**MINUTES OF 289th MEETING OF CENTRAL LICENSING BOARD HELD ON 23rd JANUARY, 2023**

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289th meeting of the Central Licensing Board (CLB) was held on 23rd January, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Mr. Muhammad Akhtar Abbas Khan, Chairman Central Licensing Board, Drug Regulatory Authority of Pakistan, Islamabad presided the meeting. Following members attended the meeting: -

| S.No | Name & Designation | Status |
|---|---|---|
| 1. | Dr. Najam-us-Saquib, Additional Director, Drug Regulatory Authority of Pakistan, Islamabad. | Secretary/ Member |
| 2. | Mr. Azher Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore | Member |
| 3. | Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Balochistan, Quetta | Member |
| 4. | Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Peshawar Government of Khyber Pakhtun Khwa | Member |
| 5. | Mr.Ghulam Ali Lakho, Drug Inspector, Government of Sindh, Karachi | Member |
| 6. | Mr. Ajmal Sohail, Director, Division of Quality Assurance and Lab Testing, Drug Regulatory Authority of Pakistan, Islamabad | Member |
| 7. | Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad | Member |
| 8. | Mr. Nadeem Alamgir, Representative of Pharma Bureau. | Observer |
| 9. | Mr. Adnan Hirani Representative of PPPMA | Observer |
| 10. | Mr. Usman Shoukat, Representative of PPPMA | Observer |
| 11. | Mr. Kamran Anwar Representative PCDA | Observer |

The meeting started with the recitation of Holy verses. The Chairperson stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes thereof. The Central Licensing Board considered, discussed and decided cases on merit. Secretary Licensing Board presented the agenda before the Board. Ms. Zunaira Faryad, AD (Lic), Mr. Muhammad Yaqoob AD (Lic) Mr. Muhammad Usman, AD (Lic), Mr. Muhammad Ansar Deputy Director QA, Mr. Muhammad Umar Latif AD (QA) Mr. Shahrukh Ali, AD (QC) and Ms. Mehwish Tanveer,

AD (QA) DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

**Item-I** **CONFIRMATION OF THE MINUTES OF 288thMEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 288th meeting of the Central Licensing Board (CLB) held on 18th October, 2022

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

(Evaluator: Mst. Zunaira Faryad AD-I, Sr. No. 1-3)

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

| S # | Name of the firm | Date of Inspection | Ranking/ Evaluation | Inspection Panel Members |
|---|---|---|---|---|
| **1** | M/s Auspec Pharmaceuticals, 21-Km Raiwind Road, behind Alamgeer Marble factory, Lahore<br><br>**Sections (06):**<br>i. Tablet (General) Section.<br>ii. Capsule (General) Section.<br>iii. Semi-Solid (General) Section.<br>iv. Dry Powder Suspension (General) Section.<br>v. Sachet (General).<br>vi. Oral Liquid (General) Section. | 27-10-2022 | Good | 1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab.<br>2. Dr. Syed Zia Husnain, FID, DRAP, Lahore.<br>3. Ms. Mehwish Jamil,, AD, DRAP, Lahore. |
| | **Recommendations of the panel:**<br><br>Panel inspected the unit thoroughly and evaluated various documents revealed by the firm management in connection with Quality assurance, Quality Control and Production operations. | | | |

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| | Different technical aspects were also discussed with firm management at length. Based on the physical inspection of the unit, evaluation of the documents revealed by the firm management and discussion with the technical staff, panel was of the opinion to recommend the grant of Drug Manufacturing License to M/s Auspec Pharmaceuticals (Pvt) Ltd, 21-Km Raiwind Road, behind Alamgeer Marble factory, Lahore for the following six sections.<br><br>1. Tablet (General) Sections<br>2. Capsule (General) Sections<br>3. Semi-Solid (General) Section<br>4. Dry Powder suspension (General) Section<br>5. Sachet (General)<br>6. Oral Liquid (General) Section.<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>Based on the recommendations of the panel of experts,the Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Auspec Pharmaceuticals, 21-Km Raiwind Road, behind Alamgeer Marble factory, Lahore for the following sections:<br><br>**Sections (06)**<br><br>1. Tablet (General) Section.<br>2. Capsule (General) Section.<br>3. Semi-Solid (General) Section.<br>4. Dry Powder Suspension (General) Section.<br>5. Sachet (General).<br>6. Oral Liquid (General) Section. | | | |
| **2** | M/s DS Pharma, Plot No.13, Sher Shah Industrial Estate, Qila Sattar Shah, Sheikhupura.<br><br>**Sections (02):**<br><br>i. Liquid injectable (SVP) Ampoule Section (General).<br>ii. Liquid injectable (SVP) Ampoule Section (Steroid). | 22-11-2022 | Good | 1. Ch. Muhammad Shamoon, Expert Member.<br>2. Ms. Majida Mujahid, Additional Director, DRAP, Lahore.<br>3. Dr. Syed Zia Husnain, , FID, DRAP, Lahore. |
| | **Recommendations of the panel:**<br><br>Panel inspected the firm comprehensively and assessed various documents revealed by the firm management in connection with Quality assurance, Quality Control and Production | | | |

<table>
<tr><td></td><td colspan="4">operations. Different technical aspects were also discussed with firm management at length. Based on the physical inspection of the unit, evaluation of the documents revealed by the firm management and discussion with the technical staff, panel was of the opinion to recommend the grant of Drug Manufacturing License to M/s DS Pharma Plot No.13, Sher Shah Industrial Estate, Qila Sattar Shah, Sheikhupura for the following two sections.<br><br>i. Liquid injectable (SVP) (Ampoule) Section (General)<br>ii. Liquid injectable (SVP) (Ampoule) Section (Steroid).<br><br><u>Decision of the Central Licensing Board in 289th meeting</u><br><br>Based on the recommendations of the panel of experts, the Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s DS Pharma, Plot No.13, Sher Shah Industrial Estate, Qila Sattar Shah, Sheikhupura for the following sections:<br><br><u>Sections (02)</u><br><br>i. Liquid injectable (SVP) (Ampoule) Section (General)<br>ii. Liquid injectable (SVP) (Ampoule) Section (Steroid).-</td></tr>
<tr><td>3</td><td>M/s. High-Cure Research Laboratories, 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.<br><br><u>Sections (03):</u><br><br>i. Capsule Section (Cephalosporin).<br>ii. Dry Powder Suspension (Cephalosporin).<br>iii. Dry Powder for Injection (Cephalosporin).</td><td>05-12-2022</td><td>Good</td><td>1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore.<br>2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.<br>3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u><br>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,</td></tr>
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| | building, equipment, Quality Control and Quality Assurance, the panel is of the opinion to recommend the grant of Drug Manufacturing License, by way of formulation to M/s. High-Cure Research Laboratories, situated at 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore for the following sections:<br><br>i. Capsule Section (Cephalosporin).<br>ii. Dry Powder Suspension (Cephalosporin).<br>iii. Dry Powder for Injection (Cephalosporin).<br><br>Decision of the Central Licensing Board in 289th meeting<br><br>Based on the recommendations of the panel of experts ,the Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s High-Cure Research Laboratories, 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore. for the following sections:<br><br>**Sections (03)**<br><br>i. Capsule Section (Cephalosporin).<br>ii. Dry Powder Suspension (Cephalosporin).<br>iii. Dry Powder for Injection (Cephalosporin). | | | |
| 4. | M/s ACME Pharmaceuticals, Plot No. 29, Street SS- 2, RCCI, Industrial Estate Rawat. | 19-12-2022 | **Very Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Dr. Qurban Ali, Expert Member.<br>3. Fahad Nadeem, Deputy Director (LT), DRAP, Islamabad. |
| | **Recommendations of the panel:**<br><br>The firm has maintained SOPs for internal audit and to handle the market complaints. They are concerned with the training of the employees; procedures for waste management are defined. It is advised to strengthen the QA to meet the requirements of existing / new sections and to devise a mechanism for approval of SOPs through MR. Keeping in view the facts observed during inspection, the panel (constituted vide Letter No. F.1-31/2021-Lic dated 05-11-2022) unanimously recommends grant of DML by way of formulation to M/s ACME Pharmaceuticals, Plot No. 29, Street SS- 2, RCCI, Industrial Estate Rawat, with following | | | |

sections whereas Oral Dry Powder & Ware House (Penicillin) are deferred with reason as they were not ready;

| Sections/Formulations | Pharmacological Categories | Remarks |
|---|---|---|
| Oral Dry Powder-l | General | Veterinary |
| Oral Dry Powder-II | General | Veterinary |
| Oral Liquid-I | General | Veterinary |
| Oral Liquid-II | General | Veterinary |
| Ware House | General | Veterinary |
| Quality Control Laboratory | General | Veterinary |
| Microbiology Laboratory | General | Veterinary |

**Decision of the Central Licensing Board in 289th meeting**

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s ACME Pharmaceuticals, Plot No. 29, Street SS- 2, RCCI, Industrial Estate Rawat. assigning the DML NO 000 on the recommendations of the panel of experts for the following sections:

**Sections (04)**

| Sections/Formulations | Pharmacological Categories | Remarks |
|---|---|---|
| Oral Dry Powder-l | General | Veterinary |
| Oral Dry Powder-II | General | Veterinary |
| Oral Liquid-I | General | Veterinary |
| Oral Liquid-II | General | Veterinary |
| Ware House | General | Veterinary |
| Quality Control Laboratory | General | Veterinary |
| Microbiology Laboratory | General | Veterinary |

(Evaluator: Muhammad Usman, Assistant Director (AD-III) Sr. 4)

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

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

<table>
<tr><th>S #</th><th>Name of the firm</th><th>Date of Inspection</th><th>Ranking/ Evaluation</th><th>Inspection Panel Members</th></tr>
<tr><td>1</td><td>M/s Bliss Industries (Pvt) Ltd., Plot No.G-A-52-A6, National Industrial Park, Karachi.</td><td>05-01-2023</td><td>Good</td><td>1. Mr. Ghulam Ali Lakho, Senior DI Karachi.<br>2. Dr. Najam Us Saqib, Additional Director (Licensing), DRAP, Islamabad.<br>3. Ms. Sanam Kausar, AD, DRAP, Karachi.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u><br><br>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 :<br>During the inspection, panel observed that the firm has constructed as per approved layout plan approved by the DRAP authorities.<br><br>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.<br><br>“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><th>S.No.</th><th>Name of Section</th><th>S.No.</th><th>Name of Section</th></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>
<u>Decision of the Central Licensing Board in 289th meeting</u><br><br>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</td></tr>
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<tr><td></td><td colspan="4">board decided to get the latest status of the court case filed by the firm and place before the CLB in its next meeting.</td></tr>
<tr><td>2</td><td>M/s QAS International, Plot No. 153/155, Mustafaabad Tehsil Kamoki, District Gujranwala.</td><td>22-12-2022</td><td>Good</td><td>1. Chief Drugs Controller, Government of Punjab, Lahore.<br>2. Federal Inspector of Drugs, DRAP, Lahore.<br>3. Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u><br><br>“Panel has inspected the unit thoroughly and assessed documentation revealed by the firm management in connection with Quality assurance, Quality Control and Production operations. Different technical aspects were also discussed with firm management at length. Based on the physical inspection of the unit, evaluation of the documents revealed by the firm management and discussion with the technical staff, panel decided to recommend the grant of Drug Manufacturing License to M/s QAS International, Plot No. 153/155, Mustafaabad Tehsil Kamoki, District Gujranwala, only for following four veterinary sections:<br><br>i. Oral Liquid (General) Veterinary Section.<br>ii. Oral Liquid (General/Antibiotic) Veterinary Section.<br>iii. Oral Powder (General) Veterinary Section.<br>iv. Oral Powder (General/Antibiotic) Veterinary Section.<br><br><u>Decision of the Central Licensing Board in 289th meeting</u><br><br>Based on the recommendations of the panel of experts, the Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s QAS International, Plot No. 153/155, Mustafaabad Tehsil Kamoki, District Gujranwala. for the following sections:<br><br><u>Sections (04)</u><br><br>i. Oral Liquid (General) Veterinary Section I<br>ii. Oral Liquid (General) Veterinary Section II.<br>iii. Oral Powder (General) Veterinary Section I<br>iv. Oral Powder (General) Veterinary Section II</td></tr>
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(Evaluator: Muhammad Yaqoob AD-IV, Sr. 5)

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

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

| S # | Name of the firm | Date of Inspection | Ranking/ Evaluation | Inspection Panel Members |
|---|---|---|---|---|
| **1** | M/s University of Veterinary and Animal Sciences (UVAS), Ravi Campus, Pattoki, District Kasur.<br>(By way of formulation) | **11-10-2022** | **Good** | 1. Dr. Zaka-ur-Rehman, COO, PDTRC Lahore<br>2. Dr. Syed Zia Husnain, FID, DRAP, Lahore.<br>3. Uzma Barkat, Assistant Director, DRAP, Lahore. |

**Production Area**

Management informed that the FMD vaccine as per BP specification was intended to be manufactured. Different Laboratories have been established including Media Preparation Lab (MPL), Cell Culture Lab (CCL), Vaccine Formulation Lab (VPL) and Vaccine Filling & Packaging Lab (VFPL). Entries to said different areas were through buffers. HVAC was installed and found operational. Management has given undertaking that at present suspension culture technology shall not be used.

*"1. We will not use suspension culture laboratory without prior permission from DRAP*
*2 We will provide HVAC supply in store in one month"*

**Conclusion**

"Panel has thoroughly evaluated the various documents in connection with production, quality control and quality assurance systems of the unit. Panel also inspected the plant and discussed various technical aspects at length with the technical staff intended to be involved in production of vaccine and also discussed the protocols and production design of FMD vaccine intended to be manufactured. After thorough evaluation of documents provided by the management and inspection of the unit panel was of the view that UVAS has made lot of progress to obtain the manufacturing License for veterinary vaccine. Management has also up-graded the unit as advised during last inspection. Some up-gradations and improvements advised during this inspection were also done and in this regard pictorial evidence duly signed by the firm management is attached herewith alongwith signed documentary submission by the Director TCBP-FMD, UVAS Ravi Campus, Pattoki. Panel has given some advises for further up-gradations as mentioned above in the report. Management was also advised that further latest equipment also be installed time to time based on the need and international practices. Quality Assurance is day to day consistent effort required to be done by the management of the firm while the unit will become operational as per law. Panel recommends that pilot scale manufacturing required to be done at initial stage for proper stability studies and clinical trials as per law and legal and scientific protocols. **Basic infrastructure for the production and testing of FMD veterinary vaccine had been provided, however, it is the responsibility of UVAS (TCBP-FMD) to comply with the standard guidelines and fulfil the standard requirements like OIE Terrestrial Manual, British Pharmacopoeia / European Pharmacopoeia.**

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| | Under the explained circumstances mentioned above in the report; panel was of the view to **recommend** the facility of Training Center for Biologics Production (TCBP-FMD), at Ravi Campus, University of Veterinary and Animal Sciences, Pattoki, Kasur for grant of Drug Manufacturing License to manufacture the FMD veterinary vaccine after due authorization as per law.<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>Based on the recommendations of the panel of experts, the Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s University of Veterinary and Animal Sciences (UVAS), Ravi Campus, Pattoki, District Kasur. for the manufacture the FMD veterinary vaccine through cell culture technique only.<br><br>The Board also decided to refer the recommendation of the panel that pilot scale manufacturing required to be done at initial stage for proper stability studies and clinical trials as per law and legal and scientific protocols to Drug Registration Board for further trial and stability studies. |

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

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

(Evaluator Mst. Zunaira Faryad, AD-I. Sr. 1-4)

| S # | Name of the firm | Date of Inspection / Type of License | Ranking/ Evaluation | Inspection Panel Members |
|---|---|---|---|---|
| 1 | M/s. Medella Pharmaceuticals (Pvt) Ltd., 569/570, Sunder Industrial Estate, Raiwind Road, Lahore<br><br>DML No.000749 (Formulation).<br><br>**Section (04):**<br><br>i. Tablet (General) Section (New)<br>ii. Capsule (General) Section (New)<br>iii. Dry Powder Suspension (General) Section (New).<br>iv. Sachet (General) Section (New). | 24-11-2022 | **Good** | 1. Mr. Zeeshan Nazir Bajar, Secretary, Registration Board, DRAP, Islamabad.<br>2. Mr. Abdul Rashid Sheikh, FID DRAP, Lahore<br>3. Ms. Uzma Barkat, Assistant Director, DRAP Lahore. |
| | **Recommendations of the panel: -**<br><br>In view of above inspection proceedings and facilities verified, such as building, production, quality control testing, machinery/equipment, air handling, water treatment system and documentation etc the panel recommends the Renewal of Drug Manufacturing License and grant of additional sections to M/s. Medella Pharmaceuticals (Pvt.) Ltd., 569/570, Sunder Industrial Estate, Lahore by way of formulation for the following sections:<br><br>i. Tablet (General) Section (New)<br>ii. Capsule (General) Section (New)<br>iii. Dry Powder Suspension (General) Section (New)<br>iv. Sachet (General) Section (New) | | | |

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| | v. Oral Liquid Section (Renewal).<br><br>**Decision of the Central Licensing Board in 289th meeting**<br>The Board considered and approved the grant of following additional sections in the name of M/s Medella Pharmaceuticals (Pvt) Ltd., 569/570, Sunder Industrial Estate, Raiwind Road, Lahore under DML No.000749 (Formulation)on the recommendations of the panel of experts.<br><br>**Section / facility (04):**<br>i. Tablet (General) Section (New)<br>ii. Capsule (General) Section (New)<br>iii. Dry Powder Suspension (General) Section (New)<br>iv. Sachet (General) Section (New) | | | |
| 2 | M/s. Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozepur Road, Lahore.<br><br>DML No.000559 (Formulation)<br><br>**Section (02):**<br>i. Tablet (General) Section (Revised).<br>ii. Tablet (Steroidal Hormone) Section (Revised). | **03-11-2022** | **Good** | 1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore.<br>2. Dr. Syed Zia Husnain, FID, DRAP, Lahore.<br>3. Ms. Ufaq Tanveer, Assistant Director, DRAP, Lahore. |
| | **Recommendations of the panel:**<br>Firm has been inspected by the panel comprehensively and assessed various documents revealed by the firm management in connection with new approved layout, Quality assurance, Quality Control and Production operations. Diverse technical aspects were also deliberated with firm management at length. Based on the physical inspection of the unit, evaluation of the documents revealed by the firm management and discussion with the technical staff, panel was of the opinion to recommend the grant of revised following two sections to M/s. Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozepur Road, Lahore: -<br>i. Tablet (General) Section.<br>ii. Tablet (Steroidal Hormone) Section.<br><br>**Decision of the Central Licensing Board in 289th meeting** | | | |

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| | The Board considered and approved the grant of following revised sections in the name of M/s Dyson Research Laboratories (Pvt.) Ltd 28-Km Ferozepur Road, Lahore. under DML No.000559 (Formulation)on the recommendations of the panel of experts.<br><br>**Section / facility (02):**<br><br>i. Tablet (General) Section (Revised).<br>ii. Tablet (Steroidal Hormone) Section (Revised). | | | |
| 3 | M/s. Citi Pharma (Pvt.) Ltd, 3-Km Head Balloki Road, Phool Nagar, District Kasur.<br><br>DML No.000429 (Semi Basic Manufacture)<br><br>**API (04):**<br><br>i. Sulphamethoxazole (USP)<br>ii. Moxifloxacin HCl (USP)<br>iii. Mefenamic Acid (USP)<br>iv. Montelukast Sodium (USP)<br>v. Diclofenac Sodium (USP). | 30-08-2022 | Good | 1. Mr. Muhammad Shamoon, Expert member<br>2. Syed Zia Husnain, FID, DRAP, Lahore.<br>3. Ms. Ufaq Tanveer, Assistant Director, DRAP, Lahore. |
| | It is hereby submitted that Panel was constituted for inspection of the firm for grant of following APIs:<br><br>i. Updated process flow of Cefixime (USP)<br>ii. Moxifloxacin (Ph. Eur.)<br>iii. Mefenamic Acid USP.<br>iv. Sulfamethoxazole USP.<br>v. Betamethasone USP.<br>vi. Diclofenac Sodium BP/USP.<br>vii. Trimethoprim USP.<br>viii. Montelukast Sodium USP.<br><br>**Recommendations of the panel:** | | | |

M/s Citi Pharma (Pvt) Ltd 3-Km Head Balloki Road, Phool Nagar Kasur has been granted a Drug Manufacturing License No 000429 by Way of Semi Basic Manufacturing under the Drugs Act 1976. Panel had thoroughly inspected the unit, evaluated the documentation provided by the firm on demand and discussed various technical aspects at length. Laboratory scale accelerated stability studies were conducted by the firm. On the panel's query; firm has given an undertaking that long term stability studies shall be conducted before start of commercial manufacturing of these new APIs (Original undertaking of the firm is attached with this report for perusal of Central Licensing Board). Manufacturing processes, process flow charts, differential specifications of main input materials and final API, list of materials / chemicals intended to be used, undertaking by the firm to ensure the authorized use of all materials / chemicals with proper records, details of equipment of production and quality control and list of technical staff duly signed by the management of the firm are attached with this report for perusal of the Central Licensing Board.

In view of the technical discussion held at length with the firm's management, documentations scrutinized as submitted by the management of the firm, physical inspection of the Multi-purpose block of the unit; Panel was of the view that Trimethoprim manufacturing from Trimethoprim crude needs some technical justification with proper cost effectiveness and differential specifications of main input material and final output material to be submitted to Central Licensing Board for perusal as policy decision for all such type of APIs as it may have potential to impact on import duties of the Government. Moreover, as betamethasone itself is an API to be used in various formulations hence its procurement as raw material for manufacturing of Betamethasone Valerate may have misuse potential, therefore; panel was of the view that this matter also needs to be evaluated at the level of Central Licensing Board as policy decision for all such type of APIs as it may have potential to impact on import duties of the Government. Under the explained circumstances mentioned above; panel deferred consideration of Trimethoprim and Betamethasone at this stage with the advice to be given to firm through Central Licensing Board to proceed beyond simple purification / N-1 steps for consideration of these APIs. Panel recommends new process flow for Cefixime API manufacturing. Panel also recommends the grant of approval for the following five new APIs by way of semi basic manufacturing method.

i. Sulphamethoxazole (USP)
ii. Moxifloxacin HCL (USP)
iii. Mefenamic Acid (USP)
iv. Montelukast Sodium (USP)
v. Diclofenac Sodium (USP).

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of following API (s) in the name of M/s Citi Pharma (Pvt.) Ltd, 3-Km Head Balloki Road, Phool Nagar, District Kasur.. under DML No.000429 (Semi Basic Manufacturer) on the recommendations of the panel of experts. The

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| | firm shall conduct long term stability studies before start of commercial manufacturing of following APIs.<br><br>i. Updated process flow of Cefixime (USP)<br>ii. Moxifloxacin HCL (USP)<br>iii. Mefenamic Acid (USP)<br>iv. Montelukast Sodium (USP)<br>v. Diclofenac Sodium (USP).<br><br>The Board further decided to refer the cases of Trimethoprim and Betamethasone to the DRAP authority for a policy decision. | | | |
| 4 | M/s. Advanced Pharmaceuticals, Plot No.38. Street No. S-4, National Industrial Zone, RCCI, Rawat<br><br>DML No. 000686 (Formulation)<br><br>Section (01):<br><br>i. Cream / Ointment (General) (New) Section. | **16-11-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Mr. Mubashir Iqbal, Deputy Director (CD), Islamabad.<br>3. Mr. Zubair Masood, Assistant Director, DRAP, Islamabad. |
| | **<u>Recommendations of the panel:</u>**<br><br>The panel is of the opinion that the establishment meets the requirements of renewal of license as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel **recommends** the establishment for renewal Drug Manufacturing License w.e.f 24-06-2020 for their following approved sections including the new section namely "Cream / Ointment (General).<br><br>Further the Central Licensing Board, DRAP is requested to carry-out a follow up inspection for verification / confirmation of the procurement of FTIR by the establishment within three months.<br><br>i. Tablet (General) Section.<br>ii. Capsule (General) Section.<br>iii. Capsule (Cephalosporin) Section | | | |

iv. Dry Powder Injection (Cephalosporin) Section.

v. Dry Powder Suspension (Cephalosporin) Section.

vi. Cream / Ointment (General) (New) Section."

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of following new section in the name of M/s Advanced Pharmaceuticals, Plot No.38. Street No. S-4, National Industrial Zone, RCCI, Rawat under DML No.000686 (Formulation) on the recommendations of the panel of experts.

**Section (01):**

i. Cream / Ointment (General) (New) Section

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|---|---|---|---|---|
| 5 | M/s. Neutro Pharma (Pvt.) Ltd situated at Khewat No 50, Khatooni No. 278, Khaki Kot Abdul Malik, Tehsil Ferozewala, District Sheikhupura<br><br>DML No. 000877 (Semi-Basic Manufacture). | 19-01-2023 | **Good** | 1. Dr. Zaka Ur Rehman, Chief Operating Officer, PDTRC, Lahore.<br>2. Abdul Rashid Sheikh, Fedral Inspector of Drugs, DRAp, Lahore.<br>3. Ufaq Tanveer, Assistant Director, DRAP, Lahore. |

**Recommendations of the panel:**

Keeping in view that the facility is for semi-basic manufacturing (palletization) and in view of the building, HVAC, production equipment, personnel met, documentation and the commitment of the management of the firm, the panel of inspectors recommends the grant of API to M/s. Neutro Pharma (Pvt.) Ltd situated at Khewat No 50, Khatooni No. 278, Khaki Kot Abdul Malik, Tehsil Ferozewala, District Sheikhupura for semi-basic manufacturing (palletization) only for following molecule:

| Sr. No. | Name of API | Specification |
|---|---|---|
| 1. | Itopride HCl 32% Pellets | In House |
| 2. | Diclofenac Sodium 32% EC Pellets | In House |
| 3. | Ferrous Sulphate 50%IR Pellets | In House |
| 4. | Folic Acid 50% IR Pellets | In House |
| 5. | Isosorbide Mononitrate 30% Pellets | In House |
| 6. | Isosorbide Dinitrate 30% Pellets | In House |

| | | | | | |
|---|---|---|---|---|---|
| | | 7. | Glyceryl Trinitrate 2.5 % SR Pellets | In House | |
| | | 8. | Doxycycline Hyclate 30% Pellets | In House | |
| | | 9. | Diclofenac Potassium 32% SR Pellets | In House | |
| | | 10. | Diclofenac Sodium 32% SR Pellets | In House | |
| | | 11. | Cyclobenzaprine HCl 15% SR Pellets | In House | |
| | | 12. | Rabeprazole 22.5% DDL Pellets | In House | |
| | | 13. | Clarithromycin Taste masked 25% Micro pellets | In House | |
| | | 14. | Levofloxacin Taste masked 25% Micro pellets | In House | |
| | | 15. | Mebeverine Hcl Taste masked 33% Micro Pellets | In House | |
| | | 16. | Piperaquine 25% Taste Masked Micro Pellets | In House | |
| | | 17. | Ofloxacin 25% Taste Masked Micro Pellets | In House | |
| | | 18. | Grazoprevir 25% Dispersion | In House | |
| | | 19. | Misoprostol 26% Dispersion | In House | |
| | | 20. | Ledipasvir 25% Dispersion | In House | |
| | | 21. | Clopidogrel 30% IR Pellets | In House | |
| | | 22. | Domperidone 30% IR Pellets | In House | |
| | | 23. | Fexofenadine HCl 30% IR Pellets | In House | |
| | | 24. | Itraconazole 22.5% IR Pellets | In House | |
| | | 25. | Orlistat 50% IR Pellets | In House | |
| | | 26. | Memantine 50% IR Pellets | In House | |
| | | 27. | Paracetamol 20% Taste Masked Micro Pellets | In House | |
| | | 28. | Linezolid 20% Taste Masked Micro Pellets | In House | |
| | | 29. | Famotidine 26% Taste Masked Micro Pellets | In House | |
| | | 30. | Microcrystalline Cellulose Pellets | In House | |
| | | 31. | Ciprofloxacin HCl 35% Taste Masked Micro Pellets | In House | |
| | | 32. | Azithromycin 35% Taste Masked Micro Pellets | In House | |

| | | |
|---|---|---|
| 33. | Aspirin 75% EC Pellets | In House |
| 34. | Diclofenac Potassium 32% EC Pellets | In House |
| 35. | Aceclofenac 15% SR Pellets | In House |
| 36. | Velpatasvir 30% Dispersion | In House |
| 37. | Elbasvir 30% Dispersion | In House |
| 38. | Mebeverine HCl 60% SR Pellets | In House |
| 39. | Tamsulosin HCl 0.2% SR Pellets | In House |
| 40. | Tizanidine HCl 3.5% SR Pellets | In House |
| 41. | Nitroglycerine 2.5% SR Pellets | In House |
| 42. | Venlafaxine HCl 14% SR Pellets | In House |
| 43. | Pantoprazole 22.5% DDL Pellets | In House |
| 44. | Omeprazole 22.5% EC Pellets | In House |
| 45. | Esomeprazole Magnesium 22.5% EC Pellets | In House |
| 46. | Esomeprazole 22.5% EC Pellets | In House |
| 47. | Dexlansoperazole 22.5% DDL Pellets | In House |
| 48. | Ketoprofen 70% SR Pellets | In House |
| 49. | Ciprofloxacin Base 35% Taste Masked Micro Pellets | In House |
| 50. | Duloxetine HCl 22.5% EC Pellets | In House |
| 51. | Lansoprazole 22.5% DDL Pellets | In House |

The process flow charts, manufacturing methods and testing methods of above mentioned product as provided by the management and duly signed and stamp by the firm's representative

**The case is hereby submitted for consideration and orders of the Board, please.**

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of following revised section/facility in the name of M/s Neutro Pharma (Pvt.) Ltd situated at Khewat No 50, Khatooni No. 278, Khaki Kot Abdul Malik, Tehsil Ferozewala, District Sheikhupura (Formulation) under DML No. 000877 (Formulation) on the recommendations of the panel of experts.

| Sr. No. | Name of API | Specification |
|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| | | 1. | Itopride HCl 32% Pellets | In House | |
| | | 2. | Diclofenac Sodium 32% EC Pellets | In House | |
| | | 3. | Ferrous Sulphate 50%IR Pellets | In House | |
| | | 4. | Folic Acid 50% IR Pellets | In House | |
| | | 5. | Isosorbide Mononitrate 30% Pellets | In House | |
| | | 6. | Isosorbide Dinitrate 30% Pellets | In House | |
| | | 7. | Glyceryl Trinitrate 2.5 % SR Pellets | In House | |
| | | 8. | Doxycycline Hyclate 30% Pellets | In House | |
| | | 9. | Diclofenac Potassium 32% SR Pellets | In House | |
| | | 10. | Diclofenac Sodium 32% SR Pellets | In House | |
| | | 11. | Cyclobenzaprine HCl 15% SR Pellets | In House | |
| | | 12. | Rabeprazole 22.5% DDL Pellets | In House | |
| | | 13. | Clarithromycin Taste masked 25% Micro pellets | In House | |
| | | 14. | Levofloxacin Taste masked 25% Micro pellets | In House | |
| | | 15. | Mebeverine Hcl Taste masked 33% Micro Pellets | In House | |
| | | 16. | Piperaquine 25% Taste Masked Micro Pellets | In House | |
| | | 17. | Ofloxacin 25% Taste Masked Micro Pellets | In House | |
| | | 18. | Grazoprevir 25% Dispersion | In House | |
| | | 19. | Misoprostol 26% Dispersion | In House | |
| | | 20. | Ledipasvir 25% Dispersion | In House | |
| | | 21. | Clopidogrel 30% IR Pellets | In House | |
| | | 22. | Domperidone 30% IR Pellets | In House | |
| | | 23. | Fexofenadine HCl 30% IR Pellets | In House | |
| | | 24. | Itraconazole 22.5% IR Pellets | In House | |
| | | 25. | Orlistat 50% IR Pellets | In House | |
| | | 26. | Memantine 50% IR Pellets | In House | |
| | | 27. | Paracetamol 20% Taste Masked Micro Pellets | In House | |

| | | | | | |
|---|---|---|---|---|---|
| | | 28. | Linezolid 20% Taste Masked Micro Pellets | In House | |
| | | 29. | Famotidine 26% Taste Masked Micro Pellets | In House | |
| | | 30. | Microcrystalline Cellulose Pellets | In House | |
| | | 31. | Ciprofloxacin HCl 35% Taste Masked Micro Pellets | In House | |
| | | 32. | Azithromycin 35% Taste Masked Micro Pellets | In House | |
| | | 33. | Aspirin 75% EC Pellets | In House | |
| | | 34. | Diclofenac Potassium 32% EC Pellets | In House | |
| | | 35. | Aceclofenac 15% SR Pellets | In House | |
| | | 36. | Velpatasvir 30% Dispersion | In House | |
| | | 37. | Elbasvir 30% Dispersion | In House | |
| | | 38. | Mebeverine HCl 60% SR Pellets | In House | |
| | | 39. | Tamsulosin HCl 0.2% SR Pellets | In House | |
| | | 40. | Tizanidine HCl 3.5% SR Pellets | In House | |
| | | 41. | Nitroglycerine 2.5% SR Pellets | In House | |
| | | 42. | Venlafaxine HCl 14% SR Pellets | In House | |
| | | 43. | Pantoprazole 22.5% DDL Pellets | In House | |
| | | 44. | Omeprazole 22.5% EC Pellets | In House | |
| | | 45. | Esomeprazole Magnesium 22.5% EC Pellets | In House | |
| | | 46. | Esomeprazole 22.5% EC Pellets | In House | |
| | | 47. | Dexlansoperazole 22.5% DDL Pellets | In House | |
| | | 48. | Ketoprofen 70% SR Pellets | In House | |
| | | 49. | Ciprofloxacin Base 35% Taste Masked Micro Pellets | In House | |
| | | 50. | Duloxetine HCl 22.5% EC Pellets | In House | |
| | | 51. | Lansoprazole 22.5% DDL Pellets | In House | |
| 6 | M/s. Kohinoor Industries, 159-160/B, Small Industries Estate, Sahiwal. | | 17-01-2023 | Good | 1. Azhar Jamal Saleemi, Drugs Controller, Government of Punjab, Lahore. |

| | | | | |
|---|---|---|---|---|
| | DML No. 000197 (Formulation).<br><br>**Sections (05):**<br><br>i. Oral Liquid General (Veterinary) (Revised).<br>ii. Powder Repacking (Human) (Revised).<br>iii. Liquid Repacking (Human) (Revised).<br>iv. Oral Liquid (Human) (New).<br>v. Capsule (Human) (New). | | | 2. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore.<br>3. Hafiz Sanaullah Babar, 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 and Microbiology Laboratory, Testing Facilities, Technical Personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation and grant of additional section to M/s. Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal for the following sections:

i. Cream / Ointment (General).
ii. Sachet (General). Oral Dry Powder (General) (Veterinary).
iii. Oral Liquid General (Veterinary) (Revised).
iv. Powder Repacking (Human) (Revised).
v. Liquid Repacking (Human) (Revised).
vi. Oral Liquid (Human) (New).
vii. Capsule (Human) (New).
viii. Liquid Preparation Section

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of following sections in the name of M/s. Kohinoor Industries, 159-160/B, Small Industries Estate, Sahiwal under DML No. 000197 (Formulation) on the recommendations of the panel of experts Cream / Ointment (General).

i. Oral Liquid General (Veterinary) (Revised).
ii. Powder Repacking (Human) (Revised).
iii. Liquid Repacking (Human) (Revised).
iv. Oral Liquid (Human) (New).
v. Capsule (Human) (New).

(Evaluator: Muhammad Usman, AD-III, Sr. 5-13)

| S # | Name of the firm | Date of Inspection / Type of License | Ranking/ Evaluation | Inspection Panel Members |
|---|---|---|---|---|
| 7 | M/s Rasco Pharma, Plot No.27, Holiday Park, Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore.<br>**Sections (02):**<br>i. Oral Liquid (Psychotropic) Regularization<br>ii. Warehouse-Revised | 21-10-2022 | Good | 1. Mr. Azahar Jamal Saleemi, Chief Drugs Controller, Punjab.<br>2. Mr. Abdul Rashid Sheikh, FID, DRAP, Lahore.<br>3. Ms. Ufaq Tanveer, Assistant Director, DRAP, Lahore. |

**Recommendations of the panel:**

"Keeping in view the building, HVAC system, machinery and equipment, personnel, documentation, and Quality Control Testing facilities, the panel of inspectors is of the opinion to recommend the grant of additional section and regularization of layout plan of M/s Rasco Pharma, situated at Plot No.27, Holiday Park, Near Ali Raza Abad, 5.5-km, Raiwind Road, Lahore for the following sections:

i. **Oral Liquid (Psychotropic) Regularization**
ii. **Warehouse-Revised**

**Decision of the Central Licensing Board in 289th meeting**

Based on the recommendations of the panel of experts ,the Board considered and approved the grant of following section/facility 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. in the name of M/s Rasco Pharma, Plot No.27, Holiday Park, Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore. under DML No.000530(Formulation).

**Section/Facility (02):**

i. Oral Liquid (Psychotropic) Regularization
ii. Warehouse-Revised

| | | | | |
|---|---|---|---|---|
| 8 | M/s Bosch Pharmaceuticals (Pvt) Ltd., Plot No.221-223, Sector-23, Korangi Industrial Area, Karachi<br><br>DML No. 000350 (Formulation)<br><br>**Sections (04):**<br>i. Tablet (Penicillin)<br>ii. Capsule (Penicillin)<br>iii. Dry Powder Suspension (Penicillin)<br>iv. Warehouse (Penicillin) | 27-10-2022 | Good | 1. Abdul Rasool Sh Additional Director (Field)/ FID, DRAP, Karachi<br>Hira Bhutto Assistant Director, DRAP, Karachi<br>2. Mr. Abdul Waheed, AD, DRAP, Karachi |

**Recommendations of the panel:**

"Based on above-stated observations, people met, documents reviewed and physical inspection of dedicated facilities for Penicillin Plant, the Panel is of the opinion to recommend the grant of amendments & expansion made under DML No.000350 (Formulation) for the following sections;

i. Tablet (Penicillin)
ii. Capsule (Penicillin)
iii. Dry Powder Suspension (Penicillin)
iv. Ware-House (including RMS, PMS & FGS) (Penicillin)

**Decision of the Central Licensing Board in 289th meeting**

Based on the recommendations of the panel of experts, the Board considered and approved the grant of following revised sections in the name of M/s Bosch Pharmaceuticals (Pvt) Ltd., Plot No.221-223, Sector-23, Korangi Industrial Area, Karachi under DML No.000350 (Formulation):

**Section/Facility (04):**

i. Tablet (Penicillin)
ii. Capsule (Penicillin)
iii. Dry Powder Suspension (Penicillin)

| | | | | |
|---|---|---|---|---|
| | iv. Warehouse (Penicillin) | | | |
| 9 | M/s Stallion Pharmaceuticals (Pvt) Ltd., 581-Sunder Industrial Estate, Lahore.<br><br>(DML #000783)<br><br>**Sections (01):**<br><br>i. Tablet (Penicillin)-**New** | | Good | 1. Mr. Muhammad Shamoon, Expert Member.<br>2. Mr. Abdul Rashid Sheikh, FID, DRAP, Lahore.<br>3. Hafiz Sana Ullah Babar, Assistant Director, DRAP, Lahore. |
| | **Recommendations of the panel:**<br><br>"Keeping in view the manufacturing facility like, building, production, machinery, equipment in Quality Control and microbiology laboratory, testing facilities, utilities and documentation reviewed, the panel of inspectors recommends the grant of additional section by way of formulation for the Tablet section (Penicillin) to M/s Stallion Pharmaceuticals (Pvt) Ltd., 581-Sunder Industrial Estate, Lahore;<br><br>i. Tablet (Penicillin)<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>Based on the recommendations of the panel of experts, the Board considered and approved the grant of following additional sections in the name of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581-Sunder Industrial Estate, Lahore. under DML No.000783 (Formulation) on the recommendations of the panel of experts.<br><br>**Section/Facility (01):**<br><br>i. Tablet (Penicillin)- New | | | |
| 10 | M/s Getz Pharma (Pvt) Ltd., Plot No.01, Korangi Industrial Area, Karachi.<br><br>DML No. 000933(Formulation)<br><br>**Sections (07):**<br><br>i. Tablet (Cephalosporin) | 16-11-2022 | Good | 1. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi.<br>2. Dr. Ghulam Ali Lakho, Chief Drug Inspector, Sindh.<br>3. Dr. Shoaib Ahmed, FID-III, DRAP, Karachi. |

| | | | | |
|---|---|---|---|---|
| | ii. Capsule (Cephalosporin)<br>iii. Dry Powder Suspension (Cephalosporin)<br>iv. Sterile Dry Powder Injectable (Cephalosporin)<br>v. Product Development Laboratory (Cephalosporin)<br>vi. Warehouse (Cephalosporin)<br>vii. Quality Control Laboratory (Cephalosporin) | | | |

**Recommendations of the panel:**

M/s Getz Pharma (Pvt) Ltd situated at Plot No. 01, Sector 25, Korangi Industrial Area Karachi was inspected with reference to the direction contained in DRAP Islamabad Letter No. 2-9/2014-Lic(Vol-I) dated 26th October 2022 and 15th November 2022 in connection with grant of new sections (Cephalosporin):

i. Tablet (Cephalosporin)
ii. Capsule (Cephalosporin)
iii. Dry Powder Suspension (Cephalosporin)
iv. Sterile Dry Powder Injectable (Cephalosporin)
v. Product Development Laboratory (Cephalosporin)
vi. Warehouse (Cephalosporin)
vii. Quality Control Laboratory (Cephalosporin)

"Based on the people met, documents reviewed and considering the findings of the inspection, the dedicated Cephalosporin manufacturing facility of M/s Getz Pharma (Pvt) Ltd., Plot No.01, Korangi Industrial Area, Karachi is considered to be designed and established at an excellent level of compliance of GMP requirements. Therefore, the panel recommends the approval for the grant of new Sections (Cephalosporin Manufacturing Facility).

| | | | | |
|---|---|---|---|---|
| | **Decision of the Central Licensing Board in 289th meeting**<br>Based on the recommendations of the panel of experts, the Board considered and approved the grant of following additional sections in the name of M/s Getz Pharma (Pvt) Ltd., Plot No.01, Korangi Industrial Area, Karachi under DML No.000933 (Formulation) :<br>**Section/Facility (07):**<br>i. Tablet (Cephalosporin)<br>ii. Capsule (Cephalosporin)<br>iii. Dry Powder Suspension (Cephalosporin)<br>iv. Dry Powder vial Injection (Cephalosporin)<br>v. Product Development Laboratory (Cephalosporin)<br>vi. Warehouse (Cephalosporin)<br>vii. Quality Control Laboratory (Cephalosporin) | | | |
| 11 | M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi.<br>DML No. 000267 (Formulation)<br>**Sections (01):**<br>i. Tablet Section (General) – Revised | 22-11-2022 | Good | 1. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi.<br>2. Dr. Shoaib Ahmed, FID-III, DRAP, Karachi.<br>3. Mr. Affan Ali, Assistant Director, CDL, DRAP, Karachi. |
| | **Recommendations of the panel:**<br>During the targeted inspection, the panel physically inspected in detailed their newly developed/built coating sections & WIP stores. The premises were found constructed as per approved design and have been provide with required necessary machineries, equipment and adequate utilities. A better % separate MAL & PAL is kept in coating section. A robust , well monitored and well maintained HVAC system was seen in place for better personnel & Product safety. WIP interim stores are also inspected under the current TORs which were made also observed suitability built and adequately maintained. These changes were made after complying | | | |

<table>
<tr><td></td><td colspan="4">necessary change control SOPs in place to enhance their current capacity and to attain a better level of compliance.<br><br>“Based on the stated facts, observations and keeping in view the dedication of the entire management of the firm for constant improvements the panel unanimously recommends the grant of amendments in Tablet Coating Section (G) & in WIP Stores under DML No.000267 Formulation.<br><br><u>Decision of the Central Licensing Board in 289th meeting</u><br>Based on the recommendations of the panel of expert, the Board considered and approved the grant of following revised section in the name of M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi. under DML No.000267 (Formulation) :<br><br><u>Section/Facility (01):</u><br>i. Tablet (General) Coating area - Revised</td></tr>
<tr><td>12</td><td>M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km, Adyala Road, Post Office Dhagal, Rawalpindi.<br><br>(DML # 000333)<br><br><u>Sections (01)</u>:<br>i. Soft Gelatin Capsule Section (General)</td><td>18-11-2022</td><td>Good</td><td>1. Additional Director (QA/LT), DRAP, Islamabad.<br>2. Area FID, DRAP, Islamabad.<br>3. Assistant Director (CD), DRAP, Islamabad.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u><br><br>“Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously <u>Recommended</u> M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km, Adyala Road, Rawalpindi for the grant of additional section namely Soft Gelatin Capsule (General) under Drug Manufacturing License No.000333 (formulation) for the following one section only.<br><br>i. Soft Gelatin Capsule (General) New</td></tr>
</table>

| | | | | |
|---|---|---|---|---|
| | **Decision of the Central Licensing Board in 289th meeting**<br>Based on the recommendations of the panel of experts , the Board considered and approved the grant of following revised section in the name of M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km, Adyala Road, Post Office Dhagal, Rawalpindi. under DML No.000333 (Formulation):<br>**Section/Facility (01):**<br>i. Soft Gelatin Capsule (General)- New | | | |
| 13 | M/s Geofman Pharmaceuticals, 20/23, Korangi Industrial Area, Karachi.<br>(DML # 000090 Required)<br>**Sections (01):**<br>i. Sterile Liquid Infusion LVP/SVP (General) – Revised & Regularized<br>ii. Dry Powder Suspension (General) – Regularized<br>iii. Liquid Nebulization Solution (General) – New/Regularized<br>iv. Sterile Liquid Injectable vial (Steroidal Hormone) – Revised<br>v. Withdrawal of Tablet Antibiotic Section | 16-12-2022 | Good | 1. Dr. Najam-us-Saquib, Additional Director (Licensing), DRAP, Islamabad.<br>2. Mr. Abdul Rasool Shaikh, Additional Director (E&M), DRAP, Karachi.<br>3. Dr. Kirshan, Assistant Director, DRAP, Karachi. |
| | **Recommendations of the panel:** | | | |

In the light of the directions contained in DRAP Islamabad Letter No. F.2-11/85-Lic (Vol-I) Dated: 12th December 2022, the constituted panel members inspected in detail the premises of M/s Geofman Pharmaceuticals, situated at Plot No. 20, Sector 23, Korangi Industrial Area, Karachi. During opening meeting their site master File , layout design, HVAC design and QMS were discussed at length and found an appropriate level of compliance . During detail tour of their subject production and revised sections the panel observed those sections built as per approved design and adequately maintained. Overall an optimal level of compliance was noted during the inspection.

"Keeping in view the above, people met, documents reviewed and attitude of the management towards continuous improvement, the panel is of the opinion to recommend the Grant/Regularization/Revised/Additional/section as follows:

| | |
|---|---|
| Sterile Liquid Infusion LVP/SVP (General) – Revised & Regularized | Dry Powder Suspension (General) – Regularized |
| Liquid Nebulization Solution (Genera) – New/Regularized | Sterile Liquid Injectable (Steroidal Hormone) – Revised & Regularized |
| Withdrawal of Tablet Antibiotic Section | ---------- |

The recommendations of the panel for grant of section namely Liquid Injectable ampoule SVP (General) – III as additional section are not mentioned in panel inspection report.

**Decision of the Central Licensing Board in 289th meeting**

Based on the recommendations of the panel of experts, the Board considered and approved the grant of following revised/additional sections in the name of M/s Geofman Pharmaceuticals, 20/23, Korangi Industrial Area, Karachi under DML No.000090 (Formulation):

**Section/Facility (04):**

i. Sterile Liquid Infusion LVP/SVP (General) – Revised & Regularized
ii. Dry Powder Suspension (General) – Regularized
iii. Liquid Nebulization Solution (General) – New
iv. Sterile Liquid Injectable vial (Steroidal Hormone) – Revised

**The board also acceded the request of the firm regarding withdrawal of Tablet Antibiotic Section and also decided to intimate the Drug Registration Board regarding surrender/withdrawal of section.**

| | | | | |
|---|---|---|---|---|
| 14 | M/s Medimarker's Pharmaceuticals (Pvt) Ltd. Plot No. A-104, S.I.T.E Area Hyderabad.<br><br>DML No.000615 (Formulation)<br><br>Capsule (General) -New | 02-01-2023 | Good | 1. Additional Director, DRAP, Karachi.<br>2. Mr. Ghulam Ali Lakho, Senior Inspector of Drugs, Karachi.<br>3. Area FID, DRAP, Karachi. |

**Recommendations of the panel:**

The panel inspected the premises of M/s Medimarker's Pharmaceuticals (Pvt) Ltd. Plot No. A-104 S.I.T.E Area Hyderabad in compliance to DRAP Islamabad letter No. F.2-4/2003-Lic (V-II) dated 17th December 2022.

The firm is constructed as per approved revised layout plan. Good level of sanitation and hygiene was noted.

Therefore, based on the people met, areas inspected, export enhancement interntion and commitment of management for continuous improvement and up-gradation, the panel is of the view to recommend the Renewal of Drug Manufacturing License #000615 (By way of Formulation) due from April 2022 for following Sections:

| | | |
|---|---|---|
| Tablet (General)-**Revised** | Capsule (General)-**New** | Dry Powder Suspension (General) |
| Sachet (General) | Cream/Ointment/Gel (General)- **Revised** | Liquid Syrup (General) |
| Sterile Liquid injection ampoule (General) | Sterile Liquid injection vial (General) | Sterile Eye & Ear Drops (General) |
| Capsule (cephalosporin)-**Revised** | Dry Powder Suspension (cephalosporin)-**Revised** | Dry Powder Injection (cephalosporin) |
| Capsule (Penicillin) | Oral Dry Syrup (Penicillin) | Tablet (Psychotropic)-**Revised** |
| Raw Material (General)-**Revised** | Raw Material (Cephalosporin)-**Revised** | Raw Material (Psychotropic)-**Revised** |

**Decision of the Central Licensing Board in 289th meeting**

Based on the recommendations of the panel of experts, the Board considered and approved the grant of following additional sections in the name of M/s Medimarker's Pharmaceuticals (Pvt) Ltd. Plot No. A-104 S.I.T.E Area Hyderabad under DML No.000615 (Formulation):

| | | | | |
|---|---|---|---|---|
| | **Section/Facility:**<br>i. Capsule (General)- **New** | | | |
| 15 | M/s Scilife Pharma (Pvt) Ltd, Plot No. FD-57/58-A2, Korangi Creek Industrial Area, Karachi.<br>DML No. 000837 (Formulation)<br>**Sections (01):**<br>i. Tablet (Psychotropic) – New | 19-01-2023 | Good | 4. Mr. Ghulam Ali Lakho, SDI, Karachi.<br>5. Mr. Abdul Rasool Sheikh, Addl.Dir/FID, DRAP, Karachi.<br>6. 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 inspected with reference to the direction contained in DRAP Islamabad Letter No. 2-4/2011-Lic(Vol-I) dated 17th January 2023 in connection with grant of new sections Tablet (Psychotropic)).

The firm is constructed as per approved revised layout plan by DRAP authorities vide letter dated 28th April 2022. Necessary utilities, machineries, and equipment's as required under guidelines are seen installed on site.

Based on the facts, the panel unanimously recommends the grant of additional section Tablet (Psychotropic)) under DML No. 000837(Formulation)

**Decision of the Central Licensing Board in 289th meeting**

Based on the recommendations of the panel of experts. the Board considered and approved the grant of following additional section 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) 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.

**Section/Facility (01):**

| | |
|---|---|
| | 1. Tablet (Psychotropic) – New |

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 The Searle Company Limited, Plot No. 319, SITE, Karachi.<br>DML No. 000016 (Formulation)<br>**Sections (03):**<br>i. Finished Goods Store- Revised<br>ii. Research & Development Laboratory- Revised<br>iii. Tablet (Psychotropic) - Revised | 20-1-2023 | Good | 1. Additional Director (E&M), DRAP, Karachi.<br>2. Area Federal Inspector of Drugs, DRAP, Karachi.<br>3. Mr. Krishan, AD, DRAP, Karachi. |
| | **Recommendations of the panel:**<br>M/s The Searle Company Ltd situated at Plot No. 319, SITE, Karachi. was inspected with reference to the direction contained in DRAP Islamabad Letter No. 2-6/2018-Lic(Vol-V) dated 16th January 2023 in connection with grant of revised following sections:<br>i. Finished Goods Store- Revised<br>ii. Research & Development Laboratory- Revised<br>iii. Tablet (Psychotropic) - Revised | | | |

<table>
<tr><td></td><td colspan="4">"Based on the people met, documents reviewed and considering the commitments of team for improvement the panel recommends the grant of Tablet (Psychotropic) and also recommends the changes as per approved revised design in their R & D Laboratory & FG Store.<br><br><u>Decision of the Central Licensing Board in 289th meeting</u><br><br>The Board considered and approved the grant of following revised section/facility in the name of M/s The Searle Company Limited, Plot No. 319, SITE, Karachi. under DML No.000016 (Formulation) on the recommendations of the panel of experts.<br><br><u>Section/Facility (03):</u><br><br>i. Finished Goods Store- Revised<br>ii. Research & Development Laboratory- Revised<br>iii. Tablet (Psychotropic) - Revised</td></tr>
<tr><td>2</td><td>M/s Popular Chemical Works (Pvt) Ltd., 9-Km, Lahore Sheikhupura Road, Lahore.<br><br>DML No. 000076 (Formulation).<br><br>Period: Commencing on 30-08-2020 ending on 29-08-2025.</td><td>12-12-2022</td><td>Good</td><td>1. Mr. Ch. Muhammad Shamoon, Expert Member.<br>2. Area Federal Inspector of Drugs, DRAP, Lahore.<br>3. Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u><br><br>During inspection some points were discussed with the management and advised for improvement and the management agreed. Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production Machinery, Equipment in Quality Control and Microbiology Laboratory, Testing Facilities, Technical Personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation, regularization of layout plan and grant of additional section to M/s Popular Chemical Works (Pvt.) Ltd., 9.5-km, Sheikhupura Road, Lahore for the following sections :<br><br>1. Tablet Section (General) (Renewal)<br>2. Tablet Section (Psychotropic) (Renewal)<br>3. Capsule Section (General) (Renewal)<br>4. Oral Liquid Section (General) (Renewal)<br>5. Liquid Injectable Ampoule Section (General) (Renewal)<br>6. Dry Powder Suspension Section (Penicillin) (Renewal)<br>7. Capsule Section (Penicillin). (Renewal)</td></tr>
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| | 8. Liquid Injectable (Psychotropic) (Additional)<br>The panel did not give any recommendations on two sections.<br>1. Oral Dry Powder for suspension (Cephalosporin)<br>2. Capsule (Cephalosporin)<br><br>**Decision of the Central Licensing Board in 289th meeting**<br>The Board considered and approved the grant of additional section in the name of M/s Popular Chemical Works (Pvt) Ltd., 9-Km, Lahore Sheikhupura Road, Lahore on the basis of.the recommendations of the panel of experts subject to submission of NOC for Psychotropic Section 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:<br><br>1. Liquid Injectable (Psychotropic) (Additional) |

**Item-IV**: **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.

(Evaluator: Mst. Zunaira Farya, AD-I, Sr. 1-12)

| S # | Name of the firm | Date of Inspection | Ranking/ Evaluation | Inspection Panel Members |
|---|---|---|---|---|
| 1 | M/s. Medella Pharmaceuticals (Pvt) Ltd., 569/570, Sunder Industrial Estate, Raiwind Road, Lahore. | 24-11-2022 | **Good** | 1. Mr. Zeeshan Nazir Baig Secretary, Registration Board, DRAP, Islamabad.<br>2. Mr. Abdul Rashid Sheikh, FID DRAP, Lahore |

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| | DML No.000749 (Formulation).<br><br>Period: Commencing on 31-08-2017 & ending on 30-08-2022. | | | 3. Ms. Uzma Barkat, Assistant Director, DRAP Lahore. |
| | **Recommendations of the panel: -**<br><br>In view of above inspection proceedings and facilities verified, such as building, production, quality control testing, machinery/equipment, air handling, water treatment system and documentation e.t.c the panel recommends the Renewal of Drug Manufacturing License and grant of additional sections to M/s. Medella Pharmaceuticals (Pvt.) Ltd., 569/570, Sunder Industrial Estate, Lahore by way of formulation for the following sections:<br><br>i. Tablet (General) Section (New)<br>ii. Capsule (General) Section (New)<br>iii. Dry Powder Suspension (General) Section (New)<br>iv. Sachet (General) Section (New)<br>v. Oral Liquid Section (Renewal).<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>As the period 31-08-2017-30-08-2022 for which panel inspection was conducted has expired the Board accepted the report of grant of renewal of DML No. 000749 by way of Formulation in the name of M/s Medella Pharmaceuticals (Pvt) Ltd., 569/570, Sunder Industrial Estate, Raiwind Road, Lahore. | | | |
| 2 | M/s. CSH Pharmaceuticals (Pvt.) Ltd., 32-km Ferozepur Road, Lahore.<br><br>DML No. 000737 (Formulation)<br><br>**Period**: Commencing on 01-08-2022 & ending on 31-07-2027. | **18-11-2022** | **Good** | 1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore.<br>2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Karachi.<br>3. Ms. Anam Saeed, Assistant Director, DRAP, Karachi. |
| | **Recommendations of the panel:**<br><br>Keeping in view the manufacturing facility like, building, production machinery, Equipment in Quality Control and microbiology laboratory, testing facilities, utilities and documentation reviewed, the company was given some advises for further improvement and the panel of inspectors recommends the renewal of Drug Manufacturing License by | | | |

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| | way of formulation for the following sections to M/s. CSH Pharmaceuticals (Pvt.) Ltd., 32-km Ferozepur Road, Lahore:<br><br>i. Tablet (Penicillin)<br>ii. Capsule (Penicillin)<br>iii. Dry Powder suspension (Penicillin).<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000737 by way of Formulation in the name of M/s. CSH Pharmaceuticals (Pvt.) Ltd., 32-km Ferozepur Road, Lahore on the recommendations of the panel of experts for the period Commencing on 01-08-2022 & ending on 31-07-2027 for the following sections: -<br><br>i. Tablet (Penicillin)<br>ii. Capsule (Penicillin)<br>iii. Dry Powder suspension (Penicillin). | | | |
| 3 | M/s Linear Pharma, Plot No.18, St No. S-4, National Industrial Zone, RCCI, Rawat.<br><br>DML No. 000670 (Formulation)<br><br>**Period:** Commencing on 29-07-2019 & ending on 28-07-2025<br><br>**Sections (07):**<br>i. Tablet (General) Section.<br>ii. Capsule (General) Section.<br>iii. Dry Powder Suspension (Cephalosporin) Section.<br>iv. Sterile Dry Powder Injection (Cephalosporin) Section.<br>v. Capsule (Cephalosporin) Section. | **02-11-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad.<br>2. Dr. Akbar Ali, Deputy Director, DRAP, Islamabad.<br>3. Ms. Zunaira Faryad, Assistant Director, DRAP, Islamabad. |

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| | vi. Liquid Injectable (Ampoule) (General) Section.<br>vii. Liquid Injectable (Vial) (General) Section. | | | |
| | **Recommendations of the panel:**<br><br>The panel is of the opinion that the establishment meets the requirements of renewal of license and GMP as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f. 29-07-2019, for all the approved sections.<br><br>It is pertinent to mention here that as per record of Licensing Division, the detail of approved sections is as under:<br><br>i. Tablet (General) Section.<br>ii. Capsule (General) Section.<br>iii. Dry Powder Suspension (Cephalosporin) Section.<br>iv. Sterile Dry Powder Injection (Cephalosporin) Section.<br>v. Capsule (Cephalosporin) Section.<br>vi. Liquid Injectable (Ampoule) (General) Section<br>vii. Liquid Injectable (Vial) (General) Section.<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000670 by way of Formulation in the name of M/s Linear Pharma, Plot No.18, St No. S-4, National Industrial Zone, RCCI, Rawat on the recommendations of the panel of experts for the period Commencing on 29-07-2019 & ending on 28-07-202 for the following sections: -<br><br>i. Tablet (General) Section.<br>ii. Capsule (General) Section.<br>iii. Dry Powder Suspension (Cephalosporin) Section.<br>iv. Sterile Dry Powder Injection (Cephalosporin) Section.<br>v. Capsule (Cephalosporin) Section.<br>vi. Liquid Injectable (Ampoule) (General) Section<br>vii. Liquid Injectable (Vial) (General) Section. | | | |
| 4 | M/s. Medley Pharmaceuticals, Plot No. 41/A, Punjab Small Industrial Estate, Jhang Bahtar Road, Wah Cantt. | **09-12-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. |

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| | DML No. 000237(Formulation)<br><br>**Period**: Commencing on 01-07-2019 & ending on 30-06-2024.<br><br>**Section (05):**<br><br>1. Liquid Injectable (Ampoule) Section.<br>2. Capsule (General) Section.<br>3. Tablet (General) Section.<br>4. Tablet (Antibiotic) Section.<br>5. Syrup (General) Section. | | | 2. Mr. Muneeb Ahmed Cheema, Deputy Director, DRAP, Islamabad.<br>3. Ms. Mahvish Tanveer, Assistant Director, DRAP, Islamabad (Could not join the inspection team due to risk-based inspection). |

**Recommendations of the panel:**

The panel is of the opinion that the establishment meets the requirements of renewal of License and GMP as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed thereunder. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f 01-07-2019.

**It is pertinent to mention here that as per record of Licensing Division, the detail of approved sections is as under:**

1. Tablet (General)/ (Antibiotic) Section.
2. Capsule (General) Section.
3. Syrup (General) Section.
4. Liquid Injectable (Ampoule) Section.

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and deferred the application for grant of renewal for re-inspection by all three members of the panel of inspectors.

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| 5 | M/s Elegance Pharmaceuticals, Pindori Road, Chakbeli, Rawalpindi.<br>DML No. 000739 (Formulation)<br>Period: Commencing on 27-08-2022 & ending on 26-08-2027. | **02-12-2022** | **Good** | 1. Dr. Qurban Ali, Expert Member.<br>2. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT-I Field), DRAP, Islamabad.<br>3. Mr. Khalid Mahmood, Area Federal Inspector of Drugs. |
| | **Recommendations of the panel:**<br>Keeping in view the above facts, detailed visit of facility and supporting documents (attached with report) provided by the company, the panel unanimously recommended M/s Elegance Pharmaceuticals, Pindori Road, Chakbeli Khan, Rawalpindi for the grant of Renewal of DML No 000739 for the following two sections (Vet) Only:<br>i. Dry Powder Section (Vet)<br>ii. Oral Liquid Section (Vet).<br>**Decision of the Central Licensing Board in 289th meeting**<br>The Board considered and approved the grant of renewal of DML No. 000739 by way of Formulation in the name of M/s Elegance Pharmaceuticals, Pindori Road, Chakbeli, Rawalpindi on the recommendations of the panel of experts for the period Commencing on 27-08-2022 & ending on 26-08-2027 for the following sections: -<br>i. Dry Powder Section (Vet)<br>ii. Oral Liquid Section (Vet). | | | |
| 6 | M/s. Ottoman Pharma., 10-km, Raiwind Road, Lahore.<br>DML No. 000502(Formulation).<br>**Period:** Commencing on 05-08-2022 & ending on 04-08-2027. | **07-12-2022** | **Good** | 1. Mr. Shoaib Hakeem, Expert Member.<br>2. Ms. Majida Mujahid, Additional Director, DRAP, Lahore.<br>3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. |

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| | **Recommendations of the panel:**<br><br>Keeping in view the manufacturing facility like, building, production machinery, Equipment in Quality Control and microbiology laboratory, testing facilities, utilities and documentation reviewed, the panel of inspectors recommends the renewal of Drug Manufacturing License No. 000502 by way of formulation for M/s. Ottoman Pharma., 10-km Raiwind Road, Lahore for Inactivated Viral Vaccine Section only.<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000502 by way of Formulation in the name of M/s. Ottoman Pharma., 10-km, Raiwind Road, Lahore on the recommendations of the panel of experts for the period Commencing on 05-08-2022 & ending on 04-08-2027 for the following sections: -<br><br>**1. Inactivated Viral Vaccine Section** | | | |
| 7 | M/s. Jupiter Pharma, Plot No. 25, Street No. S-6, National Industrial Zone, RCCI, Rawat.<br><br>DML No. 000838 (Formulation)<br><br>Period: Commencing on 01-06-2021 & ending on 31-05-2026. | **14-11-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Mr. Abdullah, Deputy Director, DRAP, Islamabad (Could not join the panel due to official engagements)<br>3. Zunaira Faryad, Assistant Director, DRAP, Islamabad. |
| | **Recommendations of the panel:**<br><br>The panel is of the opinion that the establishment meets the requirements of renewal of license as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f 01-06-2021 with following sections.<br><br>i. Tablet Section (General).<br>ii. Capsule Section (General)<br>iii. Dry Powder Suspension Section (General)<br>iv. Capsule Section (Cephalosporin)<br>v. Dry Suspension Section (Cephalosporin)<br>*vi.* Dry Injection Vial (Cephalosporin).<br><br>**Decision of the Central Licensing Board in 289th meeting** | | | |

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| | The Board considered and deferred the application for grant of renewal for re-inspection by all three members of the panel of inspectors. | | | |
| 8 | M/s. Nimrall Laboratories, Plot No.24, Street No. SS-3, Rawat Industrial Estate, Rawat.<br>DML No. 000611 (Formulation)<br>Period: Commencing on 21-03-2022 & ending on 20-03-2027. | **23-11-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Ms. Mahvash Ansari, Director (NCLB), Islamabad.<br>3. Ms. Zunaira Faryad, Assistant Director, DRAP, Islamabad. |

**Recommendations of the panel:**

On seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f 21-03-2022 for following sections only and considering the fact that sterile products are sensitive and require full compliance to manufacturing requirements, therefore, follow-up inspection for sterile sections, namely, Eye Drops, Liquid Injection (SVP) and Liquid Injection (Infusion) may be carried out once the Establishment makes rectification / Corrective & Preventive Action for the above pointed shortcomings / non-conformities.

i. Tablet (General) Section.
ii. Capsule (General) Section.
iii. Liquid Syrup & Suspension (General) Section
iv. Cream/Ointment (General) Section
v. Dry Powder Suspension (General) Section
vi. Capsule (Cephalosporin) Section.
vii. Dry Powder Oral Suspension (Cephalosporin) Section.

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000611 by way of Formulation in the name of M/s. Nimrall Laboratories, Plot No.24, Street No. SS-3, Rawat Industrial Estate, Rawat on the recommendations of the panel of experts for the period Commencing on 21-03-2022 & ending on 20-03-2027 for the following sections: -

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

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| | vi. Capsule (Cephalosporin) Section.<br>vii. Dry Powder Oral Suspension (Cephalosporin) Section.<br><br>The Board further decided to serve the Show cause notice to the firm and to stop the production till rectification of the observations made during inspection for following sections: -<br><br>i. Eye Drops<br>ii. Liquid Injection (SVP)<br>iii. Liquid Injection (Infusion) | | | |
| 9 | M/s. Advanced Pharmaceuticals, Plot No.38. Street No. S-4, National Industrial Zone, RCCI, Rawat<br><br>DML No. 000686 (Formulation)<br><br>Period: Commencing on 24-06-2020 & ending on 23-06-2025. | **16-11-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Mr. Mubashir Iqbal, Deputy Director (CD), Islamabad.<br>3. Mr. Zubair Masood, Assistant Director, DRAP, Islamabad. |
| | **<u>Recommendations of the panel:</u>**<br><br>The panel is of the opinion that the establishment meets the requirements of renewal of license as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f 24-06-2020 for their following approved sections including the new section namely "Cream / Ointment (General).<br><br>Further the Central Licensing Board, DRAP is requested to carry-out a follow up inspection for verification / confirmation of the procurement of FTIR by the establishment within three months.<br><br>i. Tablet (General) Section.<br>ii. Capsule (General) Section.<br>iii. Capsule (Cephalosporin) Section<br>iv. Dry Powder Injection (Cephalosporin) Section. | | | |

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| | v. Dry Powder Suspension (Cephalosporin) Section.<br>vi. Cream / Ointment (General) (New) Section.<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000686 by way of Formulation in the name of M/s. Advanced Pharmaceuticals, Plot No.38. Street No. S-4, National Industrial Zone, RCCI, Rawat on the recommendations of the panel of experts for the period Commencing on 24-06-2020 & ending on 23-06-2025 for the following sections: -<br><br>i. Tablet (General) Section.<br>ii. Capsule (General) Section.<br>iii. Capsule (Cephalosporin) Section<br>iv. Dry Powder Injection (Cephalosporin) Section.<br>v. Dry Powder Suspension (Cephalosporin) Section. | | | |
| 10 | M/s. Derma Techno Pakistan, Plot No. 528, Sunder Industrial Estate, Lahore.<br><br>DML No. 000728 (Formulation)<br><br>Period: Commencing on 15-06-2021 & ending on 14-06-2026. | **06-12-2022** | - | 1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller Punjab.<br>2. Dr. Syed Zia Husnain, FID, DRAP, Lahore.<br>3. Hafiz Sanaullah Babar, Assistant Director, DRAP, Lahore. |
| | **Observations & Recommendations of the panel:**<br><br>**Observations related to premises:**<br><br>i. Experience of QA Manager is 4.5 years which is a violation of S.R.O 1460(1)/2019 which requires that QA Manager should have at least 06 years of experience.<br>ii. The documentation system of the firm was poor i.e. SOPs were missing and the SOPs that were available were not being adhered to. The documentation retrieval system was also poor.<br>iii. The facility was not designed as per layout plan approved by the division of Drugs Licensing DRAP Islamabad i.e. the firm had made new raw material stores, receiving bays, dispensing areas and liquid material store that were not approved by the concerned division. | | | |

iv. Specifications were not mentioned on the containers of API present in the Raw Material Store. Moreover, the API quarantine area was inappropriate which blocked the entrance of the cold storage area.

v. Sampling booth was not installed properly. There was space constraint. Common weighing balance was being used in both the dispensing booths and the sampling booth.

vi. There were huge gaps between the doors and the door closure system were also faulty that resulted in loss of differential pressure between the different sections. Doors also needs to be replaced.

vii. IPQC Lab in the steroidal cream section was incomplete. Only a weighing balance was provided the lab.

viii. There were no fixtures or change over facility provided in the male and female change room of the steroidal cream section.

ix. The firm had constructed a newly approved area i.e. Dry powder suspension (Macrolide). However, on inspection it was revealed that the firm had installed a liquid sachet filling machine and Tomato Ketchup labeled reel was fitted on the machine for packing. Panel suspected that the firm fill the tomato ketchup with that machine installed in dry powder suspension (macrolide) section (Pictorial evidence attached).

**Observations related to the Quality Control Laboratory:**

i. Quality control laboratory did not have appropriate equipment ie. Karl Fischer Titrey and Potentiometer were not available which are required for testing as per approved specifications of the registered products of the firm.

ii. No reference standard for test/analysis was present for any product. Moreover, the working standards were also derived from raw material of unknown source rather than the reference standard. No impurity testing for APIs was being conducted.

iii. Log books were not properly maintained and Quality control lab did not had any reagent balance sheet.

iv. Firm is not following official specifications for testing of products that are in official Pharmacopoeia.

v. Microbiology lab has only 02 buffers.

**CONCLUSIONS**

Panel has thoroughly evaluated the various documents in connection with production, Quality Control and Quality assurance systems of the unit. Panel also inspected the plant and discussed various technical aspects at length with the technical staff. After thorough evaluation of documents provided by the management and inspection of the unit panel was of the view that besides many other observations mentioned above firm has made major changes in the layout without approval of Licensing Division of DRAP. Moreover, Quality Control department was without the necessary equipment required for testing of registered

products as mentioned above. Tomato Ketchup labeled reel was fitted on the machine for packing. Panel suspected that the firm fill the tomato ketchup with that machine installed in dry powder suspension (macrolide) section. Under the explained circumstances mentioned above in the report; panel was of the view to not recommend the facility at this stage for grant of renewal of Drug Manufacturing License to M/s. Derma Techno Pakistan Sunder Industrial Estate Lahore.

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and decided to serve the Show cause notice to the firm and to stop the production activity till rectification of the observations made during inspection.

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| 11 | M/s Olive Laboratories, Plot NO. 52, Street No. S-6, NIZDA, Rawat, Rawalpindi<br>DML No. 000524 (Formulation)<br>Period: Commencing on 21-09-2018 & ending on 20-09-2023. | 12-01-2023 | Good | 1. Ch. Zeeshan Nazir Bajar, Secretary, Registration Board DRAP, Islamabad;<br>2. Mr. Adnan Shahidullah, Deputy Director, DRAP, Islamabad;<br>3. Mr. Muhammad Yaqoob, AD, DRAP, Islamabad |

**Recommendations of the panel:**

The panel is of the opinion that the establishment meets the requirements of renewal of license as laid down in Drug Act, 1976, DRAP Act, 2012 and Rules framed their under. The panel unanimously **recommends** for Renewal of Drug Manufacturing License No. 000524 of M/s Olive Laboratories, Plot NO. 52, Street No. S-6, NIZDA, Rawat, Rawalpindi w.e.f 21.09-2018 for following sections only.

| S. No. | Name of Sections |
|---|---|
| 1. | Capsule Section (General) |
| 2. | Tablet Section (General) |
| 3. | Liquid Syrup (General) Section. |

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000524 by way of Formulation in the name of M/s Olive Laboratories, Plot NO. 52, Street No. S-6, NIZDA, Rawat, Rawalpindi on the recommendations of the panel of experts for the period Commencing on 21-09-2018 & ending on 20-09-2023 for the following sections: -

i. Tablet (General) Section.

ii. Capsule (General) Section.

| | | | | |
|---|---|---|---|---|
| | iii. Liquid Syrup (General) Section | | | |
| 12 | M/s Evolution Pharmaceuticals (Pvt) Limited, Plot NO. 25-26, Street No. S-3, NIZDA, Rawat<br>DML No. 000867 (Formulation)<br>Period: Commencing on 22-06-2022 & ending on 21-06-2027 | 11-01-2023 | Very Good | 1. Ch. Zeeshan Nazir Bajar Secretary Registration Board, DRAP, Islamabad<br>2. Mr. Adnan Shahidullah, Deputy Director, DRAP, Islamabad;<br>3. Mr. Muhammad Yaqoob, AD (Lic), DRAP, Islamabad. |

**Recommendations of the panel:**

The panel is of the opinion that the establishment meets the requirements of renewal of license as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under. The panel unanimously **recommends** for Renewal of Drug Manufacturing License No. 000867 of M/s Evolution Pharmaceuticals (Pvt) Limited, Plot NO. 25-26, Street No. S-3, NIZDA, Rawat, w.e.f 21st June, 2022 for following sections only.

| S. No. | Name of Sections |
|---|---|
| 1. | Dry powder for Suspension (General) |
| 2. | Capsule Section (General) |
| 3. | Tablet Section (General) |
| 4. | Sachet (General) |
| 5. | Ointment / Cream / Gel (General) |
| 6. | Topical Lotion (General) |
| 7. | Topical Liquid (Spray) Solution (General) |
| 8. | Dry Powder for Suspension (Cephalosporin) |
| 9. | Dry Powder for Injection (Cephalosporin) |
| 10. | Capsule Dry Powder (Cephalosporin) |
| 11. | Dry Powder for Suspension (Penicillin) |
| 12. | Dry Powder for Injection (Penicillin) |
| 13. | Capsule Dry Powder (Penicillin) |

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000867 by way of Formulation in the name of M/s Evolution Pharmaceuticals (Pvt) Limited, Plot NO. 25-26, Street No. S-3, NIZDA, Rawat on the recommendations of the panel of experts for the period Commencing on Commencing on 22-06-2022 & ending on 21-06-2027 for the following sections: -

| | | | | | |
|---|---|---|---|---|---|
| | | i. Dry powder for Suspension (General)<br>ii. Capsule Section (General)<br>iii. Tablet Section (General)<br>iv. Sachet (General)<br>v. Ointment / Cream / Gel (General)<br>vi. Topical Lotion (General)<br>vii. Dry Powder for Suspension (Cephalosporin)<br>viii. Dry Powder for Injection (Cephalosporin)<br>ix. Capsule Dry Powder (Cephalosporin)<br>x. Dry Powder for Suspension (Penicillin)<br>xi. Dry Powder for Injection (Penicillin)<br>xii. Capsule Dry Powder (Penicillin) | | | |
| 13 | M/s Karsons Pharmaceuticals, Plot No.1, Street No. SS-3, National Industrial Zone, Rawat.<br><br>DML No. 000854 (Formulation).<br><br>Period: Commencing on 11-04-2022 ending on 10-04-2027. | 09-01-2023 | **SATISFACTORY** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Fahad Nadeem, Deputy Director (LT), DRAP, Islamabad.<br>3. Miss. Zunaira Faryad | |

**Recommendations of the panel:**

The Panel agree that the Establishment meets the minimum requirement of renewal of license as laid down in Drugs Act 1976, and DRAP Act 2012, and the rules framed there under. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal of Drug Manufacturing License w.e.f 11-04-2022 for following sections:

| Sr. No. | Name of Section |
|---|---|
| 1. | Tablet Section (General) |
| 2. | Capsule Section (General) |
| 3. | Cream /Ointment/Gel Section (General) |
| 4. | Dry Powder Suspension Section (General) |

**Decision of the Central Licensing Board in 289th meeting**

The Board observed that the panel has rated "satisfactory" to the firm and decided to defer the case for re-inspection of the premises.

| | | | | |
|---|---|---|---|---|
| 14 | M/s. Irza Pharma (Pvt) Ltd, 10.2 Km Sheikhupura Road, Lahore.<br><br>DML No. 000108 (Formulation).<br><br>Period: Commencing on 12-07-2019 ending on 11-07-2024. | 25-11-2022 | **Good** | 1. Dr. Zaka Ur Rehman, Chief Operating Officer, PDTRC, Lahore.<br>2. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore.<br>3. Hafiz Sanaullah Babar, Assistant Director, DRAP, Lahore. |

**Recommendations of the panel:**

Keeping in view the manufacturing facility like, building, production, machinery, Equipment in Quality Control and microbiology laboratory, testing facilities, utilities and documentation reviewed, the panel of inspectors recommends the renewal of Drug Manufacturing License and Regularization of Layout Plan to M/s. Irza Pharma (Pvt) Ltd, 10.2 Km Sheikhupura Road, Lahore for the following sections only:

i. Tablet (General) Section
ii. Capsule (General)Section.
iii. Tablet (Steroid) Section
iv. Syrup Section (General).
v. Capsule (Penicillin) Section

vi. Dry Powder Suspension (Penicillin) Section.
vii. Liquid External Preparation Section.
viii. Capsule (Cephalosporin) Section.
ix. Dry Powder Suspension (General) Section.
x. Dry Powder Suspension (Cephalosporin) Section.

And the firm also given undertaking for the following sections which are under revamping/renovation (copy of undertaking is attached) and they will not start production till the inspection of these sections:

i. Liquid Injectable (Ampoule) (General)
ii. Liquid Repacking.
iii. Drop Section.
iv. Ointment (General)

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000108 by way of Formulation in the name of M/s. Irza Pharma (Pvt) Ltd, 10.2 Km Sheikhupura Road, Lahore.

on the recommendations of the panel of experts for the period Commencing on Commencing on 12-07-2019 ending on 11-07-2024. for the following sections: -

i. Tablet (General) Section
ii. Capsule (General)Section.
iii. Tablet (Steroid) Section
iv. Syrup Section (General).
v. Capsule (Penicillin) Section
vi. Dry Powder Suspension (Penicillin) Section.
vii. Liquid External Preparation Section.
viii. Capsule (Cephalosporin) Section.
ix. Dry Powder Suspension (General) Section.
x. Dry Powder Suspension (Cephalosporin) Section.

The Board further decided that to serve the Show Cause to the firm and stop the production till rectifications of the observation made during inspection for following sections:

i. Liquid Injectable (Ampoule) (General)
ii. Liquid Repacking.
iii. Drop Section.
iv. Ointment (General) Signature

| | | | | |
|---|---|---|---|---|
| 15 | M/s. Kohinoor Industries, 159-160/B, Small Industries Estate, Sahiwal.<br><br>DML No. 000197 (Formulation).<br><br>Period: Commencing on 25-10-2020 ending on 24-10-2025. | 17-01-2023 | **Good** | 1. Azhar Jamal Saleemi, Drugs Controller, Government of Punjab, Lahore.<br>2. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore.<br>3. Hafiz Sanaullah Babar, 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 and Microbiology Laboratory, Testing Facilities, Technical Personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation and grant of additional section to M/s. Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal for the following sections:

i. Cream / Ointment (General).
ii. Sachet (General).
iii. Oral Dry Powder (General) (Veterinary) Revised
iv. Oral Liquid General (Veterinary) (Revised).
v. Powder Repacking (Human) (Revised).
vi. Liquid Repacking (Human) (Revised).
vii. Oral Liquid (Human) (New).
viii. Capsule (Human) (New).
ix. Liquid Preparation Section

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000197 by way of Formulation in the name of M/s. Kohinoor Industries, 159-160/B, Small Industries Estate, Sahiwal on the recommendations of the panel of experts for the period Commencing on Commencing on 25-10-2020 ending on 24-10-2025 for the following sections: -

i. Cream / Ointment (General).
ii. Sachet (General).
iii. Oral Dry Powder (General) (Veterinary). Revised
iv. Oral Liquid General (Veterinary) (Revised).
v. Powder Repacking (Human) (Revised).
vi. Liquid Repacking (Human) (Revised).
vii. Oral Liquid (Human) (New).
viii. Capsule (Human) (New).
ix. Liquid Preparation Section

| | |
|---|---|
| | |

(Evaluator: Muhammad Usman, AD-III. Sr. No. 13-21)

| S # | Name of the firm | Date of Inspection | Ranking/ Evaluation | Inspection Panel Members |
|---|---|---|---|---|
| 16 | M/s Delux Chemical Industries, LT-26/A-1, Landhi Industrial Area, Karachi.<br><br>DML No.000033 (Formulation)<br><br>**Period:** Commencing on 09-01-2021 & ending on 08-01-2026. | 26-10-2022 | Good | 1. Prof. Dr. Abdullah Dayo, Expert Member<br>2. Federal Inspector of Drugs, DRAP, Karachi.<br>3. Mr. Sajjad Ahmad Abbasi, DD, CDL, Karachi. |

**Recommendations of the panel:**

Keeping in view people met, documents reviewed and findings of inspection and positive intention of the management towards further compliance of DRAP Act 2012 and intentions towards export to various countries, the panel recommends Renewal of Drug Manufacturing License No.000033 (By way of Formulation) for following sections:

| Sr.No. | Sections | Sr.No. | Sections |
|---|---|---|---|
| 1. | Tablet (General) | 2. | Ointment/Cream (General) |
| 3. | Capsule (General) | 4. | Oral Liquid (General) - Vet |
| 5. | Oral Liquid Syrup (General) | 6. | Oral Powder (General)-Vet |

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000033 by way of Formulation in the name of M/s Delux Chemical Industries, LT-26/A-1, Landhi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 09-01-2021 & ending on 08-01-2026 for the following sections: -

| Sr.No. | Sections | Sr.No. | Sections |
|---|---|---|---|
| 1. | Tablet (General) | 2. | Ointment/Cream (General) |
| 3. | Capsule (General) | 4. | Oral Liquid (General) - Vet |
| 5. | Oral Liquid Syrup (General) | 6. | Oral Powder (General)-Vet |

<table>
<tr><td>17</td><td>M/s Palpex Pharmaceuticals (Pvt) Ltd., Plot No. FD-46-A8, Street-I, Sector 38, Korangi Creek Industrial Park, Karachi .<br><br>DML No. 000858 (Formulation)<br><br>Period: Commencing on 12.06.2022 & ending on 11.06.2027</td><td>08-11-2022</td><td>Good</td><td>Abdul Rasool Sh. Additional Director, DRAP, Karachi.<br>1. Ghulam Ali Lakho Chief Drug Inspector, CDO, Sindh, Karachi.<br>2. Ms Sanam Kausar Assistant Director, DRAP, Karachi.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u><br><br>Based on the stated facts and keeping in view the attitude of the management of the firm towards continuous improvements the Panel unanimously recommends the grant of renewal of their DML No.000858 (Formulation) for the next five years for the following sections;<br><br>
<table>
<tr><td>Tablet (G)</td><td>Capsule (G)</td><td>Dry Powder Oral Suspension (G)</td></tr>
<tr><td>Sterile Dry Powder Injection (Cephalosporin)</td><td>Capsule (Cephalosporin)</td><td>Dry Power Oral Suspension (Cephalosporin)</td></tr>
<tr><td>Sterile Dry Powder Injection (G)</td><td>Sterile Liquid Injection (Ampoules)</td><td>Sterile Liquid Infusion (G)</td></tr>
</table>
<br><u>Decision of the Central Licensing Board in 289th meeting</u><br><br>The Board considered and approved the grant of renewal of DML No. 000858 by way of Formulation in the name of M/s Palpex Pharmaceuticals (Pvt) Ltd., Plot No. FD-46-A8, Street-I, Sector 38, Korangi Creek Industrial Park, Karachi 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: -<br><br>
<table>
<tr><td>Tablet (G)</td><td>Capsule (G)</td><td>Dry Powder Oral Suspension (G)</td></tr>
<tr><td>Sterile Dry Powder Injection (Cephalosporin)</td><td>Capsule (Cephalosporin)</td><td>Dry Power Oral Suspension (Cephalosporin)</td></tr>
<tr><td>Sterile Dry Powder vial Injection (G)</td><td>Sterile Liquid Injection (Ampoules)</td><td>Sterile Liquid Infusion (G)</td></tr>
</table>
</td></tr>
<tr><td>18</td><td>M/s Epoch Pharmaceuticals Plot No 83-85, Sector 15 Korangi Industrial Area Karachi<br><br>DML# 000425 (Formulation).</td><td>21-11-2022</td><td>Good</td><td>1. Mr. Abdul Rasool Shaikh Additional Director, DRAP, Karachi.<br>2. Mr. Ghulam Ali Lakho, Senior Provincial Inspector of Drugs, Karachi.</td></tr>
</table>

| | | | | |
|---|---|---|---|---|
| | **Period:** Commencing on 25-03-2021 & ending on 24-03-2026. | | | 3. Mrs. Sanam Kasuer Jahan, Assistant Director, DRAP, Karachi. |

**Recommendations of the panel:**

M/s Epoch Pharmaceuticals, Plot NO. 83-85, Korangi Industrial Area, Karachi was visited and inspected in detail on 21-11-2022 in compliance to the directions contained in DRAP Islamabad letter No. F.2-1/94-Lic (Vol-III) dated 5th July 2022.

The panel inspected the firm in detail including all the manufacturing sections stores and QC Lab and found the facility as per approved layout 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.

QC Lab has been shifted to First floor and built as per approved design alongside the lab the firm has separately designed R&D areas with the required equipment. Cephalosporin sections are now made well dedicated by providing separate entry for working personnel, primary and secondary change room facilities, sampling and dispensing areas are also separate as per approved layout. Total 22 AHUs are installed in all sections with air balancing report verified during the inspection.

The firm posses the registrations of Penicillin containing products for which they have to develop a well dedicated area thus they assured to halt the manufacturing of Penicillin containing products.

Based on stated observations, people met, documents reviewed and utilities provided at the facilities, the panel unanimously recommends the regularization of existing layout plan and grant of renewal of Drug Manufacturing License No.000425 (Formulation) due from March 2021 for the following sections:

| **Ser.** | **Name of Section** | **Ser.** | **Name of Section** |
|---|---|---|---|
| i. | Tablet (General) | ii. | Cream and Ointment (General) |
| iii. | Lotions (General) | iv. | Oral Liquid Syrup (General) |
| v. | Capsule (General) | vi. | Dry Powder Suspension (General) |
| vii. | Capsule (Cephalosporin) | viii. | Dry Powder Suspension (Cephalosporin) |
| ix. | Sterile Dry Powder Injectable (Cephalosporin) | x. | Oral Powder (general) (Veterinary) |
| xi. | Liquid Syrup (Veterinary) | xii. | Liquid Injection (ampoule/Vial) (Veterinary) |

| | | | | |
|---|---|---|---|---|
| xiii. | Sterile Liquid Injection (Amps/Vials) | xiv. | Sterile Eye/Ear Drops (general) | |
| xv. | QC Lab (Regularization) | xvi. | R&D Laboratory | |
| xvii. | Warehouse (General) | xviii. | Warehouse (Veterinary) | |
| xix. | Raw Material Store (Cephalosporin) | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx | | |

The panel was given mandate for two (02) separate sections namely Liquid Injection (ampoule) (Veterinary) & Liquid Injection (Vial) (Veterinary) while the panel in its inspection report has mentioned the same as one section namely Liquid Injection (ampoule/Vial) (Veterinary)

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000425 by way of Formulation in the name of M/s Epoch Pharmaceuticals Plot No 83-85, Sector 15 Korangi Industrial Area Karachi on the recommendations of the panel of experts for the period Commencing on 25-03-2021 & ending on 24-03-2026 for the following sections.

| **Ser.** | **Name of Section** | **Ser.** | **Name of Section** |
|---|---|---|---|
| i. | Tablet (General) | ii. | Cream and Ointment (General/Steroidal) |
| iii. | Lotions (General) | iv. | Oral Liquid Syrup (General) |
| v. | Capsule (General) | vi. | Dry Powder Suspension (General) |
| vii. | Capsule (Cephalosporin) | viii. | Dry Powder Suspension (Cephalosporin) |
| ix. | Sterile Dry Powder Injectable (Cephalosporin) | x. | Oral Powder (general) (Veterinary) |
| xi. | Liquid Syrup (Veterinary) | xii. | Sterile Eye/Ear Drops (general) |
| xiii. | Sterile Liquid Injection (Amps/Vials) | xiv. | R&D Laboratory |
| xv. | QC Lab (Regularization) | xvi. | Warehouse (Veterinary) |
| xvii. | Warehouse (General) | xviii. | Raw Material Store (Cephalosporin) |
| xix. | | | |

The Board decided to refer the case to the panel for clarification whether the Liquid Injection (ampoule/Vial) (Veterinary) section is one or separate area.

| | | | | |
|---|---|---|---|---|
| 19 | M/s Reko Pharmacal (Pvt) Ltd., 13-Km, Multan Road, Lahore DML# 000037 (Formulation). | 24-11-2022 | Good | 1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore.<br>2. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab.<br>3. Mrs. Anam Saeed, Assistant Director, DRAP, Lahore. |

| | | | |
|---|---|---|---|
| Period : Commencing on 30-04-2020 & ending on 29-04-2025. | | | |

**Recommendations of the panel:**

In the light of the inspection conducted by the panel and based on the findings and registered products of the firm, the panel of inspectors is of the opinion that renewal of drug manufacturing license by way of formulation may be granted to M/s Reko Pharmacal (Pvt) Ltd., 13-Km, Multan Road, Lahore for the following sections **subject to fulfillment of the rectification of observations mentioned above and revisit of the panel for the confirmation of the rectifications:**

i. Tablet Section (General)
ii. Capsule section (General)
iii. Cream/Ointment/lotion (General and Steroid)
iv. Syrup Section (General)
v. Eye drop section (General)
vi. Liquid injectable section (General)
vii. Capsules (Cephalosporin)
viii. Oral Dry Powder for Suspension (Cephalosporin)
ix. Tablet Section (Psychotropic)

**The panel was also given mandate for inspection of firm for renewal of Sachet (General) section but the same is not mentioned/recommended by the panel in the inspection report.**

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of M/s Reko Pharmacal (Pvt) Ltd., 13-Km, Multan Road, Lahore DML# 000037 (Formulation).
by way of Formulation on the recommendations of the panel of experts for the period Commencing from 30-04-2020 & ending on 29-04-2025.for the following sections subject to the report by Additional Director on rectification of the observations. The Board authorized Chairman CLB to decide on the report and place the case in next meeting for ratification: -

i. Tablet Section (General)
ii. Capsule section (General)
iii. Cream/Ointment (General)
iv. Syrup Section (General)
v. Eye drop section (General)
vi. Liquid injectable section (General)
vii. Capsules (Cephalosporin)
viii. Oral Dry Powder for Suspension (Cephalosporin)
ix. Tablet Section (Psychotropic)

| | | | | |
|---|---|---|---|---|
| | The renewal is also subject to submission of NOC for Psychotropic Section 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 | | | |
| 20 | M/s Inventor Pharma (Pvt) Ltd., Plot No.K-196, S.I.T.E , Super Highway, Phase-II, Karachi.<br>DML# 000866 (Formulation).<br><br>**Period:** Commencing on 22.06.2022 & ending on 21.06.2027 | 13-12-2022 | Good | 1. Mr. Ghulam Ali Lakho, Senior Inspector of Drugs, Karachi.<br>2. Mr. Abdul Rasool Sheikh, Area FID- II, DRAP, Karachi.<br>3. Mrs. Hira Bhutto, AD, DRAP, Karachi. |

**Recommendations of the panel:**

Keeping in view of the above, people met, documents reviewed and attitude of the management towards continuous improvement, the panel is of the opinion to **recommend the grant of renewal of their DML No.000866 (By way of Formulation)** for the next five years for the following sections;

| | | |
|---|---|---|
| Tablet (G) | Capsule (G) | Oral Liquid (G) |
| Sterile Liquid Ampule (G) | Ointment (G) | Sterile Liquid Vial Injectable SVP (G) |
| Capsule (Cephalosporin) | Oral Dry Powder Suspension (Cephalosporin) | Sterile Dry Powder Vial Injection (Cephalosporin) |
| Liquid External (G) | *** | *** |

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000866 by way of Formulation in the name of M/s Inventor Pharma (Pvt) Ltd., Plot No.K-196, S.I.T.E , Super Highway, Phase-II, Karachi 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: -

| | | |
|---|---|---|
| Tablet (G) | Capsule (G) | Oral Liquid (G) |
| Sterile Liquid Ampoule (G) | Ointment (G) | Sterile Liquid Vial Injectable SVP (G) |

| | | | | | |
|---|---|---|---|---|---|
| | | Capsule (Cephalosporin) | Oral Dry Powder Suspension (Cephalosporin) | Sterile Dry Powder Vial Injection (Cephalosporin) | |
| | | Liquid External (G) | *** | *** | |
| 21 | M/s Kaizen Pharmaceuticals (Pvt) Ltd., Plot No. E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority, Karachi.<br><br>DML No.000755 (Formulation)<br><br>**Period:** Commencing on 24-09-2022 & ending on 23-09-2026. | 03-01-2023 | Good | 1. Dr. Noor Us Saba, Director Biological, DRAP, Islamabad.<br>2. Abdul Rasool Sh Additional Director, DRAP, Karachi.<br>3. Hakim Masood Area FID, DRAP, Karachi. | |

**Recommendations of the panel:**

Based on the people met, areas inspected, export enhancement intention and commitment of management for continuous improvement and up-gradation, the panel is of the view to recommend the Renewal of Drug Manufacturing License #000755 (By way of Formulation) to the firm of M/s Kaizen Pharmaceuticals (Pvt) Ltd., for following Sections:

| | | |
|---|---|---|
| Tablet (General) | Capsule (General) | Dry Powder Suspension (General) |
| Sachet (General) | Soft Gelatin Capsule (General) | Liquid Section |
| Oral Hygiene (Mouth Wash) | Semisolid and Tooth Paste | |

The panel was given mandate for inspection of section namely Liquid section/oral hygiene (Mouth wash), Semi-Solid & Tooth Paste while the panel in its inspection report has mentioned the same as separate three (03) sections.

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000755 by way of Formulation in the name of M/s Kaizen Pharmaceuticals (Pvt) Ltd., Plot No. E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority, Karachi on the recommendations of the panel of experts for the period Commencing on 24-09-2022 & ending on 23-09-2026 for the following sections: -

| | | |
|---|---|---|
| Tablet (General) | Capsule (General) | Dry Powder Suspension (General) |

| | | | | |
|---|---|---|---|---|
| | Sachet (General) | Soft Gelatin Capsule (General) | Liquid Section | |
| | Oral Hygiene (Mouth Wash)/ Semisolid and Tooth Paste | | | |
| | | | | |
| 22 | M/s Medimarker's Pharmaceuticals (Pvt) Ltd. Plot No. A-104, S.I.T.E Area Hyderabad.<br><br>DML No.000615 (Formulation)<br><br>**Period:** Commencing on 07-04-2022 & ending on 06-04-2027. | 02-01-2023 | Good | 1. Sh Abdul Rasool Additional Director, DRAP, Karachi.<br>2. Mr. Ghulam Ali Lakho, Senior Inspector of Drugs, Karachi.<br>3. Mr Hakim Masoos Area FID, DRAP, Karachi. |

**Recommendations of the panel:**

The panel inspected the premises of M/s Medimarker's Pharmaceuticals (Pvt) Ltd. Plot No. A-104 S.I.T.E Area Hyderabad in compliance to DRAP Islamabad letter No. F.2-4/2003-Lic (V-II) dated 17th December 2022.

The firm is constructed as per approved revised layout plan. Good level of sanitation and hygiene was noted.

Therefore, based on the people met, areas inspected, export enhancement intention and commitment of management for continuous improvement and up-gradation, the panel is of the view to recommend the Renewal of Drug Manufacturing License #000615 (By way of Formulation) due from April 2022 for following Sections:

| | | |
|---|---|---|
| Tablet (General) -**Revised** | Capsule (General)- **New** | Dry Powder Suspension (General) |
| Sachet (General) | Cream/Ointment/Gel (General)- **Revised** | Liquid Syrup (General) |
| Sterile Liquid injection ampoule (General) | Sterile Liquid injection vial (General) | Sterile Eye & Ear Drops (General) |
| Capsule (cephalosporin)-**Revised** | Dry Powder Suspension (cephalosporin)-**Revised** | Dry Powder Injection (cephalosporin) |
| Capsule (Penicillin) | Oral Dry Syrup (Penicillin) | Tablet (Psychotropic)-**Revised** |
| Raw Material (General)-**Revised** | Raw Material (Cephalosporin)-**Revised** | Raw Material (Psychotropic)-**Revised** |

The panel was not given mandate for inspection of the firm for Dry Powder Suspension (General) section, however, the panel has recommended the said section in its panel inspection report as well.

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. #000615 (By way of Formulation) and grant of revised sections in the name of M/s Medimarker's Pharmaceuticals (Pvt) Ltd. Plot No. A-104 S.I.T.E Area Hyderabad due from April 2022 on the recommendations of the panel of experts for the following sections subject to submission of NOC for Psychotropic Section 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: -

| | | |
|---|---|---|
| Tablet (General) -**Revised** | Capsule (General)- **New** | Liquid Syrup (General) |
| Sachet (General) | Cream/Ointment/Gel (General)- **Revised** | Sterile Eye & Ear Drops (General) |
| Sterile Liquid injection ampoule (General) | Sterile Liquid injection vial (General) | Dry Powder Injection (cephalosporin) |
| Capsule (cephalosporin)-**Revised** | Dry Powder Suspension (cephalosporin)-**Revised** | Tablet (Psychotropic)-**Revised** |
| Capsule (Penicillin) | Oral Dry Syrup (Penicillin) | Raw Material (Psychotropic)-**Revised** |
| Raw Material (General)-**Revised** | Raw Material (Cephalosporin)-**Revised** | |

Moreover, The panel was not given mandate for inspection of the firm for Dry Powder Suspension (General) section, however, the panel has recommended the said section in its panel inspection report as well. The CLB decided to verify from the case file and report form FID and board authorize the Chairman CLB for taking decision accordingly.

| | | | | |
|---|---|---|---|---|
| 23 | M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd. Plot No. 4/116, Sector 21, Korangi Industrial Area, Karachi.<br><br>DML No.000356 (Formulation)<br><br>**Period:** Commencing on 04-10-2019 & ending on 03-10-2024. | 13-01-2023 | Good | 1. Abdul Rasool Sh. Additional Director, DRAP, Karachi.<br>2. Mr. Shoaib Ahmed, FID-III, DRAP,Karachi<br>3. Mr. Krishan, Area AD, DRAP, Karachi. |

**Recommendations of the panel:**

During the inspection the panel thoroughly inspected their production areas, QC Labs, Stores, utilities and reviewed several control documents. The panel met their technical personnel in respective areas as well to know their expertise, trainings and job responsibilities. The panel reviewed QA documents during the inspection. In all the sections, panel observed substantial level of GMP compliance and based on that panel recommend the Renewal of Drug Manufacturing License #000356 (By way of Formulation) to the firm for next five years w.e.f. September 2019 for following sections.

| | | |
|---|---|---|
| Tablet (General) | Capsule (General) | Sterile Liquid injection ampoule (General) |
| Sterile Liquid infusion (General) | Tablet (Psychotropic) | Capsule (cephalosporin) |
| Dry Powder Suspension (cephalosporin) | Dry Powder Injection (cephalosporin) | ********** |
| | | |

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000356 by way of Formulation in the name of M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd. Plot No. 4/116, Sector 21, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 04-10-2019 & ending on 03-10-2024 for the following sections subject to submission of NOC for Psychotropic Section 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: -

| | | |
|---|---|---|
| Tablet (General) | Capsule (General) | Sterile Liquid injection ampoule (General) |
| Sterile Liquid infusion (General) | Tablet (Psychotropic) | Capsule (cephalosporin) |
| Dry Powder Suspension (cephalosporin) | Dry Powder Injection (cephalosporin) | ********** |
| | | |
| | | |

| | | | | |
|---|---|---|---|---|
| 24 | M/s Panacea Pharmeuticals, Plot No.4, Street No. S-6, National Industrial Zone, Rawat.<br><br>DML No. 000600 (Formulation) | 24-11-2022 | Good | 1. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT) DRAP, Islamabad<br>2. Mr. Sardar Shabir Ahmed, SDI, ICT.<br>3. Mr. Ayoob Naveed , DRAP, Islamabad |

| | | | |
|---|---|---|---|
| Period : Commencing on 15-09-2021 & ending on 14-09-2026. | | | |

**Recommendations of the panel:**

GMP is a continual process of improvement in context to the current inspection and keeping in view of the above stated observations made during the inspection, areas visited, documents reviewed and commitment shown by the management of M/s Panacea Pharmaceuticals for further improvement, the panel unanimously concluded that the DML of firm located at Plot No.4, Street No. S-6, National Industrial Zone, Rawat having DML No. 000600 may be renewed for following sections :

| | | |
|---|---|---|
| Tablet (General) | Capsule (General)- **I** | Capsule (General)- **II** |
| Tablet (Psychotropic) | Cream/Ointment/Gel/Lotion (General) | Dry Powder Suspension (General) |
| Sachet General) | Sterile Ophthalmic (General) | Dry Powder Suspension (cephalosporin) |
| Capsule (cephalosporin) - Revised | ********** | |

The panel was given **mandate for inspection of section namely Cream/Ointment (General)**, however, the panel has recommended the section as Cream/Ointment/Gel/Lotion (General)

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000600 by way of Formulation in the name of M/s Panacea Pharmeuticals, Plot No.4, Street No. S-6, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period Commencing on 15-09-2021 & ending on 14-09-2026 for the following sections subject to submission of NOC for Psychotropic Section 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 :: -

| | | |
|---|---|---|
| Tablet (General) | Capsule (General)- **I** | Capsule (General)- **II** |
| Tablet (Psychotropic) | Cream/Ointment/(General) | Dry Powder Suspension (General) |
| Sachet General) | Sterile Ophthalmic (General) | Dry Powder Suspension (cephalosporin) |

| | | | | |
|---|---|---|---|---|
| | Capsule (cephalosporin) | ********** | | |
| 25. | M/s Popular Chemical Works (Pvt) Ltd., 9-Km, Lahore Sheikhupura Road, Lahore.<br><br>DML No. 000076 (Formulation).<br><br>Period: Commencing on 30-08-2020 ending on 29-08-2025. | 12-12-2022 | **Good** | 1. Mr. Ch. Muhammad Shamoon, Expert Member.<br>2. Area Federal Inspector of Drugs, DRAP, Lahore.<br>3. Assistant Director, DRAP, Lahore. |

**Recommendations of the panel:**

During inspection some points were discussed with the management and advised for improvement and the management agreed. Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production Machinery, Equipment in Quality Control and Microbiology Laboratory, Testing Facilities, Technical Personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation, regularization of layout plan and grant of additional section to M/s Popular Chemical Works (Pvt.) Ltd., 9.5-km, Sheikhupura Road, Lahore for the following sections :

1. Tablet Section (General) (Renewal)
2. Tablet Section (Psychotropic) (Renewal)
3. Capsule Section (General) (Renewal)
4. Oral Liquid Section (General) (Renewal)
5. Liquid Injectable Ampoule Section (General) (Renewal)
6. Dry Powder Suspension Section (Penicillin) (Renewal)
7. Capsule Section (Penicillin). (Renewal)
8. Liquid Injectable (Psychotropic) (Additional)

The panel did not give any recommendations on two sections.
1. Oral Dry Powder for suspension (Cephalosporin)
2. Capsule (Cephalosporin)

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000076 by way of Formulation in the name of M/s Popular Chemical Works (Pvt) Ltd., 9-Km, Lahore Sheikhupura Road, Lahore on the basis of.the recommendations of the panel of experts for

| | |
|---|---|
| | the period Commencing on 30-08-2020 ending on 29-08-2025 subject to submission of NOC for Psychotropic Section 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:<br><br>1. Tablet Section (General) (Renewal)<br>2. Tablet Section (Psychotropic) (Renewal)<br>3. Capsule Section (General) (Renewal)<br>4. Oral Liquid Section (General) (Renewal)<br>5. Liquid Injectable Ampoule Section (General) (Renewal)<br>6. Dry Powder Suspension Section (Penicillin) (Renewal)<br>7. Capsule Section (Penicillin). (Renewal)<br>8. Liquid Injectable (Psychotropic) (Additional) |

**(**Evaluator: Muhammad Yaqoob, AD-IV. Sr. No 22-24)

| **S #** | **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
|---|---|---|---|---|
| 26 | M/s Shazal's Pharmaceuticals, Plot No.41/1-A, Phase-I, Industrial Estate, Hattar.<br><br>DML No.000592 (Formulation).<br><br>Period: Commencing on 15-10-2019 ending on 14-10-2024. | **07-12-2022** | **Good** | 1. Mr. Younis Khattak, Chief Drug Inspector, Peshawar.<br>2. Mr. Faisal Shahzad, Area FID, DRAP, Peshawar. |
| | Inspection of Ms. Shazal Pharmaceuticals was conducted by the following panel on 13-10-2022.<br>1. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Bannu.<br>2. Federal Inspector of Drugs, DRAP, Peshawar.<br>3. Assistant Director, DRAP, Peshawar.<br><br>The case was presented in 288th meeting of CLB and the Board observed that the rating of the firm was satisfactory. Hence the Board considered and decided to re-inspect the premises, for which the following panel was constituted: | | | |

| | | | | |
|---|---|---|---|---|
| | 1. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Peshawar.<br>2. FID, DRAP, Peshawar<br><br>The newly constituted panel inspected the firm and given following recommendations.<br>**Conclusion:**<br><br>"Based on documentation reviewed, technical / management people met, materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, allied facilities and commitment shown by the firm's management to continuously improve the facility in line with GMP guidelines, for which they shall submit quarterly reports to area FID, the panel is of the view that the firm is operating at good level of GMP compliance and recommends grant of renewal of Drug Manufacturing License to the firm from 09-09-2020 for following mentioned four sections:-<br>1. Tablet (General).<br>2. Capsule (General).<br>3. Capsule (Cephalosporin).<br>4. Dry Powder Suspension (Cephalosporin).<br><br>**<u>Decision of the Central Licensing Board in 289th meeting</u>**<br><br>The Board considered and approved the grant of renewal of DML No. 000592 by way of Formulation in the name of M/s Shazal's Pharmaceuticals, Plot No.41/1-A, Phase-I, Industrial Estate, Hattar on the recommendations of the panel of experts for the period Commencing on 15-10-2019 ending on 14-10-2024. for the following section: -<br><br>1. Tablet (General).<br>2. Capsule (General).<br>3. Capsule (Cephalosporin).<br>4. Dry Powder Suspension (Cephalosporin). | | | |
| 27 | M/s Unimark Pharmaceutical (Pvt) Ltd, Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat.<br><br>DML No. 000557 (Formulation).<br><br>Period: Commencing on 08-12-2019 ending on 07-12-2024. | **14-12-2022** | **Good** | 1. Dr. Ghazanfar Ali Kha, Additional Director, DRAP, Islamabad.<br>2. Dr. Zaka ur Rehman, Expert Member, Lahore.<br>3. Ms. Haleema Sharif, Assistant Director, DRAP, Islamabad. |

| | | | | |
|---|---|---|---|---|
| | **Summary & Conclusion:**<br><br>"The panel is of the opinion that the establishment meets the requirements of renewal of license and GMP as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under. **Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f. 08-12-20219 for their all approved sections and shifting of Quality Control Department with Microbiology Lab from ground floor to first floor.**<br><br>**For Renewal:**<br>1. Tablet (General) – I.<br>2. Tablet (General) – II.<br>3. Ointment & Cream (General).<br>4. Capsule (General).<br>5. Dry Powder Suspension (General).<br><br>**Revised Section.**<br>Quality Control Department **(Revised)** (Shifted from Ground Floor to 1st Floor).<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000557 by way of Formulation in the name of M/s Unimark Pharmaceutical (Pvt) Ltd, Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period Commencing on 08-12-2019 ending on 07-12-2024. for the following sections: -<br><br>**For Renewal:**<br>1. Tablet (General) – I.<br>2. Tablet (General) – II.<br>3. Ointment & Cream (General).<br>4. Capsule (General).<br>5. Dry Powder Suspension (General).<br><br>**Revised Section.**<br>Quality Control Department **(Revised)** (Shifted from Ground Floor to 1st Floor). | | | |
| 28 | M/s Danas Pharmaceuticals (Pvt) Ltd, 312-Industrial Triangle, Kahuta Road, Islamabad.<br><br>DML No. 000569 (Formulation).<br><br>Period: Commencing on 13-05-2020 ending on 12-05-2025. | **23-12-2022** | **Very Good** | 1. Dr. Ghazanfar Ali Kha, Additional Director, DRAP, Islamabad.<br>2. Mr. Adnan Shahidullah, Deputy Director (QA&LT), DRAP, Islamabad. |

| | | | | |
|---|---|---|---|---|
| | | | | 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Islamabad. |

**Summary & Conclusion:**

"The panel is of the opinion that the establishment meets the requirements of renewal of license as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under, **Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f. 13-05-2020 for following sections: -**

1. Liquid Injection Ampoule (Steroidal) **– Revised.**
2. Liquid Injection Vial (Steroidal) **– Revised.**
3. Liquid Injection Ampoule (General) **– Revised.**
4. Liquid Injection Vial (General) **– Revised.**
5. Tablet Section-II **(New in place of Psychotropic Tablet Section).**
6. Capsule Section (General) **– Revised.**
7. Tablet Section (General) **– Revised.**
8. Topical Cream / Ointment Section (General) **– Revised.**
9. Topical Lotion / Solution **– Revised.**
10. Expansion of warehouse-**Revised**
11. Quality Control Laboratory and Microbiology-**Revised**

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal of DML No. 000569 by way of Formulation in the name of M/s Danas Pharmaceuticals (Pvt) Ltd, 312-Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period Commencing on 13-05-2020 ending on 12-05-2025. for the following sections: -

1. Liquid Injection Ampoule (Steroidal) **– Revised.**
2. Liquid Injection Vial (Steroidal) **– Revised.**
3. Liquid Injection Ampoule (General) **– Revised.**
4. Liquid Injection Vial (General) **– Revised.**
5. Tablet Section-II **(New in place of Psychotropic Tablet Section).**
6. Capsule Section (General) **– Revised.**
7. Tablet Section (General) **– Revised.**
8. Topical Cream / Ointment Section (General) **– Revised.**
9. Topical Lotion / Solution **– Revised.**
10. Expansion of warehouse-**Revised**
11. Quality Control Laboratory and Microbiology-**Revised**

| | | | | |
|---|---|---|---|---|
| 29 | M/s Pearl Pharmaceuticals, Plot No. 204, Street 1, I-10/3, Industrial Area, Islamabad.<br><br>DML No. 000479 (Formulation).<br><br>Period: Commencing on 02-09-2020 ending on 01-09-2025. | **03-11-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Mr. Fahad Nadeem, Deputy Director (LT), DRAP, Islamabad.<br>3. Mr. Muhammad Sarfaraz, AD, DRAP, Islamabad. |

**Recommendations:**

"The firm has maintained SOPs for internal audit and to handle the market complaints. They are concerned with the training of the employees; procedures for waste management are defined. It is advised to strengthen the QA to meet the requirements of existing / new sections and to devise a mechanism for approval of SOPs through MR. Keeping in view the facts observed during inspection, the panel (constituted vide letter No.F 1-18/90-Lic Vol-III dated 02-11-2022) unanimously recommends renewal of DML by way of formulation to M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10/3, Industrial Area, Islamabad (DML No. 000479) with following sections;

1. Tablet General – **Regularization.**
2. Tablet (Antibiotic) – **Regularization**
3. Capsule (General) – **Regularization.**
4. Capsule (Cephalosporin).
5. Dry Powder Suspension (General).
6. Dry Powder Suspension (Cephalosporin).
7. Dry Powder Injection (Cephalosporin).
8. Cream/Ointment/Gel (Steroidal).
9. Cream/Ointment/Gel (General) – **Regularization.**
10. Lotion (Steroid).
11. Liquid Syrup/Suspension (General) – **Regularization.**
12. Ampoule (General) – **New.**
13. Infusion SP (General) – **New.**
14. Dry Powder for Injection (General) – **New.**
15. Quality Control & Microbiology Lab – **Revised.**

**Note: Soft Gelatin Capsule (General) yet not ready.**

**Decision of the Central Licensing Board in 289th meeting**

The Board considered and approved the grant of renewal/ additional /Regularization of DML No. 000479 by way of Formulation in the name of M/s Pearl Pharmaceuticals, Plot No. 204, Street 1, I-10/3, Industrial Area, Islamabad on the recommendations of the panel of experts for the period Commencing on 02-09-2020 ending on 01-09-2025 for the following sections: -

1. Tablet General – **Regularization.**
2. Tablet (Antibiotic) – **Regularization**
3. Capsule (General) – **Regularization.**
4. Capsule (Cephalosporin).

| | | | | |
|---|---|---|---|---|
| | 5. Dry Powder Suspension (General).<br>6. Dry Powder Suspension (Cephalosporin).<br>7. Dry Powder Injection (Cephalosporin).<br>8. Cream/Ointment/Gel (Steroidal).<br>9. Cream/Ointment/Gel (General) – **Regularization.**<br>10. Lotion (Steroid).<br>11. Liquid Syrup/Suspension (General) – **Regularization.**<br>12. Ampoule (General) – **New.**<br>13. Infusion SVP (General) – **New.**<br>14. Dry Powder for Injection (General) – **New.**<br>15. Quality Control & Microbiology Lab – **Revised/relocation** | | | |
| 30 | M/s Swan Pharmaceutical (Pvt) Ltd, 11-E, Industrial Triangle, Kahuta Road, Islamabad.<br><br>DML No. 000669 (Formulation).<br><br>Period: Commencing on 03-07-2019 ending on 02-07-2024. | **13-12-2022** | **Good** | 1. Dr. Ghazanfar Ali Kha, Additional Director, DRAP, Islamabad.<br>2. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Islamabad.<br>3. Mr. Muhammad Usman, Assistant Director, DRAP, Islamabad. |
| | **Summary & Conclusion:**<br><br>"The establishment has been inspected by the panel for renewal of DML. 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 for following sections: -<br><br>1. Tablet Section (General).<br>2. Capsule Section (General).<br>3. Liquid Ampoule Section (General).<br>4. Injection Section (Psychotropic).<br>**Decision of the Central Licensing Board in 289th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000669 by way of Formulation in the name of M/s Swan Pharmaceutical (Pvt) Ltd, 11-E, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period Commencing on 03-07-2019 ending on 02-07-2024 for the following sections subject to submission of NOC for Psychotropic Section 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: -<br><br>1. Tablet Section (General).<br>2. Capsule Section (General).<br>3. Liquid Ampoule Section (General). | | | |

| | | | | |
|---|---|---|---|---|
| | 4. Injection Section (Psychotropic). | | | |
| 31 | M/s Biorific Pharma, Plot No. 143, Industrial Triangle Kahuta Road, Islamabad.<br><br>DML No. 000818 (Formulation).<br><br>Period: Commencing on 25-11-2021 ending on 24-11-2026. | **12-12-2022** | **Satis-factory** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Ishtiaq Shafiq, Assistant Director, DRAP, Islamabad.<br>3. Saima Hussain, Assistant Director (Reg), DRAP, Islamabad. |
| | **Summary & Conclusion:**<br><br>"The establishment has been inspected by the panel for renewal of DML. During the inspection various observations were made which were reported above in detail. In view of the inspection, reviewing the documents, intent of the management and that they meet the minimum requirements for manufacturing of products in below mentioned sections; the panel recommends the Establishment for renewal Drug Manufacturing License for following sections: -<br><br>1. Dry Powder (General-Vet) Section.<br>2. Liquid Syrup (General-Vet) Section.<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>The Board considered and decided to defer the case for re-inspection of the premises by the same panel. | | | |
| 32 | M/s Innvotek Pharmaceutical, Plot No. 35, Industrial Triangle Kahuta Road, Islamabad.<br><br>DML No. 000487 (Formulation).<br><br>Period: Commencing on 05-05-2021 ending on 04-05-2026. | **16-12-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Muhammad Arif Ch. Additional Director (Controlled Drug Division), DRAP, Islamabad.<br>3. Ishtiaq Shafiq, Assistant Director, DRAP, Islamabad. |
| | **Summary & Conclusion:**<br><br>"The establishment has been inspected by the panel for renewal of DML. During the inspection various observations were made which were reported above in detail. In view of the inspection, reviewing the documents, intent of the management that they meet the requirements for manufacturing of products in below mentioned sections; the panel recommends the Establishment for renewal Drug Manufacturing License for following sections: - | | | |

| | | | | |
|---|---|---|---|---|
| | 1. Tablet Section (General).<br>2. Capsule Section (General.<br>3. Eye Drop (General Sterile).<br>4. Eye Ointment & Cream (General Sterile).<br><br>**Decision of the Central Licensing Board in 289th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000487 by way of Formulation in the name of M/s Innvotek Pharmaceutical, Plot No. 35, Industrial Triangle Kahuta Road, Islamabad on the recommendations of the panel of experts for the period Commencing on 05-05-2021 ending on 04-05-2026 for the following sections: -<br><br>1. Tablet Section (General).<br>2. Capsule Section (General.<br>3. Eye Drop (General Sterile).<br>4. Eye Ointment & Cream (General Sterile). | | | |
| **33** | M/s Fredmann Pharmaceuticals (Pvt) Ltd, Plot No. 82/83-B, Old Industrial Area, Mirpur, Azad Kashmir.<br><br>DML No. 000760 (Formulation).<br><br>Period: Commencing on 24-12-2017 ending on 23-12-2022. | **10-11-2022**<br><br>**&**<br><br>**03-12-2022** | **Good** | 1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br><br>2. Muhammad Arif Ch, Additional Director (Controlled Drug Division), DRAP, Islamabad.<br><br>3. Ishtiaq Shafiq, Assistant Director, DRAP, Islamabad. |
| | **Summary & Conclusion:**<br><br>"The panel agree that the establishment meets the minimum requirement of renewal of license as laid down in Drugs Act 1976, and DRAP Act 2012, and the rules framed there under. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal of Drug Manufacturing License w.e.f. 24-12-2017 for following sections: -<br><br>1. Tablet Section (General).<br>2. Capsule Section (General.<br>3. Tablet (Hormones Section).<br><br>The establishment is not interested in renewal of (cream / Ointment General Section) and the said section should not be renewed.<br><br>**Note: The tenure of renewal of Drug Manufacturing License No. 000760 (Formulation) has already been expired on 24-12-2022 and inspection report is issued on 20th January, 2023.** | | | |

<table>
<tr><td></td><td colspan="4"><u>Decision of the Central Licensing Board in 289th meeting</u><br>The Board accepted the panel inspection report and decided to refer the inspection report to Registration division to deregister products cream / Ointment General Section.</td></tr>
<tr><td>34</td><td>M/s Winilton Pharmaceuticals (Pvt) Ltd, Plot No. 45, Street S-5, National Industrial Zone, Rawat.<br><br>DML No. 000721 (Formulation).<br><br>Period: Commencing on 14-06-2021 ending on 13-06-2026.</td><td>21-11-2022</td><td>Good</td><td>1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.<br>2. Sardar Shabir Ahmed, Senior Drug Inspector, ICT.<br>3. Mr. Muhammad Usman, AD, DRAP, Islamabad.</td></tr>
<tr><td></td><td colspan="4"><u>Summary & Conclusion:</u><br>“The panel is of the opinion that the establishment meets the requirements of renewal of license and GMP as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f. 14-06-20221”.<br>1. Tablet Section (General).<br>2. Capsule Section (General).<br>3. Tablet Section (Antibiotic).<br><br><u>Decision of the Central Licensing Board in 289th meeting</u><br>The Board considered and approved the grant of renewal of DML No. 000721 by way of Formulation in the name of M/s Winilton Pharmaceuticals (Pvt) Ltd, Plot No. 45, Street S-5, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period Commencing on 14-06-2021 ending on 13-06-2026 for the following sections: -<br><br>1. Tablet Section (General).<br>2. Capsule Section (General).<br>3. Tablet Section (Antibiotic).</td></tr>
</table>

## Change of management

(Evaluator: Mst. Zunaira Faryad, AD-I. Sr. 1-2)

Case No. 1 **CHANGE OF MANAGEMENT OF M/S BASEL PHARMACEUTICALS, 227-PHASE-II, MULTAN INDUSTRIAL ESTATE, MULTAN UNDER DML NO 000726 (FORMULATION).**

M/s Basel Pharmaceuticals, 227-Phase-II, Multan Industrial Estate, Multan submitted the documents for change in management. The firm has deposited fee of Rs. 75,000/- for change of management and submitted following documents along with application:

i. Attested copy of partnership deed dated 05-11-2021.
ii. Attested copy of Form-C from Registrar of firms.
iii. Attested copies of CNICs of owners

. The detail of management is as under;

| Previous Management | New Management as per Partnership Deed |
|---|---|
| 1. Mr. Muhammad Nadeem Khalid S/o Khalid Mahmood CNIC No. 36302-3951680-3. | 1. Mr. Naeem Ahmad Sheikh S/o Sheikh Abdul Latif CNIC No. 36302-4237475-5.<br>2. Mr. Muhammad Asif Habib S/o Sheikh Habib Ahmad CNIC No.36302-0464540-3.<br>3. Mr. Muhammad Nadeem Khalid S/o Khalid Mahmood CNIC No. 36302-3951680-3. |

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of management of M/s Basel Pharmaceuticals, 227-Phase-II, Multan Industrial Estate, Multan DML No.000726 (By way of Formulation) subject to submission of Undertaking on stamp paper regarding change of management as under.

| Previous Management | New Management as per Partnership Deed |
|---|---|
| 1. Mr. Muhammad Nadeem Khalid S/o Khalid Mahmood CNIC No. 36302-3951680-3. | 1. Mr. Naeem Ahmad Sheikh S/o Sheikh Abdul Latif CNIC No. 36302-4237475-5.<br>2. Mr. Muhammad Asif Habib S/o Sheikh Habib Ahmad CNIC No.36302-0464540-3.<br>3. Mr. Muhammad Nadeem Khalid S/o Khalid Mahmood CNIC No. 36302-3951680-3. |

Case No. 2 **CHANGE OF MANAGEMENT OF M/S OTTOMAN PHARMA, 10-KM RAIWIND ROAD, LAHORE UNDER DML NO 000502 (FORMULATION).**

M/s Ottoman Pharma, 10-Km Raiwind Road, Lahore submitted the documents for change in management. The firm has deposited fee of Rs. 75,000/- for change of management and submitted following documents along with application:

i. Attested copy of amended partnership deed dated 17th August, 2021.
ii. Attested copy of Form-D from Registrar of firms.
iii. Attested copies of CNICs of partners

The detail of management is as under;

| Previous Management | New Management as per Partnership Deed |
|---|---|
| 1. Mr. Rehman Khalid S/o Khalid Aziz CNIC# 35202-7316312-7.<br>2. Mr. Khurram Malik S/o Muhammad Badar Munir NIC#265-90-346622.<br>3. Usman Khalid S/o Khalid Aziz CNIC#35202-8048278-9.<br>4. Mr. Usman Farooq Khalid S/o Rauf Khalid CNIC No. 61101-5465021-6. | 1. Mr. Usman Farooq Khalid S/o Rauf Khalid CNIC No. 61101-5465021-6.<br>2. Mr. Abdullah Bin Khalid S/o Rauf Khalid CNIC No.61101-0833739-1.<br>3. Dr. Muhammad Danish Mehmood S/o Sardar Mehmood CNIC No. 13501-1317441-3. |

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of management of M/s Ottoman Pharma, 10-Km Raiwind Road, Lahore DML No.000502 (By way of Formulation) subject to submission of Undertaking on stamp paper regarding change of management as under.

| Previous Management | New Management as per Partnership Deed |
|---|---|
| 1. Mr. Rehman Khalid S/o Khalid Aziz CNIC# 35202-7316312-7.<br>2. Mr. Khurram Malik S/o Muhammad Badar Munir NIC#265-90-346622.<br>3. Usman Khalid S/o Khalid Aziz CNIC#35202-8048278-9. | 1. Mr. Usman Farooq Khalid S/o Rauf Khalid CNIC No. 61101-5465021-6.<br>2. Mr. Abdullah Bin Khalid S/o Rauf Khalid CNIC No.61101-0833739-1. |

| | |
|---|---|
| 4. Mr. Usman Farooq Khalid S/o Rauf Khalid CNIC No. 61101-5465021-6. | 3. Dr. Muhammad Danish Mehmood S/o Sardar Mehmood CNIC No. 13501-1317441-3. |

(Evaluator: Muhammad Usman, AD-III. Sr. 3-6)

Case No. 03 **CHANGE OF MANAGEMENT M/S PCP LABORATORIES, 98-KM, AKHTARABAD, DISTRICT OKARA**

M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara has submitted application for change of management under Drug Manufacturing License No. 000814 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

| **Previous management** | **New management as per partnership deed** |
|---|---|
| 1. 1. Dr. Mehmood Ahmad Mirza S/o Chaudry Barkat Ali.<br>2. 2. Dr. Noor Ahmad Noor S/o Haji Barkat Ali.<br>3. 3. Dr. Saeed Ahmad S/o Faqir Muhammad.<br>4. 4. Dr. Muhammad Ali Bukhari S/o Syed Khursheed<br>5. Hussan.<br>6. 5. Dr. Abdu Salam Arshad S/o Muhammad Rafiq.<br>7. 6. Doctor Khan S/o Behram Khan.<br>8. 7. Mr. Rehan Manzoor S/o Manzoor Afshar.<br>9. 8. Dr. Muhammad Yousuf S/o Abdul Rehman Sodager.<br>10. 9. Dr. Tariq Rasheed S/o Rasheed Ahmed.<br>11. 10. Dr. Muhammad Aslam S/o Muhabat Ali.<br>12. 11. Dr. Naqshab Ahmed S/o Atta Ahmed.<br>13. 12. Dr. Tarin Nadeem S/o Syed Karamat Ali Shah.<br>14. 13. Mrs. SafiaBano w/o Taj Muhammad Zahid.<br>15. 14. Mr. Muhammad Shahzad Ilyas S/o Muhammad Ilyas | 1. Salman Hassan S/o Muhammad Hassan CNIC No. 91509-0173536-9.<br>2. Mst. Amber Saeed W/o Salman Hassan CNIC No. 91509- 0245525-6. |

| | |
|---|---|
| 16. Sajid.<br>17. 15. Dr. Zulfagar Ali S/o Allah Rakha.<br>18. 16. Dr. Muhammad Faisal Javed S/o Abdul Qadeer Javed.<br>19. 17. Mr. Muhammad Manzoor S/o Muhammad Hussain.<br>20. 18. Syed Mir Zaman Ali Shah S/o Abdul Hameed Shah. | |

**Decision of the Central Licensing Board in 288th meeting:**

The Board observed that the partnership deed dated 4-02-2022 and partnership deed 20-08-2015 does not match the details of the partners. The Board deferred the case for clarification.

Accordingly, a letter was issued to the firm on 17-11-2022 to clarify the details of the partners in the partnership deed dated 4-02-2022 and partnership deed 20-08-2015.

In reply to the above refer letter the firm has submitted following documents:

i. Old Partnership Deed dated 20th August 2015.
ii. Form-V dated 11-11-2015.
iii. Revised Partnership Deed dated 04/02/2022.

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of management of M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara DML No.000814 (By way of Formulation) subject to submission of undertaking on stamp paper regarding change of management as under.

| Previous management | New management as per partnership deed |
|---|---|
| 1. 1. Dr. Mehmood Ahmad Mirza S/o Chaudry Barkat Ali.<br>2. 2. Dr. Noor Ahmad Noor S/o Haji Barkat Ali.<br>3. 3. Dr. Saeed Ahmad S/o Faqir Muhammad.<br>4. 4. Dr. Muhammad Ali Bukhari S/o Syed Khursheed<br>5. Hussan.<br>6. 5. Dr. Abdu Salam Arshad S/o Muhammad Rafiq. | 1. Salman Hassan S/o Muhammad Hassan CNIC No. 91509-0173536-9.<br>2. Mst. Amber Saeed W/o Salman Hassan CNIC No. 91509- 0245525-6. |

| | |
|---|---|
| 7. 6. Doctor Khan S/o Behram Khan.<br>8. 7. Mr. Rehan Manzoor S/o Manzoor Afshar.<br>9. 8. Dr. Muhammad Yousuf S/o Abdul Rehman Sodager.<br>10. 9. Dr. Tariq Rasheed S/o Rasheed Ahmed.<br>11. 10. Dr. Muhammad Aslam S/o Muhabat Ali.<br>12. 11. Dr. Naqshab Ahmed S/o Atta Ahmed.<br>13. 12. Dr. Tarin Nadeem S/o Syed Karamat Ali Shah.<br>14. 13. Mrs. SafiaBano w/o Taj Muhammad Zahid.<br>15. 14. Mr. Muhammad Shahzad Ilyas S/o Muhammad Ilyas<br>16. Sajid.<br>17. 15. Dr. Zulfagar Ali S/o Allah Rakha.<br>18. 16. Dr. Muhammad Faisal Javed S/o Abdul Qadeer Javed.<br>19. 17. Mr. Muhammad Manzoor S/o Muhammad Hussain.<br>20. 18. Syed Mir Zaman Ali Shah S/o Abdul Hameed Shah. | |

**Case No. 04. <u>CHANGE OF MANAGEMENT OF M/S SAMI PHARMCEUTIACLS (PVT) LTD, KARACHI</u>**

**M/s. Sami Pharmaceuticals (Pvt) Ltd, F-95, Off Hub River Road, Karachi** DML No. 000072 (by way of formulation) has submitted request for change in management of the firm as per Digital Certified True Copy of Form-29 (Year 2022) along with prescribed Fee as under: -

| **Current Management** as per Form-29 of SECP (Year 2020) | **New Management** as per Digital Certified True Copy of Form-29 (Year 2022) |
|---|---|

| | |
|---|---|
| 1. Mr. Shamim Ahmed S/o S.M.Rafi CNIC No. 42201-0709868-7<br>2. Mr. Zubair Shamim S/o Shamim Ahmed CNIC No. 42201-0709872-3<br>3. Mr. Junaid Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3<br>4. Mr. Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3<br>5. Mr. Abdul Salam S/o Zik-ur-Rehman CNIC No. 42201-6555398-5<br>6. Muhammad Yasin Malik S/o Hameed Eid Muhammad<br>CNIC No. 42301-0668555-7 | 1. Mr. Shamim Ahmed S/o S.M.Rafi CNIC No. 42201-0709868-7<br>2. Mr. Ovais Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-7<br>3. Mr. Junaid Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3<br>4. Mr. Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3<br>5. Mr. Abdul Salam S/o Zik-ur-Rehman CNIC No. 42201-6555398-5<br>6. Muhammad Yasin Malik S/o Hameed Eid Muhammad<br>CNIC No. 42301-0668555-7 |

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of management of M/s **Sami Pharmaceuticals (Pvt) Ltd, F-95, Off Hub River Road, Karachi** DML No.000072 (By way of Formulation) subject to submission of Undertaking on stamp paper regarding change of management as under.

| **Current Management** as per Form-29 of SECP (Year 2020) | **New Management** as per Digital Certified True Copy of Form-29 (Year 2022) |
|---|---|
| 1. Mr. Shamim Ahmed S/o S.M.Rafi CNIC No. 42201-0709868-7<br>2. Mr. Zubair Shamim S/o Shamim Ahmed CNIC No. 42201-0709872-3<br>3. Mr. Junaid Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3<br>4. Mr. Shoaib<br>5. Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3<br>6. Mr. Abdul Salam S/o Zik-ur-Rehman CNIC No. 42201-6555398-5<br>7. Muhammad Yasin Malik S/o Hameed Eid Muhammad<br>CNIC No. 42301-0668555-7 | 1. Mr. Shamim Ahmed S/o S.M.Rafi CNIC No. 42201-0709868-7<br>2. Mr. Ovais Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-5<br>3. Mr. Junaid Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3<br>4. Mr. Shoaib Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3<br>5. Mr. Abdul Salam S/o Zik-ur-Rehman CNIC No. 42201-6555398-5<br>6. Muhammad Yasin Malik S/o Hameed Eid Muhammad<br>CNIC No. 42301-0668555-7 |

**Case No. 05 CHANGE OF MANAGEMENT OF M/S ESPOIR PHARMCEUTIACLS PCSIR KLC, KARACHI**

**M/s. Espoir Pharmaceuticals (Pvt) Ltd, PCSIR KLC, Karachi** DML No. 000754 (by way of formulation) has submitted request for change in management) along with prescribed Fee as under: -

| **Current Management** (Sole Proprietorship) | **New Management** (Sole Proprietorship) |
|---|---|
| Mr. Muhammad Imran S/o Mr. Abdul Razzaq<br>CNIC No.42101-1604482-7<br><br>**Sole Proprietor** | Mr. Rajesh S/o Mr. Jhaman Das CNIC No. 42301-4555210-9<br><br>**Sole Proprietor** |

The firm has submitted following documents:

1. Copy of Sale Agreement dated 11-10-2022 endorsed by Civil Judge/Judicial Megistrate-Karachi and notarized by Tariq Iqbal Meher Advocate High Court.
2. Undertaking by the previous Sole Proprietor regarding sale of firm to new owner duly signed by Civil Judge/Judicial Megistrate-Karachi.

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of management of M/s **Espoir Pharmaceuticals (Pvt) Ltd, PCSIR KLC, Karachi** DML No. 000754 (By way of Formulation) subject to submission of Undertaking on stamp paper regarding change of management as under.

| **Current Management** (Sole Proprietorship) | **New Management** (Sole Proprietorship) |
|---|---|
| Mr. Muhammad Imran S/o Mr. Abdul Razzaq<br>CNIC No.42101-1604482-7<br><br>**Sole Proprietor** | Mr. Rajesh S/o Mr. Jhaman Das CNIC No. 42301-4555210-9<br><br>**Sole Proprietor** |

Case No. 6 **CHANGE OF MANAGEMENT M/S RAZEE THERAPEUTICS (PVT) LTD, 48-KM, LAHORE KASUR ROAD, KASUR**

The firm, M/s Razee Therapeutics (Pvt) Ltd, 48-KM, Lahore Kasur Road, Kasur, wherein the firm has submitted application for change of management under Drug Manufacturing License No. 000437 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

| **Existing management** | **New management as per Form-29**<br>Issuing date 28-10-2020 |
|---|---|

| | |
|---|---|
| 1. Mr. Muhammad Hassan Razzee S/o Kh. M. Arif CNIC No. 35201-3926312-3.<br>2. Kh. Muhammad Asif Razee S/o Kh. M. Arif CNI No. 35201-2703742-1.<br>3. Mr. Muhammad GhalibRazzee S/o Muhammad Arif CNIC No. 35201-5586575-5.<br>4. Mrs. Misbah Arif. | 1. Kh. MuhammadAsif Razee S/o Kh. M. Arif CNI No. 35201-2703742-1.<br>2. Mr. Muhammad Ghalib Razzee S/o Muhammad Arif CNIC No. 35201-5586575-5.<br>3. Mr. Muhammad Hassan Razzee S/o Kh. M. Arif CNIC No. 35201-3926312-3.<br>4. Mr. Hameeda Bano Raazee S/o Muhammad Arif CNIC No. 35201-9891933-2. |

**Decision of the Central Licensing Board in 288th meeting:**

The Board observed that the details of the directors (ceasing of officer/retirement/resignation) is not mentioned in Form-29. The case is deferred for clarification by the firm.

Accordingly, a letter was issued to the firm on 15-11-2022 to submit certified true copy of form-29 with the details of the directors (ceasing of officer/retirement/resignation).

In reply to the above refer letter the firm has submitted Form-29 for the year 2021 stamped in 2022 and also submitted the copy of Form-29 wherein the detail of retiring directors is mentioned.

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of management of M/s Razee Therapeutics (Pvt) Ltd, 48-KM, Lahore Kasur Road, Kasur under DML No. 000437 (By way of Formulation) subject to submission of Undertaking on stamp paper regarding change of management as under.

| **Existing management** | **New management as per Form-29**<br>Issuing date 28-10-2020 |
|---|---|
| 1. Mr. Muhammad Hassan Razzee S/o Kh. M. Arif CNIC No. 35201-3926312-3.<br>2. Kh. Muhammad Asif Razee S/o Kh. M. Arif CNI No. 35201-2703742-1.<br>3. Mr. Muhammad GhalibRazzee S/o Muhammad Arif CNIC No. 35201-5586575-5.<br>4. Mrs. Misbah Arif. | 1. Kh. Muhammad Asif Razee S/o Kh. M. Arif CNI No. 35201-2703742-1.<br>2. Mr. Muhammad Ghalib Razzee S/o Muhammad Arif CNIC No. 35201-5586575-5.<br>3. Mr. Muhammad Hassan Razzee S/o Kh. M. Arif CNIC No. 35201-3926312-3.<br>4. Mr. Hameeda Bano Raazee S/o Muhammad Arif CNIC No. 35201-9891933-2. |

(Evaluator: Muhammad Yaqoob, AD-IV. Sr. 7)

**Case No. 7** **CHANGE OF MANAGEMENT OF M/S FARM AID GROUP, PLOT NO. 3/2, PHASE-I & II, HATTAR INDUSTRIAL ESTATE, HARIPUR UNDER DRUG MANUFACTURING LICENSE NO. 000298 BY WAY OF (FORMULATION).**

M/s Farm Aid Group, Plot No. 3/2, Phase-I & II, Hattar Industrial Estate, Haripur, DML No.000298 by way of formulation has submitted request for change in management of the firm as per partnership deed with prescribed fee. The firm has submitted the following documents.

ii. NOC for change of management
iii. Sale agreement
iv. FORM-D
v. Partnership Deed New dated 7th November, 2022.
vi. Partnership Deed old
vii. Requisite Fee. 75,000/=

The detail of management of the firm is as under:-

| Existing management as per partnership Deed | New management as per partnership Deed |
|---|---|
| 1. Mr. Usman Zafar S/o Chaudhry Zafarullah Khan, CNIC No. 34202-7190569-9.<br>2. Mr. Aamir Usman Waqas S/o Muhammad Aslam, CNIC 37102-1250050-7.<br>3. Mr. Abdul Razaq S/o Abdul Rehman, CNIC No. 13101-9333563-5.<br>4. Mr. Muhammad Aftab S/o Haji Muhammad Iqbal, CNIC No. 37405-0652232-9. | 1. Mr. Muhammad Ilyas Akhtar S/o Muhammad Siddique, CNIC No. 34104-8521637-1.<br>2. Mr. Muhammad NaeemUllah S/o Manzoor Hussain, CNIC No. 34104-2348480-5.<br>3. Hafiz Nisar Ahmad S/o Ghafoor Hussain, CNIC No. 34104-1011360-9. |

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of management of M/s Farm Aid Group, Plot No. 3/2, Phase-I & II, Hattar Industrial Estate, Haripur, under DML No. 000298 (By way of Formulation) subject to submission of Undertaking on stamp paper regarding change of management as under.

| Existing management as per partnership Deed | New management as per partnership Deed |
|---|---|

| | |
|---|---|
| 1. Mr. Usman Zafar S/o Chaudhry Zafarullah Khan, CNIC No. 34202-7190569-9.<br>2. Mr. Aamir Usman Waqas S/o Muhammad Aslam, CNIC 37102-1250050-7.<br>3. Mr. Abdul Razaq S/o Abdul Rehman, CNIC No. 13101-9333563-5.<br>4. Mr. Muhammad Aftab S/o Haji Muhammad Iqbal, CNIC No. 37405-0652232-9. | 1. Mr. Muhammad Ilyas Akhtar S/o Muhammad Siddique, CNIC No. 34104-8521637-1.<br>2. Mr. Muhammad NaeemUllah S/o Manzoor Hussain, CNIC No. 34104-2348480-5.<br>3. Hafiz Nisar Ahmad S/o Ghafoor Hussain, CNIC No. 34104-1011360-9. |

**VI. Miscellaneous Cases**

(Evaluator: Mst. Zunaira Faryad, AD-I. Sr. No.1- 11)

Case No. 1 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MUNAWAR PHARMA (PVT) LTD, LAHORE.**

M/s Munawar Pharma (Pvt) Ltd, 31-Km Ferozepur Road, Lahore had applied for renewal of DML No. 000379 by way of Formulation for the period of 12-01-2019 to 11-01-2024 on 19-12-2018.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 15-02-2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Properly filled, signed and stamped Form-1A (as per format)
iii. Duly attested CNIC copies of all Directors.

The firm did not reply and Reminder letter was issued on 15-09-2020 to the firm for completion of application for renewal of DML.

The firm did not reply and application for renewal of DML is still incomplete with following documents being deficient:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Properly filled, signed and stamped Form-1A (as per format)
iii. Duly attested CNIC copies of all Directors.

**Decision of the Central Licensing Board in 288th 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 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No.000379 by way of formulation of M/s Munawar Pharma (Pvt) Ltd, 31-Km Ferozepur Road, Lahore 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.

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

The Show Cause Notice was issued to M/s Munawar Pharma (Pvt) Ltd, 31-Km Ferozepur Road, Lahore on 21st November, 2022.

The firm has replied to Show Cause Notice on 29-12-2022 and submitted all the deficient documents.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

Case No. 2 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S IDEAL PHARMACEUTICAL INDUSTRIES, LAHORE.**

M/s Ideal Pharmaceutical Industries, 18-Km Ferozepur Road, Lahore had applied for renewal of DML No. 000146 by way of Formulation for the period of 30-10-2019 to 29-10-2024 on 28-10-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 18-02-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Update NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iii. Duly attested Form-C, partnership deed & CNIC Copies of all Directors.
iv. Section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm did not reply and Reminder letter was issued on 15-09-2020 to the firm for completion of application for renewal of DML.

The firm did not reply and application for renewal of DML is still incomplete with following documents being deficient:

i. Update NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iii. Duly attested Form-C, partnership deed & CNIC Copies of all Directors.
iv. Section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

**Decision of the Central Licensing Board in 288th 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 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000146by way of formulation of M/s Ideal Pharmaceutical Industries, 18-Km Ferozepur Road, Lahore 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.

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

The Show Cause Notice was issued to M/s Ideal Pharmaceutical Industries, 18-Km Ferozepur Road, Lahore on 21st November, 2022.

The firm has replied to Show Cause Notice on 06-12-2022 and submitted all the deficient documents approved by CLB.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

Case No. 3 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDICEENA PHARMA (PVT) LTD, LAHORE.**

M/s Mediceena Pharma (Pvt) Ltd, 27-Km, Raiwind Road, Lahore had applied for renewal of DML No. 000475 by way of Formulation for the period of 05-05-2020 to 04-05-2025 on 04-05-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 23rd June, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Detail of management, if any change, apply for change of management along with all pre-requisites.
iv. Duly attested CNIC copies of all Directors.
v. Latest certified true copy of Form-29duly attested by SECP (original).
vi. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.

The firm did not reply to this letter and reminder letter was issued on 28thSeptember, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Detail of management, if any change, apply for change of management along with all pre-requisites.
iv. Duly attested CNIC copies of all Directors.
v. Latest certified true copy of Form-29 duly attested by SECP (original).
vi. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.
vii. Duly attested valid / renewed copy of registration certificate from pharmacy council of Production Incharge.
viii. Complete set of duly attested documents of proposed Quality Control Incharge (as per checklist) (except undertaking as whole-time employee).

The firm replied to reminder on 19thOctober, 2020 but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by SECP (original).
ii. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.
iii. Properly filled, signed & stamped Form-1A (as per format).

**Proceedings and Decision by the Central Licensing Board in 278th 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 , of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000475 (by way of formulation) of M/s Mediceena Pharma (Pvt) Ltd, 27-Km, Raiwind Road, Lahore 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.

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

The Show Cause Notice was issued to M/s Mediceena Pharma (Pvt) Ltd, 27-Km, Raiwind Road, Lahore on 1st January, 2021.

The firm replied but application is still deficient of following documents:

i. Latest certified true copy of Form-29 duly attested by SECP without stamp that SECP does not take responsibility of contents of Form. (original).
ii. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.
iii. Properly filled, signed & stamped Form-1A (as per format).

A letter of Personal hearing has been issued on 17th August, 2021.

**Proceedings and Decision of the Central Licensing Board in 282nd meeting**

Mr. Riaz Ali Accountant appeared before the Board. He contended that they have submitted required documents but Form 29 issued by the SECP contains the disclaimer which is beyond their control. He further submitted that Central Licensing Board may seek clarification from SECP regarding their disclaimer. The Board after hearing the representative of the firm and considering case background decided to seek clarification from the SECP before taking any final decision.

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

A letter was issued to Deputy Registrar of Companies (SECP), Lahore for clarity of disclaimer of SECP on Form.

Deputy Registrar of Companies (SECP) clarified that reason for posting such stamp (qualification stamp) is that this office has not accepted the documents as filed by the company as yet due to possibility of any mistakes/errors in the company documents. This is a usual practice to issue certified copies with qualification stamp when companies apply for certified copies early and the documents are not yet scrutinized by the concerned dealing registrar. However, in order to get certified true copies without qualification stamp, the company needs to take up the matter with the concerned registrar to resolve any issues in the company documents so that they are accepted and certified true copies can be issued without qualification.

**Decision of the Central Licensing Board in 288th meeting:**

The Board while considering the facts on the record and after thread bare deliberation decided that the firm shall submit updated Form-29 attested as true copy (in original) without disclaimer/qualification stamp within 15days. The case shall be placed before the Board in its upcoming meeting for decision.

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

Letter was issued to M/s Mediceena Pharma (Pvt) Ltd, 27-Km, Raiwind Road, Lahore on 29th November, 2022.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board after perusal of record and facts decided to suspend Drug Manufacturing License No 000475 (by way of formulation) of M/s Mediceena Pharma (Pvt) Ltd, 27-Km, Raiwind Road, Lahore till fulfillment of codal formalities/submission of required documents 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(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The Board authorized Chairman CLB to revoke suspension orders on completion of codal formalities and case may be placed before the board for ratification.

Case No.4 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s DIVINE PHARMACEUTICALS, LAHORE.**

M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000850 by way of Formulation for the period of 25-11-2021 to 24-11-2026 on 14-12-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 11-01-2022 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Deposit late fee surcharge of Rs. 142, 500/ (19 days * 7500/day).
ii. Properly filled, signed and stamped Form-1A (as per format) along with signed annexures of names, classes and dosage forms of drugs manufactured.
iii. Detail of management, if any change, apply for change of management.
iv. Duly attested CNIC copies of all partners.

The firm replied to this letter on 14-02-2022 and reminder letter was issued on 14-03-2022 to the firm for completion of application:

i. Deposit late fee surcharge of Rs. 142,500/-.
ii. Properly filled, signed and stamped Form-1A (as per prescribed format).
iii. Duly attested revised partnership deed issued by registrar of firms & CNIC copies of all partners.

The firm replied to this letter on 08-04-2022 but application for renewal of DML is still incomplete.

i. Deposit late fee surcharge of Rs. 142,500/-.
ii. Properly filled, signed and stamped Form-1A (as per prescribed format).

Moreover, the firm has requested to waive off fine. The request of the firm is reproduced as under:

"Sir with due respect, late fee surcharge is not due to our fault because first time when we came at DRAP office for submitting all these renewals related documents on 23rd November, 2021 your reception desk (R &I) staff refused to receive the file saying that the licensing applications are now applied by online portal and they asked us to submit these documents online. After that we tried a lot to upload all documents online but your website was not responding due to some technical fault in your online system. Then again, we visited your office for this issue and the I.T staff also tried to upload and apply online yet failed. Then they suggested us to submit these documents manually in DRAP Office and upon request of I.T Dept. the file was received by R&I desk. Hence, you are

requested to waive off all late fee surcharge as the fee was submitted in due time and file submission got delayed due to some I.T issues."

**Decision of the Central Licensing Board in 286th 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000850 by way of formulation of M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore, may not be cancelled by Central Licensing Board.

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

The Show Cause Notice was issued to M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore on 9th June, 2022.

The firm has replied and requested to waive off late fee surcharge. Application for renewal of DML is deficient of late fee surcharge of Rs. 142,500/-.

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

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

Mr. Amin Farooq GM of the firm appeared before the Board. The Board while considering the facts on record did not accede to the request of the firm and directed to pay late fee/surcharge for renewal of DML, without delay.

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

The firm has submitted fee challan of Rs. 142,500/- and application for renewal of DML is now complete.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

Case No. 05 **RENEWAL OF DRUG MANUFACTURING LICENCE OF LAHORE CHEMICAL & PHARMACEUTICALS WORKS (PVT) LTD, LAHORE.**

M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore had applied for renewal of DML No. 000064 by way of Formulation for the period of 31-12-2021 to 30-12-2026.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 29-10-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Prescribed fee of Rs.75000/- as there is change in management of firm.
ii. Latest certified true copy of Form-29 or Form-A duly attested by SECP (Original).
iii. Duly attested CNIC copies of all Directors.

The firm replied to this letter on 16-12-2021 and reminder letter was issued on 14-01-2022 to the firm for completion of application:

i. Prescribed fee of Rs.75,000/- as there is change in management of the firm.
ii. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original) without stamp that "SECP does not take responsibility of content of Form".

The firm replied that due to sudden death of Managing Director of the firm, issuance of Form-A & Form-29 is in process and application for renewal of DML is still incomplete.

**Decision of the Central Licensing Board in 285th 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000064 by way of formulation of M/s Lahore Chemical &Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore, 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.

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

The Show Cause Notice was issued to M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore on 4th June, 2022.

The firm has replied but application for renewal of DML is deficient of latest certified true copy of Form-A or Form-29 duly attested by SECP (Original) without stamp that "SECP does not take responsibility of contents of Form.

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

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

Mr. Ijaz Hussain Regulatory Manager of the firm appeared before the Board. He contended that they will provide/submit all requisite documents and prescribed fee. The Board decided that the firm will complete all codal formalities such from within 15days and the case be placed before Board in its upcoming meeting for its consideration.

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

Letter was issued to M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore on 28th November, 2022.

The firm has replied on 08-12-2022 that they have applied for issuance of Form-29 from SECP and the firm will submit certified true copy once issued from SECP.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board after perusal of record and facts decided to suspend Drug Manufacturing License No 000064 (by way of formulation) of **M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore** till fulfillment of codal formalities/submission of required documents 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(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The Board authorized Chairman CLB to revoke suspension orders on completion of codal formalities and case may be placed before the board for ratification.

Case No. 06 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000156 OF M/S OVAL PHARMACEUTICALS, 112/11, QUAID-E-AZAM INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.**

M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore had applied for renewal of DML No. 000156 by way of formulation for the period of 21-07-2019 to 20-07-2024. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 2nd October, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

**For Renewal of DML.**

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Detail of management at the time of previous renewal, and at present, if any change, apply for change of management.
iv. Duly attested copy of partnership deed and CNIC copies of all partners.

The firm did not submit their reply in response to this Division's letter dated 2nd October, 2019 and Final reminder was issued to the firm on 9th November, 2021 with following shortcomings: -

i. Properly filled, signed and stamped Form-1A (as per format).

ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Detail of management at the time of previous renewal, and at present, if any change, apply for change of management.
iv. Duly attested copy of partnership deed and CNIC copies of all partners.

The firm has submitted their reply on 15th January, 2022 in response to this Division's Final Reminder. However, application of Renewal of Drug Manufacturing License is still deficient of following documents:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Prescribed fee of Rs.75,00/- for change in management of firm.
iv. Duly attested CNIC copies of all partners.
v. Duly attested Form D from Registrar of firms.

**Decision of the Central Licensing Board in 285th 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000156 by way of formulation of M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore, 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.

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

The Show Cause Notice was issued to M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore on 26th May, 2022.

The firm has not replied and application for renewal of DML is incomplete.

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

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

Mr. Tahir CEO and Mr. Naseem Haider, QC Incharge of the firm appeared before the Board. They contended that they will provide/submit all requisite documents at the earliest. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

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

A letter was issued to M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore on 28th November, 2022 for completion of application.

The firm has not replied and application for renewal of DML is still deficient of following documents:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Prescribed fee of Rs.75,00/- for change in management of firm.
iv. Duly attested CNIC copies of all partners.
v. Duly attested Form D from Registrar of firms.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board after perusal of record and facts decided to suspend Drug Manufacturing License No 000064 (by way of formulation) of **M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore** till fulfillment of codal formalities/submission of required documents 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(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The Board authorized Chairman CLB to revoke suspension orders on completion of codal formalities and case may be placed before the board for ratification.

Case No. 7 **RENEWAL OF DRUG MANUFACTURING LICENCE OF MOON PHARMACEUTICALS, RAWAT.**

M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat had applied for renewal of DML No. 000833 by way of Formulation for the period of 23-08-2021 to 22-08-2026.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 10-09-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format),
ii. Updated Nothing Due Certificate (CRF) from STO, DRAP.
iii. Detail of management, if any change, apply for change of management.
iv. Duly attested partnership deed & CNIC copies of all partners.
v. Approval letters of Production Incharge & Quality Control Incharge, if not approved, submit application along with prescribed fee.
vi. Approval letter of sections approved by CLB.

The firm replied to this letter on 18-10-2021 and reminder letter was issued on 23-11-2021 to the firm for completion of application:

i. Prescribed fee of Rs. 75,000/- for change of management.
ii. Duly attested revised partnership deed & CNIC copies of all partners & Form-D.
iii. Complete set of duly attested documents (as per checklist) along with prescribed fee of Rs.7500/- of proposed Quality Control Incharge.
iv. Duly attested CNIC and undertaking on stamp paper of proposed Production Incharge.
v. Duly attested resignation of earlier Production Incharge.

The firm replied on 13-12-2021 and requested for some extra time for submission of deficient documents. Application for renewal of DML is still incomplete.

**Decision of the Central Licensing Board in 285th 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 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000833 by way of formulation of M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, 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.

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

The Show Cause Notice was issued to M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat on 4th June, 2022.

The firm has replied to Show Cause Notice but application for renewal of DML is still deficient of following documents:

i. Complete set of duly attested documents (as per checklist) of proposed Quality Control Incharge.
ii. Submit original fee challan of Rs.7500/-of proposed Quality Control Incharge.
iii. Duly attested CNIC and undertaking on stamp paper of proposed Production Incharge.
iv. Duly attested resignation of earlier Production Incharge.

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

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

No one on behalf of the firm appeared before the Board. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000443 (by way of formulation) of M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat till fulfillment of the codal formalities 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(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

Letter of DML suspension was issued to M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat on 28th November, 2022.

The firm has replied and submitted all the required documents for renewal of DML.

**The case is hereby submitted for ceasing suspension order, please.**

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the suspension orders issued to the firm.

**Case No. 8 SITE VERIFICATION OF M/S INCEPTA PHARMA, TAXILA.**

M/s Incepta Pharma, Plot No.17-A, Punjab Small Industrial Estate, Taxila applied for site verification of proposed plot. After application was completed by the firm, FID was requested to conduct site inspection of proposed site and submit report regarding suitability of plot for establishment of pharmaceutical unit.

The inspection was conducted by Ms. Tehreem Sara, FID-IV, DRAP, Islamabad and the recommendations of the inspection report are as under: -

1. **Location** **:** The premises of M/s Incepta Pharma, Plot No.17-A, Punjab Small Industrial Estate, Taxila is located in the industrial Area approved by Punjab Small Industrial Estate. The site is away from residential and commercial area.

2. **Surrounding** **:** Premises/Plot (at present) is situated in an industrial area & open environment surrounded by other industries which is **marble** and **Granite** which produces large quantities dust (causing unsuitability of surrounding), may result in contamination if the drugs will be manufactured or adversely affect its quality. The firm is responsible in future for the environmental control of their manufacturing unit

3. **Size** **:** Total area of the plot is18000 square feet = 04 kanals (as reported by Regional Director, Punjab Small Industries Corporation, Rawalpindi.

4. **Recommendations** **:** The location under consideration is "**Not Suitable**" for a pharmaceutical unit as per requirements laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(1)/98 dated 15-5-1998 under rule 16 (a) of the Drugs (Licensing, Registering and Advertisement) Rules, 1976 with reference to the **Surroundings & Size** requirement in the above stated Rules.

**5. Other Observations noted by the inspector(s):**

**5.1** At present, the details are as under:

**a) in-front** of the site there is a street road.

**b) At the back** there is storage area of tough tiles.

**c) On the left** is **Granite industry.**

**d) Right side**. There is a **Marble industry**.

**5.2** The firm has already approved Health and OTC unit from DRAP having appox.70 enlisted products which covered the approx. 2 kanals of the total area of plant.

**5.3** Mr. Jawad Naeem (Managing Partner) of M/s Incepta Pharma, Plot No. 17-A, Punjab Small Industrial Estate, Taxila was present at the site and accompanied during the visit.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to give an opportunity of Personal hearing to the firm in upcoming meeting of the Central Licensing Board.

**Case No. 9 CHANGE OF MANAGEMENT OF M/S OBSONS PHARMACEUTICALS IN THE RECORDS OF DRAP:**

It is submitted that an application for change of management of M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Lahore under DML N0. 000416 (Formulation) was received on 28-01-2019. The firm has submitted fee challan of Rs.50, 000/-, copies of agreement, Form-C, Partnership deed, CNICs of partner and NOC from S.M Naeem Ullah. The Central Licensing Board in its 269th meeting held on 26th February, 2019 considered the case and decided as under:

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and endorsed the change of management of M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, under DML No. 000416 by way of formulation as under;

| Previous management | Interim management | New Management |
|---|---|---|
| 1. Mr. S.M Naeem Ullah S/o Shaikh Ubaid Ullah CNIC No. 35201-7048684-3.<br>2. Mr. S.M Inam Ullah.<br>3. Ms. Mumtaz Begum. | 1. Mr. S.M Naeem Ullah S/o Shaikh Ubaid Ullah CNIC No. 35201-7048684-3. | 1. Mr. Salah-ud-din Gondal S/o Haji Muhammad Ishaq Gondal CNIC No. 35202-7730120-5.<br>2. Mr. Muhammad Abu Bakar Gondal S/o Salah-ud-din Gondal CNIC No. 35202-7529670-5.<br>3. Ms. Asma Salah-ud-din D/o Salah-ud-din Gondal CNIC No. 35202-4330935-8.<br>4. Mr. Noor Hussain Gondal S/o Muhammad Ibrahim Gondal CNIC No. 35202-3033622-3. |

A letter was received Sheikh Muhammad Inaamullah which is reproduced as under:

1- *"A firm "OBSONS PHARMACEUTICALS" was established and registered on30th October 1999, bearing no. 5384 dispatch No. R/LD-869, having registered address at 209- S, Township Industrial Estate, Kot Lakhpat, Lahore with the Office of Registrar of Firms, Lahore Division. Copy of registration of Firm, Form-C.*
2- *Till date a valid Partnership under the Law exists with Sheikh Muhammad Inaamullah a bonafide partner, and there is no change in the partners.*
3- *That undersigned, Sheikh Muhammad Inaamullah, was designated as Managing Partner of the Firm.*
4- *The Partners entered in to an agreement on 10-10-2010 to settle the accounts between them, provided Sh. Muhammad Naeemullah perform his part in the said agreement. However, Sh. Muhammad Naeemullah failed to perform and discharge his obligations under the said agreement, and therefore the agreement became invalid and voidable at the option of undersigned.*
5- *For the purpose of record, the undersigned is not involved in the active affairs of Firm since then.*
6- *Alleged purchase of Obsons Pharmaceuticals by New management is without prior written authorization/consent of the Complainant, who neither himself nor through any other person has ever entered in to any agreement dated 10-01-2013 alleged by new management.*
7- *That Mr. Salahudin Gondal and Mr. Noor Hussain Gondal, allegedly asserting an agreement dt: 10-01-2013, has instituted a Suit for Specific Performance of Agreement to Sell dated 10-01-2013, which clearly shows that the said agreement is not a qualified and absolute agreement, and is subject to decision of Court. Certified copy of Suit is annexed as Annexure-C.*
8- *The Complainant has also instituted a Suit for Partition Declaration, Possession, Cancellation of Agreement to sell dated 10-01-2013 Mesne Profits and Permanent Injunction, in which Court has ordered to maintain status quo between parties. Certified copy of Suit is annexed as Annexure-D.*
9- *Recently it has come to the knowledge of the undersigned that someone has pretended to be "New Management" asserting that they have purchased the Firm on 10-01-2013.*
10- *The contention of the purchase of Firm by new management is incorrect as registration of Firm is still intact and valid under the Law.*

*It is therefore respectfully requested that Authority may kindly be pleased not to Transfer the Business of Firm to alleged "New Management" or incorporate or entertain "New Management" at all in records of DRAP."*

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to defer the matter till next meeting to inquire the updated status of legal proceedings pending before the court from the firm.

Case No. 10 **VOLUNTARY DISCONTINUING PRODUCTION ACTIVITIES FOR MAINTENANCE & REVAMPING OF M/S CORTEX PHARMACEUTICALS, RAWAT.**

M/s Cortex Pharmaceuticals (Pvt) Ltd, Plot No. 16-A, Road SS-4, National Industrial Zone, Rawat under DML No. 000826 (Formulation) has intimated that they are voluntarily stopping all manufacturing activities in their premises from 14th March, 2022 as they are planning to change machinery, equipment and addition of some new sections to follow latest GMP practices.

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

The Board while considering the facts on the record decided that FID, DRAP, Islamabad shall inspect the licensed premises for updated status of the production and submit report thereof.

Additional Director (QA & LT) has reported that he along with Assistant Director (QA-II) visited the firm on 09-01-2023 and there were no production activities seen during visit and Mr. Ashraf Nazir (CEO) was present at that time and renovation maintenance activities were observed.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to direct the firm to intimate CLB after completion of renovation works and till then their production shall be stopped. The firm shall inform the CLB before resuming any manufacturing activity.

**Case No.11 CHANGE OF TITLE OF M/S ICI PAKISTAN LTD, 45 KM, OFF MULTAN ROAD, LAHORE**

M/s Lucky Core Industries Limited, 45km, Off Multan Road, Lahore [*Formerly* ICI Pakistan Ltd,.] wherein the firm has submitted an application for change of title of the company under Drug Manufacturing License No.000811 by way of (Formulation). The firm has submitted the following documents :-

1. Requisite fee of Rs.75,000/-
2. Form-29 issued by SECP in the name of M/s ICI Pakistan Ltd.
3. ID Cards of management.
4. Certificate of Incorporation on change of name issued by SECP in the name of M/s Lucky Core Industries Limited.
5. Nothing Due Certificate regarding CRF up to 31-12-2022.
6. Undertaking on stamp paper stated that the due to same management of the firm SECP does not issue Form-29 in the new proposed name.

**Change of Title.**

| Previous Title of the firm. | Current Title of the firm. |
|---|---|
| M/s ICI Pakistan Ltd, 45km, Off Multan Road, Lahore | M/s Lucky Core Industries Limited, 45km, Off Multan Road, Lahore |

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of title of M/s Lucky Core Industries Limited, 45km, Off Multan Road, Lahore [*Formerly* ICI Pakistan Ltd,.] DML No.000811 (By way of Formulation) as under.

| Previous Title of the firm. | Current Title of the firm. |
|---|---|
| M/s ICI Pakistan Ltd, 45km, Off Multan Road, Lahore | M/s Lucky Core Industries Limited, 45km, Off Multan Road, Lahore |

**j**

(Evaluator: Muhammad Usman, AD-III. Sr. 12-16)

**Case No.12 SITE VERIFICATION OF M/S NABIQASIM INDUSTRIES (PVT) LTD, A-39 & D-11, ESTERN INDUSTRAL ZONE, PORT QASIM, KARACHI**

M/s NabiQasim Industries (Pvt) Ltd, submitted request for site verification of site A-39 & D-11, Eastern Industrial Zone, Port Qasim, Karachi.

After completion of codal formalities, FID Karachi was requested to conduct site inspection of proposed land and the report of FID Karachi is reproduced as below:

"Keeping in view the facts, it can be safely concluded that premises is situated in an environment which may cause contamination of raw materials or products as it is close to a factory which produces a disagreeable /obnoxious odor / fumes /large quantities of soot, dust/ smoke that may adversely affect the quality of drugs/ products. Therefore. the proposed SITE may Not be **considered/ deem** fit for establishment of pharmaceutical unit"

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to give an opportunity of Personal hearing to the firm in upcoming meeting of the Central Licensing Board.

CASE NO. 13 **RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000407 (BASIC-MANUFACTURE) OF M/s DRUG PHARMA CHEMICALS (PVT) LTDKARACHI.**

M/s Drug Pharma Chemicals (Pvt) Ltd, Karachi had filled application for renewal of DML No. 000407 (Basic Manufacture) for the period commencing on 16-07-2020 and ending on 15-07-2025. The application was received on 16-07-2020. The application for the renewal of DML of the firm was evaluated. Following documents were found deficient.

i. Additional surcharge fee of Rs. 5,000 for late submission (01 day) of application for renewal of DML.
ii. Dully retained fee challan by AD (Revenue) DRAP, Islamabad.
iii. All attested annexure/enclosures of Form-1A.
iv. Approval letters of API's issued by CLB or if not available then submit layout plan for regularization of manufacturing facility.
v. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
vi. Complete set of attested documents (as per checklist) for approval of production In charge & Quality Control In charge as required under Rule 15 of the Drugs (L,R&A) Rules, 1976.
vii. Updated NDC of CRF issued from statistical officer DRAP, Islamabad

A letter dated 06th October 2020 was issued to the firm to submit the above mentioned shortcoming/deficient documents.
No reply was received from the firm and a Reminder dated 25th January 2021 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.
**Submitted for consideration of the Board, please.**

**Decision of the Central Licensing Board in 280th 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, 12, Rule, 15 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000407 (by way of Basic Manufacture) of M/s Drug Pharma Chemicals (Pvt) Ltd, Karachi, may not be suspended or cancelled by the Central Licensing Board.

The show cause notice dated 31st May 2021 was issued to the firm. No reply is received from the firm and the application for renewal of DML is still incomplete.
The firm is also called for Personal Hearing vide letter dated 24th August 2021.

**Proceedings and Decision of the Central Licensing Board in 282nd meeting**

Maj (Rtd) Mubashar Jamal, Manager Regulatory appeared before the Board. He contended that no letter of shortcoming and showcause Notice is received in the Company. He further contended that

he had come to know regardrding personal hearing through a friend.He requested for giving further time for submission of documents.

The Board after hearing the representative of the firm and considering case background decidedto suspend the Drug Manufacturing License 000407(by way of basic manufacture of Drug Pharma Chemicals (Pvt) Ltd, Karachiunder 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(2A), Rule 12, Rule 15 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till completion of codal formalities / submission of documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

In the light of decision of the CLB, Suspension orders dated 24th September 2021 were issued to the firm.

The firm later on has filed Suit No. 941/2022 in the Honorable High Court of Sindh, Karachi. The Honorable High Court of Sindh Court vide its order dated 16.11.2022 disposed the matter and directed DRAP to decide the application of the firm as *de-novo within 04 weeks*.

The Orders are reproduced as below:

In appears that the plaintiff's license to manufacture drugs which was issued by the Drug Regulatory Authority under the law was suspended. The record reveals that the license to manufacture drugs was issued to the plaintiff who was operating from Plot No. 226, sector 23, Korangi Industrial Area Karachi, however, all correspondence by the defendants was made at the address disclosed as g from Plot No. 266, Sector 23, Korangi Industrial Area Karachi hence plaintiff had no information about the proceedings of the case ended as suspending their license. No notice of hearing or show cause is disclosed to have been issued at the correct address and as a result it ended up in suspension of drug manufacturing license and that has virtually halted operation of the factory for manufacturing drugs which was otherwise in accordance with law earlier since they were operating under the license.

Since the suspension of license is prima facie in violation of Article 10-A of the constitution of Islamic Republic of Pakistan and as the plaintiff has been deprived of a fundamental right and as agreed by Assistant Attorney General the case is remanded back to the CLB issuing suspension order to decide the question as to why the plaintiff shall not operate on the basis of license issued and what other cause would prevent plaintiff from operating under the subject license. It is expected that this issue be decided in four weeks time and till such time the "suspension order" as impugned in this suit shall not operate and fate of this suspension order shall be determined in the proceedings afresh/denovo, before the concerned Authority referred above.

With the above observations the suit met its fate and is accordingly disposed of along with pending application(s)."

In compliance to the orders of the court a letter dated 6th December 2022 was issued to the firm to submit following documents for completion of application for the renewal of DML of the firm was evaluated.

i. Additional surcharge fee of Rs. 5,000 for late submission (01 day) of application for renewal of DML.
ii. Dully retained fee challan by AD (Revenue) DRAP, Islamabad.
iii. All attested annexure/enclosures of Form-1A.
iv. Approval letters of API's issued by CLB or if not available then submit layout plan for regularization of manufacturing facility.
v. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
vi. Complete set of attested documents (as per checklist) for approval of production In charge & Quality Control In charge as required under Rule 15 of the Drugs (L,R&A) Rules, 1976.
vii. Updated NDC of CRF issued from statistical officer DRAP, Islamabad

In response, the firm had submitted the documents which are evaluated and following documents are still found deficient for which Reminder dated 11th January is also issued to the firm :

1. Updated NDC of CRF issued from statistical officer DRAP, Islamabad as the firm has submitted copy of letter dated 19-12-2022 addressed to Statistical officer, DRAP for issuance of NDC
2. Complete set of attested documents (as per checklist) for approval of production In charge & Quality Control In charge as required under Rule 15 of the Drugs (L,R&A) Rules, 1976.
3. All attested annexure/enclosures of Form-1A.

**The firm was issued a Reminder letter dated 11th January 2023 to furnish the deficient documents within seven (07) days of issuance of letter. The due date for submission of documents has passed on 18th January 2023.**

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to serve the show cause notice to the firm for completion of application for renewal of DML No. 000407(Formulation).

Case No-14 **CHANGE OF MANAGEMENT OF M/S AHSONS DRUG COMPANY SINDH**

**M/s. Ahsons Drug Company, T/1, SITE, Tando Adam Sindh** DML No. 000138 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee as under: -

| **Current Management Form-1A** | **New Management (Year 2021)** |
|---|---|
| i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1.<br>ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5.<br>iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1.<br>iv. Mr. Abdul Saleem S/o Abdul Hakeem CNIC No. 44206-0143901-1.<br>v. Mst. Shakooran Begum Wd/o Late Abdul Hakeem | i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1.<br>ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5.<br>iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1. |

**Decision of the Central Licensing Board in 284th meeting:**

The Board considered and accepted for record the change of management of M/s **Ahsons Drug Company, T/1, SITE, Tando Adam Sindh** DML No. 000138 (By way of Formulation) as under: -

| **Current Management Form-1A** | **New Management (Year 2021)** |
|---|---|
| i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1.<br>ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5.<br>iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1.<br>iv. Mr. Abdul Saleem S/o Abdul Hakeem CNIC No. 44206-0143901-1.<br>v. Mst. Shakooran Begum Wd/o Late Abdul Hakeem | i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1.<br>ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5.<br>iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1. |

Requests are received from Mr. Abdul Saleem (previous partner of the firm), Ms. Khairunsia and legal heirs of Mst Zaineb claiming that that their mother was also a share holder of the firm and they have requested to suspend the DML of the firm and **add their names in the license of M/s Ahsons DC, Tando Adam Sindh.**

Meanwhile, a representation from Dr Abdul Saleem Ansari FRCS and others are received which are reproduced as under:

> "The AHSONS DRUG CO was granted the Drug Manufacturing license in 1962. You will be pleased to know that the undersigned is Surgeon (Urologist) by Profession and the lawful Partner of AHSONS DRUG CO plot no T-1 at SITE Area, Tehsil Tando Adam District Sanghar Sindh.
>
> After the death of three basic legal partners, my Mother, Zainab Bibi and Two Brothers, (Abdul Razzaq and Abdul Hameed), I am the only alive basic partner.
>
> Now after the death of my previous partners, their legal heirs entered in the firm. As I a Legal Partner My visits in the firm are essential to check the affairs of the Company relating to Machines, Building and Land, but the legal heirs of my previous partners are not giving me excess to the account books and some time they even stopped me to enter in the factory.
>
> As you know that the valuable rights of the applicant are involved in this firm but the hurdles created by the legal heirs of my previous partners are against the law And natural justice as well.
>
> As per facts mentioned above you are requested to suspend the manufacturing License of firm Ahsons Drug Co, Tehsil Tando Adam District Sanghar, Sindh As soon as possible till the resolution of our disputes".
>
> Meanwhile the complainant filed another application
>
> "The AHSONS DRUG CO was granted the Drug Manufacturing license in 1962. That the undersigned is lawful partner of AHSONS DRUG CO plot no T-1 (1.00 Acre) tehsil Tando Adam District Sanghar which was leased through Sindh Industrial Estate Limited.
>
> After the death of three basic legal partners, (My Mother, Zainab Bibi and Two brothers, Abdul Razzaq and Abdul Hameed), undersigned was the only alive basic partner and then Addenda deed was made by undersigned along with the legal heirs of my previous partners in September 2006.
>
> After that an agreement/settlement deed was made between the partners on 9th September 2015 regarding all affairs and shares of the company. Annex-D.
>
> Now the partners are not complying that agreement and they are not giving me the excess to check the building, equipment and plant which is clear violation of agreement/settlement deed dated 9th September 2015. So the undersigned do not allow to work on this leased plot mentioned above.

As per facts mentioned above the undersigned is not interested to continue the manufacturing process through the Drug Manufacturing license.

You are requested to cancel the manufacturing License of Ahsons Drug Co. Tehsil Tando Adam District Sanghar, Sindh in the interest of Justice.

"2. Letter is received from Ms. Khairunisa D/o Late Abdul Hameed, CNIC 35201-0214701-6, wherein she has requested that her father Abdul Hameed was the registered executive partner of Ahsons Drug Co, expired in 2005 and I am the legal heir of Abdul Hameed. I therefore requested please add my name in the license of Ahsons Drug Co.

3. Letter is received from Mst. Kulsoom D/o Late Abdul Hakeem, District Sanghar, wherein she has requested to please add a name in the license of Ahsons Drug Company, Tando Adam.

4. Letter is received from **(i)**Mst, Badar Un Nisa D/o Mst Zainab, **(ii)** Ms. Zahida Khatoon D/o Mst Zainab, **(iii)** Ms. Bilquees Khalid D/o Mst Zainab, Dist, Sanghar, Sindh, wherein they are requested to please add a name in the license No. 000138 of Ahsons Drug Company, Tando Adam."

**Decision of the Central Licensing Board in 285th 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 Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000138 by way of formulation of M/s. Ahsons Drug Company, T/1, SITE, Tando Adam Sindh may not be suspended or cancelled by Central Licensing Board.

In the light of decision of the Board, show cause notice dated 11th May 2022 was issued to the firm.

In the meanwhile application for cancellation of DML of the Ahsons Drug Company is received from Mr. Mubashir Hassan S/o Mushtaq Hussain special power of attorney of original partner Mr. Abdul Saleem S/o Abdul Hakeem wherein it is requested to cancel the DML of Ahsons DC Tehsil Tando Adam District Sanghar Sindh in the interest of Justice. Also request to investigate the matter and refer the case to relevant agency for further action as per criminal laws. Otherwise we have no other option to knock the door of the relevant court of law. Any other relief which deems fit and proper may also be granted".

**Decision of the Central Licensing Board in 289th meeting:**

On the opinion taken from Mr. Abid Ali, Representative of Ministry of law, Government of Pakistan the Board considered the matter and decided to verify the partnership deed and Form-E from the Registrar of firm and decided to defer the matter till verification".

**Case No:15 STORAGE OF OUR OWN MATERIAL IN OUR ANOTHER LICENSED FACILITY BY M/S SAMI PHARMACEUTICALS (PVT) LTD, KARACHI UNDER DML NO.000072(FORMULATION)**

M/s. Sami Pharmaceuticals has applied which is reproduced as under.

1. With reference to the above, it is respectfully submitted that:

    a. Our licensed unit is situated in an area where height of the buildings is limited by Pakistan Air Force up to 20 meters only (Annex-A), as we fall in descending area of their aircrafts; vertical expansion is thus impossible.

    b. The adjacent plot is also occupied by another firm due to which horizontal expansion is not possible as well.

2. With such limitations, we were forced to develop another licensed facility very close to our existing unit with ample space for storage of material; Panel of Experts comprising of M/s. Dr. Abdullah Dayo (Member CLB), Hira Bhutto (FID Karachi) & Sanam Kausar (Asst. Director E&M), who inspected it in respect of issuance of DML clearly stated that (Annex-B):

    *"It is a multistoried building found GMP compliant at time of inspection. The stores have a capacity to hold huge inventory. The firm intend to utilize the warehouse as a shared facility for storage of material of different licensed premises of M/s. SAMI Pharmaceutical (Pvt.) Ltd."*

    *"Keeping in view the good facilities of storage, production, quality control, sanitation and hygiene, HVAC operations, calibration, validation of all equipment and process and other utilities, the panel recommends the grant of Drug Manufacturing License, by way of formulation of manufacturing facility for following sections:*

    1. *Spansules (General)*
    2. *Ware house*
    3. *Quality control lab*

**The Central Licensing Board, after considering this Report in its entirety, granted DML No. 000938 without any reservation / limitation.**

3. Another Panel of Experts comprising of Dr. Saif ur Rehman Khattak, Mrs. Hira Bhutto and Ms. Sanam Kausar Jahan visited us in respect of Renewal of DML No. 000072; relevant extract (Annex-C) of its recommendation is appended below:

> *2.3 A compact raw material and packaging material storage area has also been provided with appropriate HVAC system and other control arrangements at F-95 site.*
>
> *Moreover, another facility situated at walking distance on plot No. F-140-A has been granted DML No. 000938 by DRAP. This facility has been authorized to share for materials belonging to DML No. 000072 also. Hence, DML No. 000938 is housing manufacturing areas for spansules and dedicated, large, three storeys storage are for raw material, packaging material and finish goods. The storage areas are provided with arrangements such as HVAC system, dedicated staff and other control and monitoring systems.*

4. The case was considered by CLB in its 287 Meeting; relevant decision (Annex-D) is reproduced below:

> *"The Board did not accept the remarks/ recommendations of the panel regarding keeping raw material of one licensed facility at another as such activity is not in accordance with law. The Board therefore advised that manufacturer should avoid and remove such material without delay. The Federal Inspector of Drugs is advised to ensure compliance of the decision of the Board without delay and report."*

It is pertinent to state that:

a. The Honourable Central Licensing Board granted DML No. 000938 only after approval of the Report presented by the worthy Panel, reproduced in para no. 6 above; it clearly states that:

> *"The firm intend to utilize the warehouse as a shared facility for storage of material of different licensed premises of M/s. SAMI Pharmaceutical (Pvt.) Ltd."*

b. We, vide our email of October 14th, 2022 approached FDA USA and sought their advice on this issue to which they responded as under:

> *"We have the following answers:*
> 1) *Storage of raw material in sealed containers is allowed in Plot "D" for medicines being manufactured in Plot "A", provided your quality management system is in control of the storage facility.*
> 2) *Transfer of material in sealed containers from Plot "D" to Plot "A" in temperature-controlled vehicles under lock is acceptable once again if the operation is under your firms' quality management system.*

Copies of both emails i.e. our query and their reply thereto, are attached herewith for kind perusal (Annex-E & F).

5. Considering the foregoing, we respectfully submit that the Central Licensing Board should be asked to:

   a) duly consider the opinion of both the Panels, the advice given by US FDA and set aside the decision taken in Meeting No. 287

   b) withdraw its letter, addressed to FID Karachi, if issued in meantime

   c) Issue letters for approval of the Sections already approved by CLB in its 287th Meeting held on 24th June 2022

   d) Provide an opportunity of personal hearing

6. **It is pertinent to add that the instructions given to FID, if followed, will create serious shortages of life saving and other essential drugs and adversely affect our exports and orders of the Armed Forces.**

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to refer the case to the Legal Affairs Division DRAP Islamabad to seek opinion on the subject matter. Afterwards, the case will be placed before the DRAP Authority for decision.

**Case No.16 CHANGE OF TITLE OF M/S ICI PAKISTAN LTD, S-33, HAWKES BAY ROAD, KARACHI**

M/s Lucky Core Industries Limited, S-33 Hawkes bay Road SITE Karachi., [*Formerly* ICI Pakistan Ltd,.] wherein the firm has submitted an application for change of title of the company under Drug Manufacturing License No.000006 by way of (Formulation). The firm has submitted the following documents :-

1. Requisite fee of Rs.75,000/-
2. Form-29 issued by SECP in the name of M/s ICI Pakistan Ltd.
3. ID Cards of management.
4. Certificate of Incorporation on change of name issued by SECP in the name of M/s Lucky Core Industries Limited.
5. Nothing Due Certificate regarding CRF up to 31-12-2022.
6. Undertaking on stamp paper stated that the due to same management of the firm SECP does not issue Form-29 in the new proposed name.

**Change of Title.**

| Previous Title of the firm. | Current Title of the firm. |
|---|---|
| M/s ICI Pakistan Ltd, S-33, Hawkes Bay Road, Karachi. | M/s Lucky Core Industries Limited, S-33, Hawkes Bay Road, Karachi. |

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of title of M/s Lucky Core Industries Limited, 45km, Off Multan Road, Lahore [*Formerly* ICI Pakistan Ltd,.] DML No.000006 (By way of Formulation) as under.

| Previous Title of the firm. | Current Title of the firm. |
|---|---|
| M/s ICI Pakistan Ltd, S-33, Hawkes Bay Road, Karachi. | M/s Lucky Core Industries Limited, S-33, Hawkes Bay Road, Karachi. |

**Case No. 17: CHANGE OF TITLE AND MANAGEMENT OF M/S FORTUNE PHARMACEUTICALS, KARACHI**

M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E (SHW) Phase-II, Karachi under DML No. 000924 (FORMULATION) has submitted request for change of title and management along with Prescribed **fee of Rs. 75000 instead of Rs. 1,50,000** and **un attested certified true copy of Form-29** as under:

| Current Title | New Title |
|---|---|
| 1. M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E (SHW) Phase-II, Karachi | 1. M/s Fortune Pharmaceuticals (Pvt) Ltd , Plot No. K/201, S.I.T.E (SHW) Phase-II, Karachi |

| Current management as per Partnership deed | New management as per Form-29 (Year 2022) |
|---|---|
| 1. Muhammad Shehmeer Imtiaz S/o Imtiaz Ahmed CNIC No. 44103-4535598-92. Dr. Noor Ahmad Noor S/o Haji Barkat Ali.<br>2. Mr. Muhammad Talib S/o Muhammad Sikandar CNIC No. 42201-2790408-5. | 1. Mr. Akber Ali S/o Khan Muhammad Babar CNIC No. 41304-42384539-1<br>2. Mr. Muhammad Sikander S/o Muhammad Usman CNIC No. 42201-3841893-5 |

| | |
|---|---|
| | 3. Muhammad Shehmeer Imtiaz S/o Imtiaz Ahmed CNIC No. 44103-4535598-9 |

The firm has submitted following documents:

1. Prescribed fee Rs. 75,000 instead of Rs. 1,50,000.
2. Un-attested CTC copy of From-29 of SECP.

Decision of the Central Licensing Board in 289th meeting

The Board decided to defer the case of the firm till submission of deficient documents and completion of application for change of title and management.

**(Evaluator: Muhammad Yaqoob. AD IV. Sr. 17-25)**

**CASE NO. 18. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000605 OF M/S SPL PHARMACEUTICALS (PVT) LTD, PLOT NO. 04, PHASE-III, HATTAR INDUSTRIAL ESTATE, HATTAR.**

M/s SPL Pharmaceuticals (Pvt) Ltd, Plot No. 04, Phase-III, Hattar Industrial Estate, Hattar had applied for renewal of DML No. 000605 by way of formulation for the period of 19-02-2022 to 18-02-2027. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 14th January, 2022 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Classes of drugs not provided.
ii. Dosage form of drugs not provided.
iii. Names of drugs registered/approved not provided.
iv. Detail of management at the time of previous renewal and current renewal not provided.
v. Copy of approved layout plan not provided.
vi. Section(s) approval letter(s) from Central Licensing Board not provided.
vii. Name and qualification of technical staff not provided.

The firm submitted their reply after evaluation of the submitted documents, final reminder was issued on 15th February, 2022 to the firm with following shortcomings:-

i. Detail of management at the time of previous renewal and current renewal.
ii. Form-29 attested as true copy (in original) by S.E.C.P.

Decision of Central Licensing Board in its 285th 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000605 by way of formulation of M/s SPL Pharmaceuticals (Pvt) Ltd., Plot No.04, Phase-III, Hattar Industrial Estate, Hattar,, 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."

In response to Show Cause Notice dated 30th May, 2022 firm has submitted Form-29 attested as true copy by SECP (in original), however they said Form is stamped as under:-

*"Certified to be true copy of the document filed by the company however this office accepts no responsibility as to the correctness of the details given in the document company registration office Lahore."*

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

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

"Mr. Abdul Aziz CEO of the firm appeared before the Board. They contended that the High Court disposed of the case and they will provide/submit updated Form-29 attested as true copy (in original) without disclaimer / qualification with in 15days. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration".

In the light of board's decision, a letter was issued to the firm on 17th November 2022.

In response to the above letter, M/s SPL Pharmaceuticals (Pvt) Ltd, Plot No. 04, Phase-III, Hattar Industrial Estate, Hattar, has submitted certified true copy of Form-29 (in original) without disclaimer / qualification issued on dated 10-11-2022 for renewal of Drug Manufacturing License. The application for renewal of Drug Manufacturing License No. 000605 for the period from **19-02-2022 to 18-02-2027** is now complete.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

**Case No. 19 COURT ORDER FOR SUSPEND LICENSE OF M/S MED ASIA PHARMACEUTICAL, RISALPUR.**

Honorable Chairman Drug Court, Quetta vide letter No. D.C/Qta./255/2022 dated 12th November, 2022, wherein it is stated that complaints / cases (Case No. 37/2020) under section 23(1)(h) of the Drug Act 1976, was filed against M/s Med Asia Pharma, Pvt Ltd, Plot No. 7, Industiral Estate Risalpur which is pending before this Court . The Court has come to the conclusion after perusal of record shows that M/s Med Asia Pharmaceutical Pvt Ltd, accused persons namely Anwar-ul-Haq, CEO, Shabir Ahmed, Production Manager and Mujeeb-ur-Rehman, QCM intentionally and deliberately are avoiding the Court proceedings. Honorable Chairman Drug Court, Quetta has directed to immediately suspend the license of M/s Med Asia Pharmaceutical Pvt Ltd, Plot No. 7, Industrial Estate Risalpur, until further orders, under intimation to this Court within fortnight time.

**Decision:** The Board considering the facts on the record and after threadbare deliberation decided to serve the show cause Notice to the firm under section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering & Advertising), Rule, 1976 for suspension of Drug Manufacturing License in compliance of the orders of Drug Court, Quetta".

**Case No. 20 <u>RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S LOTUS PHARMACEUTICALS (PVT) LTD., ISLAMABAD</u>**

The firm, M/s Lotus Pharmaceuticals (Pvt) Ltd., Islamabad, has submitted application for renewal of Drug Manufacturing License No. 000661 (by way Formulation). The application was received on 29-05-2019and due date of renewal of DML 16/06/2019. The firm has submitted a fee of Rs. 50,000. The application was evaluated as per Drugs (Licensing, Registering & Advertising) Rules 1976 and found following shortcomings;

i. Classes of drugs.
ii. Dosage forms of drugs.
iii. Name(s) of registered drugs.
iv. Detail of management at the time previous renewal and present renewal.
v. Latest original Form-29 and Form-21 certified true copy issued by SECP alongwith CNIC (s) copies of all directors.
vi. Proof of licensed section(s) from Central Licensing Board.
vii. Detail of machinery for QC lab and section wise.
viii. Up-to-date Nothing Due Certificate regarding CRF issued from STO up to 2020.

Accordingly, shortcoming letter No. 1-2/2017-Lic dated 07/11/2019 was issued to the firm to rectify above mentioned shortcomings.

In response to this office shortcoming letter, the firm has not submitted any reply and as per SOP, final reminder was issued to the firm vide No. 1-2/2017-Lic dated 10/06/2020

After issuance of shortcoming letter and final reminder, till date,the firm has not rectified following shortcomings;

i. Classes of drugs.
ii. Dosage forms of drugs.
iii. Name(s) of registered drugs.
iv. Detail of management at the time previous renewal and present renewal.
ix. Latest original Form-29 and Form-21 certified true copy issued by SECP along with CNIC(s) copies of all directors.
x. Proof of licensed section(s) from Central Licensing Board.
xi. Detail of machinery for QC lab and section wise.

**Proceedings and Decision by the Central Licensing Board in its 278th 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000551(by way of formulation) of M/s Lotus Pharmaceuticals (Pvt) Ltd., Islamabad 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".

Show-Cause Notice to the firm was issued on 08-01-2021.
The firm submitted their response. However, upon evaluation following shortcomings are still observed;

i. Section(s) approval letter(s) from Central Licensing Board are not attached.
ii. The management of the firm seems to be changed as under;

iii.

| **Previous management as per Form-A & Form-29 dated 31-10-2014** | **New Management as per Form-A & Form-29 dated 23-09-2020** |
|---|---|
| 1. Khadim Hussain.<br>2. Shaukat Ullah<br>3. Aamir Mehboob.<br>4. Muhammad Umair. | 1. Khadim Hussain.<br>2. Aamir Mehboob.<br>3. Muhammad Umair. |

Accordingly, a personal hearing letter was issued to the firm on 24-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting.

"Mr Muhammad Umair, Director and Mr. Ismael Khan, Production Manager appeared before the Board. He argued that his father Mr Khadim Hussain (late) who was looking after the affairs of the company is died. They are in process of seeking succession certificate. He further argued that as soon as succession certificate is arranged and accordingly partnership deed would be amended. He argued that time may be given on humanitarian ground. The Board after hearing

the representative of the firm and considering case background decided to defer the case till next meeting of the Board.

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

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

Mr. Umair CEO and Mr. Arsalan Ex-Finance Manager firm appeared before the Board. They contended that he will submit all requisite document/information. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

In the light of board decision, a letter was issued to the firm on 17th November, 2022.

In response to above letter, M/s Lotus Pharmaceuticals (Pvt) Ltd., Islamabad has submitted certified true copy of Form -29 dated 23-11-2022 and succession certificate for renewal of Drug Manufacturing License and change of management. The application for renewal of Drug Manufacturing License No. 000661 for the period from **16-06-2019 to 15-06-2024** is now complete.
The detail of change of management is as under; -

| Previous management as per Form-29 as on 04-02-2022. | New management as per Form-29 as on 12-09-2022. |
|---|---|
| 1. Khadim Hussain S/o Karim Bukhsh CNIC No. 61101-8790354-5. | 1. Muhammad Umair S/o Khadim Hussain CNIC No. 61101-1129200-3. |
| 2. Muhammad Umair S/o Khadim Hussain CNIC No. 61101-1129200-3 | 2. Aamir Mehboob S/o Mehboob Ellahi CNIC No. 61101-8990139-5. |
| 3. Aamir Mehboob S/o Mehboob Ellahi CNIC No. 61101-8990139-5 | 3. Muhammad Uzair S/o Khadim Hussain CNIC No. 61101-5059978-9. |

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

1. Since, the firm has completed the application for the Renewal of DML No. 000661, the Board while considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s Lotus Pharmaceuticals (Pvt) Ltd., Plot No. 118-A, St No. 8, I-10/3, Industrial Area Islamabad.

2. The Board considered and accepted for record the change of management of, M/s Lotus Pharmaceuticals (Pvt) Ltd., Plot No. 118-A, St No. 8, I-10/3, Industrial Area Islamabad DML No.000661 (By way of Formulation) as under;

| **Previous management as per Form-29 as on 04-02-2022.** | **New management as per Form-29 as on 12-09-2022.** |
|---|---|
| 4. Khadim Hussain S/o Karim Bukhsh CNIC No. 61101-8790354-5.<br>5. Muhammad Umair S/o Khadim Hussain CNIC No. 61101-1129200-3<br>6. Aamir Mehboob S/o Mehboob Ellahi CNIC No. 61101-8990139-5 | 4. Muhammad Umair S/o Khadim Hussain CNIC No. 61101-1129200-3.<br>5. Aamir Mehboob S/o Mehboob Ellahi CNIC No. 61101-8990139-5.<br>6. Muhammad Uzair S/o Khadim Hussain CNIC No. 61101-5059978-9. |

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**Case No. 21** **RENEWAL OF DRUG MANUFACTURING LICENCE 000369 BY WAY OF FORMULATION) OF M/S LIBRA (PVT) LTD., 77- INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR**.

M/s Libra (Pvt) Ltd., 77- Industrial Estate, Hayatabad, Peshawar, applied for renewal of DML No. 000369 by way of formulation for the period of **17-10-2020** to 16-10-2025.
The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 02nd November, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form-IA as per prescribed format duly signed and stamped by CEO/Owner of the firm.
ii. Section approval letter/proof of approval of sections from Central Licensing Board.
iii. Detail of management at the time of previous renewal and current renewal.
iv. Updated Form-29 certified as true copy by S.E.C.P.
v. CNIC copies of all Directors/Partners.
vi. Up-to-date Nothing Due Certificate (CRF) valid upto 31-12-2020 from STO, DRAP, Islamabad

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 26th February, 2021 to the firm with following shortcomings: -

Renewal of DML

i. Complete Form-29 and certified as "True Copy" by S.E.C.P is not provided.

Regularization of Layout plan.

i. Provision of dimensions in sachet filling area and quarantine not mentioned.
ii. Purpose of liquid raw material store either volatile or non volatile materials is not clarified.
iii. Dimension in compression (I, II & III) and coating area of tablet section is not mentioned.
iv. Entry of raw and packing material to the hormone tablet and capsule sections are not in order.
v. Provision of dosage form of psychotropic section, in case of psychotropic tablet area is less than as required.
vi. Man and material flow of cephalosporin is not in order.
vii. Sterility room and media preparation of microbiology are not provided.

Decision of the Central Licensing Board in 285th 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000369 by way of formulation of M/s Libra (Pvt) Ltd.,

77- Industrial Estate, Hayatabad, Peshawar, 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

A Show Cause Notice issued on 26th May, 2022 in the light of decision of 285th meeting of Central Licensing Board held on 17th& 18th March, 2022 and firm has not rectified shortcomings till to date.

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

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

Mr. Muhabbat Khan QC Incharge and Mr. Shah Nawaz, Manager Regulatory of the firm appeared before the Board. They contended that they will submit all requisite document/information. The Board decided that the firm will complete all codal formalities within 15 days and the case be placed before Board in its upcoming meeting for its consideration.

In the light of board decision, a letter was issued to the firm on 17th November, 2022.

In response to the above letter, M/s Libra (Pvt) Ltd., 77- Industrial Estate, Hayatabad, Peshawar, has submitted certified true copy of Form-29 issued on dated 1-12-2022 for renewal of Drug Manufacturing License. The application for renewal of Drug Manufacturing License No. 000369 for the period from **17-10-2020 to 16-10-2025** is now complete and also applied for Layout Plan for Regularization.

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**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

**Case No. 22 APPROVAL OF TECHNICAL PERSON, QC INCHARGE OF M/S ALEN PHARMACEUTICALS (PVT) LTD, RISALPUR, UNDER DRUG MANUFACTURING LICENSE NO. 000435 (BY WAY FORMULATION)**

M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur Drug Manufacturing License No.000435 (by way of formulation) has submitted the application for approval of proposed QC Incharge Mr. Naveed Muhammad S/o Yar Muhammad (Pharm-D) CNIC No.16102-9220966-9

The application was evaluated as per the Drug (Licensing, Registering & Advertising) Rules, 1976 and found following shortcomings which were asked from the firm to rectify on 20th October, 2021;

i. Resignation of previous Quality Control Incharge is not provided.
ii. Resignation letter of appointee from previous firm is not provided.

As the firm did not submit any response to above quoted letter, a final reminder was issued on 5thApril, 2022 to the firm to rectify above said shortcomings**.**

The firm did not submit their reply to Final Reminder and has not rectified above mentioned shortcomings/deficiencies.

**Decision of the Central Licensing Board in 286th 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, 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000435 by way of formulation of M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur, may not be suspended or cancelled by Central Licensing Board.

A Show Cause Notice was issued on 2nd June, 2022 in the light of decision of 285th meeting of Central Licensing Board held on 17th& 18th March, 2022 and firm has not rectified shortcomings till to date.

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

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

Mr. Shoukat Ali CEO and Abdul Rasheed Production Incharge firm appeared before the Board. They contended that they will submit all requisite document/information. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration. The Board further decided that Area FID, DRAP, Peshawar will submit report regarding

Accordingly, Board decision was communicated to the firm on 17th November, 2022.

In response to the above letter, M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur, has submitted afresh documents for approval of the change of technical staff (Quality Control In-Charge) under Drug Manufacturing License No. 000435 (Formulation). The application for QC in-charge was evaluated and found complete and the approval letter was also issued to the firm.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

**Case No. 23** **RENEWAL OF DRUG MANUFACTURING LICENCE 000244 BY WAY OF FORMULATION) OF M/S IPP (PVT) LTD, VALLEY ROAD, GULKADA NO.III, SAIDU SHARIF, SWAT**.

M/s IPP (Pvt) Ltd, Valley Road, Gulkada No. III, Saidu Sharif, applied for renewal of DML No. 000244 by way of formulation for the period of 11-11-2019 to 10-11-2024.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 26th December, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form-1A dully signed and stamped by CEO of the firm.
ii. Classes of drugs.
iii. Dosage form of drugs.
iv. Name of registered drugs.
v. Detail of management at the time of previous renewal and present renewal.
vi. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
vii. Proof of Licensed section (s) from Central Licensing Board.
viii. Detail of the section wise equipments and machinery for manufacture.
ix. Up-to-date nothing due certificate (CRF) from STO, DRAP, Islamabad.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 01st February, 2022 to the firm with following shortcomings: -

i. Form-1A dully signed and stamped by CEO of the firm.
ii. List of classes of drugs.
iii. List of dosage form of drugs.
iv. List of registered drugs.
v. Detail of management at the time of previous renewal and present renewal.
vi. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
vii. Proof of Licensed section (s) from Central Licensing Board.
viii. Detail of the section wise equipment and machinery for manufacture.

The firm submitted their reply to Final Reminder and following documents are still deficient /short and application for renewal of DML is still incomplete;

i. Detail of management at the time of previous renewal and current renewal is required along with legal documents are not provided,

ii. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNICs' copies of all director(s).

Decision of the Central Licensing Board in 285th 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000244 by way of formulation of M/s IPP (Pvt) Ltd, Valley Road, GulkadaNo.III, Saidu Sharif, 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"

A Show Cause Notice issued on 26th May, 2022 in the light of decision of 285th meeting of Central Licensing Board held on 17th& 18th March, 2022 and firm has not rectified shortcomings till to date.

In response to this Division's show cause notice dated 26-05-2022 the firm has submitted reply to the show cause notice which is re-produced as under;

*"In continuation of your letter No.F.3-10/2011-Lic dated 26 May 2022, which we have received on 7th June 2022 Respected sir, it is to brought into your kind notice that letter No.F.3-10/2011-Lic dated 1/02/22.which was received to our firm. On 6/2/2022. and our firm had replied and submitted all the required documents duly attested in our letter No IPPL/02/2022. and deposited R&I on 10th Feb 2022. Now once again Photocopy of the reply with received stamp of R&I on 10-02-2022, we are submitting to your kind consideration and fruther action*
*Kindly inform us in case of any deficiency regarding your requirement.*
*Thanking you and assuring you best of our co-operation at all time."*

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

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

Mr. Waseem Javaid, MD of the firm appeared before the Board. He contended that he will submit all requisite document/information within 2-3 weeks. The Board decided that the firm will complete all codal formalities within 15 days and the case be placed before the Board in its upcoming meeting for its consideration

Accordingly, Board decision was communicated to the firm on 17th November, 2022.

In response of above letter, the firm submitted their reply which is reproduced as under;

> *"In this connection it is submitted that due to the death of the managing director of the firm (late Mr. Javaid Iqbal), the process for changes in the record of the firm has been initiated and under process in the Securities and Exchange Commission of Pakistan (SECP). Due to of legal formalities it takes maximum three to four weeks.*
>
> *The firm further stated that this is just for reporting compliance and progress on the instructions of the Central Licensing Board and they are pursing the process actively and will submit all the required documents as soon received from the relevant department"*

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000244 by way of Formulation of M/s IPP (Pvt) Ltd, Valley Road, Gulkada No. III, Saidu Sharif till fulfillment of codal formalities 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(2A), Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

**Case No. 24 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S GILLMAN PHARMACEUTICALS, HATTAR (DML# 000683)**

M/s Gillman Pharmaceuticals, Hattar submitted application for renewal of Drug Manufacturing No. 000683 (by way of Formulation). The application was received on 11/02/2020which is well on time as validity of License is 15/02/2020.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 27th July, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976;

i. Form-1A as per format (attached) duly signed and stamped by the CEO/Owner of the firm.
ii. Classes of Drugs.
iii. Proof of approved sections from Central Licensing Board.
iv. Photocopies of documents submitted are not attested / notarized.

The firm submitted their reply to above mentioned letter and same was evaluated and following shortcoming were observed for which final reminder issued to the firm on 05th April, 2022;

i. Form-1A as per format (attached) duly signed and stamped by the CEO/Owner of the firm.
ii. Classes of Drugs.
iii. Proof of approved sections from Central Licensing Board.

iv. Photocopies of documents submitted are not attested/notarized.

It is pertinent to mention that application for renewal of Drug Manufacturing License for the period of 11/02/2020 to 10-02-2025 is still deficient due to above mentioned shortcomings;

Meanwhile, Mr. Faisal Shahzad, FID-I, DRAP, Peshawar submitted vide letter No.11-75/2010—Gillman DRAP (P)/708 dated 04/03/2022 which is re-produced as under;

> *"Please refer to the subject cited above and to inform you that the firm M/s Gillman Pharmaceuticals, Plot No.41/A, Phase I&II, Industrial Area, Hattar was inspected on 02.03.2022 for the purpose of routine GMP compliance. However, the firm was found non-operational and no technical/ non-technical staff was available at the time of inspection. Further, no production activity was observed during visit and it was noticed that civil work is under progress. Matter is submitted for information and further necessary action (if any).*

**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 for not complying the provision of Rule, 5, Rule, 12, Rule, 16 Rule, 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000683(by way of formulation) of M/s Gillman Pharmaceuticals, Hattar may not be suspended 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."

A Show Cause Notice was issued on 4th July, 2022 in the light of decision of 287th meeting of Central Licensing Board held on 24th June, 2022 and firm has not rectified shortcomings till to date.

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

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

"Mr. Hussain Ahmed CEO and Mr. Suhrab QC Incharge firm appeared before the Board. They contended that he will submit all requisite document/information. The Board decided that the firm will complete all codal formalities within 15 days and the case be placed before Board in its upcoming meeting for its consideration. The Board further decided that Area FID, DRAP, KPK will inspect the firm and will submit report there of".

In the light of board decision, a letter was issued to the firm on 17th November, 2022.

In response to the above letter, the firm has submitted documents for the completion of application for renewal of DML and the same was evaluated and the following shortcoming is still deficient.

i. Proof of approved sections from Central Licensing Board.

Later on, a letter was issued to the firm on 10-01-2022 to provide the Proof of approved sections from the Central Licensing Board if not available, apply for regularization of the layout plan with the prescribed fee.

In response to the above letter, the firm has submitted Layout Plan for regularization.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

**Case No. 25 M/S CONVELL LABORATORIES, SAIDU SHARIF, SWAT UNDER DRUG MANUFACTURING LICENSE NO. 000509 BY WAY OF FORMULATION.**

M/s Convell Laboratories, is licensed firm under Drug Manufacturing License No. 000509 by way of Formulation situated at Saidu Sharif, Swat. The Central Licensing Board in its 270th meeting held on 23rd May, 2019 has considered and approved the renewal of Drug Manufacturing License w.e.f. 26-02-2018.

2. An unfortunate incident was occurred in the premises. The Federal Inspector of Drug-I, Peshawar, DRAP vide letter No. 11-58/2005-Convell-DRAP(P) dated 18/05/2022 wherein the FID submitted inspection report and recommendation regarding said incident of M/s Convell Laboratories, Saidu Sharif, Swat which is reproduced as under;

*"Please refer to the subject cited above and to say that it was learnt from media and reliable sources that building of M/s. Convell Laboratories, Saidu Sharif Swat, having Drug Manufacturing License (DML) No. 000509, granted under the Drugs (Licensing, Registering and Advertising Rules, 1976, has collapsed on 14.05.2022 afternoon. Under the said rules, it is the responsibility of the manufacturer to maintain/ensure/comply with all the conditions required for DML.*

*2. In order to assess the factual position, the firm was visited on 17.05.2022. The firm's production manager Mr. Fazal Mabood was available at the firm's premises*

*who informed about the collapse of the building. During the site visit, it was observed that*

*;*

i. *Major building part of the firm including tablet general, capsule general, liquid syrup general, dry suspension general, tablet psychotropic, ware house, finished goods and section of H&OTC vide E.No.00121 (Tablet, Capsule, Oral Liquid syrup, Sachet) have been totally collapsed.*
ii. *Some remaining tilted walls/ major slabs are also being demolished by the firm.*
iii. *Small portion of the building having Ceph section and QC is intact, however, due to major collapse, dirt/ dust, building scrap, this area is also totally nonoperational.*
iv. *The approved management of the firm was involved in legal matters as informed by technical person and not available at the site. Inspection book was also not available at the time of visit.*

*3. In the light of above mentioned position, it is submitted that the conditions under which DML No. 000509 was granted in accordance with the Drugs (L.R.&A), Rules 1976 of the Drugs Act 1976/ DRAP Act, 2012 no more exist. Hence, the DML No. 000509 of M/s. Convell Laboratories, Saidu Sharif, Swat may be cancelled as per laid down procedure under the DRAP, Act, 2012."*

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

Mr. Abid Hameed Puri Advocate and Ikram ul Haq Managing Director appeared before the Board and contended that Unit was consist of two blocks. One block consist of Ceph section and QC and other block consist of tablet general, capsule general, liquid syrup general, dry suspension general, tablet psychotropic, ware house, finished goods. Block consist of Ceph section and QC is intact while other block is demolished due to blast. They further contended that minimum requirements for holding a license exists therefore, licence may not be cancelled. The further contended that there is no production activity carried out and they may be allowed to carry production activity in Ceph block. The Board after hearing the arguments decided to get the unit inspected by the panel of following officers before taking any conclusive decision.

1. Mr. Muhammad Younas Khattak, CDI, Peshawar.
2. Federal Inspector of Drugs, DRAP, Peshawar.
3. Assistant Director, DRAP, Peshawar

In response to this Division's letter dated 4th July, 2022 inspection report is submitted by Mr. Atiq Ul Bari, FID / Additional Director, DRAP, Peshawar of M/s Convell Laboratories, Saidu Sharif, Swat in the light of decision of Central Licensing Board in its 287th meeting held on 24th June, 2022. The inspection was carried out on 29-07-2022. The recommendations of the panel are as under:-

> *"Based on the unit inspected (Cephalosporin section and Quality Control Lab) and considering the findings of inspection, the panel verified the claim of the firm that heir above part of unit is intact and may carry production activities as per GMP guidelines described in Drugs Act, 1976 and rules framed thereunder."*

**Decision of the Central Licensing Board in 288th meeting**

The Board observed that the case requires complete investigation on the matter before further proceeding. The board further decided to refer the case to area FID Peshawar for complete investigation in the light of the case filed by the local Government, police inquiry, building fitness certificate by the concerned government department and nature of incidence, etc.

In the light of board decision, a letter was issued to the firm on 17th November, 2022.

In response to the above letter, Mr. Faisal Shahzad, FID-I, DRAP, Peshawar wherein he had submitted a complete investigation report of M/s Convell, Swat.

Case Investigation officer Mr. Jehan Alam, Thana Saidu Sharif was requested to provide complete case details (Annex-n. In response, the investigation officer submitted his report along with following documents;

a) Report of Bomb Disposal Squad dated 26.12.2022 where in incident dated 14. 05. 2022 was referred causing death of two persons along twelve injured. It was also added that after removal of scrap of collapsed building, area was examined in detail with devices. No ditch connected to any explosive was found. Further, the explosion occurred due to unknown reason.

b) Certificate No. NIL dated NIL issued by Nee/um Air Conditioning Engineers that they installed HVAC in the building on 05. 05.2010 at the firm and certified that there is no any type of explosive occur due to installed HVAC system except electric short circuit.

c) Letter of Sui Northern Gas Pipelines Limited (SNGPL) RefSWT0:24 dated 25.10.2022 wherein it is certified that M/s. Convell Laboratories is not SNG PL consumer and gas connection does not exist in the firm.

d) Letter No. BS-11970112-W dated 28.11.2022 issued by office of the Sub Divisional Officer, Building Sub Division-I, Saidu Sharif wherein it is mentioned that no data is available about the structural design and type of structure and the collapse of building structures due to blast loading is a specialized field. Hence, the reasons of building collapse could not be ascertained.

e) Letter No. 346/PDls-S (l'lT&TA) (Convel Lab Faizabad) dated 16.06.2022 issued by the Provincial Drug Inspectors, Swat wherein it is submitted that their role is related with the quality of drugs/ medicines in the market. As far as incident occurred in the premises of M/s. Convel Laboratories, Swat, the matter comes under the domain of Drug Regulatory Authority at Islamabad.

f) Letter No. 2229-19 dated 25.11.2022 issued by the Peshawar Electric Supply Company wherein it is recorded that as per site visit and investigations of this office, it was observed that there were no defect/fault in PESCO installations i.e. Transformer and energy meter at the course of time during the sad incident occurred on dated 14.05.2022.

g) Letter No. 460AIADICPC/05/SWT dated 16.05.2022 issued by Consumer Protection Council, Industries and Commerce, District Swat wherein it is reported that the factory was established in 1974 and only registered with Drug Regulatory Authority of Pakistan and license is valid till 26.02.2023. The department also referred statement of factory Manager that there was no boiler or pressure vessel in the factory and DRAP officials visit the factory. Total cost of loss is round about l 20Million. Furthermore, there is no record of said factory in their office of nor they intimated this office about their factory till date.

h) Letter No. DDL/Swat/G.Misc:l0531 dated 28.06.2022 issued by the office of the Deputy Director Labour, Swat where in it submitted that action under the prevailing Law, present case is fixed for 30. 06.2022 regarding compensation under Workmen Compensation Act, 2013. The case is sub-judiced before the Court of Commissioner Compensation Malakand Division, Swat please.

i) Copy of FIR No. 367 dated 16.05.2022 lodged against the firm by the police department.

Investigating officer in his report has replied to DRAP, Peshawar letter indicating that on 14.05.2022 a mysterious explosion occurred in the Convell Laboratories, Swat resulting in collapse of ceiling of manufacturing area and walls resulting in two deaths and twelve injured. ASI

Mr. Wazir Zada started inquiry. During inquiry, reports from above mentioned departments were sought in which electric short circuit/ building materials reasons were not indicated. Further, report of Bomb Disposal Squad is also negative for any explosives involved in the incident. In addition, no proof of any insurance matter has surfaced. Workers of the company have also submitted affidavits in favor of the owner of the company. Till date investigations, there is no evidence of any negligence by the owner of the company. As soon as investigations are complete, case shall be submitted before the court.

2. The firm M/s. Conveil Laboratories, Swat was also required to submit status of remaining portion of the building along with building fitness certificate from concerned department, local government permission to carryout/ continue production activities after collapse and any other necessary information related to the case without concealment of any facts related to case. The firm submitted their reply along with five files wherein the firm has provided following information/ documents;

**File 1:** A blast occurred in their premises of unknown reason. Scrap of collapsed building was not lifted until the local police needed it during the process of investigation and further permission of local police scrap was removed. The reconstruction of collapsed building foundation is now in progress. Copy of approved layout plan and certificate of structural soundness of building and construction specification are also attached. The remaining Ceph. Portion of the building having Ceph. Capsules and Ceph. Dry suspension and QC lab area is fully intact. However, this part of the building is also renovated with firefighting system, electric wiring in the building with all precautionary measures to avoid short circuit and all staff is being trained for rescue activities and self-help in case of any emergency. The firm has also submitted an undertaking on stamp paper for submitting genuine and correct information to the best of their knowledge and belief an nothing has been concealed.

**File 2:** The firm informed that officers of TMA inspected the premises is not attached with any other building. TMA granted permission for reconstruction of collapsed building. Copy of letter No. 84/BCAITMA dated 02.12. 2022 issued by Tehsil Municipal Administration, Babuzai (Mingora) is provided. Also provide Building Strength Certificate issued by office of C& W. Swat.

**File 3:** The firm has provided documents related to police case including FIR, letters of all the concerned departments who were approached by the police department which are already mentioned under Annexure-II above.

**File 4:** The firm provided recent documents/ personal hearing and inspection reports related to DRAP including panel report dated 29.07.2022 for submitting recommendation to resume production activities.

**File 5:** The firm has informed that a number of technical and non-technical staff members are employed in the factory who have lost their bread and butter due to this incident. A number of allied person's employment is also affected and also causing shortage of drugs provided to patients. Besides this, Swat has been the victim of terrorism and Talibanization for many years. Floods of 2010 and 2022 has also destroyed infrastructure of the area leading to poverty and unemployment. The firm has been a source of employment to number of poor people in the area. Finally, the .firm has requested to allow the resumption of production in Ceph. Area.

3. In the light of current position of the case i.e,

a) Report provided by the Investigating Officer that, until date no evidence has surfaced against the management of the firm for their negligence in the unfortunate incident of building collapse along with letters from concerned departments.

b) TMA has granted NOC for re-construction of the collapsed building as per documents provided by the firm.

c) Building strength certificate No.681 /2-M dated 16. 12.22 issued by the office of the Chief Engineer C&W Division No-I, Swat Saidu Sharif wherein it is mentioned that the building namely Convell Laboratories Pharmaceutical Manufacturers, Faizabad Saidu Sharif Swat was inspected, visually inspected the building portion-II, & found no damage done due to burst/ blast in portion-I production unit, hence the subject building portion-II is fit for intended purpose subject to the condition that no such machinery plants or other equipment likely to burst during operations shall not be placed in the same for safety purpose **(File** 2).

d) Report of the DRAP panel dated 29.07.2022 **(File 4)** for allowing production in Cephalosporin section as per GMP guidelines mentioned under The Drugs (L.R.A. Rules) 1976 of the Drug Act 1976/ DRAP Act, 2012,

Case may be placed before the CLB, along with record obtained from the 1/0 and the firm, for consideration for resumption of production in the Ceph. Sections as per DRAP panel inspection report dated 29.07.2022, if in accordance with all relevant rules. It is further added that DRAP officers conduct GMP inspection, which only ascertains the GMP compliance; manufacturing / testing procedures, protocol adopted by the firm as per the Drugs Act, 1976/ DRAP Act, 2012 and verify the facility of the firm for GMP compliance. It is not the mandate of DRAP to ascertain strength of building and safety of installed electric panels or equipment. The verification of strength of building, safety of installed electric panels/ equipment, firefighting system etc., is a technical job that pertains to civil/ electrical engineers and is responsibility of the manufacturer to comply with all such requirements as laid down by relevant/ concerned departments.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

1. The Board decided to serve the Show cause notice to the firm for following sections:
    a. Tablet General Section
    b. Capsule General Section
    c. Liquid Syrup General Section
    d. Dry Suspension General
    e. Tablet Psychotropic Section

f. Warehouse

2. Board observed that the firm has provided a scanned copy of the C&W letter and Board decided to verify the authenticity/ genuineness and validity of the letter issued by Executive Engineer.

3. Board further decided that the firm shall complete the application of renewal of DML for further period within 15 days as the renewal of DML of the firm will expired on 26-02-2023.

4. The Board shall submit an undertaking on stamp paper for taking responsibility regarding civil and electrical work and to stop production immediately in case of any mis happening.

5. The production of cephalosporin area shall be allowed after submission of undertaking and reply from C&W department Swat.

**CASE NO. 26 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S THE SCHAZOO PHARMACEUTICAL LABORATORIES (PVT) LTD, KALALWALA STOP, 20-KM, LAHORE - JARANWALA ROAD, DISTRICT, SHEIKHUPURA.**

M/s The Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore - Jaranwala Road, District, Sheikhupura application for grant of renewal of DML was approved 280th Meeting of Central Licensing Board held on 26th & 27th April, 2021 for the period from 11-06-2019 and ending on 10-06-2024 with following sections:-

1. Tablet (General)
2. Capsule (General)
3. Sachet (General)
4. Oral Liquid Section for suspension and Syrup.
5. (Ampoule) General & Psychotropic Injectable Section.
6. Ophthalmic & Nasal Drops Section.
7. Tablet, Capsule and Oral Dry Powder Suspension (Cephalosporin).

. The Board defferd following sections for clarification

1. Oral Liquid Section for Suspension & Syrup.
2. Ampoule (General & Psychotropic) Injectable Section.
3. Sachet Section.

The decision of the Central Licensing Board was issued to the firm on 09-09-2021.

In response to the above letter, the firm has informed that following three sections are missing in the above letter.
As per available record of Licensing Division the firm possess the following two sections and the approval of the Sachet section does not found in the record.

1. Liquid Ampoule (General)

2. Oral Liquid Section for suspension and syrup.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to approve the renewal of DML for following pending two (02) sections:

1. Liquid Ampoule (General)
2. Oral Liquid Section for suspension and syrup.

**Case No- 27 RENEWAL OF DRUG MANUFACTURING LICENCE 000426 BY WAY OF FORMULATION) OF M/S SB PHARMA, PLOT NO. 5-E, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s SB Pharma, Plot No. 5-E, Industrial Triangle, Kahuta Road, Islamabad, applied for renewal of DML No. 000426 by way of formulation for the period of **25-03-2021 to 24-03-2026.**

The application for the renewal of DML of the firm was evaluated and a letter for the following shortcomings/deficiencies was issued to the firm on 14/08/2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated/amended/addendum partnership not provided.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 11thApril, 2022 to the firm with following shortcomings: -

i. Updated/amended/addendum partnership not provided.

The firm did not submit their reply to Final Reminder and following documents are still deficient /short and application for renewal of DML is still incomplete;

i. Updated/amended/addendum partnership not provided.

**Decision of the Central Licensing Board in 286th 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 and Rule 12of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000426 by way of formulation of M/s, SB Pharma Plot No. 5-E, Industrial Triangle Kahuta Road, Islamabad, may not be suspended 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.

Show-Cause Notice was issued to the firm on 02-06-2022.
In response to the above Show-Cause Notice , M/s SB Pharma, Plot No. 5-E, Industrial Triangle, Kahuta Road, Islamabad has submitted required documents for renewal of Drug Manufacturing License and change of management. The application for renewal of Drug Manufacturing License No. 000426 for the period from **24-03-2021 to 23-03-2026** is now complete.

The detail of management is as under; -

| **Previous management as per partnership deed as on 11-01-2020.** | **Outgoing management as per partnership deed as on 25-04-2022.** | **New management as per partnership deed as on 25-04-2022.** |
|---|---|---|
| 1. Dr. Muhammad Sadiq S/o Ch. Fateh Muhammad.<br>2. Dr. Sadiq Foundation through Asif Zubair Sadiq (Secretary General) S/o Muhammad Sadiq CNIC No. 61101-1926942-9. | Dr. Muhammad Sadiq S/o Ch. Fateh Muhammad (died). | 1.Mr. Salman Sadiq S/o Dr. Muhammad Sadiq.<br>2.Dr. Sadiq Foundation through Asif Zubair Sadiq (Secretary General) S/o Muhammad Sadiq CNIC No. 61101-1926942-9. |

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

1. Since, the firm has completed the application for the Renewal of DML No. 000426, the Board while considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s SB Pharma, Plot No. 5-E, Industrial Triangle, Kahuta Road, Islamabad.

2. The Board considered and accepted for record the change of management of, M/s SB Pharma, Plot No. 5-E, Industrial Triangle, Kahuta Road, Islamabad., DML No.000426 (By way of Formulation) as under;

| **Previous management as per partnership deed as on 11-01-2020.** | **Outgoing management as per partnership deed as on 25-04-2022.** | **New management as per partnership deed as on 25-04-2022.** |
|---|---|---|
| 1. Dr. Muhammad Sadiq S/o Ch. Fateh Muhammad.<br>2. Dr. Sadiq Foundation through Asif Zubair Sadiq | Dr. Muhammad Sadiq S/o Ch. Fateh Muhammad (died). | 1. Mr. Salman Sadiq S/o Dr. Muhammad Sadiq.<br>2.Dr. Sadiq Foundation through Asif Zubair Sadiq (Secretary General) S/o |

| | | |
|---|---|---|
| (Secretary General) S/o Muhammad Sadiq CNIC No. 61101-1926942-9. | | Muhammad Sadiq CNIC No. 61101-1926942-9. |

**Case No.28 CHANGE OF TITLE OF M/S ICI PAKISTAN LTD, 32/2A, PHASE-III, INDUSTRIAL ESTATE, HATTAR.**

M/s Lucky Core Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar, [*Formerly* ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.] wherein the firm has submitted an application for change of title of the company under Drug Manufacturing License No.000363 by way of (Formulation). The firm has submitted the following documents :-

1. Requisite fee of Rs.75,000/-
2. Form-29 issued by SECP in the name of M/s ICI Pakistan Ltd.
3. ID Cards of management.
4. Certificate of Incorporation on change of name issued by SECP in the name of M/s Lucky Core Industries Limited.
5. Nothing Due Certificate regarding CRF up to 31-12-2022.
6. Undertaking on stamp paper stated that the due to same management of the firm SECP does not issue Form-29 in the new proposed name.

**Change of Title.**

| Previous Title of the firm. | Current Title of the firm. |
|---|---|
| M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar, | M/s Lucky Core Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar, |

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of title of M/s Lucky Core Industries Limited, 45km, Off Multan Road, Lahore [*Formerly* ICI Pakistan Ltd,.] DML No.000363 (By way of Formulation) as under.

| Previous Title of the firm. | Current Title of the firm. |
|---|---|
| M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar, | M/s Lucky Core Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar, |

Case No. 29 **CHANGE OF MANAGEMENT AND TITLE OF M/S ICE BERG PHARMACEUTICALS (PVT) LTD., PLOT NO/ 144, NOWSHERA INDUSTRIAL ESTATE, RISALPUR**

M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No/ 144, Nowshera Industrial Estate, Risalpur has submitted a Certified True copy of Form-29 for change of management in response to this Division's letter dated 21-11-2022 under Drug Manufacturing License No. 000816 by way of (Formulation). The firm has also applied for a change of Title of the firm along with the prescribed fee. The firm has submitted following documents: -

1. Certified True copy of the certificate of incorporation issued by SECP on 02-12-2022.
2. Certified True copy of Form-29 issued by SECP in the name of Ice Berg on 02-12-2022.
3. CNICs copies of previous and new directors.
4. Agreement b/w Current and new management of the firm.

**Change of Title**

| **Previous Title of the firm.** | **Current Title of the firm as per certificate of incorporation.** |
|---|---|
| M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur | M/s JSK Medica (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur |

**Change of Management**

| **Previous management as per Form-29 issued** | **New management as per Form-29** |
|---|---|
| 1. Mr. Muhammad Fayaz S/o Kachkol CNIC No. 17101-7193842-7.<br>2. Mr. Najeeb Ullah S/o Habib Ullah CNIC No. 17301-8989720-9.<br>3. Mr. Muhammad Tahir S/o Sahib Gul CNIC No. 16101-9356882-3. | 1. Mr. Kamran Anjum S/o Ihsan Ullah CNIC No. 17301-8270898-1.<br>2. Mr. Hasnain Ali Gulfam S/o Gulfam Hussain CNIC No. 17301-0101205-7. |

**Decision of the Central Licensing Board in 289th meeting:**

The Board considered and accepted for record the change of title & management of M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No/ 144, Nowshera Industrial Estate, DML No.000816 (By way of Formulation) as under.

**Change of Title**

| **Previous Title of the firm.** | **Current Title of the firm.** |
|---|---|

| | |
|---|---|
| M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur | M/s JSK Medica (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur |

**Change of Management**

| Previous management as per Form-29 issued | New management as per Form-29 |
|---|---|
| 1. Mr. Muhammad Fayaz S/o Kachkol CNIC No. 17101-7193842-7.<br>2. Mr. Najeeb Ullah S/o Habib Ullah CNIC No. 17301-8989720-9.<br>3. Mr. Muhammad Tahir S/o Sahib Gul CNIC No. 16101-9356882-3. | 1. Mr. Kamran Anjum S/o Ihsan Ullah CNIC No. 17301-8270898-1.<br>2. Mr. Hasnain Ali Gulfam S/o Gulfam Hussain CNIC No. 17301-0101205-7. |

Case No.30 **RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000486 (BY WAY OF FORMULATION). OF M/S AKSON PHARMACEUTICAL (PVT) LTD, PLOT NO. 9-B/1&2, STREET NO. D-1, OLD INDUSTRIAL ESTATE, MIRPUR, AZAD KASHMIR.**

M/s. Akson Pharmaceutical (Pvt) Ltd, Plot No.9-B/1&2, Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir submitted the application for renewal of Drug Manufacturing No. 000486 (by way of Formulation). The application was received on 02-04-2021 which is well on time as validity of License is 12/04/2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 04th August, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Proof of Table (General), Table (Antibiotic), Capsule (General), Liquid Syrup/Suspension(General) sections approval from Central Licensing Board is not provided,
ii. Updated Form-29 issued and certified as "True Copy" by SECP (in original) along with CNIC copies of all director are required,
iii. Updated (up to 31-12-2020) nothing due certificate (CRF) from STO, DRAP is not provided,

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 20th October, 2021 to the firm with following shortcomings: -

i. Proof of section approval from Central Licensing Board.

The firm submitted their reply to Final Reminder and above mentioned documents are still deficient /short and the application for renewal of DML is still incomplete.

**Decision of the Central Licensing Board in 286th 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, 5and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000486 by way of formulation of M/s. Akson Pharmaceutical (Pvt) Ltd, Plot No. 9-B/1&2, Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir, 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".

A Show Cause Notice was issued on 4th June, 2022 in the light of decision of 286th meeting of Central Licensing Board held on 2th June, 2022.

In response to the above, M/s. Akson Pharmaceutical (Pvt) Ltd, Mirpur, Azad Kashmir has submitted an application for regularization of Layout Plan and the same was approved by this Divison vide letter dated 27th June 2022 for completion of application of renewal of Drug Manufacturing License No. 000486 (Formulation). The application for renewal of DML for the period 12-04-2021 to 11-04-2026 is now complete.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

**Personal Hearings**

Case No.1 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CAYLEX PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore had applied for renewal of DML No. 000451 by way of Formulation for the period of 01-08-2020 to 31-07-2025 on 30-07-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 24-08-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 duly attested by SECP (original).
v. Duly attested CNIC copies of all Directors.
vi. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vii. Duly attested resignation of earlier production Incharge.
viii. Duly attested resignation of proposed production Incharge from previous firm.

The firm then filed application for approval of Production Incharge and Quality Control Incharge. Reminder letter was issued on 16-11-2021 to the firm for completion of application for renewal of DML and approval of technical staff:

i. Properly filled, signed and stamped Form-1 A (as per format).
ii. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management, if any change, apply for change of management.
iv. Latest true copy of Form-29 duly attested by SECP (original).
v. Duly attested CNIC copies of all directors.
vi. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vii. Complete set of duly attested documents (as per checklist) of proposed Production Incharge & Quality Control Incharge.

The firm replied on 08-12-2021 but application is still deficient of following documents:

i. Properly filled, signed and stamped Form-1 A (as per format).
i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management, if any change, apply for change of management.
iii. Latest true copy of Form-29 duly attested by SECP (original).
iv. Duly attested CNIC copies of all directors.
v. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vi. Complete set of duly attested documents (as per checklist) of proposed Production Incharge & Quality Control Incharge.

**Decision of the Central Licensing Board in 288th meeting:**

The Board while 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No. 000451 by way of formulation of M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore 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.

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

The Show Cause Notice was issued to M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore on 28th November, 2022.

The firm has replied to Show cause notice on 11-01-2023 but application for renewal of DML is still deficient of following documents:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Latest true copy of Form-29 duly attested by SECP (original).
iii. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
iv. Deposit prescribed fee of Rs.15000/- for approval of Production Incharge & Quality Control Incharge.
v. Duly attested CNIC of proposed Production Incharge & Quality Control Incharge.
vi. Duly notarized undertaking as whole time employee on stamp paper (Quality Control Incharge).

A letter of personal hearing has been issued on 17-01-2023.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

No one appeared on behalf of the firm before the Board. The Board while considering the facts on the record decided to offer final opportunity to the firm. The Board further decided that Area FID shall submit updated status of the firm to the Board in its upcoming meeting.

Case No. 2 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MIRACLE PHARMACEUTICALS (PVT) LTD, RAWAT.**

M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat had applied for renewal of DML No. 000593 by way of Formulation for the period of 29-06-2021 to 28-06-2026 on 28-06-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 02-08-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing due certificate regarding CRF from STO.
iii. Detail of management, if any change, apply for change of management.
iv. Duly attested CNIC copies of Directors.
v. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original).
vi. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.
vii. Approval letters of technical staff.

The firm did not reply and reminder letter was issued on 18-10-2021 to the firm for completion of application for renewal of DML:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing due certificate regarding CRF from STO.
iii. Application for change of management along with prescribed fee of Rs. 75,000/-.
iv. Duly attested CNIC copies of Directors.
v. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original).
vi. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.
vii. Approval letters of technical staff.

The firm has not yet reply and application for renewal of DML is not complete.

**Decision of the Central Licensing Board in 288th 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000593 by way of formulation of M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street 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.

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

The Show Cause Notice was issued to M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat on 22nd November, 2022.

The firm has replied to Show Cause Notice on 28-12-2022 and application for renewal of DML is still deficient of following documents:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing due certificate regarding CRF from STO.
iii. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original). **(The firm has submitted digital certified copy)**
iv. Duly attested appointment letter, job acceptance letter, academic degree, undertaking as whole time employee on stamp paper and resignation of appointee from previous firm (Production Incharge).
v. Duly attested appointment letter, job acceptance letter, undertaking as whole time employee on stamp paper and resignation of appointee from previous firm (Quality Control Incharge).
vi. Duly attested resignation of earlier Quality Control Incharge and Production Incharge.

A letter of personal hearing has been issued to the firm on 17th January, 2023.

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

Mr. Muhammad Naveed and Shumila Rani of the firm appeared before the Board. They contended that they will provide/submit all requisite documents at the earliest. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

Case No. 3 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LAHORE PHARMA, LAHORE.**

M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore had applied for renewal of DML No. 000084 by way of Formulation for the period of 26-03-2021 to 31-25-03-2026 on 22-03-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 01-07-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.
ii. Detail of premises including layout plan.
iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,
iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.
v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

The firm did not reply and Reminder letter was issued on 11-10-2021 to the firm for completion of application for renewal of DML:

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.
ii. Detail of premises including layout plan.
iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,
iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.
v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

In the meanwhile, Production Incharge of the firm has resigned and letter was issued on 02-08-2022 for appointment and approval of Production Incharge. The firm did not reply and application for renewal of DML and Production Incharge is still incomplete.

**Decision of the Central Licensing Board in 288th 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 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000084 by way of formulation of M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore 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.

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

The Show Cause Notice was issued to M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore on 21st November, 2022.

The firm has not replied to Show Cause Notice and application for renewal of DML is still deficient of following documents:

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.
ii. Detail of premises including layout plan.
iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,
iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.
v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

A letter of personal hearing has been issued to the firm on 17th January, 2023.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000084 by way of Formulation of M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore till fulfillment of codal formalities 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(2A), Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 4 **M/S MEDISYNTH PHARMACEUTICALS, RAWAT.**

A legal notice received from Malik Khalid Mahmood, Advocate Supreme Court of Pakistan addressed to Chief Executive Officer **M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat.** The detail of legal notice is reproduced as under: -

1. That my client entered into a written Rent Deed Agreement No. 17 dated 16-06-2010 ("agreement") on 14th May 2010 for the Plot No. 55 (Ground Floor inclusive of roof for HVAC System with temporary MS Sheet covering only) street No. S-05, Industrial Estate, Rawat, Rawalpindi (hereinafter" plot") registered in Court of learned Special Judge Rent, Rawalpindi on 10-06-2010. The premises specification has been mentioned in the agreement, Pursuant to the agreement, the relationship of Landlord and tenant was established between my client and you.

2. That my client is the sole owner of the plot. It has been written in the agreement that Rent Deed / Agreement shall be valid between both the parties (my client & you) for the maximum period of 12 years ending on 13th May, 2022. It has also been settled / written in the agreement that it is discretionary right of my client to extend or not extend the period after its expiry.

3. That it is stated the agreement is going to be expired on 13th May 2022 having discretion of my client to extend it or otherwise. My client does not intend to extend the agreement anymore and do not want to have Rent Deed Agreement with you for further period in respect of the plot.

4. That it is pertinent to mention here that during the subsistence of agreement my client has always abided by the terms and conditions of the instant agreement. Nothing is outstanding against him.

5. That my client has verbally requested you that he is no more interested to extend the agreement and therefore, requested you to vacate the premises mentioned above after expiry of agreement but you are not ready to hear anything reasonable.

6. That through this legal notice to evict you are advised to vacate the said plot after expiry of agreement, otherwise, my client has positively instructed me to file a suit for eviction against you in the Court of Law oat your risk and costs.

It is submitted for information that M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat under DML NO. 000718 (by Way of Formulation) has applied for renewal of DML for the period of 14-06-2021 to 13-06-2026 and panel of experts/inspector has been constituted, accordingly.

**Decision of the Central Licensing Board in 286th 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000000by way of formulation of M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat, may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause Notice was issued to M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat on 9th June, 2022.

The firm has replied which is reproduced as under:

*"In fact the owner of the plot has concealed material facts from his counsel which led to misconception on the part of DRAP and resultantly issuance of the instant show Cause Notice.*

*In this regard, it is submitted that Mr. Ishtiaq Ahmed Khan S/o Abdul Ghafoor Khan plot owner entered into the agreement with the then owner of Medisynth Pharmaceuticals encompassing different obligations on the part of the owner and tenant. That vide article 2, the purpose of the agreement was to construct two independent Human and Veterinary Units. It was mutually agreed that Mr. Ishtiaq Ahmad owner of the plot will be liable to construct an independent unit of Veterinary Medicines on the first floor on the said premises/plot (Article 8). That Mr. Arshad Hussain will construct a Quality Control Laboratory, which will be used by Mr. Ishtiaq Ahmed Khan for its veterinary medicines as well. That Mr. Arshad Hussain has thus raised a QC Laboratory with the state of the art technology so as to meet the requirement of the Pharmaceuticals and Veterinary section of the Mr. Ishtiaq Ahmed Khan.*

***However, Mr. Ishtiaq Ahmad lingered on the matter where after Mr. Arshad Hussain couldn't sustain the continuous loss and as such offered the sale of its pharmaceutical to some third party.***

*In the circumstances, Mr. Arshad Hussain in the presence of Mr. Ishtiaq Ahmed Khan strike down an agreement of sale of firm with us. Mr. Ishtiaq Ahmed Khan assured us that he will extend the lease agreement for another 5 years after the expiry of the current agreement and will also construct the Veterinary Section so as to divide the rent and other expenditures on the two units as per provision of the clause 8 of the agreement.*

*As such in good faith and his personal assurance that this issue of liability will be adjusted in the extended period (14th May, 2027) of agreement, we kept on paying the total rent with 10% annual increase from 2010 till date. As per our calculation an over payment of Rs. 9,565,455/- is outstanding against him.*

*The malafide intention of the Land Owner is further evident from the fact that he has not served any prior notice of one year as required in the registered rent agreement. For your kind perusal the relevant clause i.e Clause 7 is reproduced as under;*

*"After the initial 5 year & within expiry period of this agreement, either party willing to terminate the agreement will serve a notice of one year and liable to pay the penalty/compensation of rupees Two million to the other party."*

*Neither the land owner Mr. Ishtiaq Ahmed Khan has given any notice as required above nor has compensated the penalty provided in the said clause of the agreement. The said notice has placed our firm in a very embarrassing situation and as such on the receipt of the legal notice we had no alternative but to seek legal remedy against this illegal blackmailing and nefarious design. Thus we filed a suit with Special Judge (Rent)/Civil Judge 15 Class, Rawalpindi.*

*The matter was fixed before the court on 14.06.2022, which has passed the following orders*

*"Till the next date of hearing subject to notice, the respondent is restrained from interfering into the peaceful possession of applicant illegally; unlawfully, otherwise, due course of law"*

*In view of the situation explained above, the notice of the legal Counsel is misleading, unlawful and tantamount to blackmailing, embarrassing and maligning of the goodwill of our firm and is therefore is requested to file the same."*

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

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

No one appeared on behalf of the firm before the Board. The Board while considering the facts on the record decided to offer final opportunity to the firm. The Board further decided that Area FID shall submit updated status of the firm to the Board in its upcoming meeting.

**Proceeding of Licensing Division in compliance of Central Licensing Board's Decision:**

A letter of personal hearing has been issued on 17th January, 2023.

The firm has submitted a reply that on 16-07-2022, the matter was again fixed before the Court whereby the Counsel of the respondent (Mr. Ishtiaq Ahmed Khan) stated before the Court that the respondent will not illegally interfere into possession. Hence on the statement of respondent, Court accordingly disposed off their application being infructuous.Additional Director (QA & LT) ha informed that he along with AD (QA-II) visited the firm on 09-01-2023. The Tablet Betanec Reg No 078621 was being manufactured in the Tablet section. Mr. Arif Jan (CEO) of M/s Medisynth Pharmaceuticals informed that they are going to move to the new premises in two months.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

Mr Hazrat Ali Director of the firm appeared before the Board and submitted written commitment to shift the existing licensed unit into the new approved site within 06 Months and the Board decided to give personal hearing to owners of the Land / Plot.

**Item-V**: **MISC. CASES**

**Case No. 1 GRANT OF ADDITIONAL SECTION OF M/S MTI MEDICAL (PVT) LTD, LAHORE.**

**Case Background:**

M/s MTI Medical (Pvt) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Lahore got approval of DML with the following sections.

i. Lyophilized vial injectables
ii. Dry Powder injectable Cephalosporin
iii. Oral liquid General
iv. Tablet General
v. Capsule General
vi. Oral dry powder suspension general
vii. Liquid vial injectable general

The firm submitted layout plan for relocation of their Liquid Injectable (Vial) & Lyophilized Vial Injectable Section to Ground Floor on 15-11-2019 and layout plan of the same was approved on 02-10-2020 with the title of Liquid Injectable (Vial) (Lyophilized) (Revised) section.

Then, the firm submitted request on 30-03-2021 for approval of Biological vaccine (Liquid & Lyophilized) (General) section in place of Injectable (Lyophilized) (Revised) section and layout plan of the same was approved on 05-04-2021. A panel of experts/Inspectors was constituted on 08-04-2021 for inspection of the aforesaid section.

Then layout of Injectable (Vial) (Liquid & Lyophilized) (General) Section in place of unlicensed Biological vaccine (Liquid & Lyophilized) (General) section was again submitted by the firm on 24-12-2021 and layout plan approval was granted on 14-02-2021.

A panel of experts/Inspectors was constituted for inspection of the firm for grant of renewal of DML. Inspection report was received which was placed before CLB in its 285th meeting. Proceeding are as under:

**Clarification from the Firm:**

The firm has submitted reply which is reproduced as under:

| | | | |
|---|---|---|---|
| M/s MTI Medical (Pvt) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Lahore.<br><br>DML No. 000801 (Formulation).<br><br>Period: Commencing on 19-09-2019 & ending on 18-09-2024. | **09-02-2022** | **Good** | 1. Dr. Ikram ul Haq, Expert Member.<br>2. Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. |

**Recommendations of the panel:**

Keeping in view the facilities like building, HVAC system, equipment, Instrument, Machinery, Personnel, Documentation, Quality Assurance department, Quality Control and testing facilities, the panel of Inspectors **recommend** the grant of following new section to M/s MTI Medical (Pvt) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Lahore.

i. Injectable (Vial) Liquid & Lyophilized Section (General) (New).

Panel also **recommend** the renewal of Grant of Drug Manufacturing License for the following sections:

1. Lyophilized Vials Injectable (General) (already existing section)
2. Dry Powder Injectable (Cephalosporin)
3. Oral Liquid
4. Tablet (General)
5. Capsule (General)
6. Dry Suspension (General)
7. Liquid Vial Injectable (General) (SVP).

It is pertinent to mention here that as per available record of Licensing Division, Injectable (Vial) Liquid & Lyophilized Section (General), Lyophilized Vials Injectable (General) and Liquid Vial Injectable (General) (SVP) are same licensed section and revised layout plan of this section is approved with the title "Injectable (Vial) (Liquid & Lyophilized) (General) Section.

**Decision of the Central Licensing Board in 285th meeting:**

The Board considered and approved the grant of renewal of DML No. 000801 by way of Formulation in the name of M/s MTI Medical (Pvt) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Lahore on the recommendations of the panel of experts for the period Commencing on 19-09-2019 & ending on 18-09-2024 for the following sections: -

1. Injectable (Vial) (Liquid & Lyophilized) (General) Section
2. Dry Powder Injectable (Cephalosporin)
3. Oral Liquid
4. Tablet (General)

5. Capsule (General)
6. Dry Suspension (General)

*"In 2013, company was Established and on 12th April 2016, additional section of liquid vial (General) was granted on 2nd floor which was further amended to lyophilized section on 11" April 2017. On 13th Nov, 2019 we requested for replacement of this liquid and lyophilized section in place of Cephalosporin, Tablet, Capsule and Dry Syrup whereas in actual we were developing new section in place of the said areas of Ceph in extension of previous section on 2nd floor. Layout plan was approved consisting of both facilities but we mistakenly wrote letter in April 2021 to your good office to consider General liquid & Lyophilized section in place of Biological section and soon we reverse it as we were in process of developing new facility for Biological and we requested to conduct DML inspection according to previously approved layout plan on 02-10-2020. We got letter for the said purpose from your good office on 14-02-2022. In June 2022 our inspection report was received with both previously approved General liquid & lyophilized section and newly Developed Liquid & Lyophilized section copy of inspection report. But DML letter issued by your good office only consist renewal areas and is deficient of new general Liquid & Lyophilized section"*

**Decision of the Central Licensing Board in 289th meeting**

The Board considered the application and decided to get verification/ clarification from Additional Director Lahore who was a penal member during inspection of the Injectable (Vial) Liquid & Lyophilized Section (General) (New) section to clarify whether the said section is a separate facility or a relocation at an existing section.

(Evaluator: Muhammad Yaqoob AD IV)

**CASE NO. 4. <u>RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000496 OF M/S VALOR PHARMACEUTICALS, PLOT NO. 124/A, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.</u>**

M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad wherein the firm has application renewal of Drug Manufacturing License No. 000496 (Formulation). The application was received on 27-07-2022 after validity of the DML as the validity of License is 28-03-2022. The firm has deposited a fee of Rs. 75,000/-. Therefore, DML No. 000496 (Formulation) M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad, is no more valid.

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. 7,500/- 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."

**<u>Decision of the Central Licensing Board in 288th meeting</u>**

"The Board while considering the facts on the record 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 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000496 by way of formulation of M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad, 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".

In the light of board decision, a Show Cause Notice was issued to the firm on 14th November, 2022.

In response to above Show Cause Notice M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad has submitted following submission for renewal of Drug Manufacturing License.

6. We received Show Cause Notice via letter No. F.1-8/99-Lic (Vol-II) copy attached, stating that our application for renewal of Drug Manufacturing License was received after validity of stipulated time. Please note that our last DML we have

submitted the renewal fee for DML on 16-03-2022 (copy of which is attached herewith) & submitted the application in hard form to R&I Department on 21st March, 2022 that is before the expiration of our DML but R&I Department first stamped our application then asked us to proceed the file via online submission, copy of letter also attached herewith.

7. We have started online submission data for renewal of our DML before time on PIRIMS, during process of Data authentication we received different deficiency letters from our concerned AD Mr. Abdullah dated 31-03-2022, 21-04-2022, 30-05-2022, 13-07-2022, 26-09-2022 (copies attached) & we have submitted their replies & also done discussion with our AD during various visits.

8. After that we request the Secretary Licensing Board to allow us to submit the application in hard form as our process is taking time in online submission. The Secretary Licensing Board allowed us to submit the hard application file which we submitted in R&I department on 27-07-2022 which was mentioned on Show Cause Notice as the date of submission of our request for renewal of DML. As explained we have started our process for online submission of DML renewal before expiration of certificate & proof of our all steps are attached herewith this reply.

9. Therefore, it is requested to remove the show cause notice as we timely proceed the renewal of our DML & completed all the formalities.

A letter of personal hearing was served on 11-01-2023 to the said firm for 289th meeting of the Central Licensing Board scheduled to be held on 23rd January 2023.

The physical/hard copy of the application was submitted on dated 27-07-2022 which is 121 Days late from the due date for submission of application (28-03-2022).

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

Ms. Sadaf Yasmeen Regulatory Manager and Mr. Asif Iqbal Quality Control Manager of the firm appeared before the Board. They contended that they have submitted all the requisite document/information within time on PIRMIS for data authentication. The Board observed that the firm has deposited fee on 16-03-2022 and try to submit the receipt in R&I of DRAP on 21-03-2022 and the documents were not received because the firm was asked to apply on PIRIMS. The procedure to apply renewal application on PIRIMS start with data authentication. The firm submitted the documents on PIRIMS on 22-03-2022. Focal Person of the PIRMIS was approached to check the application for grant of renewal of DML in PIRMIS data and he retrieve that the firm uploaded the renewal application on dated 26-03-2022.

The board further decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad and to accept the firm application for grant of renewal of DML.

(Evaluator: Muhammad Yaqoob AD IV)

**Case. No. 5. <u>RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000572 OF MEDIZAN LABORATORIES (PVT) LTD, PLOT NO. 313, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.</u>**

M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad had applied for renewal of DML No. 000572 by way of (formulation) on 8th May, 2020 for the period of 13-05-2020 to 12-05-2025. On scrutiny of application for renewal following observations have been observed:-

i. Proof of Licensed Section from CLB.
ii. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

A shortcoming letter was issued to the firm on 31st August, 2020 for rectification of above-mentioned shortcoming.

Firm has not rectified shortcoming and final reminder was issued on 26the February, 2021.

In response to this Division's final reminder firm has submitted their reply on 18th March, 2021. On scrutiny of submitted documents for renewal of Drug Manufacturing License is still deficient / short and application for renewal of Drug Manufacturing License is still incomplete for following documents: -

i. Up to date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

**<u>Decision of the Central Licensing Board in 288th meeting</u>**

The Board while considering the facts on the record 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 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000572 by way of formulation of M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad, 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.

Accordingly, a Show-Cause Notice was issued to the firm on 15-11-2022. But no reply of the firm received so far.

In response to Show-Cause Notice letter, firm has submitted documents and stated that they have deposited the CRF for the year 2018, 2019, 2020 and 2021 and when CRF letter will issue from Statistical section of DRAP then will submit it in the Licensing Division.

A letter of personal hearing was served on 11-01-2023 to the said firm for 289th meeting of Central Licensing Board schedule to be held on 23rd January 2023.
The firm has provided the Up to date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad issued on 23rd January, 2023.

**Proceedings and Decision by the Central Licensing Board in 289th meeting:**

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

**Item-V**: **MISC. CASES**

**Case No. 6: CHANGE OF TITLE AND MANAGEMENT OF M/S FORTUNE PHARMACEUTICALS, KARACHI**

M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E (SHW) Phase-II, Karachi under DML No. 000924 (FORMULATION) has submitted request for change of title and management along with Prescribed **fee of Rs. 75000 instead of Rs. 1,50,000** and **un attested certified true copy of Form-29** as under:

| **Current Title** | **New Title** |
|---|---|
| 2. M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E (SHW) Phase-II, Karachi | 2. M/s Fortune Pharmaceuticals (Pvt) Ltd , Plot No. K/201, S.I.T.E (SHW) Phase-II, Karachi |

| **Current management as per Partnership deed** | **New management as per Form-29 (Year 2022)** |
|---|---|

| | |
|---|---|
| 3. Muhammad Shehmeer Imtiaz S/o Imtiaz Ahmed CNIC No. 44103-4535598-92. Dr. Noor Ahmad Noor S/o Haji Barkat Ali.<br>4. Mr. Muhammad Talib S/o Muhammad Sikandar CNIC No. 42201-2790408-5. | 4. Mr. Akber Ali S/o Khan Muhammad Babar<br>CNIC No. 41304-42384539-1<br>5. Mr. Muhammad Sikander S/o Muhammad Usman CNIC No. 42201-3841893-5<br>6. Muhammad Shehmeer Imtiaz S/o Imtiaz Ahmed CNIC No. 44103-4535598-9 |

The firm has submitted following documents:

1. Prescribed fee Rs. 75,000 instead of Rs. 1,50,000.
2. Un-attested CTC copy of From-29 of SECP.

**Decision of the Central Licensing Board in 289th meeting**

**Duplicate case at page No. 108**

# Draft Minutes of Quality Control Cases – 289th Meeting of Central Licensing Board (CLB) HELD ON 23rd January, 2023.

| Case No | Subject |
|---|---|
| **01** | MANUFACTURE AND SALE OF UNREGISTERED NRUFEN SUSPENSION BY M/S. PERFECT PHARMA (Pvt.) Ltd., LAHORE. |
| **02** | REQUEST OF SHIFA INTERNATIONAL HOSPITAL REGARDING PURCHASE AND USE OF DRUG COMPOUNDED BY A LOCAL PHARMACEUTICAL COMPANY FOR THEIR HOSPITAL USE |
| **03** | UNREGISTERED DRUG "SUDOCREAM ANTISEPTIC HEALING CREAM" MANUFACTURED BY M/S. TOSARA PHARMA, LTD., IRELAND |
| **04** | MANUFACTURE AND SALE OF SPURIOUS AND SUBSTANDARD DRUGS- M/S. HOORAIN IMPEX, KARACHI |

**MANUFACTURE AND SALE OF UNREGISTERED NRUFEN SUSPENSION BY M/S. PERFECT PHARMA (Pvt.) Ltd., LAHORE.**

A complaint was received from M/s. Abbott Laboratories Pakistan regarding manufacture and sale of product namely "Nrufen suspension" by M/s. Perfect Pharma (Pvt.) Ltd., Lahore, name and packaging desing of which is similar to registered product of M/s. Abbott Laboratories Karachi namely "Brufen Suspension".

02. A letter vide F. No. 13-196/2019-QC (Vol-I) dated 27-04-2021 was issued to area FID Lahore for investigation of the matter. Area FID Lahore submitted a report of inspection conducted on 08-06-2021 for verification of the said complaint. The report is reproduced as under:

"***Purpose of inspection:***

*With reference to DRAP Islamabad's Letter No.F.No. 13-196/2019-QC (Vol- I) dated 27-04-2021 on the subject, "Manufacturing/ Sale of Unregistered Drugs by M's Perfect Pharma (Pvt) Ltd,5km Manga Road, Raiwind, Lahore", a panel comprising of Mrs. Majida Mujahid (Area Federal Inspector of Drugs) and Ms. Maham Misbah (Assistant Director, DRAP, Lahore) conducted a surprise visit of M/s Perfect Pharma (DML No. 00469) located at 5km Manga Raiwind Road, Lahore an 08-06-2021.*

***Firm's representatives present during the inspection:***

*The representatives of the firm who were present at the time of inspection included Mr. Salman Shafi (CEO), Mr, M. Yamin (Production Incharge), Mr. M. Nasir (Quality Control Manger) and Mr. Ashfaq Ahmad (Manager), among others. Proceedings of the inspection dated 08-06-2021:*

*The firm was asked about the production of its purported product Nrufen Suspension. The firm's management responded that they had recently taken over the firm from the previous management. The Central Licensing Board in its 273rd meeting held on 15-01-2020 had endorsed the change of management and the decision had been communicated vide DRAP, Islamabad letter No. F.l-15/98-Lic (Vol-III) dated 10-06-2020. (Letter of change of management attached, Annex 1). The CEO of the firm informed the panel that his firm had not manufactured Nrufen Suspension (Ibuprofen Suspension) since the change of management neither had they received any record of production (BMR) of Nrufen Suspension from the previous management, at the time of change of management. He further stated that his team did not receive any registration letter of Nrufen Suspension from the previous management, therefore, the same could not be produced before the panel.*

*Nrufen Suspension was not included in the Section-wise registered product list of the firm, as shown to the panel. No Ibuprofen API, unit carton or label of Nrufen suspension was found in the premises at the time of inspection. Further, no production record of Nrufen Suspension, testing record of Ibuprofen API, testing record of finished Nrufen suspension or any retained samples of Nrufen Suspension were found in the premises at the time of inspection.*

*However, the panel conducted an Inspection to check the firm's conformance to cGMP on 08-06-2021 and concluded as follows:*

*"Overall, the sanitaryand hygenic conditions of the firm were poor at the time of inspection. The civic work, working of HVAC and condition of equipment was found unsatisfactory at the time of*

*inspection. Firm did not comply with the current GMP requirements as per Schedule B-II of the Drugs (Licensing, Registraton and Advertisement) Rules, 1976."*

*Accordingly, the report was forwarded to Additional Director (QC), DRAP, Islamabad vide Ref No.8485 dated 10-06-2021 for further necessary action (Copy of report attached Annex 2). Subsequently, the firm was directed vide DRAP, Islamabad letter No. F.4-43/98-QA (Pt) dated 08-07-2021 to "Not to resume production prior to the approval of this Directorate, subject to relevant proceeding as deemed necessary by the Competent Authority and to show cause in writing within 15 days of issuance ofthis notice".*

*Subsequently, the Central Licensing Board in its 282nd meeting after thorough deliberation, considering compliance report ofthe firm and personal hearing of the firm's representative decided to constitute the following panel to verify the rectification of observations reported by the FID in her report dated 08-06-2021, as communicated vide DRAP, Islamabad letter No.F.8-8/2021-QA (M-282-CLB) dated 14-09-2021:*

*a. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab.*

*b. Area FID, DRAP, Lahore.*

*c. Ms. Maham Misbah, Assistant Director, DRAP. Lahore*

***Proceedings of the inspection dated 22-09-2021***

*The above panel, along with Ms. Uzma Barkat, Assistant Director. DRAP, Lahore, on the directions of Additional Director, DRAP. Lahore, conducted the inspection of M/s Perfect Pharma on 22-09-2021 to verify the rectification status of the firm. The representatives ofthe firm who were present at the time of*

*inspection included Mr. Salman Shafi (CEO), Mr. Shehzad Ali Shah (Patter), Mr. M Yamin (Production In-charge), Mr. M. Nasir (Quality Control Manger), Mr. Waqas bin Aftab (Quality Assurance Manager) and Mr. Ashfaq Ahmad (Manager), among others.*

*The matter of complaint was once again investigated by the panel on 22-09-2021 and the same observations were noted as on 08-06-2021, in the instant matter. Meanwhile, this office's record of import of Ibuprofen API by M/s Perfect Pharma was also scrutinized. As per available office record of DRAP, Lahore office, the firm had applied for import clearance of 1000kg Ibuprofen raw material vide letter Ref No. 220/PPL/202I dated 18-03-2021 (Diary No. 4544 dated 22-03-2021) for purported use in the manufacturing ofNrufen Suspension (Drug Registration No. 093957), as stated in application by the firm. The firm had got clearance certificate for import vide Dispatch No. 4739/2021-DRAP dated 30-03-2021. Further, the firm had submitted undertaking with their application that they will submit the original documents later on but till date they have not provided original documents.*

*Accordingly, the firm was directed to clarify its position vide this office's letter No. 14339/2021-DRAP-AD dated 23-09-2021 regarding the manufacturing of unregistered drug and importing material based on mis-declaration made in its application submitted in this office for clearance certificate of Ibuprofen API for purported use in the manufacturing of Nrufen Suspension, having Drug Registration No. 093957 (as mentioned in the firm's application). (Copy of letter attached, Annex 3.)*

*The firm submitted its response vide letter No. REF: 322/PPU2021 dated 24-09-2021 (Diary No. 14115 dated 27-09-2021) wherein they have stated the following:*

*"Please refer to your letter: 14339/2021-DRAP-AD dated 23-09-2021 regarding the afore mentioned subject. Ever since we have taken over the factory from the previous management, as per DRAP Islamabad Letter No. F.l-15/98-Lic (Vol-Ill) dated 10-06-2020, we have never manufactured the product Nrufen Suspension.*

*Our stance regarding the manufacturing of the said product has been extremely straightforward. Our commitment has been assured since the day of the surprise visit of FID Lahore on 08-06-2021 and on personal hearing in front of the Central Licensing Board, in its 282nd meeting held on 31-08-2021. Furthermore, it was also evidentfrom the report of FID sent to DRAP Islamabad, mentioned in the Letter No: F.8-8/2021-QA (M-282-CLB) of DRAP, Islamabad dated 14th September 2021. The product was also not included in the registered product list of the firm, as shown to the FID.*

*After acquisition, the previous management informed us that the product has been registered in 284th meeting of Registration Board held on 31 July to 1 August 2018 and that they will provide us with the necessary registration letters. Due to certain notable factors, C0VID-I9, primarily, and base of operations of new management in Karachi, no communication could be established with the previous management for over a year.*

*In the interim, we applied for the import of raw material of Ibuprofen based on the previous management's claim of*

*possession of the required registration letter. After the raw material was acquired, we demanded for the registration letters, however, the previous management failed to deliver on this promise. After repeated notifications there was no response from them. In the interim, the previous owner passed away.*

*The absence of the registration letter for the said product came as an immediate shock for us and signaled lack of professionalism on their part. Currently, we possess the entirety of the raw material and the relevant documentation. This affirms our Integrity and work ethic to not allow unethical business activity. We hope that this letter clarifies the issue at hand." (Reply attached at Annex 4)."*

*Submitted again for further necessary action, please."*

03. In the light of information provided by area FID Lahore in the above-mentioned report, names of both new and old management of M/s. Perfect Parma Lahore were obtained from the division of Drugs Licensing DRAP which are given as under:

| | |
|---|---|
| **Old management** | Aijaz Ahmad S/o Malik Muhammad Hussain<br><br>Asad Aijaz Malik S/o Aijaz Ahmad<br><br>Azhar Aijaz S/o Aijaz Ahmad. |
| **New management** | Salman Shafi S/o Muhammad Jameel, CEO M/s. Perfect Pharma (Pvt.) Ltd., Lahore<br><br>Farhan Jawed S/o Jawed Iqbal |

04. Show-cause notice vide letter F. No. 04-04/2021-QC dated 14-03-2022 was also issued to both old and new management of M/s. Perfect Pharma Lahore. Replies of both are given as under:

**Reply of old management:**

*"Dear Sir,*

*Please refer to you Lettet No: F.04-04/2021-QC dated 14th March, 2022 regarding above mentioned subject. It is stated that we have absolutely no knowledge of the above mentioned case as we have already sold our factory on 17-04-2019.*

*It is also for your information that the Chief Executive at that time Mr. Aijaz Ahmad has passed away on 16-02-2021. It is therefore requested that above refer notice be recalled."*

**Reply of new management:**

*"In light of the show cause notice issued on grounds of manufacturing and sale of Nrufen suspension please acknowledge our response below. As per inspection conducted on 8th June 2021, by Mrs. Majida Mujahid – Area FID and Ms. Maham Misbah – AD DRAP, the following was quoted by the inspectors in relation to our response submitted under F.88/2021-QA (M-282-CLB) of DRAP, Islamabad, dated 14th Sep 2021:*

*"Nrufen Suspension was not included m the Section-wise registered product list of the firm, as shown to the panel. No Ibuprofen API, unit carton or label of Nrufen suspension was found in the premises at the time of inspection. Further, no production record of Nrufen suspension, testing record of Ibuprofen API, testing record of finished, Nrufen suspension or any retained samples of Nrufen suspension were found in the premises at the time of inspection."*

*In view of all above submissions we have clarified our position that we have not manufactured Ibuprofen Suspension (Nrufen)*

*However, we are also willing to appear personally before the relevant authority or board for further clarification, if required.*

*It is therefore requested that SHOW CAUSE Notice under reply dated March 14th 2022 be*

*recalled."*

05. The representatives of the firm are called before personal hearing.

Proceedings and Decision of 287th meeting of the Central Licensing Board:

06. In response to the personal hearing notice issued, Mr. Salman Shafi, CEO M/s. Perfect Pharma, 5-Km Manga Raiwind road Lahore alongwith Mr. Sarfaraz Sajid Advocate appeared before the Board. In response to the allegations leveled against him, Mr. Salman Shafi submitted before the Board that the clearance of 1000kg Ibuprofen API was made strictly in accordance to law and till date the firm has not utilized the material. Moreover, he denied that firm was involved in the manufacturing and sale of product namely "Nrufen Suspension" since it is not registered till date. No one on behalf of old management of M/s. Perfect Pharma Lahore appeared before the Board.

07. The Board after considering the facts of case, reply of management and thorough deliberations decided as under:

The considering the arguments of the firm decide to call certified photocopy of the set of documents submitted with DRAP, Lahore for clearance of raw material. Moreover, DRAP Karachi would be requested in the light of documents received from DRAP, Lahore office to verify lying of the said material at given address in Karachi. The Board also decided to seek surveillance of the market in Karachi and Lahore for existence of product under investigation. The Drug Registration Board may be requested to provide detail of filling of registration application and proposed name of the drug.

i. Board decided to call certified photocopy of the set of documents submitted by M/s. Perfect Pharma Lahore with DRAP, Lahore for clearance of raw material.

ii. DRAP Karachi would be requested in the light of documents received from DRAP, Lahore office to verify lying of the said material at given address in Karachi House No. 215, Haji Fareer Dad Village (Goth) Liaqatabad, Karachi.

iii. The Board also decided to seek surveillance of the market in Karachi and Lahore for existence of product under investigation

iv. The Drug Registration Board may be requested to provide detail of filling of registration application and proposed name of the drug

08. FID-II DRAP, Karchi in compliance to decision of the board communicated vide letter No. F.03-31/2022-QC (287-CLB) dated 26th july, 2022 visited the said premises House No. 215 Haji Faqer Dad Goth Liaqatabad Karachi on 19-08-2022, to verify the goods laydown there as per the claim of the manufacteurer. *During the visit it was found that 40 drums each of 25Kg of Ibuprofen raw material having Batch No. 20123232 with manufacturing date 27-12-2020 and expiry date 12-2024 were stored there.*

. The Drug Registration Board was requested to provide detail of filling of registration application and proposed name of the drug requisite information is as under:

i. As per available record of PE&R Division, Nrufen Suspension is not found registered in the name of M/s. Perfect Pharma.

ii. Firm has submitted application for registration of Nrufen Suspension 100mg/5ml which was approved in 284th meeting of Registration Board. Furthermore, registration letter of said product has not yet been issued due to brand name resemblance.

. Additional Director DRAP, Lahore in compliance to decision of the board communicated vide letter No. F.10941/2022-DRAP (Add.Dir) dated 13th October, 2022 following certified photocopy of the set of documents submitted by M/s. Perfect Pharma Lahore with DRAP, Lahore for clearance of raw material:

i) Form-8

ii) Undertaking of source approval

iii) Undertaking for consumpaton of said material in registered product

iv) Undertaking for submission of original documents

v) Commercial invoice

vi) Packing and weight list

vii) Form 3

viii) Form 7

ix) Certificate of analysis

x) Certificate of GMP

xi) License DML copy

xii) Renewal of DML

xiii) Fee deposit slip DIL

xiv) Form 2 Application for license to import drugs

**Proceedings and Decision of 289th meeting of the Central Licensing Board**:

i) ***To direct area FID for 100% Sampling (all containers) of illegally imported API Ibuprofen having Batch No. 20123232 held at Karachi for identification testing by CDL for confirmation of Ibuprofen.***

ii) ***After sampling, seizure of small quantity (1 -2 Containers) as case property (evidence of illegal import) and remaining quantity to be ordered not to dispose at the storage premises.***

iii) ***Assistant Director DRAP Lahore to investigate the matter of illegal import of API Ibuprofen by the firm based on mis-declaration/fake/forged documents and to submit a comprehensive report with clear recommendations and fixing the responsibility of unlawful import with reference to relevant provisions of Act/Rules.***

**REQUEST OF SHIFA INTERNATIONAL HOSPITAL REGARDING PURCHASE AND USE OF DRUG COMPOUNDED BY A LOCAL PHARMACEUTICAL COMPANY FOR THEIR HOSPITAL USE.**

Brief facts of the case are under;

02. Mrs. Salwa Ahmed, Chief of Pharmacy, Shifa International Hospital Ltd; H-8/4, Islamabad has forwarded a letter regarding no objection certificate (NOC) for purchase and use of drugs compounded by a local pharmaceuticals company, for their hospital use. She has added that M/s. Wilshire Laboratories (Pvt) Ltd; Quaid-e-Azam Industrial Estate, Kotlakhpat, Lahore are compounding some clinically needed (both registered and unregistered) drugs under license # 05-352-0070039102P (under form 9, Rule # 16) valid until

09th June, 2021 issued by competent authority of Chief Drug Controller Punjab Licensing Authority, Lahore.

03. The Routine procedure of such license holder pharmacies usually is; they compound and sell medicines directly to patients according to proper physician prescription. But here being a pharmaceutical company, they are also offering these compounded products to hospitals under warranty and invoice to that hospital can further dispense these to patients according to perception. As M/s. Wilshire is offering products that are either chronically short in market or not yet registered, and are of high clinical importance for treating patients.

04. They therefore, requested for No Objection Certificate, if their hospital procures the stock to facilitate their patients. The case was dicussed in 85th Meeting of the policy Board wherein the policy board decided as under;

> *"The Authority directed the Division of QA&LT to initiate the legal proceedings against M/s Wilshire Laboratories (Pvt.) Ltd, Lahore on account of manufacturing and selling unregistered drugs with unapproved MRP under the umbrella of MRP."*

05. The decision of the Authoriy was forwarded to the Area FID vide letter F. No. 04-11/2020-QC dated 28-07-2020 for investigation of the matter and to take appropriate action under the law in the matter and report to the division of QA&LT for further necessary action in the matter.

06. In response to the above-mentioned letter, Area FID Lahore conducted an inspection of M/s. Wilshire Laboratories and submitted report vide letter No. 10919/2020-DRAP (L-VII) dated 07-08-2020 contentes of which are as under;

> *"The inspection of M/s. Wilshire Laboratory (Pharmacy) was conducted on 29-07-2020, with reference to DRAP, Islamabad letter No. 04-11/2020-QC dated, 28-07-2020.*
>
> *M/s. Wilshire Laboratory (Pharmacy) was issued Form 9 License No. 05-352-0070-039102P dated, 19-01-2019, by Chief Drugs Controller, Punjab Licensing Authority, Lahore. Hence the firm is hereby licensed to sell/compound or prepare on prescriptions the drugs and sell or distribute all types of registered drugs on the premises situated at plot No. 124/1, Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore.*

*The pharmacy is situated in a separate block with separate entry from the pharmaceutical manufacturing plant, which was also located on the same plot i.e., 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore. At the time of inspection, the following products were displayed for sale in Wilshire Labs (Pvt.) Ltd., (Pharmacy) and were Not to Dispose off Under Section 18 (1) of the Drug Act, 1976 and DRAP Act, 2012 (copy of Form-1 attached): -*

| S. No. | Name of Drugs/Articles | Batch No./Lot No. | Mfg. Date | Exp. Date | Manufactured/Dispensed by | Quantity |
|---|---|---|---|---|---|---|
| 01 | Cabergoline 0.5mg Tablets | 001 | Jan.2020 | Jan. 2021 | M/s. Wilshire Labs (Pharmacy), Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore | 1x8x5 |
| 02 | Acetazolamide 250mg Tablets | 001 | April 19 | April 2020 | -do- | 1x10x6 |
| 03 | Phenytoin Sodium 100mg Capsule | 001 | 07/19 | 06-2020 | -do- | 1x20x5 |
| 04 | Mesalamine (USP) 4g/100ml Rectal suspension Enema | 006 | Oct.2019 | Sep. 2020 | -do- | 1x5 |
| 05 | Fludrocortisone 0.1mg Tablets | 001 | Dec.2019 | Dec. 2020 | -do- | 1x30x5 |
| 06 | Purcalopride 2mg Tablets | 002 | Dec. 2019 | Dec. 2020 | -do- | 1x10x4 |
| 07 | Hydrocortisone 10mg Tablets | 001 | Nov. 2019 | Nov. 2020 | -do- | 1x30x5 |

*The above-mentioned drugs were Not to Dispose off in the presence of Mr. Muhammad Faisal Javed, Qualified person (person present) and Mr. Saqlain Arshad, Manager Regulatory (Person present). The witnesses were also recorded on the form. The reasons for Not to Dispose off are:*

*i) The drugs at S. No. 2-3 were expired.*

*ii) The products were compounded drugs as per firm's claim and were meant for immediate patient use on prescription. However, the drugs were compounded in January 2020 and in the year 2019 and were placed on*

*the shelves of pharmacy for sale. The prescriptions of patients were also not available.*

*iii) The drugs were not registered, brand names were printed, prices were also mentioned on the unit cartons.*

*iv) The compounded drugs were also supplied to different hospitals such as Shifa International Hospital Islamabad, Aga Khan Hospital, Karachi etc., The record of patients were not available at the time of inspection.*

*The firm was directed to explain its position in this regard.*

*The Competent Authority i.e. Chairman Registration Board is requested to grant permission to keep the stock as evidence of offense for further three months or till the decision of case under section 18(1) of the Drugs Act, 1976, and rule framed thereunder.*

*The case is being referred to the Competent Authority under Section 18(1) of the DRAP Act, 2012 and DRAP Act,. 2012 to seek further orders as to the action to be taken in this regard. The complete case will be submitted after completion of investigation and other codal formalities in this regard please."*

07. In the above-mentioned report, area FID Lahore has requested to grant the permission to keep the stock ordered not to dispose. In this regard, the Director QA&LT is empowered to grant extension in period not to dispose of for a period of 3 months by the Central Licensing Board in its 273rd meeting held on 15th January, 2020. Since the post of Director QA&LT is vacant, the case is presented before the Central Licensing Board for grant of extension in order not to dispose of to FID VII Lahore for further processing of the case.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

08. The Board after considering the facts of the case and thororugh delibration aceeded the request of are FID Lahore and decided to grant permission of safe custody of the seized stock till the decision of the case.

09. The Board also decided to direct Federal Inspector of Drugs to complete the investigation and submit comprehensive report with recommendations without further delay for consideration of the Board.

10. FID VII Lahore vide letter No. 11315/2020-DRAP (L-VII) dated 12-08-2020 on the subject ***"Request of Shifa International Hospital Regarding Purchase and use of Drugs Compounded by a local Pharmaceutical Company for Their Hospital Use."*** Wherein has stated as under;

> *"Inspection of M/s. Wilshire Laboratory (Pharmacy) was conducted with reference to DRAP, Islamabad letter No. F.04-11/2020-QC dated 28-07-2020, dated on the subject cited above.*
>
> *At the time of inspection Mr. Faisal Javed, Qualified Person, Mr. Saqlain Arshad, Manager Regulatory were present along with other technical staff.*
>
> *The findings of the inspection proceedings are cited below:*
>
> *1 M/s. Wilshire was issued Form 9 License No. 05-352-0070-039102P dated, 19-01-2019, by Chief Drugs Controller, Punjab Licensing Authority, Lahore. Hence the firm is hereby licensed to sell/compound or prepare on prescriptions the drugs and sell or distribute all types of registered drugs on the premises situated at plot No. 124/1, Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore.*
>
> *2 The pharmacy is situated in a separate block with separate entry from the pharmaceutical manufacturing plant, which was also located on the same plot i.e., 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.*
>
> *3 In the pharmacy, it was observed that compounded / unregistered drugs were placed in shelves for sale, Some drugs were expired and compounded / manufactured in January 2020 and in the years 2019. The prescription of patients for whom the drugs were manufactured were also not available.*
>
> *4 The brand names and unapproved prices were also mentioned on the unit carton. The drugs were Not to Dispose off under section 18 (1) of the Drugs Act 1976 and DRAP Act, 2012.*

*The detail is cited below:*

| ***S. No.*** | *Name of Drugs/Articles* | *Batch No./Lot No.* | *Mfg.Date* | *Exp. Date* | *Manufactured/Dispensed by* | *Quantity* |
|---|---|---|---|---|---|---|
| ***01*** | *Cabergoline 0.5mg Tablets* | *001* | *Jan.2020* | *Jan.2021* | *M/s.Wilshire Labs (Pharmacy), Quaid-e- Azam Industrial Estate, Kot Lakhapt, Lahore* | *1x8x5* |
| ***02*** | *Acetazolamide 250mg Tablets* | *001* | *April 19* | *April 2020* | *-* | *1x10x6* |
| ***03*** | *Phenytion Sodium 100mg Capsules* | *001* | *07/19* | *06-2020* | *-* | *1x20x5* |
| ***04*** | *Mesalamine (USP) 4g/100ml Rectal suspension Enema* | *006* | *Oct.2019* | *Sep.2020* | | *1x5* |
| ***05*** | *0.1 mg Fludrocortisone Tablets* | *001* | *Dec.2019* | *Dec.2020* | *-* | *1x30x5* |
| ***06*** | *2mg Prucalopride Tables* | *002* | *Dec.2019* | *Dec.2020* | *-* | *1x10x4* |
| ***07*** | *Hydrocortisone 10mg Tablets* | *001* | *Nov. 2019* | *Nov.2020* | *-* | *1x30x5* |

*5 On the ground floor of pharmacy the compounded products were displayed for sale, and on the first floor the manufacturing facility was situated, the facility was divide into two sections:*

*i) Non sterile area.*

*ii) Sterile area.*

*In the non sterile area, a small rotatory compression machine of 8400 tablet /hr capacity cone mixer of 2 kg capacity, ribbon blade mixer 2kg capacity and blister machine of 30*

*blister/min capacity were installed. The dispensing booth installed was without air circulation. Weighing balance was not available. The capsule filing machine was not available in the last inspection and in this inspection as well. The firm manufacture phenytoin sodium (phenzen) capsule. A solution preparation vessel was used in injectable area as well as for enema preparation. HVAC system was not installed in non sterile area.*

*6 In the sterile area, after buffer, one room was provided for manufacturing, filling and sealing of injectable. One safety cabinet was installed, under which manual filling /sealing facility for injectable, was provided. HVAC system was installed in the area. Small autoclave was installed. No storage area for compounding raw materials / chemicals was provided.*

*7 Regarding the Quality Control Testing the firm has developed SOP, in which it was mentioned that "for analytical testing, the pharmacist will submit samples of compounded preparations to analytical testing laboratory, at a frequency deemed suitable or at the request of the institution to the nominated out source lab with valid agreement in place" which indicates that quality control testing of all batches were not being performed. However, upon query, the qualified person, informed that there is no agreement of quality control testing between any institution and laboratory. Moreover, as per routine practice the compounded drugs were not being tested in quality control.*

*8 The firm has developed SOPs for fixation of prices, procedure for institutional sale and procedure for street sale* ***(copies attached as Annex-6)***

*9 In the firm's SOP for institutional sale it is mentioned at S. No. 3.7 that "prescription will be required for record fde at site However during inspection the qualified person informed that hospitals just provide purchase orders and the record of prescriptions in the case of hospital/ institutional supply was not available.*

*10 It was observed that on the unit carton the* ***"best before"*** *term is used instead of expiry date or beyond use date. As per USP 795 CNS Beyond Use Dates (BUD) of compounded drugs*

*should be given and the drugs are meant to be used immediately, however the firm was giving one year expiry for every product and claimed that one year expiry date can be given, provided stability testing is being performed (No reference provided) . The firm informed that they are conducting stability studies for all the compounded products. Stability data has not been provided by the firm.*

*11 As per SOP of the firm regarding purchase of raw materials, the raw materials required for the compounded products are procured from authorized supplier/vendor and are transported through an international courier. It was observed that the NOC or clearance of raw material intended to be used in compounding of drugs was not taken by the firm. The firm informed that the raw material is imported directly through courier service, as the quantity required is small. The qualified person informed that the raw material testing was being performed by quality control laboratory of Wilshire Labs.*

*12 The Wilshire pharmacy was mainly involved in the compounding / manufacturing of following products namely:*

| ***S. No.*** | ***Products*** | ***Packing*** | ***MRP*** |
|---|---|---|---|
| *1* | *Cabergoline 0.5mg Tablets* | *8's* | *Rs. 3900/-* |
| *2* | *Acetazolamide 250mg Tablets* | *10's* | *Not mentioned* |
| *3* | *Phenytion Sodium 100mg Capsules* | *20's* | *Rs. 350/-* |
| *4* | *Mesalamine (USP) 4g/100ml Rectal suspension Enema* | *l's* | *Rs. 798/-* |
| *5* | *Fludrocortisone 0.1 mg Tablets* | *30's* | *Rs. 5500* |
| *6* | *Prucalopride 2mg Tables* | *10's* | *Rs. 683/-* |
| *7* | *Hydrocortisone 10mg Tablets* | *30's* | *Rs. 2800/-* |
| *8* | *Ascorbic Acid Vials* | *l's* | *-* |

*13 With regard to high prices of compounding products, the firm informed that they receive standing orders from institutions and hence it is not possible to import the raw material in large quantities, so they import the raw material through courier service*

*and the cost incurred in very high. The institutions I hospital agreed with these prices as they are still cheap as compared to the lawfully imported medicines.*

*14 The firm has signed MOU with Fatimiyah hospital, Karachi to aid hospital in emergency management by compounding the medicines as needed by the hospital for patients.*

*15 The firm also provided purchase orders from Shifa International Hospital, Islamabad, Agha Khan Hospital, Karachi and Liaquat National Hospital, Karachi patient names were not mentioned in any P.O. In the "request status" of P.O of Shifa International Hospital, Islamabad it was mentioned "Normal" which clearly indications that there was no emergency for any particular patient.*

*16 It was also observed that the firm has given warranties for the compounded drugs and claimed that "the goods referred to here in do not contravene in any way the provision of section 23 of the Drugs Act 1976. This practice is also questionable that how come a warranty be given for compounded / unregistered drugs.*

***Conclusion:***

*Keeping in view, the above mentioned observations, the mater may be forwarded for further necessary action in the light of the decision of Authority. However, it was also noted that the Punjab Licensing Authority, Lahore has granted License (Form-9) to establish pharmacy situated at 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhapt, Lahore, where as the Drug Manufacturing License to the firm was also issued at the same address, before Form-9. Hence this matter may also required clarification, whether Form-9 can be issued at the same premises, where a pharmaceutical manufacturing plant has already been granted DML under the Drugs Act 1976. The matter may also be referred to Provincial Government being Licensing Authority."*

. FID VII Lahore further requested clarification regarding that whether Form-9 (issued by the Government of Punjab) can be issued at the same premises and address of a Licensed Pharmaceutical Manufacturing Plant having Drug Manufacturing License

issued under the Drugs Act, 1976. File was forwarded to the division of Drugs Licensing for their views/comments regarding the query of FID VII Lahore.

12.Legal opinion was seeked and the said division informed that Division of Drug Licensing of DRAP under section 4(b) and 7 (u) of the DRAP Act, 2012 read with section 5 of the Drugs Act 1976 and rules made there under, issues the Drug Manufacturing License (DML), after approval by the Central Licensing Board. Furthermore, under Section 6 of the Drugs Act, 1976 the Provincial Governments regulate the sale of drugs in prescribed manner and may for that purpose make such orders and issue such directions to the importers, manufacturers, stockiest, retailers or other dealers of drugs, as they may deem fit. Therefore, Punjab Drugs Rules 2007 were notified by the Provincial Government in super-session of the Punjab Drugs Rules 1988, the Rule 16 of the ibid rules is given here below as a ready reference: -

> *16. Forms of licenses to sell drugs. — The licensing authority shall issue a licence of a pharmacy in Form 9 and a licence of a medical store in Form 10 and a license of distributor in Form 11.*

13. The Conditions for License to Sell a drugs are given in Rule 19 and Rule 20 of the Punjab Drugs Rules 2007. Manufacturing of drugs and sell of drugs are two distinct functions. License to manufacture drugs is issued by Division of Drug Licensing of DRAP for any pharmaceutical unit established in an industrial area with minimum area requirement 2000 sq yard under LRA Rules 1976. Moreover, Drug Manufacturing License is neither issued on residential area nor on commercial area. On the other hand, specific area (residential, commercial, industrial) is not mentioned for issuance f a license to sell a drug under the Punjab Drugs Rules 2007. In fact, it is clear thats of drug is a commercial activity, therefore, prima fascige regarding the area, there is conflict between the Drug (Licensing Registration & Advertising) Rules, 1976 and the Punjab Drugs Rules 2007.

. Moreover, both the Drugs Act, 1976 and LRA Rules 1976 made under the said act are part of Schedule VI of the DRAP Act, 2012. Furthermore, it is specifically mentioned in the Section 32 (2) of the DRAP Act, 2012, "In case of inconsistency between the provisions of this Act and any other law for the time being in force, the provisions of this Act shall prevail". In this regard if Form 9 is issued on the area which is already approved by Central Licensing Board for purpose of manufacturing of drugs, then it is violation of condition mentioned in Schedule B & B1 of the (Licensing Registration & Advertising) Rules, 1976.

. Firm has provided false warranty, Manufactured without DML, without registeration of the products, under the umbrella of compounding.

**Proceedings and decision of 289th meeting of CLB held on 23-01-2023:**

**"The Board after considering the facts of the case and thorough deliberations decided to show cause the firm and call them for personal hearing "**

**Case No. 03: UNREGISTERED DRUG "SUDOCREAM ANTISEPTIC HEALING CREAM" MANUFACTURED BY M/S. TOSARA PHARMA, LTD., IRELAND**

FID-III Karachi visited premises of M/s; Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi_on 20-05-2021 wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3

| S. No. | Name of Drug | Reg No | Lot No. | Mfg. Date | Exp. Date | Mfg.by |
|---|---|---|---|---|---|---|
| 01 | Sudocrem Antiseptic Healing Cream | Nil | 135838 | Nil | 09-04-2023 | M/s. Tosara Pharma Ltd,<br>Baldoyle Ind. Est, Dublin 13, Ireland. |

02. The sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis vide memorandum No. DHB-16/2021 to 17/2021-FID-111 (K) dated 20th, May, 2021.

03. Portion of Sealed sample was sent to Chairman, Registration Board, DRAP Islamabad vide this office letter of even number dated 20th, May, 2021.

04. M/s; Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi_was asked to provide bill

warranty in connection with the purchase of above said drug vide this office letter of even number dated 20th May 2021, Reminder-I on dated 21th June 2021, reminder-II on dated 16th July 2021 and reminder-III on dated 26th July 2021.

05. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared above said samples "Sudocream Antiseptic Healing Cream" sent to CDL Karachi by FID-III Karachi as **"Unregistered drug"** vide test report No. R.KQ.121/2020 dated 19-07-2021. Wherein Federal Government Analyst, CDL Karachi, has informed that the sample of product. Details of the test report are given as under:

*"Desscription: Off white cream*

*Identification: Zinc (Oxide) identified*

*Assay for Zinc Oxide:*

*Determined amount/100gm: 15.8534gm*

***Remarks: -** 1) The assay result for Zinc Oxide has been calculated as 15-8534gm per 100gm.*

*2) Since, Zinc Oxide is an allopathic drug and the sample (Sudocream Antiseptic Healing Cream). Manufactured by M/S. Tosara Pharma Ltd. Ireland is not registered with DRAP (Directorate of Registration), Islamabad, Government of Pakistan.*

*Hence, the sample is declared **"Un-Registered Drug Product"** under the Drugs Act, 1976."*

06. An explanation letter of even number dated 20 *July 2021* was accordingly issued to M/s; Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi for explaining their position in the matter of manufacturing/selling of above mentioned UN-REGISTERD DRUG PRODUCT.

07. M/s; Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi vide their letter No. Nil dated 13th, August 2021 Provided the Bill/warranty No. 746 dated 17 May 2021 from Mr. Muhammad Hussain (Owner) Haroon center Ist, Floor Marriot Road near chat laine Boulton Market Karachi in connection with the purchase of above said drug

08. Undersigned vide this office letter of even number dated 20th August 2021, Reminder -01 on dated 03rd September 2021 and Reminder -02 on dated 04th, February 2022 was asked Mr. Muhammad Hussain (Owner) Haroon center lst, Floor Marriot Road near chat Laine Boulton Market Karachi to verify the same and provide subsequent bill warranty in connection with purchase of above said drug. (Annexure-M, N, & 0) But no any reply has been received till date.

09. Fid reported in the light of Federal Governmnt Analyst, Central Drug Laboratory test report No. R. KQ.121/2021 dated 19'h July 2021 M/s; Danish Brothers, Shop #14, Maji Market, Marriot Road, Kuichi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi was found involved in selling UNREGISTERD DRUG PRODUCT and violated the section 23(1)(a)(vii), 23(1)(i) of the Drugs Act 1976, punishable under section 27(1)(a) and 27(4) of the Drugs Act 1976 and *rules* framed thereunder.

Recommendation: -

Following accused may kindly be prosecute in Drug Court of Sindh, Karachi: -

1. M/s; Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso lall M.A. Jinnah Road, Karachi.

2. Danish S/0 Abid Hussain, Proprietor of Mis. Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi

   CNIC No.42301-8035242-9

14 M/s; Danish Brothers was Show caused vide letter no. 04-03/2021-QC dated , *December 9, 2022* in the light of above-mentioned laboratory report, found involved in selling Un-registered drug which is a prohibited under Section 23(1)(a)(vii) of the Drugs Act 1976 read with Schedule-II of the DRAP Act, 2012 and punishable under Section 27(1)(a) and 27(4) of the Drugs Act 1976 read with Schedule-III of the DRAP Act, 2012, therefore, you are hereby required to show cause in writing that, why the following action(s) should not be initiated against you.

i. Prosecution in Drug court.

ii. Any other action the Board may deem fit.

15 Reply of M/s; Danish Brothers was received vide letter No.892/22 dated 19-12-22 in reply to show cause in which he briefed that he was ignorant of the fact that the said item is a allopathic medicine and considered it as a general item. He has now stopped the selling of this item and ensures he will not be involved in its selling again.

**Proceedings and decision of 289th meeting of CLB held on 23-01-2023:**

**"The Board after considering the facts of the case and thorough deliberation decided to show cause following accused and called them for personal hearing:**

i. **Ms. Danish Brothers, Shop#14, Maji Market, Marriot Road, Kutchi Gali no. 01, Denso Hall M.A. Jinnah Road, Karachi**
ii. **Danish S/o Abid Hussain, Proprietor of Ms. Danish Brother, Shop#14, Maji Market, Marriot Road, Kutchi Gali no. 01, Denso Hall M.A. Jinnah Road, Karachi**
iii. **Muhammad Hussain, Harron Center 1st Floor, Marriot Road near Chat Lane Boulton Market Karachi."**

**4**: **MANUFACTURE AND SALE OF SPURIOUS AND SUBSTANDARD DRUGS- M/S. HOORAIN IMPEX, KARACHI**.

Area FID along with FIA team raided the premises of M/s. Hoorain Impex Lasani Arcade Mezzanine floor, Ranchore line, Karachi on 18-01-2022 as per information received from FIA Office, Corporate Crime Circle, Karachi that Muhammad Zeeshan of M/s. Hoorain Impex Lassani Arcade Mezzanine floor, Neckless Street Ramswami, Ranchore line, Karachi is involved in manufacturing of fake/spurious medicines in the name of different Pharmaceutical Industries.

At the time of visit Muhammad Zeeshan was found available and huge stock of following suspected spurious/ fake/ counterfeit medicine were recovered which were taken in custody by FIA officials.

| S.No. | Name of medicine |
|---|---|
| 01 | Disprin Tablet |
| 02 | Aldactone atbelet |
| 03 | Cefixime Suspension |
| 4 | Cefim Suspension |

| | |
|---|---|
| 5 | Ventoline expectorant |
| 6 | Inocef injection |
| 7 | Cefim DS suspension |
| 8 | Kinz Injection |
| 9 | Water for injection |
| 10 | Norvasc Tablet |

On enquiry Muhammad Zeeshan admitted that he is the owner of above mentioned premises and engaged in the business of supply of medicine. He also admitted that he has purchased the raw material (Cefixime) from local market and repack the same product with the label of Cefim and Cefim DS suspension of M/s Hilton Pharma Karachi. He further disclosed that the repacking activity is being carried out at the premises of Muhammad Moiz situated at Liaquatabad Karachi. He further admitted that Mr Sikander pick the bottles without labelling and return the same in packing of Cefim and Cefim DS suspension of M/s Hilton Pharma. On further inquiry Mr Zeeshan admitted that the printing material of Hilton Pharma and other brands were provided to him By Mr Mirza Nadeem Baig. Mr zeeshan informed that Mr Adnan is his brother and he is also involved in purchasing and selling of medicine in question.

FID along with FIA team immediately raided the premises situated at House No.ROW-7, Street 1, C-1 Area Liaquatabad Dakhana Karachi. Moiz Ahmed was available at the time of raid and in his presence the team searched the premises and found powder filled and empty bottles of suspected Cefixime suspension without any label in bulk quantity. Moiz Ahmed admitted that Mr Sikandar provides him filled bottles of suspected cefixime suspension without labelling to him for repacking and he return the same to Mr Sikander after labelling/repacking into Cefim suspension and cefim DS suspension of M/s Hilton Pharma

FID alongwith FIA team also raided the premises of Mr Nadeem Baig situated at House No.B-11/75, Bismillah Hotel, Asif Colony Manghopir Road, Karachi. Mirza Nadeem Baig was found available at the premises. On enquiry he

admitted that he had supplied the printing material of M/s Hilton Pharma and other brands to Mr Muhammad Zeeshan. During search various unit cartons and literatures of M/s Hilton & Other brands were recovered from the premises which were taken in custody by FIA officials. Mirza Nadeem Baig also disclosed that Mr.Hameed provided the printed material to him.

Several samples of drugs suspected to be fake/spurious were taken for the purpose of test/analysis on prescribed Form-3 and sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis

At the time of inspection Muhammad Zeeshan, & Mirza Nadeem Baig were asked to provide bill warranty or legal documents in connection with the medicines & printing material available in the said premises but they failed to provide the same.

In the light of above Mr. Muhammad Zeeshan of M/s. Hoorain Impex Lassani Arcade Mezzanine floor, Neck lass Street Ramswami, Ranchore line, Karachi and others found involved in manufacturing in unlicensed premises, labelling & repacking of suspected fake/spurious drug and violated the Section 23 & 27 of Drugs Act, 1976 and rules framed thereunder.

**FID's RECOMMENDATION:-**

Grant permission to register FIR against following accused:-

| S.No. | Name of Accused | CNIC No. | ADDRESS |
|---|---|---|---|
| 01 | M/s. Hoorain Impex | Nil | Lassani Arcade Mezzanine floor, Neckeass Street Ramswami, Ranchore line, Karachi. |
| 02 | Muhammad Zeeshan S/O Muhammad Haroon Memon | 42301-7632141-7 | Flat No.601, Madina Corner Nakcless Street, Nashtar Road,Ranchoe line, Karachi. |
| 03 | Muhammad Adnan S/o Muhammad Haroon Memon | 42301-4370766-9 | Flat No. 501, Safa Marwa Tower Ranchorline Arba Arcade Karachi. |
| 04 | Sikandar Abdul Aziz S/o Abdul Aziz | Nil | Flat No. 08, Seema Manzil, Meethadar Karachi. |
| 05 | Moiz Ahmed S/o Iftikhar Ahmed | 42101-5352131-7 | House No. ROW-7, Street 1, C-1 Area Liaquatabad Dakhkhana Karachi |

| | | | |
|---|---|---|---|
| 06 | Mirza Nadeem Baig S/o Mirza Abdul Salam | Nil | House No. B-11/75, Bismillah Hotel Asif Colony, Manghopir Road Karachi |

Permission to lodge FIR was granted with approvals and communicated vide office letter of even number dated 28-01-2022.

Area FID submitted investigation report of FIA and requested for grant of permission of prosecution against the accused.

In view of report, a joint raid was conducted by DRAP & FIA team comprising of Ms.Hira Bhutto and concerned officials of Federal Inspector of Drugs alongwith Inspector Asfandyar Khan, Sub-Inspector Muhammad Tahir, Sub-Inspector Mehwish Iftikhar visited M/s.Hoorain Impex Lassani Arcade Mezzanine Floor Necklass Street Ramswami Karachi, where Muhammad Zeeshan was found available. During the raid huge quantity of following suspected to spurious/ counterfeit, altered drugs/medicine were recovered.

FID took following samples for test/analysis purpose.

1. Disprin Tablets
2. Aldactone Tables
3. Cefim Suspension
4. Ventoline Expectorant
5. Inocef Injection (Vial)
6. Cefim DS Suspension
7. Kinz Injection
8. Cefixime Suspension
9. Norvasc Tablets
10. Cefixime suspension

CDL, Karachi declared Disprin Tablet, Cefim Suspension and Cefim DS Suspension as Spurious/ Substandard. After that FID submitted complaint in FIA.

Following were involved in illegal manufacturing / alteration / sale & purchase of spurious / sub-standard drugs / medicine, thereby committed

the offence punishable U/s 23 & 27 r/w Section 30 of Drug Act-1976 R/w 109 PPC.

1. Muhammad Zeeshan S/o Muhammad Haroon Memon
2. Muhammad Adnan S/o Muhammad Haroon Memon
3. Sikandar Abdul Aziz S/o Abdul Aziz
4. Moiz Ahmed S/o Iftikhar Ahmed
5. Mirza Nadeem Baig S/o Mirza Abdu Salam

Further accused from serial No 01 to 05 had been arrested while one accused namely Hameed s/o Unknown is still at large who used to give printed material to above mentioned accused.

Conclusion of report :

"During investigation, it has been concluded so far that accused Muhammad Zeeshan in connivance of accused Sikander, Muhammad Moiz, Mirza Nadeem and Muhammad Adnan and others are involved in illegal manufacturing /alteration / sale & purchase of spurious / sub-standard drugs / medicine."

**Proceedings and Decision of 289th Meeting of Central Licensing Board:**

The Central Licensing Board considered the facts of the case and decided to show cause the accused persons under Section 23 of the Drugs Act 1976 read with Schedule III of DRAP Act 2012 and called them for personal hearing in next meeting. Board further directed that area FID will coordinate with FIA for necessary arrangements into the matter.

## MINUTES FROM QA DIVISION

**Case No. 01: ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S. EG PHARMCEUTICALS 13-A INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

Federal Inspector of Drugs-I Islamabad inspected the premises of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad on 25th January 2022 to investigate PM portal complaint regarding the import of illegal raw material, lack of qualified persons and non-compliance of GMP by M/s. EG Pharmaceuticals Islamabad. During the inspection following Raw Material was recovered from the Raw Material Store (RMS) of the M/s EG Pharmaceutical Islamabad without import documents/NOCs issued by DRAP R&I Section as well as evidence of purchase:

| S. | Name of Drug | Batch No. | Quantity | Mfg. by |
|---|---|---|---|---|
| 01. | Amlodipie Besylate powder | AMB/057/03/21 | 0.29kg | M/s. Prudunce Chemical |
| 02. | Diclofenac Potassium | 20190810 | 109.125 | M/s. Zanghai Gindjiuzhou Pharma Henan Dongtai Pharma Co Ltd |
| 03. | Diclofenac Sodium | 20200520 | 3.135 | N/A |

| | | | | |
|---|---|---|---|---|
| 04. | Tizanodium powder | N/A | 2.50 | N/A |
| 05. | Ketorolac Trtonetamol/ Tronethamine | 0361220 | 0.800 | M/s. Satyalidivis Pharma |
| 06. | Lidocaine HCl | N/A | 0.804 | N/A |
| 07. | Metronidazole | | 13.000 | N/A |
| 08. | Paroxetine Calcium | | 1.000 | N/A |
| 09. | Rosuvastatine Calcium | | 36.0 gm | N/A |
| 10. | Vitamin B3 | | 3.10gm | N/A |
| 11. | Valsartan | | 0.36 | N/A |
| 12. | Metformin | MEF/1010233 | 598.950 | AARTI Begus Ltd India |
| 13. | Loratidine | NRHB0534 | 5.000 | Morepan Lab India |
| 14. | Sitagliptin | | 3.734 | N/A |

02. The mentioned raw materials were ordered "Not to Dispose of' on Form-1 dated 25-01-2022 under schedule-V Section (l)(i) of DRAP Act 2012. Permission in order not to dispose of was granted to FID I Islamabad vide letter F.03-05/2021-QC dated 21st February 2022.

03. M/s. EG Pharmaceuticals Islamabad was directed by FID I to submit import documents/NOCs issued by the DRAP I&E Department or as well as evidence of purchase of the above-mentioned raw materials vide letter No. F. 03-07/2004-FID-I(ISD) dated 31st January, 2022 with subsequent reminders on 17th March 2022 and 13th April 2022.

## **Firm's Response**

04. The firm replied vide letter dated 12th April 2022 and admitted that they are obtaining raw material on loan from the local manufacturers/local markets as they are producing their products in small quantities to fulfill institutional commitments and to avoid market shortage and hence small amount required did not warrant import. Furthermore, Reference to the letter No. F.03-07/2004-FID-1(ISD) dated 13th April 2022, M/s EG Pharmaceuticals through its letter dated 12th April 2022, stated, "we have to get locally either because

of their equipment in very low quantity, hence not possible to import, or we had to get them to avoid shortage in the market. As you know that because of International scenario, consignments now a days are delayed and even cancelled. Almost all Pharmaceutical companies do this in Pakistan and Internationally."

05. In light of the firm's response, FID I Islamabad directed the firm vide letter No. F.03-07/2004-FID-I(ISD) dated 25th April 2022 to disclose the sources from which they had procured the above-mentioned raw material on loan in order to identify the culprits & to discourage such practices since it is violation of Import & Export rules 1976 & Section 23(l)(e) and punishable under Section 27(c) of the Drugs Act, 1976. The firm was further directed to provide complete information regarding batch sizes of the aforementioned items as well as the institutional orders placed with the firm. The firm has failed to respond till date and verbally the representatives of the firm refused to provide further cooperation in this matter.

06. Considering the circumstances mentioned above, FID-I Islamabad has concluded that the firm is in violation of Import & Export rules 1976 & Section 23(1)(e) of the Drugs Act, 1976 read with Schedule-II(1)(A)(x)(e) punishable under Section 27(c) of the Drugs Act, 1976 read with Schedule-III(l)(c) of the DRAP Act, 2012 and cognizable under Section 30(1)(a) of Drugs Act,1976 read with Schedule-lV (l)(a) of the DRAP Act, 2012, and has requested as under:

v. Cancellation of Registration of the above-mentioned products
vi. Cancellation of DML of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad
vii. Grant permission for prosecution M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad through its CEO Mr. Shaukat Hayat Khan and its QC manager Mr. Ihtisham-ul-Haq.

07. Subsequently case was forwarded to the Registration Board and proceeding of Board are as under:

**Proceedings and Decision of 320th meeting:**

The case has been deferred due to paucity of time.

## Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion and thorough deliberations decided as under:

- Import and export of raw materials does not fall under the mandate of Registration Board. Hence, the case is referred back to QA&LT Division to decide the case under the Drugs (import & Export) Rules, 1976 under Drugs Act, 1976.
- Recommendation of FID to cancel DML of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad pertains to Licensing Division. Hence the QA&LT Division is advised to forward the case to Licensing Division.

08. The firm had violated the following clauses:

xv) The Drugs Act 1976 states in Chapter III under section 23, sub-section (e) as

**CHAPTER III**
**PROHIBITIONS**

**23. Import, manufacture and sale of drugs.–**(1) No person shall himself or by any other person on his behalf-

**(e) import or export any drug for the import or export of which a licence is required, except under, and in accordance with the conditions of, such licence;**

**&**

(B) The Section 6 sub-section (6.2 (6.2.2)) of Schedule B-II under The Drugs (Lic, Reg & Adv.) rules 1976.

**SECTION--6**
**MATERIALS**

**6.2.2 Purchase from producer or established supplier**

Starting material shall be purchased directly from the producer or only from established suppliers.

09. In light of above the firm has violated Section 23(1)(e) of Drug Act 1976 punishable under section 27 of Drug Act 1976 and violated the section 6 of Schedule B-II of Drugs (LR&A) rules 1976.

10. Submitted for the consideration of the Board.

**Decision of 289th CLB meeting:** The case was discussed and deliberated in detail and the Central Licensing Board directed the Division of Quality Assurance & Laboratory Testing (QA&LT) to issue show cause notice and personal hearing to M/s

EG Pharmaceutical, 13-A Industrial Triangle Kahuta Road Islamabad, regarding illegal import/storage of raw materials without Drug Import Licence (Form-5) and clearance certificate from DRAP.

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