**MINUTES OF 270th MEETING OF CENTRAL LICENSING BOARD HELD ON 23rd MAY, 2019**

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270th meeting of the Central Licensing Board (CLB) was held on 23rd May, 2019 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Ghulam Rasool Dutani, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad.

Following members attended the meeting: -

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| **S. No.** | **Name & Designation** | **Status** |
|  | Dr. Ikram UL Haq, Expert in testing of drugs. | Member |
|  | Prof. Dr. Abdullah Dayo, Faculty of Pharmacy, University of Sindh, Jamshoro | Member |
|  | Prof. Dr. Mohammad Usman, Expert in manufacturing of drugs | Member |
|  | Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar. | Member |
|  | Dr. Hafsa Karam Ellahi  Representative Director (QA/LT), DRAP, Islamabad | Member |
|  | Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad. | Secretary/Member |
|  | Mr. Abid Ali, Representative of Minsitary of Law & Justice. | Member |
|  | Mr. Nadeem Alamgir, Representative of Pharma Bureau | Observer |
|  | Mr. Farooq Bukhari, Representative of PPMA. | Observer |
|  | Mr. Kamran Anwar, Representative of PCDA | Observer |

The meeting started with the recitation of verses from the Holy Qura’an. The Chairman Central Licensing Board welcomed the honorable members and participants of the meeting. He 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. Mr. Abdul Sattar Sohrani Deputy Director (QC) Mr. Ayyaz Ahmad, Deputy Director (Lic), Mr. Muhammad Yaqoob AD (Lic.), Mr. Muhammad Usman, AD (Lic) and Ms. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

**Item-I CONFIRMATION OF THE MINUTES OF 269thMEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of 269thmeeting of the Central Licensing Board (CLB) which was held on 26thFebruary, 2019.

1. **DRUG LICENSING DIVISION**

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

The Board considered the following cases of grant of new drug manufacturing licenses in the light of recommendations of respective panel of experts/inspectors and decided as under:

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| **S #** | **Name of the firm** | **Date of Inspection / Type of License** | | Ranking/ Evaluation | | | **Inspection Panel Members** | |
| 1 | M/s Pacific Pharmaceuticals Ltd, Plot No. 384, Sunder Industrial Estate, Lahore.  **Name of Sections (03)**   1. LVP (General) Section 2. SVP (General) (Ampoule) Section 3. Ophthalmic (General) Section. | **29-04-2019**  **&**  **10-05-2019** | | **Good** | | | 1. Prof. Dr. Mehmood Ahmed, Ex. Dean, University of Bahawalpur. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore. | |
| **Recommendations of the panel: -**  Keeping in view the findings of inspectors, the building, quality control and manufacturing facilities, technical Personnels etc. panel of inspectors is of the opinion to **recommend** the grant of drug manufacturing license to manufacture by way of formulation to M/s Pacific Pharmaceuticals Ltd, Plot No. 384, Sunder Industrial Estate, Lahore for aforementioned sections.  **Decision of the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of Drug Manufacturing License by way of Formulation in the name of M/s Pacific Pharmaceuticals Ltd, Plot No. 384, Sunder Industrial Estate, Lahore with following sections:  **Section (03)**   1. LVP (General) Section 2. SVP (General) **(**Ampoule**)**Section. 3. Ophthalmic (General) Section. | | | | | | |
| 2 | M/s Health Care Pharmaceutical, 40-Km, Lahore Road, Multan.  **Name of Sections (08)**   1. Tablet (General) Section 2. Capsule (General) Section. 3. Sachet (General) Section. 4. Dry Powder Suspension (General) Section. 5. Cream and Ointment (General) Section. 6. External Application (General) Section. 7. Liquid Repacking Section. 8. Oral Liquid Syrup / Suspension (General) Section. | | **04-05-2019** | | **Good** | 1. Mr. Munawar Hayat, Chief Drug Controller, Govt. of Punjab, Lahore. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. | | |
| **Recommendations of the panel: -**  Keeping in view the facility like building, HVAC system, Machinery, equipment in Quality Control and Microbiology Laboratory, Water Treatment System, testing Facilities, Technical Personnels met, documentation, the panel of inspectors **recommends** the grant of Drug Manufacturing License by way of formulation for aforementioned sections.  **Decision of the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of Drug Manufacturing License by way of Formulation in the name of M/s Health Care Pharmaceutical, 40-Km, Lahore Road, Multan with following sections:  **Section (08)**   1. Tablet (General) Section 2. Capsule (General) Section. 3. Sachet (General) Section. 4. Dry Powder Suspension (General) Section. 5. Cream and Ointment (General)Section. 6. External Application(General) Section. 7. Liquid Repacking Section. 8. Oral Liquid Syrup / Suspension(General) Section. | | | | | | |

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| 3 | M/s K.M. Int (Pvt) Ltd., Plot No.74-A, Hayatabad, Industrial Estate, Peshawar  **Section (03)**   1. Capsule (Cephalosporin) 2. Dry Powder Suspension (Cephalosporin) 3. Dry Powder Injection (Cephalosporin) | **14-05-2019** | | **Good** | | | 1. Prof. Dr. Jamshed Ali Khan, Department of Pharmacy, Peshawar University, Peshawar. 2. Mr. Abdul Sattar Sohrani, Additional Director (E&M) DRAP, Peshawar. 3. Mr. Atiq ul Bari, Area FID, DRAP Peshawar. | |
| **Recommendations of the panel: -**  Keeping in view the above, the panel unanimously recommends the grant of Drug Manufacturing License (Formulation) for following sections to M/s K.M. Int (Pvt) Ltd., Plot No.74-A, Hayatabad, Industrial Estate, Peshawar.   1. Capsule (Cephalosporin) 2. Dry Powder Suspension (Cephalosporin) 3. Dry Powder Injection (Cephalosporin)   **Decision of the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of Drug Manufacturing License by way of Formulation in the name of M/s K.M. Int (Pvt) Ltd., Plot No.74-A, Hayatabad, Industrial Estate, Peshawar with following sections:  **Section (03)**   1. Capsule (Cephalosporin) 2. Dry Powder Suspension (Cephalosporin) 3. Dry Powder Injection (Cephalosporin) | | | | | | | |
| 4 | M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Road, Gujjar Khan.  **Sections 02**   1. Liquid Section (Veterinary) (General) 2. Powder Section (Veterinary(General) | | 13-05-2019 | | **Good** | | 1. Dr. Gul Majeed Khan, Quaid-e-Azam University, Islamabad. 2. Additional Director (QA), DRAP, Islamabad. 3. Area, FID, DRAP, Islamabad. | |
| “Keeping view the above facts the panel unanimously **recommended** M/s Shine Laboratories, Masa Kaswal, 9-KM, Sohawa, Main GT Road, Gujar Khan for the grant of Drug Manufacturing License by way of formulation for sections namely Liquid Section (Veterinary) and Powder Section (Veterinary) as of today**.**  **Decision of the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of Drug Manufacturing License by way of Formulation in the name of M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Road, Gujjar Khan with following sections:  **Section (02)**   1. Liquid Section (Veterinary).(General) 2. Powder Section (Veterinary**)**(General) | | | | | | | |
| 5. | M/s KBR Pharmaceuticals, Plot No. 123-B Phase-V Industrial Estate Hattar, Haripur.  **Sections 08**   1. Liquid Injection Section (General) 2. Cream/Ointment Section (General) 3. Sachet Section (General) 4. Dry Powder Suspension Section (General) 5. Capsule Section (General) 6. Dry Powder Injection Section (Cephalosporin) 7. Dry Powder Suspension Section (Cephalosporin) 8. Capsule Section (Cephalosporin) | | 20-02-2019  &  20.05.2019 | | | **Good** | | 1. Prof. Dr. Jamshed Ali Khan, Department of Pharmacy, Peshawar University, Peshawar. 2. Additional Director (E&M), DRAP, Peshawar. 3. Chief Drugs Inspector, KPK 4. Area, FID, DRAP, Peshawar. 5. Assistant Director III, Licensing DRAP, Islamabad |
| “In compliance to licensing Division, DRAP Islamabad letter No. F. 3-3/2014-Lic dated 18.03.2018. The constituted panel inspected factory premised of M/s. KBR Pharmaceuticals, Plot No. 123-B, Phase-V, Industrial Estate Hattar for the grant of Drug Manufacturing License (Formulation).  The panel conducted through inspection of the firm’s premises and observed that the building has been constructed as per layout plan **approved** vide Licensing Division, DRAP Islamabad letter No. F.3-3/2014-Lic dated 03rd May, 2019.  Separate change rooms for the male and female staff have been provided for the cephalosporin and general sections with the required changing facilities. They have provided separate storage areas for the raw materials, packing materials and finished products in the general and cephalosporin sections. All the manufacturing sections are separate from each other and requisite machinery have been installed for manufacturing of respective dosage forms. The sections have been provided with HVAC supply and buffer areas have been provided. Sterile sections have been provided with HEPA filters. Epoxy paint has been done in the sterile sections as well. In the quality control, the firm has provided sufficient equipments for testing and analysis purpose. Equipments have been caliberated, SOPs, Official books/pharmacopoeias are available.  As per manufacturing, quality control and environmental facilities provided, observations made during inspection, the qualified staff interviewed and various storage facilities available, premises inspected, the panel unanimously recommends the grant of Drug Manufacturing License (DML) by way of formulation to M/s KBR Pharmaceuticals, Plot No.123/B, Phase-V, Industrial Estate, Hattar for the above mentioned sections.  **Decision of the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of Drug Manufacturing License by way of Formulation in the name of M/s KBR Pharmaceuticals, Plot No. 123-B Phase-V Industrial Estate hattar, Haripur with following sections:  **Section (08)**   1. Liquid Injection Section (General) 2. Cream/Ointment Section (General) 3. Sachet Section (General) 4. Dry Powder Suspension Section (General) 5. Capsule Section (General) 6. Dry Powder Injection Section (Cephalosporin) 7. Dry Powder Suspension Section (Cephalosporin) 8. Capsule Section (Cephalosporin) | | | | | | | |

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

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

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| **S #** | **Name of the firm** | | | **Date of Inspection** | | Ranking/ Evaluation | | **Inspection Panel Members** |
| 1. | M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, 47-Sunder Industrial Estate, Lahore.    DML No. 000787 (Formulation)  **Name of Facility (01)**   1. Research & Development facility. | | | **Nil** | | **Good** | | 1. Prof. Dr. Mehmood Ahmed, Ex. Dean, University of Bahawalpur. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore. |
| **Recommendations of the panel: -**  Keeping in view the facility like building, HVAC system, Machinery & equipment, instruments, personal documentation and testing facilities the panel of inspectors is of the opinion to **recommend** the grant of additional section Design & Development section to M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, 47-Sunder Industrial Estate, Lahore.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following facility in the name of M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, 47-Sunder Industrial Estate, Lahore.  **Facility (01)**   1. Research& Development facility. | | | | | | | |
| 2. | M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.  DML No. 000150 (Formulation)  **Name of Section (05)**   1. Sachet (General) Section. 2. Tablet (Psychotropic) Section. 3. Capsule (Psychotropic) Section. 4. Liquid Injectable (Ampoule) (Steroid) Section. 5. Ophthalmic (General) Section. | | | **19-03-2019** | | **Good** | | 1. Dr. Ikram Ul Haq, Member CLB. 2. Mr. Munawar Hayat, Chief Drugs Controller, Govt. of the Punjab, Lahore. 3. Ms. Anam Saeed, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Uzam Barkat, Assistant Director, DRAP, Lahore. |
| **Recommendations of the panel: -**  The panel of inspector also **recommends** grant of following additional sections of M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.   1. Sachet (General) Section. 2. Tablet (Psychotropic) Section. 3. Capsule (Psychotropic) Section. 4. Liquid Injectable (Ampoule) (Steroid) Section. 5. Ophthalmic (General) Section.   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following five (05) additional sections in the name of M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.  **Section (05)**   1. Sachet (General) Section. 2. Tablet (Psychotropic) Section. 3. Capsule (Psychotropic) Section. 4. Liquid Injectable (Ampoule) (Steroid) Section. 5. Ophthalmic (General) Section. | | | | | | | |
| 3. | M/s Masfa Industries (Pvt) Ltd, 17-Km, Sheikhupura Road, District Sheikhupura.  DML No. 000713 (Formulation)  **Name of Section (07)**   1. Dry Powder Suspension (General) (New) 2. Cream / ointment / gel (General) (New). 3. Tablet Section (General) (New). 4. Capsule Section (General) (New). 5. Sachet (General) Section (New). 6. Packing material Store (revised / amended). 7. Microbiology Laboratory (revised / amended). | | | | **29-03-2019** | | **Good** | 1. Dr. Nadeem Irfan, Chairman, Pharmacy Department Punjab University, Lahore. 2. Dr. Zaka-ur-Rehman, Secretary Punjab Pharmacy Council. 3. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 4. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. |
| **Recommendations of the panel: -**  Keeping in view, the above observations, the members of the panel are of the opinion to **recommends** the grant of Renewal of Drug Manufacturing License (000713) by way of formulation of M/s Masfa Industries (Pvt) Ltd, 17-Km, Sheikhupura Road, District Sheikhupura with the grant of following additional sections only:   1. Dry Powder Suspension. 2. Cream / ointment / gel. 3. Tablet Section. 4. Capsule Section. 5. Sachet Section. 6. Packing material Store (revised / amended). 7. Microbiology Laboratory (revised / amended).   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following five (05) additional sections and two (02) amended facilties in the name of M/s Masfa Industries (Pvt) Ltd, 17-Km, Sheikhupura Road, District Sheikhupura.  **Section (07)**   1. Dry Powder Suspension (General) (New) 2. Cream / ointment / Gel (General) (New). 3. Tablet Section (General) (New). 4. Capsule Section (General) (New). 5. Sachet (General) Section (New). 6. Packing material Store (Revised / Amended). 7. Microbiology Laboratory (Revised/ Amended). | | | | | | | |
| 4. | M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km, Lahore Road, Multan.  DML No. 000578 (Formulation)  **Name of Section (02)**   1. Oral Liquid / Suspension (General) Section. 2. Tablet (Psychotropic / Narcotic) Section. | | **03-05-2019** | | | | **Good** | 1. Dr. Mahmood Ahmed, Ex-Dean, Islamia University of Bhawalpur. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore. |
| **Recommendations of the panel: -**  The panel of inspectors also **recommends** grant of following additional sections to M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km, Lahore Road, Multan.   1. Oral Liquid / Suspension (General) Section. 2. Tablet (Psychotropic / Narcotic) Section.   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following two (02) additional sections in the name of M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km, Lahore Road, Multan.  **Section (02)**   1. Oral Liquid / Suspension (General) Section. 2. Tablet (Psychotropic / Narcotic) Section. | | | | | | | |
| 5 | M/s Pharma Lord (Pvt) Ltd, 12-Km, Lahore Road, Layyah    DML No. 000774 (Formulation)  **Name of Section (02)**   1. Oral Liquid (General) Section. 2. Oral Dry Powder Sachet (General) Section. | | | **03-05-2019** | | **Good** | | 1. Dr. Mahmood Ahmed, Ex-Dean, Islamia University of Bhawalpur. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. |
| **Recommendations of the panel: -**  The Panel also **Recommends** the grant of additional section as mentioned above.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following two (02) additional sections in the name of M/s Pharma Lord (Pvt) Ltd, 12-Km, Lahore Road, Layyah.  **Section (02)**   1. Oral Liquid (General) Section. 2. Oral Dry Powder Sachet (General) Section. | | | | | | | |
| 6 | M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-4, Hattar Industrial Estate, Hattar.  DML No. 000606 (Formulation)  1. Syrup Section (General).  2. Dry Suspension Section (General). | | | **04-02-2019** | | **Good** | | 1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Director DTL, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar. 4. Area Assistant Director, DRAP, Peshawar. |
| **Recommendations of the panel: -**  “The panel conducted detailed inspection of the firm and observed that the firm has modified their various areas as per their revised/amended layout plan **approved** vide letter No.F.3-9/2005 (Vol-I) dated 20-11-2018.  As per facilities of production, quality control and environment control provided, the observations made during inspection, the qualified staff employed and evaluation made of the various sections of production and quality control, the panel unanimously recommends the grant of renewal of DML No.000606 (Formulation) w.e.f. 30-12-2016 and also **recommends the grant of following additional sections;**   1. **Syrup Section (General).** 2. **Dry Suspension Section (General).”**   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following two (02) additional sections in the name of M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-4, Hattar Industrial Estate, Hattar.  **Section (02)**  1. Syrup Section (General).  2. Dry Suspension Section (General). | | | | | | | |
| 7 | | M/s Jupiter Pharma, Plot No. 25, S-6, RCCI, Rawat, Rawalpindi.  DML No. 000838 (Formulation).  **Sections 03**   1. Capsule Section (Cephalosporin). 2. Dry Suspension Section (Cephalosporin). 3. Dry Vial Injection (Cephalosporin). | | 26-04-2019 | | **Good** | | 1. Prof. Dr. Muhammad Usman, Member, CLB. 2. Additional Director (QA&LT), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad. |
| **Recommendations of the panel: -**  “Keeping in view of the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Jupiter Pharma, Plot No. 25, S-6, RCCI, Rawat, Rawalpindi DML No. 000838 (Formulation) for the following additional sections as above.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following three (03) additional sections in the name of M/s Jupiter Pharma, Plot No. 25, S-6, RCCI, Rawat, Rawalpindi  **Sections 03**   1. Capsule Section (Cephalosporin). 2. Dry Suspension Section (Cephalosporin). 3. Dry Vial Injection (Cephalosporin). | | | | | | |
| 8 | | M/s Davis Pharmaceuticals, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.  DML No. 000432 (Formulation).  **Sections / Facility.**   1. Cephalosporin / Facility. | | 15-11-2018 | | **-** | | 1. Mr. Nadeem Iqbabl, Expert. 2. Additional Director (QA&LT), DRAP, Islamabad. 3. Area, FID, DRAP, Islamabad. |
| **General Observations:**   * Laundry for the cephalosporin was advised to be separate from the general laundry. * It was advised to develop a proper system for the medical check-up of the workers / employees. * No SOP has been developed in the production area. * Design qualification has not been performed to ensure GMP flow of materials, Personnels and machines / equipment. * The technical staff has no proper concept of washing / cleaning of the area. * It was advised to install smoke alarm and fire extinguished in the section. * A point for RO water needs to be installed in the mixing area for washing / cleaning of the mixer. * The covered area seems insufficient. * The unidirectional flow as per GMP is missing in the area due to the insufficient space.   **Recommendations of the panel: -**  “Keeping in view of the facts on ground and the observations noted during inspection, the panel is of the opinion not to recommend the newly applied Cephalosporin section at present till the rectification of above said observation”.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered the case and after thread bare delibration **did not approve** the grant of following section|facility in the name of M/s Davis Pharmaceuticals, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad  **Sections / Facility.**  Cephalosporin / Facility. | | | | | | |

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| 9 | M/s Bio-Labs (Pvt) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.  DML No. 000296 (Formulation).  **Sections / Facility (03).**   * + 1. Capsule (Cephalosporin) Section **(Amendments).**     2. Oral Dry Powder Suspension (Cephalosporin) Section **(Amendments).**     3. Dry Powder Injection (Cephalosporin) Section **(Amendments).** | 24-04-2019 | **-** | 1. Dr. Gul Majeed Khan, Quaid-e-Azam University, Islamabad. 2. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad. 3. Babar Khan, Area, FID, DRAP, Islamabad. |
| **Recommendations of the panel: -**  “Keeping view the above facts on record, the panel unanimously **recommended** the approval of following sections of M/s Bio-Lab Pharmaceuticals, Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad with amendments (found as per revised layout plan):-   1. Capsule (Cephalosporin) Section. 2. Oral Dry Powder Suspension (Cephalosporin) Section. 3. Dry Powder Injection (Cephalosporin) Section.   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following three (03) amended /Revised sections in the name of M/s Bio-Labs (Pvt) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad  **Sections / Facility (03).**   1. Capsule (Cephalosporin) Section **(Amendments).** 2. Oral Dry Powder Suspension (Cephalosporin) Section **(Amendments).** 3. Dry Powder Injection (Cephalosporin) Section **(Amendments).** | | | |
| 10 | M/s Arreta Pharmaceuticals (Pvt) Ltd, Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi.  DML No. 000846 (Formulation).  **Sections / Facility (04).**   1. Sterile Dry Powder for Injections (Cephalosporin). 2. Dry Powder for Suspension Section (Cephalosporin). 3. Capsule Section (Cephalosporin). 4. Ware Houses (Cephalosporin). | 20-05-2019 | **Good** | 1. Dr. Muhammad Usman, Member, Central Licensing Board. 2. Additional Director (QA), DRAP, Islamabad. 3. Area, FID, DRAP, Islamabad. 4. Area Assistant Director (Licensing), DRAP, Islamabad.(could not join due to office engagements.) |
| **Recommendations of the panel: -**  “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 Arreta Pharmaceuticals (Pvt) Ltd, Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi, DML No. 000846 (Formulation) for the grant of additional sections namely on first floor of existing facility as of today;   1. Sterile Dry Powder for Injections (Cephalosporin). 2. Dry Powder for Suspension Section (Cephalosporin). 3. Capsule Section (Cephalosporin). 4. Ware Houses (Cephalosporin).   Note: The assessment for strength of building, Machinery, equipments, electric panels etc does not fall under the ambit mandate and scope of the inspection under the Drugs Act, 1976 and rules framed there under, for which the firm has been advised to get certification from relevant Building Control Authorities (BCA) as per prevailing laws and ensure proper emergency exits alongwith fire fighting equipments in the premises. The quality of individual batches lies with the manufacturer.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following four (04) additional sections/facility in the name of M/s Arreta Pharmaceuticals (Pvt) Ltd, Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi.  **Sections / Facility (04).**   1. Sterile Dry Powder for Injections (Cephalosporin). 2. Dry Powder for Suspension Section (Cephalosporin). 3. Capsule Section (Cephalosporin). 4. Ware Houses (Cephalosporin). | | | |

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| 11 | M/s Atco Laboratories Limited, Plot No.B-18, S.I.T.E., Karachi.  DML No. 000188 (Formulation)  **Section (04)**   1. Gel (General) Section. 2. Ointment/Cream (General) Section. 3. Lotion (General) Section. 4. Enema (General) Section. | | | | 19-03-2019 | | | Good | | 1. Mr. Ghulam Sarwar, Member Drug Registration Board. 2. Director CDL, Karachi. 3. Area FID, DRAP, Karachi. |
| **Recommendations of the panel: -**  *During the inspection the panel thoroughly inspected their production areas, QC Lab, stores, utilities, and reviewed several control documents. The panel met their technical personel in respective areas as well to know their expertise training and job responsibilities in all the sections. Panel noted all the equipments installed and qualified. Based on above panel unanimously recommends the grant of additional section(gel, ointment/cream, lotion and enema.*  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following four (04) additional sections in the name of M/s Atco Laboratories Limited, Plot No.B-18, S.I.T.E., Karachi.  **Section (04)**   1. Gel (General) Section. 2. Ointment/Cream (General) Section. 3. Lotion (General) Section. 4. Enema (General) Section. | | | | | | | | | |
| 12 | M/s Inventor Pharma, plot No.K/196,S.I.T.E (SHW) Phase-II, Karachi.  DML No. 000866 (Formulation)  **Section (02)**   1. Ointment (General) Section. 2. Liquid External (General) Section. | | | **20.03.2019** | | | **Good** | | 1. Dr. Ghulam Sarwar, Member DRB, Karachi. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi. | |
| **Recommendations of the panel: -**  *Both the section were constructed and maintained as per layout plan* ***approved*** *by the DRAP authorities vide letter No. F. 2-4/2003-Lic dated 8th January, 2019. Relevant equipments and machinery required for the production of the ointment and liquid external preparation was found installed in respective places and found well maintained. HVAC system seen installed and observed operational in both sections.*  *Keeping in view the people met, document reviewed and findings of the inspection, the panel recommends the grant of additional section as mentioned below:-*   1. *Ointment (General)* 2. *Liquid External (General).*   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following two (02) additional sections in the name of M/s Inventor Pharma, plot No.K/196,S.I.T.E (SHW) Phase-II, Karachi.  **Section (02)**   1. Ointment (General) Section. 2. Liquid External (General) Section. | | | | | | | | | |
| 13 | M/s Asian Continental (Pvt) Ltd. D/32 SITE Super Highway Karachi.  DML No. 000643 (Formulation)  **Facility (01)**  Packaging material warehouse | 14.02.2019 | | | | Good | | | 1. Dr. Abdullah Dayo, Member CLB, Karachi. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi. | |
| **Recommendations of the panel: -**  The firm is well maintained facility was granted DML during the year 2008 and is constricted as per layout plan **approved** by the DRAP authorities Islamabad. Basic equipment and machinery required for the manufacturing and quality control of registered pharmaceuticals products was found in place in respective sections.  Relevant validated methods, SOPs and other required documents were also seen in place and update. Adequate technical personal were also engaged by the firm that was observed well conversant regarding concept of GMP/cGMP. HVAC system was seen installed and operational in all the production sections.  Based on the people met, documents reviewed and observations made during the inspection, panel recommends:-   1. Tablet (General) 2. Capsule (General) 3. Dry Powder Syrup (General/Antibiotic) 4. Sterile Liquid Injection (General) 5. Liquid Syrup   Panel also recommends the regularization of changes made by the firm in layout plan **approved** by the DRAP authorities Islamabad.  Panel also inspected and recommends the additional facility (Packaging warehouse along with other recommendation)  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following additional facility in the name of M/s AsianContinental (Pvt) Ltd. D-32 SITE Super Highway Karachi.  **Facility (01)**  Packaging material warehouse | | | | | | | | | |
| 14 | M/s Getz Pharma, (pvt) limited, Plot No. 29-30, Sector 27 Korangi Industrial Area, Karachi.  DML No. 000284 (Formulation)  **Section/Facility (01)**  **Dry Powder Inhaler (DPI)** | | **10.05.2019** | | | **Good** | | | 1. Dr. Abdullah Dayo, Member CLB, Karachi. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi. | |
| **Recommendations of the panel: -**  The additional section i.e Dry Powder Inhaler (DPI), is a dedicated section, situated at the 2nd floor of the manufacturing building. The DPI sections were observed constructed as per layout plan **approved** by the DRAP authorities Islamabad. The firm has provided section with the relevant equipments and machinery required for the manufacturing and testing of the DPI products. Adequate technical personnel were seen available that were observed trained and well-conversant with the GMP requirements and guidelines. HVAC system seen installed and operational.  Based on the area inspected, people met, and documents reviewed, technology transfer and human resource development the DPI manufacturing facility was observed to be in line with GMP guidelines. Keeping in view the finding of the inspection of the DPI facility, the processing, filling, packing, water system, HVAC system, validation and qualification documents, trainings, technical skills and experience of personnel, QC and stability program etc**., Panel recommending the grant /approval of additional section namely Dry Powder Inhaler (DPI).**  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following one (01) additional section in the name of M/s Getz Pharma (Pvt) Limited, Plot No. 29-30, Sector 27 Korangi Industrial Area, Karachi.  **Section/Facility (01)**  **Dry Powder Inhaler (DPI) Section** | | | | | | | | | |

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| 15 | M/s Martin Dow Marker Ltd, Plot No. F-126, S.I.T.E, Karachi.  DML No. 000043 (Formulation)  **Amendments (09)**   1. Incorporating buffer in place of corridor. 2. Addition of door in the drying area 3. Addition of one more door for emergency. 4. Separate area for MOP washing 5. Door location is changed in staging area 6. Packing hall is extended 7. QC/QA Lab (Amendment) 8. Pedestrian Bridge is removed 9. Rest room area separated from common area | **16 .05.2019** | **Good** | 1. Dr. Abdullah Dayo, Member CLB 2. Dr. Saif-ur-Rehman Khattak, Director CDL, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi. |
| **Recommendations of the panel: -**  Based on the people met, areas visited and commitment of the management for continuous improvement, the people is of the view to recommend as follows:   1. Grant of amendments in layout as per DRAP, Islamabad letter No. F.2-14/2000-Lic (Vol-II) dated 14th May 2019 and observation of the panel noted above to the firm M/s. Martin Dow Market Ltd, Situated at Plot no. F-126, SITE, Karachi. Holding DML no. 000043 (By Way of Formulation)   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following nine (09) amendments in their excisting approved sections in the name of M/s Martin Dow Marker Ltd, Plot No. F-126, S.I.T.E, Karachi.  **Amendments (09)**   1. Incorporating buffer in place of corridor. 2. Addition of door in the drying area 3. Addition of one more door for emergency. 4. Separate area for MOP washing 5. Door location is changed in staging area 6. Packing hall is extended 7. QC/QA Lab (Amendment) 8. Pedestrian Bridge is removed 9. Rest room area separated from common area | | | |

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| 16 | M/s Metro Pharmaceuticals, Plot No. 14, SS-2, National Industrial Zone, RCCI Rawat, Islamabad.  DML No. 000772 (Formulation)  **Section (07)**   1. Capsule Section (Ceph). 2. Dry Suspension Section (Ceph). 3. Dry Vial Injection (Ceph). 4. Sachet (Ceph). 5. Liquid Vial Injection (General). 6. Liquid Ampoule (General). 7. General Sterile Dry Powder Injection (Pre Lyophilized ready to fill). | | **17 .05.2019** | **Good** | 1. Dr. Gul Majeed Khan, Quaid-e-Azam University, Islamabad. 2. Dr. Abdur Rasheed, Director (Pharmacy Services), DRAP, Islamabad. 3. Dr. Hasan Afzaal, FID-III, DRAP, Islamabad. | |
| **Recommendations of the panel: -**  “Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Metro Pharmaceuticals, Plot No. 14, SS-2, RCCI, Rawat, Rawalpindi for the renewal of Drug Manufacturing License No. 000772 (Formulation) for the following sections namely alongwith with additional sections as under;   1. Tablet Section (General). 2. Capsule Section (General). 3. Dry Powder Suspension (General). 4. Oral Liquid (General). 5. Sachet (General). 6. Ointment Cream / Gel / Lotion (General).   For the grant of additional sections namely;   1. Capsule Section (Ceph). 2. Dry Suspension Section (Ceph). 3. Dry Vial Injection (Ceph). 4. Sachet (Ceph). 5. Liquid Vial Injection (General). 6. Liquid Ampoule (General). 7. General Sterile Dry Powder Injection (Pre Lyophilized ready to fill).   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following seven (07) additional sections in the name of M/s Metro Pharmaceuticals, Plot No. 14, SS-2, National Industrial Zone, RCCI Rawat, Islamabad.  **Section (07)**   1. Capsule Section (Cephalosporin). 2. Dry Suspension Section (Cephalosporin). 3. Dry Vial Injection (Cephalosporin). 4. Sachet (Cephalosporin). 5. Liquid Vial Injection (General). 6. Liquid Ampoule (General). 7. General Sterile Dry Powder Injection (Pre Lyophilized ready to fill). | | | | | |
| 17 | M/s Amros Pharmaceuticals, Plot No. A-96, S.I.T.E Super highway, Karachi  DML No. 000406 (Formulation)  **Section/facility (05)**   1. Tablet (General) (Amendments) 2. Tablet (Psychotropic) (Amendments) 3. Injection Section (Vet) 4. Dry powder Injection(Ceph) (New) 5. Warehouse (Amendments) | | **20.05.2019** | **Good** | 1. Dr. Abdullah Dayo, Member CLB 2. Additional Director, DRAP, Karachi 3. Area Federal Inspector of Drugs, DRAP, Karachi. |
| **Recommendations of the panel: -**  As per direction the panel inspected in details production areas, stores, QC lab and reviewed in details relevant documents. The panel further noted that the firm possesses registrations in Tablet (G), Tablet (Psychotropic), Tablet (Penicillin), Capsule (G), Capsule (Penicillin), Capsule (Cephalosporin), Cream/Ointments, Ear/Eye Drops Section, Oral Liquid Section, Sterile Liquid Injection, Oral Dry Powder Suspension (G), Oral Dry powder suspension (penicillin), Oral Dry powder Syrup (Cephalosporin) and sterile liquid injection (Veterinary). In addition to these sections, the firm has applied for the grant of additional section of sterile Dry Powder Injection Cephalosporin. The new section is built as per **approved** drawing and is provided with all necessary utilities and separate HVAC system. The panel noted that necessary amendments/improvements in the LOP are made accordingly and the existing drawing is almost according to **approved** one.  Keeping in view the above observations the panel recommends that their existing drawing may be regularized as required under current SOPs and the firm may be granted an additional section of Sterile Dry Powder Injection (Cephalosporin)  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following amended sections/facility in the name of M/s Amros Pharmaceuticals, Plot No. A-96, S.I.T.E Super highway, Karachi.  **Section/facility (05)**   1. Tablet (General) (Amendments) 2. Tablet (Psychotropic) (Amendments) 3. Injection Section (Vet) (Amendments) 4. Dry powder Injection(Ceph) (New) 5. Warehouse (Amendments) | | | | |
| 18 | M/s Winbrains Research laboratories, Plot No. 69/1 Block B, Phase I & II, Industrial Estate Hattar Haripur  DML No. 000725 (Formulation)  **Section (02)**   1. Sachet (General) 2. Tablet (Psychotropic) | **20.05.2019** | | **Good** | 1. Director DTL Peshawar 2. Additional Director E&M, DRAP, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar . |
| **Recommendations of the panel: -**  As per available manufacturing and quality control facilities provided, environmental control system installed, technical and qualified staff employed, the panel unanimously recommends the grant of following additional section to M/s Winbrains Research laboratories, Plot No. 69/1 Block B, Phase I & II, Industrial Estate Hattar Haripur vide DML No. 000725 (Formulation).   1. Sachet (General) 2. Tablet (Psychotropic)   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the grant of following two (02) additional sections in the name of M/s Winbrains Research laboratories, Plot No. 69/1 Block B, Phase I & II, Industrial Estate Hattar Haripur  **Section (02)**   1. Sachet (General) section 2. Tablet (Psychotropic) section | | | | |

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

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses. The same are placed before the Board for its consideration/decision, please.

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| **S #** | **Name of the firm** | | **Date of Inspection** | **Ranking/ Evaluation** | | **Inspection Panel Members** |
| 1. | M/s Rasco Pharma, Plot No. 27-28, Holiday Park Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore.  DML No. 000530 (Formulation)  **Period**: Commencing on 26-01-2019 ending on 25-01-2024.  Sections (08)   1. Capsule (Cephalosporin) section. 2. Dry Syrup (Cephalosporin) section. 3. Tablet Antibiotic section. 4. Tablet (Psychotropic) section. 5. Liquid Injection (Small Volume Vial) (General) section. 6. Liquid Injection Ampoule (General) (Filling of one dosage form i.e, ampoule or vial at one time). 7. Capsule (General) section. 8. Syrup (General) section. | | **04-02-2019** | **Good** | | 1. Prof. Dr. Mehmood Ahmed, Ex. Dean, University of Bahawalpur. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. |
| **Recommendations of the panel: -**  The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000530 issued in favour of M/s Rasco Pharma, Plot No. 27-28, Holiday Park Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore in respect to all **approved** sections along with **regularization** of Capsule (General) and Oral Liquid (General) section.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000530 (Formulation) in the name of M/s Rasco Pharma, Plot No. 27-28, Holiday Park Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 26-01-2019 ending on 25-01-2024 for following sections as per inspection report:   1. Capsule (Cephalosporin) section. 2. Dry Syrup (Cephalosporin) section. 3. Tablet Antibiotic section. 4. Tablet (Psychotropic) section. 5. Liquid Injection (Small Volume Vial) (General) section. 6. Liquid Injection Ampoule (General) (Filling of one dosage form i.e, ampoule or vial at one time). 7. Capsule (General) section. 8. Syrup (General) section. | | | | | |
| 2. | M/s Spectrum Laboratories (Pvt) Ltd, 8-Km, Raiwind Road, Lahore.    DML No. 000364(Formulation)  **Period**: Commencing on 16-09-2010 to 15-09-2015 and 16-09-2015 ending on 15-09-2020.   1. Liquid Re-Packing 2. External Preparations sections 3. Tablet Section 4. Oral Liquid section | **22-02-2019** | | **Satisfactory / Average** | 1. Dr. Ikram Ul Haq, Member CLB. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Nusrat Rahman, Provincial Drug Inspector for Industries, Government of Punjab, Lahore. | |
| **Recommendations of the panel: -**  The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000364 issued in favour of M/s Spectrum Laboratories (Pvt) Ltd, 8-Km, Raiwind Road, Lahore in respect of Liquid Re-Packing and External Preparations sections only. The Panel of Inspectors **Does Not Recommend** the renewal in respect of Tablet and Oral Liquid sections. The Panel further recommends suspension of Production in tablet and oral liquid sections till the rectification of shortcomings and GMP compliance.  **Decision by the Central Licensing Board in 270th meeting**   1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000364 (Formulation) in the name of M/s Spectrum Laboratories (Pvt) Ltd, 8-Km, Raiwind Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 16-09-2015 and ending on 15-09-2020 in respect of Liquid Re-Packing and External Preparations sections. 2. The Board considered and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Tablet and Oral Liquid sections may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain stopped/suspended in Tablet and Oral Liquid sections till decision by CLB. | | | | | |
| 3 | M/s Jassh Pharma, 19-Km, Ferozepur Road, Lahore.  DML No. 000601 (Formulation)  **Period**: Commencing on 27-09-2016 ending on 26-09-2021  **Sections**  Haemodialysis Solution. | 14-11-2018 | | **Good** | | 1. Dr. Ikram Ul Haq, Member CLB (**Absent reason not provided**). 2. Mr. Nadim Iqbal, Expert in Production of Drugs. 3. Mr. Anjum Pervaiz, Consultant Registration & Licensing. 4. Mr. Shoaib Ahmed, Federal Inspector of Drugs, Lahore. |
| **Recommendations of the panel: -**  The Panel of inspectors **Recommends** the renewal of M/s Jassh Pharma, 20-Km, Ferozepur Road, Lahore, Pakistan, DML No. 000601 in respect to its **approved** section.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and decided that the inspection report may be referred to MD&MC Division, DRAP as the subject matter falls under the domain of MD&MC Division for further necessary action. | | | | | |

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| 4 | M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.  DML No. 000150 (Formulation)  **Period**: Commencing on 24-12-2014 ending on 23-12-2019  Sections   1. Tablet (General) Section. 2. Capsule (General) Section. 3. Oral Liquid (General) Section. 4. Antibiotic Dry Powder Suspension (General) Section. 5. Antibiotic Capsule (General) Section. 6. Dermatology Section. 7. Liquid Injectable (Ampoule / Vial) Section. 8. External Preparation Section 9. Capsule (Cephalosporin) Section. 10. Dry Powder Suspension (Cephalosporin) Section. 11. Dry Powder Injection (Cephalosporin) Section. | | | | | **19-03-2019** | | | | | | **Good** | | | | | | 1. Dr. Ikram Ul Haq, Member CLB. 2. Mr. Munawar Hayat, Chief Drugs Controller, Govt. of the Punjab, Lahore. 3. Ms. Anam Saeed, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Uzam Barkat, Assistant Director, DRAP, Lahore. | |
| **Recommendations of the panel: -**  Keeping in view the facility like building, HVAC system, production Machinery & Equipment in Quality Control and Microbiology Laboratory, Water Treatment System, Testing Facilities, Technical Personnels met, documentation, the panel of inspectors **recommends** the Renewal of Drug Manufacturing License by way of formulation for the following sections:   1. Tablet (General) Section. 2. Capsule (General) Section. 3. Oral Liquid (General) Section. 4. Antibiotic Dry Powder Suspension (General) Section. 5. Antibiotic Capsule (General) Section. 6. Dermatology Section. 7. Liquid Injectable (Ampoule / Vial) Section. 8. External Preparation Section 9. Capsule (Cephalosporin) Section. 10. Dry Powder Suspension (Cephalosporin) Section. 11. Dry Powder Injection (Cephalosporin) Section.   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000150 (Formulation) in the name of M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 24-12-2014 ending on 23-12-2019 for following sections as per inspection report:   1. Tablet (General) Section. 2. Capsule (General) Section. 3. Oral Liquid (General) Section. 4. Antibiotic Dry Powder Suspension (General) Section. 5. Antibiotic Capsule (General) Section. 6. Dermatology Section. 7. Liquid Injectable (Ampoule / Vial) Section. 8. External Preparation Section 9. Capsule (Cephalosporin) Section. 10. Dry Powder Suspension (Cephalosporin) Section. 11. Dry Powder Injection (Cephalosporin) Section. | | | | | | | | | | | | | | | | | | |
| 5 | M/s Masfa Industries (Pvt) Ltd, 17-Km, Sheikhupura Road, District Sheikhupura.    DML No. 000713 (Formulation)  **Period**: Commencing on 15-06-2016 ending on 14-06-2021 | | | **29-03-2019** | | | | | **Good** | | | | | 1. Dr. Nadeem Irfan, Chairman, Pharmacy Department Punjab University, Lahore. 2. Dr. Zaka-ur-Rehman, Secretary Punjab Pharmacy Council. 3. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 4. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. | | | | | |
| **Recommendations of the panel: -**  Keeping in view, the above observations, the members of the panel are of the opinion to **recommends** the grant of Renewal of Drug Manufacturing License (000713) by way of formulation of M/s Masfa Industries (Pvt) Ltd, 17-Km, Sheikhupura Road, District Sheikhupura.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000713 (Formulation) in the name of M/s Masfa Industries (Pvt) Ltd, 17-Km, Sheikhupura Road, District Sheikhupura on the recommendations of the panel of experts for the further period of five years commencing on 15-06-2016 ending on 14-06-2021. | | | | | | | | | | | | | | | | | | |
| 6 | M/s Care Pharmaceuticals, 8-Km, Thokar-Raiwind Road, Lahore.  DML No. 000563 (Formulation)  **Period**: Commencing on 31-12-2014 ending on 30-12-2019  Sections   1. Oral Liquid (General) Section. 2. Eye / Ear Drops (General) Section. 3. Cream / Ointment (Semisolid) Section (Steroidal / Non Steroidal). | | | | | **13-03-2019** | | | | | | **Good** | | | | 1. Dr. Ikram Ul Haq, Member CLB. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Nusrat Rahman, Provincial Drug Inspector for Industries, Government of Punjab, Lahore. 4. Mr. Ahsan ul Haq Ather, Assistant Director, DRAP, Lahore | | | |
| **Recommendations of the panel: -**  The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000563 issued in favour of M/s Care Pharmaceuticals situated at 8-Km, Thokar-Raiwind Road, Lahore in respect to below mentioned sections.   1. Oral Liquid (General) Section. 2. Eye / Ear Drops (General) Section. 3. Cream / Ointment (Semisolid) Section (Steroidal / Non Steroidal).   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000563 (Formulation) in the name of M/s Care Pharmaceuticals, 8-Km, Thokar-Raiwind Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 31-12-2014 ending on 30-12-2019 for following sections as per inspection report:   1. Oral Liquid (General) Section. 2. Eye / Ear Drops (General) Section. 3. Cream / Ointment (Semisolid) Section (Steroidal / Non Steroidal). | | | | | | | | | | | | | | | | | | |
| 7 | M/s Friends Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore  DML No. 000531 (Formulation)  **Period**: Commencing on 27-01-2014 ending on 26-01-2019 | | | | **08-03-2019** | | | | | | **Good** | | | | | | 1. Dr. Zaka-ur-Rehman, Secretary Punjab Pharmacy Council. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore. | | |
| **Recommendations of the panel: -**  The Panel of Inspectors **Recommends** the renewal of DML of M/s Friends Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore. Bearing No. 000531 in respect to its **approved** sections.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered the case and after thread bare delibration decided to defer for updation on new application for renewal of DML for next tenure. | | | | | | | | | | | | | | | | | | |
| 8 | M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km, Lahore Road, Multan.    DML No. 000578 (Formulation)  **Period**: Commencing on 12-05-2015 and ending on 11-05-2020. | | | | **03-05-2019** | | | | | | | **Good** | | | | | 1. Dr. Mahmood Ahmed, Ex-Dean, Islamia University of Bhawalpur. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore. | | |
| **Recommendations of the panel: -**  Keeping in view the facility like building, HVAC system, sanitation, production Machinery, Equipment in Quality Control and Microbiology Laboratory, Testing Facilities, Technical Personnels met and documentation, the panel of inspectors recommends the Renewal of Drug Manufacturing License by way of formulation.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000578 (Formulation) in the name of M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km, Lahore Road, Multan on the recommendations of the panel of experts for the further period of five years commencing on 12-05-2015 and ending on 11-05-2020. | | | | | | | | | | | | | | | | | | |
| 9 | M/s Pharma Lord (Pvt) Ltd, 12-Km, Lahore Road, Layyah    DML No. 000774 (Formulation)  **Period**: Commencing on 21-02-2018 ending on 20-02-2023.  Sections   1. Tablet Section (General) 2. Capsule Section (General) 3. Oral Dry Powder Suspension Section (General) | | | | **03-05-2019** | | | | | | | **Good** | | | | | | 1. Dr. Mahmood Ahmed, Ex-Dean, Islamia University of Bhawalpur. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. | |
| **Recommendations of the panel: -**  The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000774 issued in favour of M/s Pharma Lord (Pvt) Ltd, 12-Km, Lahore Road, Layyah.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000774 (Formulation) in the name of M/s Pharma Lord (Pvt) Ltd, 12-Km, Lahore Road, Layyah on the recommendations of the panel of experts for the further period of five years commencing on 21-02-2018 and ending on 20-02-2023 for following sections as per inspection report:   1. Tablet Section (General) 2. Capsule Section (General) 3. Oral Dry Powder Suspension Section (General) | | | | | | | | | | | | | | | | | | |
| 10 | M/s 3S Pharmaceuticals (Pvt) Ltd, 5-Km, Off Raiwind Manga Road, Lahore. s  DML No. 000665 (Formulation)  **Period**: Commencing on 17-06-2014 ending on 16-06-2019.  Sections   1. Tablet (General) Section. 2. Capsule (General) Section. | | | | **01-03-2019**  **&**  **13-05-2019** | | | | | | | **Good** | | | | | | 1. Dr. Ikram Ul Haq, Member CLB. 2. Dr. Farzana Chowdhary, Expert. 3. Ms. Ufaq Tanveer Butt, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. | |
| **Recommendations of the panel: -**  Keeping in view the facility like building, HVAC system, Machinery and Equipment, Instruments, Personnels, documentation and Quality Control Testing Facilities, , the panel of inspectors is of the opinion to recommend the grant of Renewal of Drug Manufacturing License to M/s 3S Pharmaceuticals (Pvt) Ltd, 5-Km, Off Raiwind Manga Road, Lahore for the following sections:   1. Tablet (General) Section. 2. Capsule (General) Section.   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000665(Formulation) in the name of M/s 3S Pharmaceuticals (Pvt) Ltd, 5-Km, Off Raiwind Manga Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 17-06-2014 and ending on 16-06-2019 for following sections as per inspection report:   1. Tablet (General) Section. 2. Capsule (General) Section. | | | | | | | | | | | | | | | | | | |
| 11 | M/s Convell Laboratories, Saidu Sharif, Swat    DML No. 000509 (Formulation)  **Period**: Commencing on 26-02-2018 ending on 25-02-2023 | | | | **02-03-2019** | | | | | **Good** | | | | 1. Prof. Dr. Jamshed Ali Khan, Department of Pharmacy, Peshawar University, Peshawar. 2. Mr. Abdul Sattar Sohrani, Additional Director (E&M) DRAP, Peshawar. 3. Mr. Atiq ul Bari, Area FID, DRAP Peshawar. 4. Mr. Muhammad Yaqoob, AD Licensing(III&IV), DRAP, Islamabad | | | | | |
| **Recommendations of the panel: -**  As per observations made during inspection, the manufacturing, quality control and environmental facilities inspected, qualified staff employed, SOPs implemented, the documentation pertaining to production and quality control reviewed and keeping in view the overall GMP compliance of the firm, the panel unanimously **recommends the renewal fo DML No.000509, by way of formulation, granted to M/s Convell Laboratories, Saidu Sharif, Swat w.e.f 26-02-2018** and regularization of the layout plan **approved** vide letter No.F.3-4/2002-Lic (Vol-I) dated 10th August, 2017 for the following sections/areas;   |  |  | | --- | --- | | Ser | Section | | **Ground Floor** | | | 1 | Tablet Section (General) | | 2 | Capsule Section (General) | | 3 | Dry Powder Suspension (General) | | 4 | Liquid Section (General) | | 5 | Tablet Section (Psychotropic) | | 6 | Capsule Section (Cephalosporin) | | 7 | Dry Powder Suspension (Cephalosporin) | | 8 | Quality Control Lab | | **First Floor** | | | 9 | Stores |   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000509 (Formulation) in the name of M/s Convell Laboratories, Saidu Sharif, Swat on the recommendations of the panel of experts for the further period of five years Commencing on 26-02-2018 and ending on 25-02-2023. | | | | | | | | | | | | | | | | | | |
| 12 | M/s Legacy Pharmaceuticals (Pvt) Ltd., Plot No.111, Industrial Estate, Hayatabad, Peshawar    DML No. 000632(Formulation)  **Period**: Commencing on 19-06-2018 ending on 18-06-2023  Sections   1. Tablet (General). 2. Capsule (General). 3. Tablet (psyhotropic ). 4. Capsule (Cephalosporin ). 5. Sachet General 6. Cream/Ointment (General). 7. Oral Liquid Syrup (General). 8. Dry Powder suspension (penicillin). 9. Dry Powder (Antibiotic) (Veterinary). 10. Tablets hormone 11. Dry Powder suspension (Cephalosporin). | | | | | **22-03-2019** | | | | | | **Good** | | | | | | 1. Prof. Dr. Jamshed Ali Khan, Department of Pharmacy, Peshawar University, Peshawar. 2. Dr. Muhammad Abbas, Chief Drug Inspector, KPK, Peshawar. 3. Mr. Atiq ul Bari, Area FID, DRAP Peshawar. | |
| **Recommendations of the panel: -**  Keeping in view the above, the panel unanimously recommends the grant of renewal of DML by way of Formulation to M/s Legacy Pharmaceutical (Pvt) Ltd., 111-A, Industrial Estate, Hayatabad, Peshawar, Drug Manufacturing License No.000632. The firm is surrendering following two sections;   |  |  |  | | --- | --- | --- | | Section Name | Pharmacological Category (ies) | Remarks | | Veterinary Liquid Syrup | General | According to the firm no registration has been granted in the section yet. No production activity is observed at the time of inspection. The firm intends to surrender the section | | Veterinary Dry Powder | General | According to the firm no registration has been granted in the section yet. No production activity is observed at the time of inspection. The firm intends to surrender the section |   **Decision by the Central Licensing Board in 270th meeting**  1 The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000632 (Formulation) in the name of M/s Legacy Pharmaceuticals (Pvt) Ltd., Plot No.111, Industrial Estate, Hayatabad, Peshawar on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 and ending on 18-06-2023for following sections.   1. Tablet (General). 2. Capsule (General). 3. Tablet (psyhotropic ). 4. Capsule (Cephalosporin ). 5. Sachet General 6. Cream/Ointment (General). 7. Oral Liquid Syrup (General). 8. Dry Powder suspension (penicillin). 9. Dry Powder (Antibiotic) (Veterinary). 10. Tablets hormone 11. Dry Powder suspension (Cephalosporin).   2. The Board after perusal of recommendation of the panel of experts decided to issue showcause notices as to why following sections may not be cancelled under section 41 of the Drug Act 1976.  1.Veterinary Liquid Syrup  2.Veterinary Dry Powder | | | | | | | | | | | | | | | | | | |
| 13 | M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-4, Hattar Industrial Estate, Hattar.  DML No. 000606 (Formulation)  **Period**: Commencing on 30-12-2016 ending on 29-12-2021  Sections:   1. Tablets section General 2. Capsule section General | | | | | 04-02-2019 | | | | | | **Good** | | | | | | 1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Director DTL, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar. 4. Area Assistant Director, DRAP, Peshawar. | |
| **Recommendations of the panel: -**  “The panel conducted detailed inspection of the firm and observed that the firm has modified their various areas as per their revised/amended layout plan **approved** vide letter No.F.3-9/2005 (Vol-I) dated 20-11-2018.  As per facilities of production, quality control and environment control provided, the observations made during inspection, the qualified staff employed and evaluation made of the various sections of production and quality control, the panel unanimously **recommends** the grant of renewal of DML No.000606 (Formulation) w.e.f. 30-12-2016 and also recommends the grant of following additional sections;   1. Syrup Section (General). 2. Dry Suspension Section (General).”   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000606 (Formulation) in the name of M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-4, Hattar Industrial Estate, Hattar on the recommendations of the panel of experts for the further period of five years Commencing on 30-12-2016 and ending on 29-12-2021 for following sections as per inspection report:   1. Tablets section General 2. Capsule section General | | | | | | | | | | | | | | | | | | |
| 14 | M/s Shawan Pharmaceuticals, Plot No. 37, Street No. NS-1, National Industrial Zone, Rawat, Rawalpindi.  DML No. 000627 (Formulation).  **Period**: Commencing on 19-06-2018 and ending on 18-06-2023  Sections   1. Tablet Section (General). 2. Capsule Section (General). 3. Capsule Section (Cephalosporin). 4. Oral Dry Powder for Suspension Section (Cephalosporin). 5. Dry Powder for Injection (Vial) Section (Cephalosporin). | | | | | | 24-04-2019 | | | | | | **Good** | | | | | 1. Prof. Dr. Muhammad Usman, Member, CLB. 2. Additional Director (QA&LT), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad. | |
| “Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Shawan Pharmaceuticals, Plot No. 37, Street No. NS-1, National Industrial Zone, Rawat, Rawalpindi for the renewal of Drug Manufacturing License No. 000627 by way of (Formulation) for further period of five years as due as of today i.e 24-4-2019 for following sections namely;   1. Tablet Section (General). 2. Capsule Section (General). 3. Capsule Section (Cephalosporin). 4. Oral Dry Powder for Suspension Section (Cephalosporin). 5. Dry Powder for Injection (Vial) Section (Cephalosporin).   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000627 (Formulation) in the name of M/s Shawan Pharmaceuticals, Plot No. 37, Street No. NS-1, National Industrial Zone, Rawat, Rawalpindi on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 and ending on 18-06-2023for following sections as per inspection report :   1. Tablet Section (General). 2. Capsule Section (General). 3. Capsule Section (Cephalosporin). 4. Oral Dry Powder for Suspension Section (Cephalosporin). 5. Dry Powder for Injection (Vial) Section (Cephalosporin). | | | | | | | | | | | | | | | | | | |
| 15 | | M/s Noa Hemis Pharmaceuticals Plot No. 154 Sector 23 Korangi Industrial Area Karachi.  DML No. 000525 (Formulation)  **Period**: 21-09-2018 to 20-09-2023  Sections   1. Tablet (General). 2. Capsule (General). 3. Tablet (Antibiotic). 4. Capsule (Antibiotic). 5. Powder & Granules (Sachet). 6. Cream/Ointment (General). 7. Cream/Ointment (Steroidal). 8. Oral Liquid (Syrup/Suspension) (General). 9. Dry Powder (General) (Veterinary). 10. Dry Powder (Antibiotic) (Veterinary). 11. Oral Liquid Syrup (Veterinary). | 28.02.2019 | | | | | Good | | | | | | | 1. Dr. Abdullah Dayo, Member CLB. 2. Additional Director (E&M) DRAP Karachi. 3. Area FID, DRAP, Karachi. | | | |
| **Recommendations of the panel: -**  ***Following are the observations:-***  *M/s. Noa Hemis Pharmaceuticals, is a multiproduct facility that involved in manufacturing and release of registered Pharmaceuticals products for Human and Veterinary use. The Production areas for products for Human use is located at the ground floor while the production sections for Veterinary products are located in the dedicated block with separate change rooms. Firm also exports pharmaceutical products to Sri-Lanka, Afghanistan, Myanmar, Cambodia and Tajikistan. At present, the firm also in process of obtaining registration in the countries including Kenya, Vietnam, Phillipines, Uzbekistan and Yemen.*  *Firm is equipped with relevant Production and Quality control facilities for the manufacturing and testing of the registered products. Technical personnel with relevant technical experience were also seen engaged in the Firm. HVAC system seen installed and observed operational in the production sections.*  *Based on the people met, documents reviewed, finding of the inspection and intension of the management for boasting the exports, the panel recommends:*   1. *The grant of renewal of Drug Manufacturing License (Formulation) for all the section as per DRAP letter No. F.2-3/98Lic (Vol-I) dated 2nd June 2016 (Annex-s) with the clarification that section mentioned at serial No. 5 i.e Sachet (powder & Granules) is existed as two separate sections in the name of:* 2. *Sachet Section* 3. *Dry Powder Suspension section:*   *The firm has products registered for both the sections as mentioned at Annex-J & Annex-L and the firm has both the sections separately.”*  *However in the copy of approved layout plan forwarded by the panel along with inspection report does not possess the dry powder suspension section.*  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000525 (Formulation) in the name of M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area Karachi on the recommendations of the panel of experts for the further period of five years commencing on 21-09-2018 and ending on 20-09-2023 for following sections:   1. Tablet (General). 2. Capsule (General). 3. Tablet (Antibiotic). 4. Capsule (Antibiotic). 5. Powder & Granules (Sachet). 6. Cream/Ointment (General). 7. Cream/Ointment (Steroidal). 8. Oral Liquid (Syrup/Suspension) (General). 9. Dry Powder (General) (Veterinary). 10. Dry Powder (Antibiotic) (Veterinary). 11. Oral Liquid Syrup (Veterinary).   Furthermore, the matter of Dry Powder Suspension (General) section required further clarification from the firm. Therfore, the Board decided to defer the section for clarification from the firm regarding Dry Powder Suspension section whether the aforementioned section is already a licensed section or otherwise. | | | | | | | | | | | | | | | | |
| **16** | | M/s AsianContinental (Pvt) Ltd. D/32 SITE Super Highway Karachi.  DML No. 000643 (Formulation)  **Period**: 24-12-2018 to 23-12-2023  **Sections**   1. Tablet (General) 2. Capsule (General) 3. Dry Powder Syrup (General/Antibiotic) 4. Sterile Liquid Injection (General) 5. Liquid Syrup | 14.02.2019 | | | | | Good | | | | | | | 1. Dr. Abdullah Dayo, Member CLB, Karachi. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi. | | | |
| **Recommendations of the panel: -**  The firm is well maintained facility was granted DML during the year 2008 and is constricted as per layout plan **approved** by the DRAP authorities Islamabad. Basic equipment and machinery required for the manufacturing and quality control of registered pharmaceuticals products was found in place in respective sections.  Relevant validated methods, SOPs and other required documents were also seen in place and update. Adequate technical personal were also engaged by the firm that was observed well conversant regarding concept of GMP/cGMP. HVAC system was seen installed and operational in all the production sections.  Based on the people met, documents reviewed and observations made during the inspection, panel recommends the grant of renewal of DML No. 000643 (Formulation) for following sections:-   1. Tablet (General) 2. Capsule (General) 3. Dry Powder Syrup (General/Antibiotic) 4. Sterile Liquid Injection (General) 5. Liquid Syrup   Panel also recommends the regularization of changes made by the firm in layout plan **approved** by the DRAP authorities Islamabad.  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000643 (Formulation) in the name of M/s AsianContinental (Pvt) Ltd. D/32 SITE Super Highway Karachi on the recommendations of the panel of experts for the further period of five years commencing on 24-12-2018 to 23-12-2023 for following sections as per insepecion report:   1. Tablet (General) 2. Capsule (General) 3. Dry Powder Syrup (General/Antibiotic) 4. Sterile Liquid Injection (General) 5. Liquid Syrup | | | | | | | | | | | | | | | | |
| 17 | | M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan  DML No. 000277 (Formulation)  **Period**: 11.02.2016 to 10.02.2021 | **20.12.2018** | | | | | **Good** | | | | | | | 1. Dr. Ghulam Sarwar Member DRB. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi. | | | |
| **Recommendations of the panel: -**  *M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Tehsil Hub, Lasbella, Baluchistan was inspected by the panel members in compliance to DRAP’s letter No. F.4-3/86-Lic (Vol-II) dated 31st October, 2018. The panel reviewed their overall documentation, inspected Manufacturing Facility, Quality Control Lab & Store and met with their technical persons. Following are the observations:*   1. *The panel observed the premises constructed as per DRAP’s* ***approved*** *LoP.* 2. ***As per record, at the time of grant of license. M/s Kaligon Agro Industries was situated at industrial area under Hub industrial Trading Estate (HITE), however at present, M/s. Kailgon Agro Industries is not covered under the said industrial estate i.e. HITE. However, the management of firm is planning to shift the facility from current site to another suitable site and submitted the affidavit*** *(enclosed as Annex-E).* 3. *An appropriate level of sanitation, cleanliness & workers hygiene was noted.* 4. *Personnel met during inspection were observed having prescribed qualification and experience and were well conversant regarding GMP compliance.* 5. *Basic equipment required for tests/analysis of the registered products seen in place and in operational condition.*   ***Based on the stated observations, the panel recommends the grant of renewal of their DML no. 000277 By way of Formulation (subject to approval of location of the facility by the Central Licensing Board) for following sections, for the next five years.***   1. ***Dry Powder (VET)*** 2. ***Liquid / Suspension (VET)*** 3. ***Tablet (VET)***   ***However, the panel does not recommend the renewal of Injection Section (as it does not comply with the GMP requirement) until the UP-gradation with necessary arrangements as required for parenteral drugs production.***  **Decision by the Central Licensing Board in 270th meeting**  The Board considered the case and afer thread bare deliberation decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Liquid vial Section (Human General) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain suspended in liquid vial injection (Human General) till decision by CLB .  The Board also d**effered the case for** the renewal of Drug Manufacturing Licence No. 000277 (Formulation) in the name of M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan for seeking clarification from Area FID regarding exact location of the firm. | | | | | | | | | | | | | | | | |

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| 18 | M/s AJM Pharma (Pvt) Ltd, Plot No. 44, sector 27, korangi In  dustrial Area, Karachi  DML No. 000234 (Formulation)  **Period**: 10.07.2015-09.07.2020  **Sections**   1. Tablet Section (General) 2. Capsule Section (General) 3. Liquid Syrup (General) 4. Cream/Ointment Section | **13.03.2019** | | **Good** | | | 1. Prof Ghulam Sarwar, Member DRB Karachi. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi. |
| **Recommendations of the panel: -**  *M/s AJM Pharma (Pvt) Ltd, was purchased by the new management from the old management while the firm was operating with the name of M/s. Meredoa Company at that time. DRAP authorities* ***approved*** *the change of management and name of company vide letter No. F. 2-31/84-Lic (Vol-III) . As per record, follow-up inspection and stamen of the new management, there was the production activated was carried out in the firm due to continuous up gradation of the production and testing facilities and due to limited number of registered pharmaceuticals products.*  *During the inspection it was observed that all the above mentioned sections of M/s. AJM Pharma are as per layout plan* ***approved*** *by the DRAP authorities except the ointment/cream section, that is neither available on site nor it mentioned on the layout plan. Relevant manufacturing and quality control sections were observed equipped with necessary equipment and machinery required for the test/analysis of the products registered so far. Senior technical personnel as* ***approved*** *by the DRAP were also available on site. HVAC system seen installed in the production areas and observed operational.*  *Moreover, management of the firm also observed involved in construction/maintenance/expansion of additional sections for which the firm has been granted approval of layout plan vide DRAP Islamabad letter No. F.2-31/84-Lic (Vol-III) dated 6th June 2018.*  ***Keeping in vies the people met, documents reviewed and finding of the inspection panel recommends the grant of renewal of following sections:***   |  |  | | --- | --- | | ***S.No*** | ***Sections*** | | ***1.*** | ***Tablet (General)*** | | ***2.*** | ***Capsule (General)*** | | ***3.*** | ***Liquid Syrup (General)*** |   ***Grant of the renewal of the Ointment/cream section is not recommended as, it doesn’t exists physically.***  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000234 (Formulation) in the name of M/s AJM Pharma (Pvt) Ltd, Plot No. 44, sector 27, korangi Industrial Area, Karachion the recommendations of the panel of experts for the further period of five years commencing on 10.07.2015to 09.07.2020 for following sectios   |  | | --- | | 1. ***Tablet (General)*** | | 1. ***Capsule (General)*** | | 1. ***Liquid Syrup (General)*** |   2. The Board after perusal of recommendation of the panel of experts decided to issue showcause notices as to why following sections may not be cancelled under section 41 of the Drug Act 1976.  1. Ointment /cream section | | | | | | |
| 19 | M/s Nawan Laboratories (Pvt) Ltd, Plot No. 136, sector 15, Korangi Industrial Area, Karachi.  DML No. 000442 (Formulation)  **Renewal of pending 02 sections:**   1. Liquid vial Section (Human General) 2. Liquid Injection (cephalosporin Vet)   **Period**: 28.06.2016-27.06.2021 | | **21.03.2019** | | **Good** | 1. Dr. Abdullah Dayo, Member CLB Karachi. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi. | |
| **Recommendations of the panel: -**  During the course of inspection the panel visited all manufacturing storage, Quality Control and utility areas in details and it was observed that all aforesaid 17 section were found constructed as per layout plan, therefore the panel recommends the regularization of layout plan which has been already **approved** by the licensing Directorate DRAP Islamabad.  Keeping in view the good facilities made available and over all well maintained in accordance with cGMP guidelines, the panel recommends the renewal of firm’s Drug Manufacturing license (by way of formulation) bearing DML No. 000442 for the pending section of Cephalosporin Liquid Injection (veterinary) having dedicated HVAC.  For the renewal of 2nd section that is liquid vial Injection (Human General), it was observed that the firm is not interested in continuing the registrations and production with respect to this section, therefore the area found not maintained as per cGMP compliance and found closed, **hence the panel does not recommend the renewal of liquid vial injection (Human General),** However the layout of this section is **approved** as found constructed as per DRAP **approved** layout plan.  Production in the above said area will remain suspended till the firm is ready for the inspection and further direction by DRAP Islamabad (undertaking of the firm is attached with the report)  **Decision by the Central Licensing Board in 270th meeting**   1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000442 (Formulation) in the name of M/s Nawan Laboratories (Pvt) Ltd, Plot No. 136, sector 15, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the further period of five years commencing on 28.06.2016 to 27.06.2021 for pending section of liquid injectable veterinary (cephalosporin). 2. The Board considered and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Liquid vial Section (Human General) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain stopped/suspended in liquid vial injection (Human General) till decision by CLB . | | | | | | |
| 20 | M/s GlaxoSmithKline Pakistan Ltd, F-268, S.I.T.E  Karachi  DML No. 000023 (Formulation)  **Period**: 10.07.2015-09.07.2020 | **26.03.2019, 27.03.2019 & 01.04.2019** | | **Good** | | | 1. Syed Muied Ahmed, Member CLB (Not available) 2. Chief Drug Inspector, Sindh. 3. Federal Govt. Analysist, Karachi. 4. Additional Director (E&M), DRAP, Karachi. 5. Area Federal Inspector of Drugs, DRAP, Karachi. |
| **Recommendations of the panel: -**  *“The firm’s facilities and systems for production, quality and storage of their registered products were inspected in detail during the three days for suitability and GMP compliance. Every section was specifically inspected for GMP, HVAC and other measures for control of contamination and cross-contamination, qualification and validation exercises. The observations of previous inspections and their CAPA were reviewed in detail and related improvements were objectively verified, Special consideration was also given to cleaning procedures related to potent products and chemical exposure studies especially in penicillin manufacturing sections. The overall GMP compliance of facilities, systems and practices of the firm were found in order and can be rated as “good”.* ***In view of the above facts the panel recommends the renewal of license No. 000233 (by way of formulation.)***  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000023 (Formulation) in the name of M/s GlaxoSmithKline Pakistan Ltd, F-268, S.I.T.E  Karachion the recommendations of the panel of experts for the further period of five years commencing on 10.07.2015 to 09.07.2020. | | | | | | |

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| 21 | M/s Akhai Pharmaceutical (Pvt) Ltd, Plot No. A-248, A-256 to A-259. H.I.T.E., Lasbella, Balochistan.  DML No. 000640 (Formulation)  **Period**: 19.06.2018 to  18.06.2023  **Sections**   1. Tablet (General) 2. Capsule (General) 3. Topical (Cream/Ontment) (General ) 4. Tablet (Psychotropic) | | | **11-04-2019** | | **Good** | 1. Dr. Abdullah Dayo, Member CLB Karachi) 2. Chief Drug Inspector, Sindh. 3. Area Federal Inspector of Drugs, DRAP, Quetta at Karachi. | |
| **Recommendations of the panel: -**  *“M/s Akhai Pharmaceuticals (Pvt) Ltd located at* Plot No. A-248, A-256 to A-259. H.I.T.E., Lasbella, Balochistan was inspected by the panel members in compliance to DRAP’s letter Dated : 07-02-2019 . The panel reiewed their overall documentation , SOP’s, inspected manufacturing facility , Quality control Laboratory & stores and met their technical persons. Following are the observations :   1. ***The panel observed the premises of M/s Akhai Pharmaceuticals*** *(Pvt) Ltd .* 2. ***An appropriate level of sanitation, cleanliness & workers hygiene was noted.*** 3. ***Personnel met during the inspection were oberserved having prescribed qualification and experience and were well conversant regarding GMP compliance.*** 4. ***Basic equipment required for tests / analysis of the registered products seen in place and in operational condition.***   ***Based on the stated observations, the panel recommends the grant of renewal of their DML No. 000640 (Formulation) by way of Formulation for following sections :***   1. ***Tablet (General)*** 2. ***Capsule (General)*** 3. ***Topical (Cream/Ontment/Gel/Lotion)*** 4. ***Tablet (Psychotropic)***   **Panel was given mandate for inspection of Cream/Ointment (General) section along with other sections for renewal of DML however in panel inspection report panel has recommended *Topical (Cream/Ontment/Gel/Lotion) instead.***  **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000640 (Formulation) in the name of M/s Akhai Pharmaceuticals (Pvt) Ltd, Plot No. A-248, A-256 to A-259. H.I.T.E., Lasbella, Balochistan on the recommendations of the panel of experts for the further period of five years commencing on 19.06.2018 to 18.06.2023 for following sectios as per inspection report :   1. Tablet (General) 2. Capsule (General) 3. Topical (Cream/Ontment)(General ) 4. Tablet (Psychotropic) | | | | | | | | |
| 22 | | M/s Metro Pharmaceuticals, Plot No. 14, SS-2, National Industrial Zone, RCCI Rawat, Islamabad.  DML No. 000772 (Formulation)  **Period**: 08-03-2018 to  07-03-2023  **Sections**   1. Tablet Section (General). 2. Capsule Section (General). 3. Dry Powder Suspension (General). 4. Oral Liquid (General). 5. Sachet (General). 6. Ointment Cream / Gel / Lotion (General). | | **17.05.2019** | | **Good** | 1. Dr. Gul Majeed Khan, Quaid-e-Azam University, Islamabad. 2. Dr. Abdur Rasheed, Director (Pharmacy Services), DRAP, Islamabad. 3. Dr. Hasan Afzaal, FID-III, DRAP, Islamabad. | |
| **Recommendations of the panel: -**  “Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Metro Pharmaceuticals, Plot No. 14, SS-2, RCCI, Rawat, Rawalpindi for the renewal of Drug Manufacturing License No. 000772 (Formulation) for the following sections namely alongwith with additional sections as under;   1. Tablet Section (General). 2. Capsule Section (General). 3. Dry Powder Suspension (General). 4. Oral Liquid (General). 5. Sachet (General). 6. Ointment Cream / Gel / Lotion (General).   For the grant of additional sections namely;   1. Capsule Section (Ceph). 2. Dry Suspension Section (Ceph). 3. Dry Vial Injection (Ceph). 4. Sachet (Ceph). 5. Liquid Vial Injection (General). 6. Liquid Ampoule (General). 7. General Sterile Dry Powder Injection (Pre Lyophilized ready to fill).   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000772 (Formulation) in the name of M/s Metro Pharmaceuticals, Plot No. 14, SS-2, National Industrial Zone, RCCI Rawat, Islamabad on the recommendations of the panel of experts for the further period of five years commencing on 08-03-2018 to 07-03-2023 for following sectios as per inspection report :   1. Tablet Section (General). 2. Capsule Section (General). 3. Dry Powder Suspension (General). 4. Oral Liquid (General). 5. Sachet (General). 6. Ointment Cream / Gel / Lotion (General). | | | | | | |
| 23 | | M/s Citi Pharma (Pvt) Ltd, 3-km, Head Balloki Road, Bhai Pheru, Distt Kasur.    DML No. 000512 (Formulation)  **Period**: Commencing on  26-06-2018 ending on  25-06-2023.  **Sections**   1. Oral Liquid (General) 2. Tablet (General) 3. Capsule (General) sections 4. Oral Dry Powder Suspension Section 5. Capsule Sections | **19-03-2019** | | **Good** (w.r.t Oral Liquid, Tablet & Capsule Sections)  **Unsatisfactory**  (w.r.t. Oral Powder Suspension & Capsule Ceph. Sections) | | | 1. Dr. Farzana Chowdhary, Expert. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 4. Mr. Shahrukh Ali, Assistant Director, DRAP, Lahore. |
| **Recommendations of the panel: -**  The panel of inspectors **recommends** the renewal of DML bearing No. 000512 issued in favour of M/s Citi Pharma, (Pvt) Ltd, Lahore in respect of Oral Liquid (General) Tablet (General) & Capsule (General) sections only, The panel of inspectors **Does Not Recommend** the renewal in respect of Cephalosporin (Oral Dry Powder Suspension and Capsule Sections).  **Decision by the Central Licensing Board in 270th meeting**   1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000512 (Formulation) in the name of M/s Citi Pharma (Pvt) Ltd, 3-km, Head Balloki Road, Bhai Pheru, Distt Kasur on the recommendations of the panel of experts for the further period of five years commencing on 26-06-2018 and ending on 25-06-2023 in respect of Oral Liquid (General) Tablet (General) & Capsule (General) sections. 2. The Board considered and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Cephalosporin (Oral Dry Powder Suspension and Capsule) Section may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain stopped/suspended in Cephalosporin (Oral Dry Powder Suspension and Capsule) Section till decision by CLB. | | | | | | |
| 24 | | M/s Derma Techno Pakistan, Plot NO. 582, Sunder Industrial Estate, Raiwind Road, Lahore.  DML No. 000728 (Formulation)  **Period**: Commencing on 15-06-2016 ending on 14-06-2021.  Sections   1. Tablet (General) Section. 2. Capsule (General) Section. 3. Cream / Ointment (General) Section. 4. Topical Lotion (General) Section. 5. Semi-solid (Steroidal) Section. | | **21-01-2019** | | **Good** | 1. Dr. Farzana Chowdhary, Expert. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore. | |
| **Recommendations of the panel: -**  Keeping in view the facility like building, HVAC system, Machinery & equipment,  instruments, personal documentation and testing facilities the panel of inspectors is of the  opinion that the Renewal of Drug Manufacturing License to M/s Derma Techno Pakistan,  528-Sunder Industrial Estate, Lahore be **recommended** for the following sections:   1. Tablet (General) Section. 2. Capsule (General) Section. 3. Cream / Ointment (General) Section. 4. Topical Lotion (General) Section. 5. Semi-solid (Steroidal) Section.   **Decision by the Central Licensing Board in 270th meeting**  The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000728 (Formulation) in the name of M/s Derma Techno Pakistan, Plot NO. 582, Sunder Industrial Estate, Raiwind Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 15-06-2016 ending on 14-06-2021 for following sections as per inspection report:   1. Tablet (General) Section. 2. Capsule (General) Section. 3. Cream / Ointment (General) Section. 4. Topical Lotion (General) Section. 5. Semi-solid (Steroidal) Section. | | | | | | |
| 24 | | M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad.  DML No. 000795 (Formulation)  **Period**: Commencing on 25-03-2019 ending on 24-03-2024.  **Sections**   1. Syrup (General) 2. Plasters. 3. Capsules (General) 4. Tablets (General) 5. Creams/Ointment (General) 6. Sachet (General) | | **21-05-2019** | | **Good** | 1. Professor Dr. Muhammad Usman, Member Central Licensing Board. 2. Deputy Director (QC), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad. 4. Dr. Muhammad Usman, Assistant Director (Licensing), DRAP, Islamabad. | |
| **Recommendations of the panel: -**  Keeping in view the facts on record, the panel unanimously ***recommends the approval of renewal of Drug Manufacturing License by way of Formulation DML N:000795 to***M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Humak, Islambad for following two (2) sections only:   1. Syrup (General) 2. Plasters.   While the approval/renewal of sections namely capsules, Tablets, Creams/Ointment and sachet will be subject to completion of work and subsequent panel inspection and approval by Licensing Board. Hence, the panel did not recommend the renewal of aforementioned sections.  **Decision by the Central Licensing Board in 270th meeting**   1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000795 (Formulation) in the name of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the further period of five years commencing on 25-03-2019 and ending on 24-03-2024 in respect of Syrup(General) section. 2. The Board considered and alsodecided to issue **showcause notice** under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for capsules, Tablet, Creams/Ointment Sections may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain **stopped/suspended** in capsules, Tablets, Creams/Ointment till decision by CLB. 3. The Board also decided to **refer** the mater of Plasters Section to MD&MC Division for further processing the case as the subject matter falls under the domain of MD&MC Division. | | | | | | |
| 25. | M/s Medicure Laboratories, Plot No. F-109, S.I.T.E, Karachi.  DML No. 000034 (Formulation)  **Period**: 30.04-15 to 29-04-2020  **Sections**   1. Tablet (General) Section 2. Liquid Suspension (General) 3. Capsule (General) 4. Re-Packing (General) Section. 5. Veterinary Liquid Section. | | | 22.03.2019 | | Good | 1. Dr. Ghulam Sarwar, Member DRB. 2. Additional Director (E&M) DRAP Karachi. 3. Area FID, DRAP, Karachi. | | |
| ***Recommendations of the panel: -***   1. *During the inspection it was observed that the firm is not involved in manufacturing and testing at present since their production was suspended with effect from 14.07.2016 after a panel inspection.* 2. *The management has brought improvement of the manufacturing and testing facility during this period at present. However,* 3. *Layout plan of the firm is not approved by the concerned DRAP, Authorities. Firm has submitted the lay out plan to the concerned Division of DRAP for which they have provided the receiving (Annexure-F)* 4. *In general necessary equipment and machines were observed available and HVAC system seen installed and operational in Tablet (General) and Liquid (General\_ Sections.* 5. *The remaining section still require up-gradation in terms of equipment, maintenance/provision of HVAC system, documentation etc.*   *Keeping in view people met, documents reviewed, and considering the facts of the inspection, panel recommends the grant of:*   1. *Renewal of Drug Manufacturing License No. 000034 (By way of formulation) to M/s Medicure Laboratories License for only following five sections:*  |  |  | | --- | --- | | 1. *Tablet (General) Section* | 1. *Liquid Suspension (General)* | | 1. *Capsule (General)* | 1. *Re-Packing (General) Section* | | 1. *Veterinary Liquid Section* | |  1. *The firm is advised to get layout plan approved from the concerned Directorate in DRAP, Islamabad and should submit the up-gradation report of the section for which a re-inspection after improvement is recommended.*   **Decision by the Central Licensing Board in 270th meeting**   1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000034 (Formulation) in the name of M/s Medicure Laboratories, Plot No. F-109, S.I.T.E, Karachi on the recommendations of the panel of experts for the further period of five years commencing on 30.04-2015 and ending on 29-04-2020 for following sections: 2. Tablet (General) Section 3. Liquid Suspension (General) 4. Capsule (General) 5. Re-Packing (General) Section. 6. Veterinary Liquid Section. T   2. The Board considered the case and also decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Ointment Section& Powder (Veterinary) Section may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain **stopped/suspended** in Ointment Section & Powder (Veterinary) Section till decision by CLB. | | | | | | | | |

**ITEM – V MISC CASES**

**CaseNo.1 CHANGE OF MANAGEMENT OF M/S AVANT PHARMACEUTICALS (PVT) LIMITED, PLOT NO. 28 HUB INDUSTRIAL ESTATE HUB BALUCHISTAN.**

M/s Avant Pharmaceuticals (Pvt) Limited, Plot No. M-28 Hub Industrial Estate Hub Baluchistan, under DML No. 000786 (By way of formulation ) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing Management** | **Retiring Management** | **New Management** |
| 1. Mr. Faraz S/O Mr. Sabir Ali  CNIC NO. 42000-4537934-1 | 1. Mr. Zakir Ali S/O Mr. Sabir Ali  CNIC NO. 42201-6817863-9 | 1. Mr. Faraz S/O Mr. Sabir Ali  CNIC NO. 42000-4537934-1 |
| 2. Mr. Zakir Ali S/O Mr. Sabir Ali  CNIC NO. 42201-6817863-9 | \*\*\*\*\*\*\*\* | 2. Ms. Shazia Begum W/O Mr. Faraz  CNIC NO. 42201-9600891-8 |

**Decision by the Central Licensing Board in 270th meeting:**

The Board considered and endorsed the change of management of M/s Avant Pharmaceuticals (Pvt) Limited, Plot No M-28 Hub Industrial Estate Hub Baluchistan, under DML No. 000786 (By way of formulation) as per Form-29 as under ;

|  |  |  |
| --- | --- | --- |
| **Existing Management** | **Retiring Management** | **New Management** |
| 1. Mr. Faraz S/O Mr. Sabir Ali  CNIC NO. 42000-4537934-1 | 1. Mr. Zakir Ali S/O Mr. Sabir Ali  CNIC NO. 42201-6817863-9 | 1. Mr. Faraz S/O Mr. Sabir Ali  CNIC NO. 42000-4537934-1 |
| 2. Mr. Zakir Ali S/O Mr. Sabir Ali  CNIC NO. 42201-6817863-9 | \*\*\*\*\*\*\*\* | 2. Ms. Shazia Begum W/O Mr. Faraz  CNIC NO. 42201-9600891-8 |

**CASE NO.2. REGULARIZATION OF LAYOUT PLAN OF M/S ASIANCONTINENTAL PLOT NO. D-32, S.I.T.E SUPER HIGHWAY KARACHI.**

M/s Asian Continental Plot No. D-32, S.I.T.E Super Highway Karachi., DML No. 000643 (Formulation), has applied for regularization of layout plan of running facility for their existing following sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory:

|  |  |  |  |
| --- | --- | --- | --- |
| **Existing Sections/New Facility.** | | | |
|  | Tablet (General) |  | Capsule (General) |
|  | Oral Liquid (General) |  | Dry Powder Suspension (General- Antibiotic) |
|  | Liquid Ampoule (General) |  | Quality Control Laboratory |
|  | Warehouse |  | \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* |

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per **approved** layout plan.

1. Abdullah Dayo, Member CLB, Karachi.
2. Additional Director (E&M), DRAP, Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the below mentioned section.

**Following are the observations:**

Panel also recommends the regularization of changes made by the firm in layout plan **approved** by the DRAP authorities Islamabad.

**Decision by the Central Licensing Board in 270th meeting:**

The Board considered and **approved** regularization of the layout plan as per recommendations of the panel of experts for following sections

|  |  |  |  |
| --- | --- | --- | --- |
| **Existing Sections/New Facility.** | | | |
|  | Tablet (General) |  | Capsule (General) |
|  | Oral Liquid (General) |  | Dry Powder Suspension (General- Antibiotic) |
|  | Liquid Ampoule (General) |  | Quality Control Laboratory |
|  | Warehouse |  | \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* |

**CASE NO.3. REGULARIZATION OF LAYOUT PLAN OF M/S NAWAN LABORATORIES (PVT) LTD, PLOT NO. 136, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI DML NO. 000442 (FORMULATION)**

M/s Nawan Laboratories (Pvt) Ltd, Plot No. 136, sector 15, Korangi Industrial Area, Karachi DML No. 000442 (Formulation)has applied for regularization of layout plan of running facility for their existing FOLLOWING sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory:

|  |  |  |  |
| --- | --- | --- | --- |
| **S.No.** | **GROUND FLOOR** | **S.No.** | **FIRST FLOOR** |
| **1.** | Tablet Section (General) | **1.** | Liquid Injection Section (General) |
| **2.** | Capsule Section (General) | **2.** | Liquid Injection Section (Veterinary) (Cephalosporin) |
| **3.** | Dry Suspension Section (General) | **3.** | Capsule Section (Cephalosporin) |
| **4.** | Oral Liquid Syrup Section (General) | **4.** | Dry Powder Suspension Section (Cephalosporin) |
| **5.** | Tablet Section (Veterinary) | **5.** | Liquid Injectable Section (Veterinary) |
| **6.** | Dry Powder Sachet Section (General) (Veterinary) | **6.** | Dry Powder Injectable Section (Cephalosporin) |
| **7.** | Oral Liquid Syrup Section (General) (Veterinary) | XXX | XXXXXXXXXXXXXXXXXXXXXXX |
|  | **THIRD FLOOR** |  | **SECOND FLOOR** |
| **1.** | Dry Powder Injectable Section (Penicillin – Veterinary) | **1.** | Quality Control Laboratory |
| **2.** | Liquid Injectable Section (Penicillin – Veterinary) | XXX | XXXXXXXXXXXXXXXXXXXXXXX |
| **3.** | Dry Powder Sachet Section (Penicillin – Veterinary) | XXX | XXXXXXXXXXXXXXXXXXXXXXX |

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per **approved** layout plan.

1. Abdullah Dayo, Member CLB, Karachi.
2. Additional Director (E&M), DRAP, Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the below mentioned section.

**Following are the observations:**

During the course of inspection the panel visited all manufacturing storage, Quality Control and utility areas in details and it was observed that all aforesaid 17 section were found constructed as per layout plan, therefore the panel recommends the regularization of layout plan which has been already **approved** by the licensing Directorate DRAP Islamabad.

**Decision by the Central Licensing Board in 270th meeting:**

The Board considered and **approved** regularization of the layout plan as per recommendations of the panel of experts for following sections

|  |  |  |  |
| --- | --- | --- | --- |
| **S.No.** | **GROUND FLOOR** | **S.No.** | **FIRST FLOOR** |
| **1.** | Tablet Section (General) | **1.** | Liquid Injection Section (General) (Te renewal of said section not recommended by Board). |
| **2.** | Capsule Section (General) | **2.** | Liquid Injection Section (Veterinary) (Cephalosporin) |
| **3.** | Dry Suspension Section (General) | **3.** | Capsule Section (Cephalosporin) |
| **4.** | Oral Liquid Syrup Section (General) | **4.** | Dry Powder Suspension Section (Cephalosporin) |
| **5.** | Tablet Section (Veterinary) | **5.** | Liquid Injectable Section (Veterinary) |
| **6.** | Dry Powder Sachet Section (General)(Veterinary) | **6.** | Dry Powder Injectable Section (Cephalosporin) |
| **7.** | Oral Liquid Syrup Section (General) (Veterinary) | XXX | XXXXXXXXXXXXXXXXXXXXXXX |
|  | **THIRD FLOOR** |  | **SECOND FLOOR** |
| **1.** | Dry Powder Injectable Section (Penicillin – Veterinary) | **1.** | Quality Control Laboratory |
| **2.** | Liquid Injectable Section (Penicillin – Veterinary) | XXX | XXXXXXXXXXXXXXXXXXXXXXX |
| **3.** | Dry Powder Sachet Section (Penicillin – Veterinary) | XXX | XXXXXXXXXXXXXXXXXXXXXXX |

**Case No.4 APPROVAL OF MASTER LAYOUT PLAN / AUTHENTICATION /  
REGULARIZATION OF EXISTING FACILITY, DRUG  
MANUFACTURING LICENSE NO. 000578 (FORMULATION) OF M/S JINNAH PHARMACEUTICALS (PVT) LTD, MULTAN**

M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km, Lahore Road, Multan under DML No. 000578 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

|  |  |  |  |
| --- | --- | --- | --- |
| **Regularization / Authentication / Amendment of Already existing Sections.** | | | |
|  | Capsule (General) Section |  | Tablet (General) Section. |
|  | Sachet (General) Section. |  | \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* |

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per **approved** layout plan.

* + 1. Dr. Mahmood Ahmed, Ex-Dean, Islamia University of Bhawalpur.
    2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore.
    3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore.

Accordingly, Panel has inspected the premises and verified the above mentioned section.

**Recommendations: -**

Keeping in view the facility like building, HVAC system, sanitation, production Machinery, Equipment in Quality Control and Microbiology Laboratory, Testing Facilities, Technical Personnels met and documentation, the panel of inspectors recommends the Renewal of Drug Manufacturing License by way of formulation along with regularization for the following sections:

1. Capsule (General) Section.
2. Tablet (General) Section.
3. Sachet (General) Section.

**Decision by the Central Licensing Board in 270th meeting:**

The Board considered and **approved** regularization of the layout plan as per recommendations of the panel of experts for following sections.

|  |  |  |  |
| --- | --- | --- | --- |
| **Regularization / Authentication / Amendment of Already existing Sections.** | | | |
|  | Capsule (General) Section |  | Tablet (General) Section. |
|  | Sachet (General) Section. |  | \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* |

**Case No. 5 M/S PHARMAWISE LABS (PVT) LTD, QA INDUSTRIAL ESTATE, LAHORE**

**Background of the case**

Mr. Abdul Rashid Shaikh, FID, Lahore conducted inspection of the company on 20.05.2016 to verify the GMP compliance and production activities. The FID noticed number of observations. Accordinlgy the firm was served a showcause notice. The case was placed in 249th Meeting of CLB held on 29.08.2016

**Decision of the 249th Meeting of CLB held on 29.08.2016**

* After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, compliance report of the firm, the Board decided to conduct panel cGMP inspection of the firm on **approved** format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members:-

1. Dr. Syed Muid Ahmed, Member CLB.
2. Dr. Abdur Rashid, CQC
3. Mr. Akbar Jan, Chief Drug Inspector, KPK.
4. Mr. Abdul Rashid Shaikh, FID, Lahore.

* The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous inspection’s observations and the current status with clear and candid recommendations.

Decision was conveyed to the panel.

**Present Status**

A panel comprising of Dr. Abdur Rashid, Chairman Quality Control and Mrs. Anam Saeed, FID, Lahore with reference to decision of the CLB in its 249th Meeting. The panel inspected of the firm on 19.07.2017.

The panel informed that Dr. Abdur Rashid communicated with panel members. Mr. Akbar Jan agreed to join the panel but at the last movement he had to go to drug court and could not join the panel. Dr. Syed Muid Ahmed also could not come.

The panel noticed number of observations, which need urgent attention and rectification. The observations includes:-

**Personnel:**

* It was advised to appoint more technical staff for each section as per Drug Act, 1976 and rules framed there under.
* In QC section, the firm had engaged four pharmacists (Quality Control   
  In-charge had 12 year experience in herbal but no experience in allopathic medicines).
* Both production In-charge and QC In-charge were not **approved** by DRAP, Islamabad till date.

**HVAC**

* There was no proper HVAC system. During last inspection, management informed the FID that they had collected different quotations for the installation of their HVAC but it was not installed till date.

**Raw material store (RMS)**

* At the entry of RMS a small change room was seen with inadequate changing facility. (Shoe covers, overalls, cabinets).
* The store was provided with a receiving bay but no de-dusting area. Door of the receiving bay was not concealed properly. The store had two ply-wood walls; one wall had gaps and holes exposing the internal environment to the external environment.
* Racks were found in the area where active and inactive materials were placed but arrangement was not proper.
* Corners of the walls were sharp. Paint was peeled off at certain places on the walls.
* Change room of this area was used for transfer of raw materials to production area.
* Overall the RMS was having inadequate space.

**It was advised to:-**

* Make the area spacious.
* Make proper change room with adequate facilities at the entry of RMS.
* Replace ply wood walls with brick masonry/impervious walls.
* Make a separate de-dusting area with the arrangement of de-dusting machine.
* Make proper rejected and quarantine areas.
* Arrange the active and inactive materials in a proper and organized way with a rack plan.
* Make the corners of the walls round and smooth.
* Redo the paint where required.
* Make raw material exit separate from personal entry.

**Liquid raw material store:**

**It was advised to:-**

* Make the area spacious.
* Improve the area with respect to sanitation and flooring
* Maintain temperature and humidity of the area.

**Packing material store**

**It was advised to:-**

* Install a split air conditioner in the area
* Maintain temperature and humidity record
* Replace tube lights with concealed lights
* Store aluminum foils in a properly covered manner.

**Finished Goods store**

**It was advised to:-**

* Arrange proper racks for storage of products.
* Arrange one more hygrometer and hand on the other corner of the store and maintain temperature and humidity record.
* Remove fan and arrange concealed lights in the area.

**It was advised to:-**

* Redo paint where required
* Improve sanitation
* Arrange proper laundry system for washing of uniforms.
* Provide proper washrooms and lavatory facility as well as hand sanitizer
* Provide air curtains at the entry point

**Female change room:-**

**It was advised to:-**

* Improve cleanliness
* Provide proper washrooms and lavatory facility as well as hand sanitizer

**Executive Entrance:-**

* It was advised to make a proper executive change room with adequate facilities.

**Granulation Area:-**

**It was advised to:-**

* Make the area spacious
* Replace FB dryer with new one
* Arrange more bags for FB dryer
* Redo paint where required
* Conceal open electric wires and lights
* Remove ceiling fans.

**Compression areas I and II**

**It was advised to:-**

* Make the area spacious.
* Replace rusted machinery with new ones.
* Replace iron stool with SS.
* Redo paint where required
* Remove gas pipeline from the area on priority basis.

**Film coating area:-**

**It was advised to:-**

* Renovate the area with proper flooring
* Remove hooks from the walls
* Replace rusted spray gun stand with new one

**Sugar coating area:-**

**It was advised to:-**

* Replace rusted equipment with a new ones
* Remove all unnecessary / irrelevant equipment from the area
* Improve flooring of the area
* Properly close the electric panel

**Blistering and packing area:-**

* It was advised to remove fans and arrange a split air conditioner and concealed lights and maintain temperature and humidity record.

**Local application filling area:-**

**It was advised to:-**

* Make proper impervious wall
* Remove unnecessary things and equipment from the area.
* Replace wooden chair with SS.

**Local application formulation area:-**

**It was advised to:-**

* Replace old and rusted machinery with new ones.
* Display status tags on each equipment
* Remove ceiling fans, arrange split air conditioner and concealed lights.
* Remove unnecessary equipment from the area.

**External preparation (local antiseptic liquid) section:-**

* It was advised to:-
* Replace rusted equipment with new ones
* Replace wooden furniture with SS.
* Maintain temperature and humidity record of the area.

**Syrup / suspension section:-**

**It was advised to:-**

* Make proper impervious wall instead of plywood wall
* Remove unnecessary water and gas pipelines from the area
* Properly place the colloidal mill and silverson mixer on the floor
* Make a separate bottle blowing area to avoid cross contamination.
* Remove irrelevant / unnecessary equipment from the area.
* Redo paint where required.

**ORS Section:-**

* Replace rusted equipment with new ones.
* Ensure safety grill for double cone mixer
* Remove unnecessary door and window
* Display status tags of clean / unclean on each equipment.
* Replace wooden furniture with SS.

**Antibiotic Tablet / Powder Section**

**It was advised to:-**

* Make separate drying and compression areas.
* Replace rusted equipment with new one.

**Capsule Section:-**

* It was advised to maintain temperature and humidity record of the area.

**Repacking Section:-**

* It was advised to place relevant machinery / equipment in the section.

**Retained sample room:-**

**It was advised to:-**

* Arrange retained samples in a proper organized way and make a rack plan also.
* Maintain temperature and humidity record or the area
* Discard samples after two years of their expiry and follow written procedure for it.
* Remove ceiling fan and arrange concealed lights in the area.
* Remove unnecessary / irrelevant equipment form the area.

**In-process quarantine area:-**

* Multiple in process materials were found in the IPQA such as Phonton tablet stored in the area since 24.05.2017 and Solprin 300 mg tablet stored since 24.04.2017. Firm management told that reprocessing was planned for these products. It was advised to avoid such practice in future.

**Quality Control:-**

**It was advised:-**

* Purchase some reference standards.
* Mention manufacturing and expiry dates on the labels of the reagents.
* Replace pHmeter and magnetic stirrer with new ones.
* Replace open dustbin within closed one.
* FTIR was not purchased yet.

**Action Taken by DRAP**: - Accordingly the firm was served show cause notice for above mentioned violations on 23.10.2017.

**Reply of the firm**:- Reply of the firm is awaited.

**Proceedings of the 256th meeting of the CLB**

Ch. Nadir, CEO, Miss Uzma Gull, Production In-charge and Mr. Numan Nadir, Director of the firm M/s Pharmawise Labs, Lahore appeared before the Board for personal hearing. Ch. Nadir informed to the Board that most of the observations noted in inspection conducted on 20.05.2017 have been rectified. The Board raised query regarding installation of HVAC in the unit and other critical observations noted during the inspection. CEO of the firm M/s Pharmawise Labs, Lahore informed that layout of new unit is under submission to the Licensing Division and the observations shall be rectified on priority basis.

**Decision of the 256th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, critical observation of the panel noted during the inspection and conclusion of the panel its report dated 19.07.2017, stating that the firm was not complying GMP guidelines satisfactorily, the Board decided to cancel the Drug Manufacturing License of the firm M/s Pharmawise Labs (Pvt) Ltd, QA Industrial Estate, Lahore, under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (L,R&A) Rules, 1976, from the date of issuance of decision of the 256th meeting of CLB.

**Proceedings of 150th meeting of the Appellate Board**

In compliance of the decision of the Central Licensing Board (CLB) taken in its 249th meeting, the inspection of M/s PharmaWise Labs (Pvt.) Limited, Lahore was conducted by a panel of experts comprising of the following members:

i) Dr. Abdur Rasheed, Chairman, Quality Control, Islamabad; and

ii) Mrs. Anam Saeed, FID Lahore.

2. The panel noticed number of critical observations during the visit and concluded that the firm was not complying with the GMP guidelines satisfactorily. Accordingly, Show Cause Notice was issued to the firm on 23.10.2017. The case was placed in 256th meeting of the CLB. The firm was issued letter for personal hearing on 26.10.2017.

3. The CLB considered the critical observation of the panel in its inspection report dated 19.07.2017 and decided to cancel the Drug Manufacturing License (DML) No. 000182 of M/s PharmaWise Labs (Pvt.) Limited, Lahore under section 41 of the Drugs Act, 1976 read with rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 from the date of issuance of decision of the meeting. Accordingly the firm was directed to suspend the production activities, surrender the DML, inspection book and registration letters to the concerned Divisions. The decision of the CLB was communicated to the Appellant vide letter No. F.8-5/2017-QA(M-256-CLB)(Pt.) dated 03.01.2018.

4. The Chairman inquired whether the panel inspection was conducted for renewal of DML? Further, four member panel was **approved** in 249th meeting of the Central Licensing Board held on 29.08.2016 while the inspection was carried out on 19.07.2017 by only two members of the panel. What was the reason for doing so?

5 The Secretary, Central Licensing Board clarified that renewal of the DML was not due at the time of inspection. The panel was constituted to verify the GMP of the firm. At the time of inspection, other members of the panel were busy in the Drug Court. The firm also did not agitate the panel at the time of inspection.

6. The counsel of the appellant stated that they have not received comments of the respondent (Secretary, CLB). The DML of the appellant was cancelled on the basis of non-compliance of GMP reflected in panel inspection. However, the firm shifted its manufacturing unit to new premises in 1988 in order to comply with GMP conditions. He further contended that the firm was GMP compliant since grant of DML that’s why renewal was granted from time to time.

7. Ch. Nadir Khan, CEO of the firm stated that during inspection conducted on 30.10.2015, it was observed that Lay-out Plan of the firm has not been approved. We agreed to submit revised Lay-out Plan in light of the inspection.

8. The Chairman asked that the firm has earlier submitted an undertaking to shift the premises. It was conceded that the firm gave undertaking to shift premises four years ago but now we intend to continue on existing premises. The revised Lay-out Plan has already been **approved** on existing premises on 18.12.2017. The firm had been granted one year to comply with the revised Lay-out Plan. The Central Licensing Board, after two months of approving the revised Lay-out Plan, cancelled the DML.

9. The Chairman further inquired about installation of HVAC. The representative of the firm informed that HVAC is being installed for each section and 60% work had been completed. The firm will be ready for inspection as per revised Lay-out Plan within one month.

10. The representative of Sindh noted that on 03.04.2012, the FID Islamabad-II drew samples of Rifacin Suspension Batch No.152 manufactured by the appellant, from T.B Center, Asghar Mall Road, Rawalpindi for test/analysis. The samples were declared substandard by the F.G Analyst vide test report No.T.B.64/2012 dated 01.08.2012. Another inspection of the appellant was conducted by a panel on 16.01.2013 and the panel observed the following:-

(i) Crystallization of Paracetamol was observed in the Fabrinol Suspension due to unstable formulation which apparently looked like glass pieces.

(ii) The difference in the shades of glass bottles suggesting that used bottles were being used.

(iii) Screw caps were being used on bottles instead of P.P caps.

(iv) The firm has adopted older, alternate / their own developed testing method on U.V Spectrophotometer for Fabrinol Suspension despite the fact that this product is now included in current USP edition.

11. The counsel of the appellant replied that the panel **approved** by the Central Licensing Board did not inspect the premises. The process was contrary to the precedents of Central Licensing Board. In 243rd meeting, Central Licensing Board rejected inspection report of panel in M/s Seagull Surgical Cotton case due to deficiency in the panel which inspected the premises. Same happened in M/s NBS case. He further stated that the panel was mandated to inspect improvement since previous inspection. The Central Licensing Board did not appreciate the fact that the revised Lay-out Plan is **approved** and firm is under renovation as per revised plan.

12. Mr. Shahid Nasir, Expert Member asked if the appellant can change the existing factory as per revised Lay-out Plan. The appellant informed that they have already changed as per revised Lay-out Plan.

13. The Board, after hearing arguments and perusing record of the case, decided to set-aside the decision of the Central Licensing Board and constituted a panel of following members to inspect the premises after 30 days of the communication of this decision:-

(i) Mr. Shahid Nasir, Expert Member, Appellate Board Head

(ii) Dr. Jamaluddin, Additional Secretary, Health Department, Sindh Member

(iii) Mr. Salim Khan, Director (PS), Khyber Pakhtunkhwa Member

(iv) Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I), DRAP Member

(v) Mr. Asim Rauf, Additional Director, DRAP, Lahore Member

14. The report of the panel will be placed before the Appellate Board for consideration in its forthcoming meeting. Meanwhile, production activities of the firm shall remain suspended till decision of the Appellate Board.

**Proceedings of 151st meeting of the Appellate Board**

15. In compliance of decision of the Appellate Board in its 150th meeting, the inspection of M/s PharmaWise Labs., (Pvt.) Ltd., Lahore was conducted by the panel on 13.08.2018 and 29.10.2018. The inspection report was received in the Secretariat on 17.12.2018**.** Considering the recommendations of the panel, the Board allowed the appeal and resumed production activities in the following sections, with immediate effect:-

(i) Oral Liquid Section (Syrup/Suspension).

(ii) Antiseptic External Preparation Section.

(iii) Cream / Ointment Section.

(iv) General Tablet Section.

16. Resumption of production activities in the following sections is allowed subject to installation of 400 KVA transformer. The installation and operation of transformer are to be verified by a panel comprising Mr. Shahid Nasir (Expert Member, Appellate Board) and Mr. Asim Rauf (Additional Director (E&M), DRAP, Lahore):

(i) Sachet Section.

(ii) Repacking Section.

(iii) Capsule Section.

(iv) General Antibiotic tablet Section.

(v) General Antibiotic Dry Powder Suspension.

(vi) Steroid Section.

17. The Board did not allow resumption of production activities in ***Penicillin*** area.

**Panel Inspector Report**

The following member inspect the firm on 05-04-2019 in compliance to decision of Appellate Board.

* + 1. Mr. Shahid Nasir, Expert Member Appellate Board.
    2. Mr. Asim Rauf, Additional Director, DRAP, Lahore.
    3. Ms. Anam Saeed (Area FID), DRAP, Lahore.

**Recommendations**

After verifying installation and operation of 400 KVA transformer along with supporting documents, the panel of inspectors is of the opinion to **recommend** the resumption of production activities of M/s Pharmawise Labs (Pvt) Ltd, Industrial Estate, Kot Lakhpat, Lahore in the following sections:

1. Sachet Section.
2. Repacking Section.
3. Capsule Section.
4. General Antibiotic Tablet Section.
5. General Antibiotic Dry Powder Suspension.
6. Steroid Section.

**Decision by the Central Licensing Board in 270th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided that inspection report may be forwarded to Appellate Board for further action as it has been submitted in compliance to the Orders of Appellate Board.

**Case No.6 CANCELLATION OF DRUG MANUFACTURING LICENSE OF   
 M/S MEDISEARCH PHARMACAL (PVT) LTD, LAHORE**

The Hon’ble Chairman, Drug Court Bahawalpur has passed an order whereby the Court directed to **cancel** the Drug Manufacturing License of the company namely M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Road, Lahore on non-compliance of Court Orders and submit compliance report in this regard on the next date of hearing i.e. **22-04-2019.**

**Decision by the Central Licensing Board in 270th meeting:**

The Board in compliance to orders of Hon’ble Chairman Honorable Drug Court, Bahawalpur 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 cancellation of Drug Manufacturing License.

**Case No. 7 SITE VERIFICATION OF M/S OERLIKON PHARMACEUTICAL INDUSTRIES, PLOT NO.31/16, ROAD-2, INDUSTRIAL ESTATE, GADOON AMAZAI**

**.**

M/s Oerlikon Pharmaceutical Industries, Gadoon Amazai vide their application dated Nil has forwarded a request for approval of site to establish a pharmaceutical unit located at Plot No.31/16, Road-2, Industrial Estate, Gadoon Amazai. Accordingly Area FID, DRAP, Peshawar was directed vide letter dated 31st January, 2019 for verification of site. Area FID, DRAP, Peshawar, after visiting the site has forwarded site verification report of the said firm. The recommendation of the Area FID, DRAP, Peshawar is as under;

|  |  |
| --- | --- |
| * **Location** | The site is located at Plot No,31/16, Road-2, Industrial Estate Gadoon Amazai. The proposed premises is suitable to construct a pharmaceutical unit as of today as per Drugs Act schedule “B” SRO 470(I)98 dated 15-05-1998, under rule 16(A) the Drugs (Licensing, Registering and Advertising) Rules, 1976. |
| * **Surroundings** * **Environment** | East side: Seasonal Drain (Barsati Nala).  West side: Empty Plot No.31/15.  North side: Road R-2.  South side: Seasonal Drain (Barsati Nala).  The plot is situated in the industrial estate of Gadoon Swabi. No pollution was found in its surroundings at the time of inspection. |
| * **Size** | The area of the plot is 01 acres. |
| * **Recommendations of FID.** * **Note:** | The proposed premise is suitable to construct a pharmaceutical unit as of today.  The plot already contains 05x halls of (50ft x 30ft) and one hall of (150ft x 70ft) previously used by Allied Batteries Industries. The firm wants to utilize these halls after amendments according to layout plan that will be **approved** from DRAP. The firm shall obtain Structural Strength Certificate from concerned department. |

**Decision by the Central Licensing Board in 270th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to call the representative of the firm for clarifaction on the subject matter.

**Case No.8 APPROVAL OF MASTER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY, DRUG MANUFACTURING LICNESE NO.000509 (FORMULATION) OF M/S CONVELL LABORATORIES, SAIDU SHARIF, SWAT.**

M/s Convell Laboratories, Saidu Sharif, Swat under DML No.000509 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May, 1998 when approval of layout plan was not mandatory;

|  |  |
| --- | --- |
| Ser | Section |
| **Ground Floor** | |
| 1 | Tablet Section (General) |
| 2 | Capsule Section (General) |
| 3 | Dry Powder Suspension (General) |
| 4 | Liquid Section (General) |
| 5 | Tablet Section (Psychotropic) |
| 6 | Capsule Section (Cephalosporin) |
| 7 | Dry Powder Suspension (Cephalosporin) |
| 8 | Quality Control Lab |
| **First Floor** | |
| 9 | Stores |

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per **approved** layout plan;

1. Prof. Dr. Jamshed Ali Khan, Department of Pharmacy, Peshawar University, Peshawar.
2. Mr. Abdul Sattar Sohrani, Additional Director (E&M) DRAP, Peshawar.
3. Mr. Atiq ul Bari, Area FID, DRAP Peshawar.
4. Mr. Muhammad Yaqoob, AD Licensing(III&IV), DRAP, Islamabad

Accordingly, panel has inspected the premises and verified the above mentioned sections.

**Recommendations of the panel: -**

“As per observations made during inspection, the manufacturing, quality control and environmental facilities inspected, qualified staff employed, SOPs implemented, the documentation pertaining to production and quality control reviewed and keeping in view the overall GMP compliance of the firm, the panel unanimously **recommends** the renewal fo DML No.000509, by way of formulation, granted to M/s Convell Laboratories, Saidu Sharif, Swat w.e.f 26-02-2018 and **regularization of the layout plan approved vide letter No.F.3-4/2002-Lic (Vol-I) dated 10th August, 2017 for the following sections/areas;**

|  |  |
| --- | --- |
| Ser | Section |
| **Ground Floor** | |
| 1 | Tablet Section (General) |
| 2 | Capsule Section (General) |
| 3 | Dry Powder Suspension (General) |
| 4 | Liquid Section (General) |
| 5 | Tablet Section (Psychotropic) |
| 6 | Capsule Section (Cephalosporin) |
| 7 | Dry Powder Suspension (Cephalosporin) |
| 8 | Quality Control Lab |
| **First Floor** | |
| 9 | Stores |

**Decision by the Central Licensing Board in 270th meeting:**

The Board considered and **approved** regularization of the layout plan as per recommendations of the panel of experts for following sections.

|  |  |
| --- | --- |
| Ser | Section |
| **Ground Floor** | |
| 1 | Tablet Section (General) |
| 2 | Capsule Section (General) |
| 3 | Dry Powder Suspension (General) |
| 4 | Liquid Section (General) |
| 5 | Tablet Section (Psychotropic) |
| 6 | Capsule Section (Cephalosporin) |
| 7 | Dry Powder Suspension (Cephalosporin) |
| 8 | Quality Control Lab |
| **First Floor** | |
| 9 | Stores |

**Case No. 9 GRANT OF DRUGS FOR RE-PACKING:**

M/s Prays Pharmaceuticals, Plot No. 10, Street SS/4, National Industrial Zone, RCCI, Rawat, Islamabad under DML No. 000719 by way of formulation has submitted request for Grant of following Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 90,000/ per product.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. | Zine Oxide | 2. | Soft Yellow Paraffin. | 3. | Sodium Salicylate. |
| 4. | Sodium Citrate. | 5. | Sodium Chloride. | 6. | Sodium Bicarbonate. |
| 7. | Sodium Benzoate. | 8. | Salicylic Acid. | 9. | Potassium Lodide. |
| 10. | Potassium Citrate. | 11. | Potassium Bromide. | 12. | Magnesium Sulphate. |
| 13. | Liquid Paraffin Heavy. | 14. | Kaolin Powder. | 15. | Glycerin. |
| 16. | Gentian Voilet. | 17. | Castor Oil. | 18. | Boric Acid. |

**Decision by the Central Licensing Board in 270th meeting:**

The Board considered and **approved** repacking items in the name of M/s Prays Pharmaceuticals, Plot No. 10, Street SS-4, National Industrial Zone, RCCI, Rawat, Islamabad as under:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. | Zine Oxide | 2. | Soft Yellow Paraffin. | 3. | Sodium Salicylate. |
| 4. | Sodium Citrate. | 5. | Sodium Chloride. | 6. | Sodium Bicarbonate. |
| 7. | Sodium Benzoate. | 8. | Salicylic Acid. | 9. | Potassium Lodide. |
| 10. | Potassium Citrate. | 11. | Potassium Bromide. | 12. | Magnesium Sulphate. |
| 13. | Liquid Paraffin Heavy. | 14. | Kaolin Powder. | 15. | Glycerin. |
| 16. | Gentian Voilet. | 17. | Castor Oil. | 18. | Boric Acid. |

**Case No.10 M/S MAKSON PHARMACEUTICALS, INDUSTRIAL AREA, I-10/3, ISLAMABAD – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

**Case background:**

M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad submitted the application for renewal of DML No. 000560 by way of formulation on 12-01-2015 for the period of 08-12-2014 to 07-12-2019.

The Central Licensing Board in its 255th meeting held on 16th& 17th August, 2017 has considered the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to M/s Makson Pharmaceuticals, 80-B, Street # 06, I-10/3, Industrial Area, Islamabad and decided as under:-

**Decision of Central Licensing Board.**

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 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000560 by way of formulation of M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad may not be rejected by Central Licensing Board or the Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

2. Accordingly a Show Cause Notice issued to firm on 21st September, 2017. In response to show cause notice the firm has submitted documents. Upon evaluation of submitted documents following shortcoming have still been observed in the DML renewal application:-

**Renewal of DML application.**

1. Name of total sections of licensed facility and their letters of grant issued after approval in meeting of Central Licensing Board.
2. Nothing due certificate regarding deposition of Central Research Fund updated.
3. Detail of management at the time of previous renewal and present renewal.

**Production Incharge.**

1. Appointment letter.
2. Job acceptance letter.
3. Registration Certificate from Pharmacy Council.
4. Resignation / retirement of earlier Production Manager.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

**Quality Control Incharge.**

1. Appointment letter.
2. Job acceptance letter.
3. Resignation / retirement of earlier Production Manager.
4. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

The firm has also been called for personal hearing.

**Proceedings and Decision of Central Licensing Board in 256th meeting.**

Mr. Kifayat Malik Chairman, M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad alongwith Mr. Sajjad Munir, Regulatory Affairs Manager appeared before the Board. He contended that there is no change of Management but at the same time he also contended that his firm is registered with SECP. He also contended that rubber stump affixed on the letters is with Private Limited. The Board also equired that letter head of the firm does not bear title with Private Limited. He also infored the Board that company has also been outsourced. He could not satisfy the Board regarding change in title of the firm as well. The Board also observed that firm has been manufacturing and selling drugs without **approved** qualified staff since years. The Board after perusal of record and facts mentioned above and delibrations made by representative of the firm decided to reject the application of renewal of the Drug manufacturing Licence No. 000560 by way of formulation of M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad with immediate effect 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, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

**Decision of Appellate Board.**

Mr. Aamar Latif, Deputy Director (Appellate Board), DRAP, Islamabad wherein he has conveyed the decision of 151st meeting of appellate Board held on 16th January, 2019 in respect of M/s Makson Pharmaceuticals, Islamabad. The decision of Appellate Board is as under:-

“The Board, after hearing arguments and perusing record of the case, decided to remand the case back to the Central Licensing Board with direction to decide a fresh the application for renewal of Drug Manufacturing License No. 000560 submitted by M/s Makson Pharmaceuticals, Islamabad in forthcoming meeting.

The Licensing Division shall ensure that inspection of the firm be carried out within 15 days of the communication of this decision. The panel so constituted may allow production if the firm is complying with Good Manufacturing Practices (GMP) guidelines”.

**Decision by the Central Licensing Board in 270th meeting:**

The Board in compliance to orders of Appelate Board decided that the firm will first get the application complete for renewal of Drug Manufacturing License and then process will be done accordingly.

**CASE NO.11 REGULARIZATION OF LAYOUT PLAN OF M/S AMROS  
PHARMACEUTICALS, PLOT NO. A-96, S.I.T.E, SUPER HIGHWAY,KARACHI DML NO. 000406 (FORMULATION)**

M/s Amros Pharmaceuticals, Plot No. A-96, S.I.T.E Super highway, Karachi DML No. 000406 (Formulation)has applied for regularization of layout plan of running facility for their existing FOLLOWING sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory:

|  |  |
| --- | --- |
| **Ground Floor** | |
| **Sr. No** | **Name of Section** |
| 1. | Tablet Section (General)- Regularizations and Amendments |
| 2. | Tablet Section (Psychotropic)- Regularizations and Amendments |
| 3. | Cream / Ointment section (General) |
| 4. | Oral Dry Powder Suspension Section (General anti biotic) |
| 5. | Capsule Section (General ) |
| 6. | Injectable Section (General) |
| 7. | Ear / Eye Drops Section (Sterile) |
| 8. | Oral Liquid Section (General) |
| 9. | Warehouse- Regularizations and Amendments |
| **First Floor** | |
| 1. | Dry Powder Suspension Section (Cephalosporin)- |
| 2. | Capsule Section (Cephalosporin) |
| 3. | Injectable section (Cephalosporin) - Regularizations and Amendments |
| 4. | Warehouse (Cephalosporin) |
| 5. | Dry Powder Suspension Section (Penicillin) |
| 6. | Capsule Section (Penicillin) |
| 7. | Injectable section (Veterinary)- Regularizations and Amendments |
| 8. | Tablet Section (Penicillin) |
| 9. | Raw Material Store (Penicillin) |

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per **approved** layout plan.

1. Abdullah Dayo, Member CLB, Karachi.
2. Additional Director (E&M), DRAP, Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the below mentioned section.

**Following are the observations:**

As per direction the panel inspected in details production areas, stores, QC lab and reviewed in details relevant documents. The panel further noted that the firm possesses registrations in Tablet (G), Tablet (Psychotropic), Tablet (Penicillin), Capsule (G), Capsule (Penicillin), Capsule (Cephalosporin), Cream/Ointments, Ear/Eye Drops Section, Oral Liquid Section, Sterile Liquid Injection, Oral Dry Powder Suspension (G), Oral Dry powder suspension (penicillin), Oral Dry powder Syrup (Cephalosporin) and sterile liquid injection (Veterinary). In addition to these sections, the firm has applied for the grant of additional section of sterile Dry Powder Injection Cephalosporin. The new section is built as per **approved** drawing and is provided with all necessary utilities and separate HVAC system. The panel noted that necessary amendments/improvements in the LOP are made accordingly and the existing drawing is almost according to **approved** one.

Keeping in view the above observations the panel recommends that their existing drawing may be regularized as required under current SOPs and the firm may be granted an additional section of Sterile Dry Powder Injection (Cephalosporin).

* **A panel was constituted for regularization of Sterile Dry Powder Injection (Cephalosporin), However in the panel inspection report panel has recommend the said section as additional section.**

**Decision by the Central Licensing Board in 270th meeting:**

The Board considered and **approved** regularization of the layout plan as per recommendations of the panel of experts for following sections

|  |  |
| --- | --- |
| **Ground Floor** | |
| **Sr. No** | **Name of Section** |
| 1. | Tablet Section (General)- Regularizations and Amendments |
| 2. | Tablet Section (Psychotropic)- Regularizations and Amendments |
| 3. | Cream / Ointment section (General) |
| 4. | Oral Dry Powder Suspension Section (General anti biotic) |
| 5. | Capsule Section (General ) |
| 6. | Injectable Section (General) |
| 7. | Ear / Eye Drops Section (Sterile) |
| 8. | Oral Liquid Section (General) |
| 9. | Warehouse- Regularizations and Amendments |
| **First Floor** | |
| 1. | Dry Powder Suspension Section (Cephalosporin)- |
| 2. | Capsule Section (Cephalosporin) |
| 3. | Injectable section (Cephalosporin) - Regularizations and Amendments |
| 4. | Warehouse (Cephalosporin) |
| 5. | Dry Powder Suspension Section (Penicillin) |
| 6. | Capsule Section (Penicillin) |
| 7. | Injectable section (Veterinary)- Regularizations and Amendments |
| 8. | Tablet Section (Penicillin) |
| 9. | Raw Material Store (Penicillin) |

**Case No. 12 SUSPENSION OF LICENSE OF M/S ONYX PHARMACEUTICALS, 30-A, SMALL INDUSTRIAL ESTATE, MANSEHRA, PAKISTAN.**

A letter No. 269 dated 10th May, 2019 is received from Hon’ble Mr. Mehta Rajesh Nath Kohli, Chairman, Drug Court Quetta, Balochistan wherein he has stated that a case No. 49/2017 is pending against Hafiz Muhammad Arif and Maaz Mehmood owners of M/s Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, Pakistan in which accused namely Mr. Maaz Mehmood being the owner has been charged with the commission of the offence and he is intentionally and deliberately avoiding to appear before this Court. It is therefore directed to suspend the license of the above mentioned company after fulfilling the requisite requirement as per law and intimate the same to this Court at your earliest.

**Decision by the Central Licensing Board in 270th meeting:**

The Board in compliance to orders of Hon’ble Chairman, Drug Court Quetta, Balochistan 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 suspension of Drug Manufacturing Licence.

**Case No.13 WITHDRAWAL OF TABLET (HORMONE) SECTION OF M/S WEATHER FOLDS PHARMACEUTICALS, HATTAR.**

M/s Weather Folds Pharmaceuticals, 69/2, Phase-II, Industrial Area, Hattar, was applied for withdrawal of Tablet (Hormone) Section which was **approved** in 255th meeting of CLB held on 16th-17th August, 2017. Now, the firm has again requested to withdraw previously issued withdrawn letter of CLB. The firm has also submitted undertaking on stamp paper, contents of which are as under;

*“It is stated that we M/s Weather Folds Pharmaceuticals submitted the letter of Withdrawn for our section (Tablet Hormones Steroidal), and later on we withdrew the previous letter.*

*We undertake that during this period we did not amend the Section, and didn’t establish any other section in the premises of Tablet Hormone (Steroidal) Section it was withdrawn only for the reason of deferment of Dydrogestrone Tablet Now as the permission of Registration of Dydrogesterone is granted by Registration Board within last two DRB meeting so it is requested to your good self to please resume our Section and allow us to restart our Production there and save us from big Financial loss because we have established this section for Tablet Hormones (Steroidal).”*

**Decision by the Central Licensing Board in 270th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to allow the request of the firm. The Board also decide that production shall be carried after after appravl of the Board. The Board constitute following panel of experts/Inspectors for inspection of the firm for verification of the GMP compliance of the Section before start of the Prodction.

1. Prof. jamshed Ali Khan member of CLB
2. Additional Director (E&M), DRAP.Pehawar.
3. Area Federal Inspector of Drugs Peshawar.

**CaseNo.14 CHANGE OF MANAGEMENT OF M/S CIRIN PHARMACEUTICALS (PVT) LTD, HATTAR.**

M/s Cirin Pharmaceuticals (Pvt) Ltd, Hattar, under DML No. 000363 (By way of formulation ) has submitted request for change in management of the firm as per Form-1A and Form-29 along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Old Management as per Form-29** | **Retiring Management** | **New Management as per Form-29** |
| 1. Mr. Asif Jooma   CNIC No.42301-3175078-7   1. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3 2. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5 3. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7 4. Mr. M.A. Samie Cashmiri   CNIC No.35201-8722191-7 | 1. Mr. M.A. Samie Cashmiri   CNIC No.35201-8722191-7 | 1. Mr. Asif Jooma   CNIC No.42301-3175078-7   1. Mr. Muhammad Ali Tabba   CNIC No.42201-6464247-3   1. Mr. Muhammad Sohail Tabba   CNIC No.42000-0568372-5   1. Mr. Muhammad Abid Ganatra   CNIC No.42201-5355492-7   1. Mr. Saboor Ahmad   CNIC No.35202-2339737-9 |

**Decision by the Central Licensing Board in 270th meeting:**

The Board considered and endorsed the change of management of M/s Cirin Pharmaceuticals (Pvt) Ltd, Hattar, under DML No. 000363 (By way of formulation ) as per Form-29 as under ;

|  |  |  |
| --- | --- | --- |
| **Old Management as per Form-29** | **Retiring Management** | **New Management as per Form-29** |
| 1. Mr. Asif Jooma   CNIC No.42301-3175078-7   1. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3 2. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5 3. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7 4. Mr. M.A. Samie Cashmiri   CNIC No.35201-8722191-7 | 1. Mr. M.A. Samie Cashmiri   CNIC No.35201-8722191-7 | 1. Mr. Asif Jooma   CNIC No.42301-3175078-7   1. Mr. Muhammad Ali Tabba   CNIC No.42201-6464247-3   1. Mr. Muhammad Sohail Tabba   CNIC No.42000-0568372-5   1. Mr. Muhammad Abid Ganatra   CNIC No.42201-5355492-7   1. Mr. Saboor Ahmad   CNIC No.35202-2339737-9 |

**QUALITY ASSURANCE CASES (GMP NON-COMPLIANCE)**

**Item No. I GMP NON-COMPLIANCE CASES (NEW)**

**Case No. i: M/S. NBS PHARMA, LAHORE.**

**Background:**

Mr. Ajmal Sohail Asif, FID, Lahore conducted inspection of the firm M/s. NBS Pharma, 8-KM, Thokar - Raiwind Road, Lahore on 04.12.2018 to check the GMP compliance and production activities of the firm.

2. The FID during inspection, noticed following critical observations:-

**Premises:-**

1. The premises was a single story building, it was an old building not very well maintained.

**Change Rooms:-**

1. Change room for executives was not provided with proper changing facility, no air curtain was installed at the entry. Female change room was not neat and clean there were gaps in the door.

**Storage Areas:-**

1. Air curtain was installed at the receiving bay but was not functional at the time of inspection. Receiving bay was directly opening outside on the road and was very dirty; door was having gaps and was full of dust and dirt. Dedusting room was also dirty. Glass and aluminum doors were broken / damaged.
2. In raw material store floor was broken false ceiling was not appropriate.
3. For sampling of materials only a hood with exhaust was placed inside the RM store, proper sampling booth was not provided.
4. Dispensing room was not properly segregated from the RM store as door was not installed in between dispensing room and RM store. Scoops were not appropriate, were dirty and GMP non-compliant.
5. Packing material store was also congested materials were placed haphazardly.

**Production Areas:-**

a). **Repacking Section:-**

1. Floor was dirty and broken tiles on walls were also broken and dirty.
2. HVAC was installed but not functional at the time of inspection. Return duct was broken. Doors were wooden.

b). **External Preparation Section:-**

1. HVAC was installed but not functional at the time of inspection. Doors were wooden.

**Quality Assurance:-**

1. QA department appeared not to be much involved and effective in the production and QC activities. The firm was advised to strengthen the QA section by hiring experienced QA manager and making it independent and fully effective.

**Sanitation & Hygiene:-**

1. Sanitation and hygiene conditions in general were not up to mark.

**Qualification and Validation:-**

1. Process and cleaning validations were not being carried out as per SOPs and no record for process / cleaning validation was provided. QC testing methods were also not validated.

**Complaints:-**

1. No records were maintained and shown.

**Product Recalls:-**

1. The firm has not developed a proper SOP for product recall only a very rudimentary procedure was available. The firm was advised to upgrade the SOP and perform a mock recall to evaluate the effectiveness of the recall system.

**Self-Inspection and Quality Audit:-**

1. No records were provided for any self-inspection.

**Personnel:-**

1. The firm has not hired adequately trained and experienced qualified persons. In Production Department there was only one Pharmacist who was approved Production In-charge but he was not present at the time of inspection and it was told that he was on leave. In QC Section the firm has hired only one MSc. Chemist as QC In-charge. The technical personnel net during the inspection were found to be in-experienced and failed to satisfy the queries and questions raised during inspection.

**Training:-**

1. No record for any training was available / provided.

**Equipment & Machinery:-**

1. Most of the equipment / machines for the manufacturing were manual / semi-automatic type and were non-GMP compliant. Bottle blowing machine was not appropriate for the purpose. In external preparation section, filling machine was no available at the time of inspection. Most of the machines were old and, in some areas, need improvement and up gradation.
2. In quality control department the firm did not possess adequate equipment required to carry out the testing / analysis. Even glass was limited. UV Spectrophotometer was very old and seemed not performing accurately. Firm has provided only one stability chamber for accelerated stability studies, which was not functioning properly as showing about 100% humidity at the time of inspection.

**Materials:-**

1. The firm was advised to improve the material management system. The labels were not having complete information of the product as required to be. It was noted that materials were placed in quarantine area since last 2 to 3 months. It was noted that drums and containers of raw materials were very dirty; materials inside the drums were placed in open poly bags without tying or knotting them.

**Documentation:-**

1. The firm has developed most of the SOPs for production & QC. But these were not signed by any person; there was no system for document control. Some of the SOPs and BMRs need review and updating. Log books for QC instruments were not maintained. Raw data of testing / analysis was not maintained. Organogram and Job descriptions of technical personnel need improvement and updating.

**Good Practices in Quality Control:-**

1. It was found that the log books were not being maintained properly. Analyst book and raw data was not maintained. The SOPs were not being implemented in true letter and spirit. Deviations from standard procedures were observed. The firm was using in house working standards for testing and was advised to purchase reference standards. In general; QC lab seems inadequate to cater the testing / analytical requirements of the firm.

**Utilities:-**

a). **Water Purification System:-**

1. The firm has not developed procedure for sanitization of water supply system. The firm was advised to prepare and implement the procedure for the sanitization of the water supply system. Firm was also not conducting proper testing for water.

b). **HVAC System:-**

1. At the time of inspection, the HVAC was not functional. Manometers were no installed. Firm was advised to validate the HVAC system.

**The FID conclude that:-**

“*Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection,* ***M/.s N.B.S. Pharma, Lahore was considered not to be operating at satisfactory level of compliance with GMP*** *guidelines as per Drugs Act, 1976 and rules framed there under and need active improvement on urgent basis.*”

**Action taken by DRAP:**

The firm M/s. NBS Pharma, Lahore was served Show Cause Notice and suspension of production activities on 07.02.2019.

**Reply of the firm:**

The firm M/s. NBS Pharma, Lahore vide letter dated 27.02.2019 submitted reply of Show Cause Notice and informed that they will be able to complete development work as per GMP requirement and as per observations made by the FID. The firm further requested for the resumption of production activities.

**Proceedings of 270th meeting:-**

Mr. Sheikh Shahzad Nabi (CEO), Mr. Muhammad Abdullah (Production In-charge) and Mr. Muhammad Momin Shehzad of the firm M/s. NBS Pharma, Lahore appeared before the Board. Mr. Sheikh Shahzad Nabi informed that they have rectified all the observations noted by the FID and they are ready for inspection.

**Decision of the 270th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to:-

1. Constitute following panel of experts for verification of the observations before resumption of production:-
2. Dr. Ikram ul Haq, Member, CLB
3. Chief Drug Controller, Punjab
4. Area Federal Inspector of Drugs, Lahore
5. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 04.12.2018, with clear and candid recommendations.
6. Production of the firm M/s NBS Pharma, Lahore shall remain suspended till recommendation by panel and subsequent approval by the Director (QA&LT).

**Item No. II CONSTITUTION OF PANEL**

**Case No. i: M/S. SARCO CHEMICAL INDUSTRY, MULTAN.**

**Background:**

Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore conducted inspection of the firm M/s. Sarco Chemical Industry, 17-KM, Peerwala More, Qadir Pur Ran, Khenewal Road, District Multan on 15.10.2018, to verify the GMP compliance and production activities.

2. The FID during inspection noted number of critical observations.

**Action taken by DRAP:-**

The firm was served Show Cause / Suspension of Production in all sections: inspection on 19.11.2018.

3. The case was placed in 267th meeting of Central Licensing Board. The Board decided as under:-

**Decision of the 267th Meeting of CLB**

After thorough discussion/deliberations, the Central Licensing Board decided to suspend the Drug Manufacturing License of the firm M/s. Sarco Chemical Industry, Multan under section 41 of the Drug Act, 1976 read with Rule 12 of the Drugs (LRA) Rules, 1976 till rectification of the observations noted by the FID in its report dated 15.10.2018 and appointment of Quality Control Manager.

4. Decision was conveyed to the firm on 22.01.2019.

**Updated Status:-**

The firm vide letter dated Nil received on 25.02.2019 inform that corrections have been made against observations of FID. The firm requested for constitution of panel for inspection of firm.

**Proceedings of 270th meeting:-**

The Deputy Director (QA&LT) presented the case before the Board.

**Decision of the 270th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to:-

1. Constitute following panel of experts for verification of the observations noted by the FID in its report dated 15.10.2018 before resumption of production:-
2. Dr. Mehmood Ahmad, Ex-Dean, Faculty of Pharmacy, Islamia University Bahawalpur
3. Deputy Director (QC-I), DRAP, Islamabad
4. Area Federal Inspector of Drugs, Lahore
5. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 15.10.2018, with clear and candid recommendations.
6. Production of the firm M/s Sacro Chemical Industry, Multan shall remain suspended till recommendation by panel and subsequent approval by the CLB.

**Item No. III RESUMPTION OF PRODUCTION**

**Case No. i: M/S LIBRA PHARMA (PVT) LTD, PESHAWAR**

**Background:**

Muhammad Arif Chaudhary, FID, DRAP, Peshawar conducted inspection of the firm M/s Libra Pharmaceuticals, Peshawar on 24.04.2018, to verify the GMP compliance and production activities.

2. The FID noticed number of observations which need urgent attention and rectification.

**Action taken by DRAP:-**

The case was placed for the approval of show cause notice and suspension of production activities on the critical observation noted by the FID. It was advised to place the case before the central licensing board for taking further necessary action in this regard.

3. The case was placed in 265th meeting of CLB. The Central Licensing Board decided as under:-

**Decision of the 265th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to serve show cause notice to the firm M/s. Libra Pharmaceuticals, Peshawar on the observations noted by the FID in its inspection conducted on 24.04.2018.

**Show Cause Notice:-**

As per decision of 265th meeting of CLB held on 10.08.2018, show cause notice was issued to the firm M/s. Libra Pharmaceuticals, Peshawar on 31.08.2018.

4. The case was again placed in 266th meeting of CLB. Wherein the CLB decided as under:-

**Decision of the 266th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case and compliance report of the firm, the Central Licensing Board decided to:-

1. Conduct GMP inspection of the firm M/s. Libra Pharmaceuticals, Peshawar by following panel of experts:-
2. Prof. Dr. Jamshaid Ali Khan, Member, CLB
3. The Additional Director, DRAP, Peshawar
4. The Area Federal Inspector of Drugs, Peshawar
5. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.
6. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 24.04.2018, with clear and candid recommendations.

**Updated Status:-**

The panel conducted inspection of the firm 25.02.2019 and submitted compliance report. The panel concluded as under:-

“Panel of experts unanimously recommends restoration of production activities of the firm M/s Libra Pharmaceuticals, Peshawar in the following sections.

1. Tablet (General/Quinolones)
2. Sachet (General)
3. Liquid Syrup (General)
4. Tablet (Ceph)
5. Capsule (Ceph)
6. Dry Syrup (Ceph)
7. Tablets (Hormones)
8. Capsules (Hormones)

However the firm needs some further improvements in the following sections and production will remain suspended in these sections till the rectification of shortcomings mentioned against;

|  |  |  |
| --- | --- | --- |
| ***S. No*** | ***Section*** | ***Shortcomings*** |
| *1* | *Dry Powder Injectable (Ceph)* | *HVAC needs revalidation and firm has also needs microbiological lab for testing of microbial testing like area monitoring, sterility testing etc.* |
| *2* | *Capsule (General)* | *No HVAC installed* |
| *3* | *Cream/Ointment (General)* | *Civil work is undergoing, and HVAC need up gradation.* |

**Proceedings of 270th meeting:-**

Deputy Director (QA&LT) presented the case before the Board. It is informed to the board that the panel conducted inspection of the firm M/s Libra Pharma, Peshawar on 25.02.2019 and allowed resumption of production. However the panel did not recommend resumption of production in some of the areas.

**Decision of the 270th Meeting of CLB**

After thorough discussion/deliberations and recommendation of the panel of experts dated 25.02.2019, the Central Licensing Board decided to:-

1. Resume production activities in the following section, from the date of issuance of decision of 270th meeting of CLB.
2. Tablet (General/Quinolones)
3. Sachet (General)
4. Liquid Syrup (General)
5. Tablet (Ceph)
6. Capsule (Ceph)
7. Dry Syrup (Ceph)
8. Tablets (Hormones)
9. Capsules (Hormones)
10. However production will remain suspended in the following sections, till the improvements suggested by the panel, verification by the panel of experts and subsequent approval by the CLB.
11. Dry Powder Injectable (Cephalosporin)
12. Capsule (General)
13. Cream/Ointment (General)

**Case No. ii M/S WISE PHARMACEUTICALS, RAWAT, RAWALPINDI.**

**Background of the case:-**

Mr. Hasan Afzaal, FID, Islamabad conducted inspection of the firm M/s Wise Pharma, Rawat on 18.09.2017 and noticed number of observations. The firm was directed to submit compliance report vide office letter dated 30.10.2017. The firm submitted compliance report on 13.11.2017.

2. The case was placed before the Director (QA & LT). The Director (QA & LT) constituted following panel of experts to conduct inspection of the firm

1. Mrs. Tahreem Sara ( Deputy Director, PE&R)
2. Dr. Hassan Afzaal FID-III Islamabad.

3. The panel conducted inspection of the firm on 02.08.2018 and concluded as under:

*“The panel is of opinion that the production in the sterile area i.e; Sterile Liquid Ampoule (General), Sterile Liquid Infusion (General) and Sterile Dry Powder (Ceph) is in major contravention of GMP guidelines including area maintenance, sanitation, hygiene and pest/insect control and therefore it is recommended that the production may be stopped till the up-gradation of highlighted points.”*

**Action taken by DRAP:**

The firm M/s Wise Pharma, Rawat was issued Show Cause Notice/ Suspension of production in Sterile Section order on 16.08.2018.

4. The case was placed in 266th meeting of CLB. The Board decided as under:-

**Decision of the 266th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case and compliance by the C.E.O. of the firm, the Central Licensing Board decided to:-

1. Constitution of following panel of experts for verification of the observations before resumption of production in sterile section:-
2. Prof. Dr. Muhammad Usman, Member, CLB
3. Additional Director-I (QA & LT), DRAP, Islamabad
4. Area Federal Inspector of Drugs, Islamabad
5. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.
6. The panel shall submit detailed inspection report to CLB including rectification status of the observations noted by the panel in their report dated 02.08.2018, with clear and candid recommendations.

5. In compliance to the decision of 266th meeting of CLB, the panel conducted inspection of the firm on 23.04.2019 and submitted detail report. The panel concluded as under:-

*“Keeping in view the above stated observations during inspection areas visited, documents reviewed and people met it may be concluded that the firm M/s Wise Pharmaceutical, RCCI Rawat has rectified majority of the observation from the previous inspections. The panel unanimously recommends the resumption of production activities in the sterile section”.*

**Proceedings of 270th meeting:-**

Deputy Director (QA) presented the case before the Central Licensing Board. Panel Inspection report of the firm M/s Wise Pharmaceuticals, Rawat dated 23.04.2019 is discussed in detail.

**Decision of the 270th Meeting of CLB**

After thorough discussion/deliberations and keeping in view the panel inspection of the firm dated 23.04.2019 and its recommendations, the Central Licensing Board decided to:-

1. Resume the production activities of the firm M/s. Wise Pharmaceuticals, Rawat in the sterile area i.e; Sterile Liquid Ampoule (General), Sterile Liquid Infusion (General) and Sterile Dry Powder (Ceph), from the date of issuance of decision of the 270th meeting of CLB.
2. Cease the operation of show cause notice dated 16.08.2018, from the date of issuance of decision of the 270th meeting of CLB.

**Case No. iii M/S STAR LABORATORIES (PVT) LTD, LAHORE**

**­­­­­­­** Following panel of experts conducted inspection of the firm M/s. Star Laboratories (Pvt) Ltd, Lahore conducted on 17.07.2018, 05.10.2018 & 12.11.2018 for grant of cGMP certificate.

1. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore
2. Ms. Uzma Barkat, FID, DRAP, Lahore
3. Ms. Maham Misbah, Assistant Director (I&E), DRAP, Lahore

2. The panel during inspection noticed number of critical observations. The panel recommended as under:-

***“****The panel recommended that the firm was operating at satisfactory level cGMP compliance except for Human Liquid Injection Section (Psychotropic) and Human Liquid Injection Section (General Ampoule)”.*

**Action taken by DRAP:**

The firm M/s Star Laboratories, Lahore was served Show Cause Notice and suspension of production orders in Human Liquid Injection Section (Psychotropic) and Human Liquid Injection Section (General Ampoule) on 15.01.2019.

3. The case was placed in 269th meeting of CLB. The Board after detailed discussion decided as under:-

**Decision of the 269th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case and compliance by the Director of the firm, the Central Licensing Board decided to:-

1. Constitute following panel of experts for verification of the observations before resumption of production:-
2. The Additional Director, DRAP, Lahore
3. Dr. Ikram-ul-Haq, Member CLB
4. Area Federal Inspector of Drugs, Lahore
5. Production in the Human Liquid Injection Section (Psychotropic) and Human Liquid Injection Section (General Ampoule) shall remain suspended till recommendation by panel and subsequent approval by the CLB.
6. The panel shall submit detailed inspection report to CLB including rectification status of the observations noted by the FID in its report dated 12.11.2018, with clear and candid recommendations.

4. The panel conducted inspection of the firm M/s Star Laboratories, Lahore on 14.05.2019 and decided as under:-

**Panel Recommendations;-**

In the light of the inspection conducted by the panel of experts and based on the people interviewed, documents reviewed and findings during inspection, the panel of experts is of the opinion that the observations in the Human Liquid Injection Section (General-Ampoule) have been rectified and the *panel recommends the resumption of production in the Human Liquid Injection Section (General-Ampoule) only. Human Injectable Section (Psychotropic) was not ready for inspection.*

**Proceedings of 270th meeting:-**

Deputy Director (QA&LT) presented the case before the Board. It is informed to the board that the panel, in compliance to the 269th meeting of CLB conducted inspection of the firm M/s Star Laboratories, Lahore on 14.05.2019 and recommended the resumption of production in Human Liquid Injection Section (General-Ampoule) only. The panel further inform that Human Injectable Section (Psychotropic) was not ready for inspection.

**Decision of the 270th Meeting of CLB**

After thorough discussion/deliberations and recommendation of the panel of experts in its report dated 14.05.2019, the Central Licensing Board decided to:-

1. Resume production activities in Human Liquid Injection Section (General-Ampoule) only.
2. However production will remain suspended in Human Injectable Section (Psychotropic), till the improvements made by the firm, verification by the panel of experts.

**Item No. IV INSPECTION REPORTS IN COMPLIANCE OF 267TH MEETING OF CLB**

**Case No. i: - M/S. LEGACY PHARMACEUTICAL, PESHAWAR**

Mr. Atiq Ul Bari, FID, Peshawar conducted inspection of the firm M/s. Legacy Pharmaceutical, Peshawar on 29.08.2018.

2. The FID during inspection noted number of observations, which need attention and rectifications.

**Action taken by DRAP:**

The firm M/s. Legacy Pharmaceutical, Peshawar was issued Show Cause Notice on 05.11.2018.

3. The case was placed in 267th meeting of CLB, wherein the Board decided as under:-

**Decision of the 267th Meeting of CLB**

After thorough discussion/deliberations, the Central Licensing Board decided to:-

1. Constitution of following panel of experts for detailed GMP inspection of the firm:-
2. Prof. Dr. Jamshaid Ali Khan, Member, CLB
3. The Area Federal Inspector of Drugs, Peshawar

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 29.08.2018, with clear and candid recommendations.

4. The panel conducted inspection of the firm on 22.02.2019 and concluded as under:-

*“The firm has rectified majority of observations noted in previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP.*

*5.* The panel advised to:-

1. *Further increase number of pharmacists in production section.*
2. *Purchase atomic absorption spectrophotometer for the analysis of their iron containing products.*
3. *Provide portable dehumidification units in sensitive areas.*

**Proceedings of 270th meeting:-**

Deputy Director (QA&LT) presented the case before the Board. The board discussed the panel inspection report of the firm M/s Legacy Pharma, Peshawar dated 22.02.2019.

**Decision of the 270th Meeting of CLB**

After thorough discussion/deliberations and recommendation of the panel of experts, the Central Licensing Board decided to:-

1. Cease the operation of show cause notice dated 05.11.2018, from the date of issuance of decision of the 270th meeting of CLB.
2. Direct the firm to submit compliance report on the advises given by the panel of experts in its report dated 22.02.2019 within 90 days. Meanwhile the products shall not be manufactured for which testing facility is not available.

**Case No. ii M/S PHARMEDIC LABORATORIES, LAHORE**

**Background:-**

Mr. Asim Rauf, Additional Director, Mr. Ajmal Sohail, FID alongwith Ms. Uzma Barkat, Assistant Director, DRAP, Lahore conducted inspection of the firm M/s Pharmedic Labs, Lahore on 21.06.2017, for the purpose of verification of the consumption of Buprenorphine HCI and GMP compliance. During inspection the panel noticed critical observations.

**Action Taken by DRAP**: - Accordingly, Show Cause Notice along-with suspension of production order in Liquid Injectable (General) Section sections was issued to the firm on 18.09.2017.

2. The case was placed in 256th meeting of CLB. Wherein the Board has decided as under:-

**Decision of the 256th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view available record and submission of the firm, the Board decided to :-

1. Conduct GMP inspection of the firm, on approved Schedule B-II format, by following panel members :-

* Dr. Farzan Chaudhary, UVAS, Lahore
* Mr. Munawar Hayat, CDI, Punjab.
* Area FID, Lahore
* Anjum Parvaiz, Consultant, Govt of Punjab, Lahore

1. Direct the panel to submit brief report in tabulated form identifying the previous observations and the current status with clear and candid recommendations.
2. Refer the case to Drug Registration Board for cancellation of the product Buprenorphine HCI injection of the firm M/s Pharmedic Labs, Lahore, as the firm does not have the required facilities for the manufacturing of said product.
3. Intimated the Controlled Drug Division regarding the decision of 256th Meeting, requesting not to allocate quota of the Buprenorphine HCI injection.

3. Decision of the 256th meeting was conveyed on 03.01.2018. However report of the panel is still awaited.

**Inspection of FID on 20.08.2018**: -

Ms. Uzma Barkat, area FID along with Mr. Shoaib Ahmed, FID and Ms. Maham Misbah, AD (DRAP), Lahore visited the firm on 20.08.2018 and informed that “she *visited the raw material store and General Injectable Section of the firm and reported that firm was manufacturing Onset (Ondensetron) 4mg and 8mg injections in their General Injectable Section, in violation of show cause / suspension of production orders in Liquid Injectable (General) Section vide letter No. F. 4-49/2004-QA (Vol-III) dated 18.09.2017 and area FID further ordered the firm for not to dispose of the stock of Ondensetron for 28 days on Form-I and requested to grant further extension for three months for not to dispose of the said stock.”*

**Updated Status**: -

The matter of extension in not to dispose of period of seized stock has been taken up by the Quality Control Section. Extension in not to dispose of period of seized stock has been conveyed to the firm, after approval from the Director (QA&LT).

4. The firm M/s. Pharmedic Laboratories (Pvt) Ltd, Lahore has violated the direction of Show Cause Notice / Suspension of production order in General Injectable Section, decision of 256th meeting of CLB and start manufacturing in the General Injectable Section without panel inspection and subsequent approval from the Central Licensing Board. The case was placed in 266th meeting of CLB. Wherein the Board decided as under:-

**Decision of the 266th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, the Board decided as to issue show cause notice to the firm M/s Pharmedic Laboratories, Lahore on manufacturing in the Injectable Section (General), which is violation of the directions of show cause notice / suspension of production order in Liquid Injectable (General) Section dated 18.09.2017.

**Action Taken by DRAP**: - Accordingly, Show Cause Notice in compliance to decision of 266th meeting was issued to the firm on 05.12.2018.

**Decision of the 267th Meeting of CLB:-**

After thorough discussion/deliberations and keeping in view the panel GMP inspection report of the firm incompliance to 256th meeting of the CLB, the Central Licensing Board decided to continue the suspension of the production activities in the Liquid Injectable (General) Section, till the decision of unauthorized manufacturing in the Liquid Injectable (General) Section. The Board further decided to direct the area FID to investigate the matter of production in the Liquid Injectable Section (General) in non-compliance to the orders of QA&LT Division dated 18.09.2017 and fix the responsibility. The FID shall submit detailed investigation report with clear and candid recommendation for consideration of the CLB.

**Reply of the FID in compliance to decision of 267th meeting of CLB:-**

The firm in their reply vide letter ref. No. PH/LHR/REG/144 dated 14th September, 2018 stated that *“at the time of said surprise inspection, the idle workers were just made busy by asking them to sort already manufactured Ondensetron HCl 4mg Injection Batch no. 299 and 8mg injection batch no. 320”.* Moreover, in their reply, the company failed to provide the party wise sales record and copies of invoices of both the batches which was required from them to submit to this office.

i. In the raw material consumption record of Ondensetron HCl (Injectable Grade) submitted by the firm, following details were given:

|  |  |  |  |
| --- | --- | --- | --- |
| **Product name** | **Batch No.** | **Batch size (ampoules)** | **Consumed quantity**  **(KG)** |
| Onset Injection 4mg | 299 | 55813 | 0.312 |
| Onset Injection 8mg | 320 | 95200 | 1.040 |

ii. However, following information was found in the BMRs provided at the time of inspection and same batch size was given on the batch COA.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product name** | **Batch No.** | **Quantity of Raw material dispensed (kg)** | **Theoretical Batch size (ampoules)** | **Actual yield (ampoules)** | **In-process stock actually present in the premises at the time of inspection (ampoules by weight)** |
| Onset Injection 4mg | 299 | 0.130 | 23,250 | 19,748 (10,958 physician sample ampoules + 8,790 Commercial ampoules) | **48,734 approx.** |
| Onset Injection 8mg | 320 | 0.520 | 47,600 | 39,600 (passed after optical checking) | **76,767 approx.** |

iii. The firm in their consumption record has stated that 21.824kg of Ondensetrone HCl (Injectable grade) raw material is in balance as of 25-05-2018. However, at the time of inspection, when it was physically verified, the raw material was found to be less than 20 kg.

iv. During investigation, it was found that M/s Babar Medicine Company, Peco Road, Lahore, is one of the distributors of the said products. Supply details of Onset 8mg Injection Batch No. 320 to M/s Clinix Plus Main warehouse, Multan Road, Lahore in throughout year 2018 are enclosed. Therefore, letter no. 3556/2019-DRAP (L-VIII) dated 14-03-2019 was sent to M/s Babar Medicine Company, Peco Road, Lahore, to provide the sale/purchase details of the said products from August 2017 onwards but they failed to provide the data despite written (letter no. 4054/2019-DRAP (L-VIII) dated 22-03-2019) and telephonic reminders.

v. From the finding of the investigation, it is concluded that the firm was involved in unauthorized manufacturing of the said products while production in the relevant section had been suspended by the competent authority. Moreover, there was misdeclaration of information and hiding of facts by the firm.

vi. The case is being referred to the competent authority and the responsibility is fixed on the following for violating the provision of Section 23 of the Drugs Act, 1976 read with Schedule II of DRAP Act, 2012, punishable under Section 27 of the Drugs Act, 1976 read with Schedule III of DRAP Act, 2012, and may be prosecuted in Drug Court.

1. M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore through its CEO
2. Management of M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore as per Form-29 of SECP
   * 1. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
     2. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3
3. Mr Jamshaid Ghani, Production Incharge S/o Abdul Ghani, CNIC No. 54400-0548981-5
4. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9

vii. The cGMP inspections of the firm were conducted on 07-08-2018, 04-09-2018 & 22-11-2018, with reference to DRAP Islamabad letter No. F. 8-5/2017-QA (M-256-CLB) (Pt) dated 03-01-2018 wherein panel was required by the Central Licensing Board in light of its 256th meeting to conduct GMP inspection of the firm on approved Schedule B-II format and also submit a brief report in tabulated form identifying previous observations and current status. Inspection report was forwarded to the concerned division with the following recommendation:

1. Based on the findings of the inspection and the improvements made by the firm, the panel of inspectors recommends resumption of production in the Liquid Injectable Section (General).
2. The matter of unauthorized production in Liquid Injectable Section (General) had already been forwarded to the directorate of Quality Assurance & Lab Testing vide letter No. 11210/2018-DRAP (L-VIII) dated 24-08-2018 for necessary action.
3. Firm was advised to rectify the observations made during the cGMP inspection and submit compliance report.

**Proceedings of 270th meeting:-**

Deputy Director (QA&LT) presented the panel inspection reports in compliance to the 256th meeting of CLB and Investigation report of FID in compliance to the 267th meeting of CLB. The board discussed in detail report of the panel of experts dated 07.08.2018, 04.09.2018 & 22.11.2018 in compliance to the decision of 256th meeting of CLB. Wherein the panel recommended the resumption of production in the liquid injectable section (General). The board also discussed investigation report of the FID in compliance to decision of 267th meeting of CLB. Wherein the FID after detailed investigation of the case fixed the responsibility of the unauthorized manufacturing of Onset Injection 4mg and Onset Injection 8mg on the following accused persons, for violating the provision of Section 23 of the Drugs Act, 1976 read with Schedule II of DRAP Act, 2012, punishable under Section 27 of the Drugs Act, 1976 read with Schedule III of DRAP Act, 2012. The FID also requested for the prosecution of the said accused persons in Drug Court, Lahore.

1. M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore through its CEO
2. Management of M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore as per Form-29 of SECP
   * 1. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
     2. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3
3. Mr Jamshaid Ghani, Production Incharge S/o Abdul Ghani, CNIC No. 54400-0548981-5
4. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9

**Decision of the 270th Meeting of CLB**

After thorough discussion/deliberations and keeping in view the recommendation of panel of experts in its report dated 07.08.2018, 04.09.2018 & 22.11.2018 in compliance to the decision of 256th meeting of CLB decided to resume the production activities of the Liquid Injectable Section (General) of the firm M/s Pharmedic Laboratories, Lahore from the date of issuance of decision of 270th meeting of CLB.

The board after detailed discussion on the investigation report of FID dated 13.05.2019, in compliance to 267th meeting of CLB, decided to issue Sow Cause notice to the following accused persons and give them opportunity of personal hearing in the next meeting of CLB on the matter of unauthorized manufacturing in the Liquid Injection Section (General).

1. M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore through its CEO
2. Management of M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore as per Form-29 of SECP
   * 1. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
     2. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3
3. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9
4. Mr Jamshaid Ghani, Production Incharge S/o Abdul Ghani, CNIC No. 54400-0548981-5

**Item No. V CHANGE OF PANEL MEMBER**

Mr. Syed Muied Ahmad, Member, CLB vide letter dated 25.04.2019 addressed to Chairman CLB informed that he could not conduct regulatory inspections due to illness of his mother.

Mr. Syed Muied Ahmad is also nominated in some of the panels constituted by the Central Licensing Board, mentioned below, in the cases of QA.

M/s Regent Pharma, Karachi in 260th meeting of CLB

M/s Eros Pharma, Karachi in 241st meeting of CLB

M/s Rex Pharma, Karachi in 259th meeting of CLB

Matter is placed before the CLB for the nomination of new member to conduct all the pending inspections in the cases of QA Section, in lieu of Mr. Syed Muied Ahmad.

**Decision of the 270th Meeting of CLB**

After thorough discussion/deliberations and keeping in view the request of Mr. Syed Muied Ahmad. The board decided to nominate Dr. Abdullah Dayo, Memebr, CLB in lieu of Mr. Syed Muied Ahmad. However, in case of Regent Pharma, Karachi the panel constituted for renewal of DML shall be given mandate to verify the status of observations noted by the FID in its report dated 16.01.2018 in compliance to decision of 260th meeting of CLB.