoxin and sterility were not performed. **Major**	been established and implemented which is delineated in doc# QA-G-SOP-012 rev#02 effective date 25-12-2023. This SOP outlines the procedures, frequency and other essential aspects required for conducting stability testing pharmaceuticals. Regarding the discrepancy noted with the two versions of the Log Form, measures had been taken to rectify the issue. Both versions of the Log Form, namely RP-R&D-L003 VERSION 01 ISSUE 2018 and RP-R&D-L003 VERSION 01 ISSUE 2020, had different ownership but had the same content; they have now been consolidated into a unified, standardized format. Regarding the specific instance highlighted concerning the Kenatex Injection stability study, corrective actions have been taken to address the deficiencies identified. Test parameters, including Bacterial Endotoxin and sterility testing, have been incorporated into the SOP for stability testing of sterile products.

Conclusion

The inspection was conducted for the purpose of verification that deficiencies noted in the Inspection report during WHO Observed Benchmarking Inspection of M/s Rotex Pharma Plot # 206 & 207, Industrial Triangle Kahuta Road, Islamabad. The unit is shared facility currently manufacturing Cephalosporin, Carbapenem, Steroidal, and Oncology products along with General products. the finding of the panel against each deficiency have been discussed in detail above. In conclusion, it was verified that significant strides had been made by the firm to address and rectify the deficiencies noted in the previous inspection by DRAP. Significant improvements had been made through the implementation of revised SOPs, enhanced recordkeeping practices, implementation of standardized procedures, training initiatives, and improvements in documentation and accountability. The efforts made by the firm in improvement of Oncology, Carbapenem, Cephalosporin Sections, water treatment system, HVAC, also the commitment of the firm in the endeavor to control the risk of contamination & cross-contamination, issues of data integrity, in particular were found to be praise worthy. Comprehensive developments in QMS have also been established by the firm to enhance monitoring and ensure compliance with cGMP, International Guidelines and applicable law; however, QRM and QA need further strengthening through external trainings. **Based on the findings of the inspection, review of documents and records, systems, utilities, physical inspection of areas in the manufacturing facility mentioned above, and interview of personnel, it is concluded that the firm is operating at an acceptable level of cGMP compliance.**

Recommendation

Based on the findings the inspection team unanimously recommends Resumption of Drug Manufacturing License and all manufacturing activities in the facility of M/s Rotex Pharma, Plot # 206 & 207, Industrial Triangle Kahuta Road, Islamabad

Azhar Jamal Saleemi **Babar Khan**, **Saadia Mahwish**

RECOMMENDATIONS OF QA&LT

In view of the scenario detailed above and the fact that the instant inspection was conducted on 22-25th January, 2024, 30th January 2024, 15th February 2024 and 20th February 2024 to verify the compliance of the decision of the CLB from its 293rd meeting held on 20th November 2023; QA&LT division recommends that the panel thoroughly inspected M/s Rotex Pharma, Plot # 206, 207, Industrial Triangle Kahuta Road,, Islamabad and the panel concluded as

"***Based on the findings of the inspection, review of documents and records, systems, utilities, physical inspection of areas in the manufacturing facility mentioned above, and interview of personnel, it is concluded that the firm is operating at an acceptable level of cGMP compliance.***"

The panel recommended as

"***Based on the findings the inspection team unanimously recommends Resumption of Drug Manufacturing License and all manufacturing activities in the facility of M/s Rotex Pharma, Plot # 206 & 207, Industrial Triangle Kahuta Road, Islamabad."***

Therefore, it is recommended to resume the DML of M/s Rotex Pharma. The firm needs to address the following observations as noted by the panel:

S. No.	Observations	Remarks
1.	**Access and privileges** The firm has to improve the adequately controlled in accordance with SOP on Access Control on Audit Trail of Software generated data in QC lab doc# QC-G-SOP-010 rev#00 effective date 19-12-2023.	
2.	**Quality Risk Management** The firm requires to undergo training from external sources in order to grasp the concept & implementation of risk assessment & quality risk management.	
3.	**Product Quality Review** SOP for Annual Product Quality Review was revised by the firm doc# QA-G-SOP-026 rev#003 effective date 08-01-2024, where the timeline for completion and actual critical process parameters as well process capability and performance should be included in the document	
4.	**HVAC** The firm was advised to either provide RO water and controlled environment for washing of filters or to replace the filter if it is choked.	

5.	**Water System and Steam** Clean steam validation should be carried out.
6.	**Compressed Air & Gases** The firm is advised to include PUPSIT at defined intervals in accordance with risk management principle.
7.	**Process validations** The firm needs to scheduled Re-validation of de-pyrogenation via DHS and sterilization via autoclave.
8.	**Water** The firm was advised to carry out re-validation and subsequent routine testing in accordance with USP monograph & general chapters

PROCEEDINGS OF 293rd MEETING OF CLB: -

Representatives of the Division of QA&LT briefed the case before the CLB. The instant matter was deliberated in detail by all the members of the board.

DECISION OF 296th MEETING OF CLB: -

After considering the comprehensive inspection report of the panel, and the recommendation of the QA&LT Division, the Board deliberated the matter and unanimously decided for resumption of DML (000651 by way of Formulation) of M/ Rotex Pharma Pvt. Ltd, Plot # 206, 207, Industrial Triangle Kahuta Road Islamabad from the date of communication of this decision and until further orders

Furthermore, the board advised the same panel of experts as constituted in its 293rd meeting to carry out a follow up inspection for the improvement of observations as pointed out by the panel.