**MINUTES OF 271st MEETING OF CENTRAL LICENSING BOARD HELD ON 12th SEPTEMBER, 2019**

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271ST meeting of the Central Licensing Board (CLB) was held on 12th September, 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 inQC/QA of drugs. | Member |
|  | Prof. Dr Abdullah Dayo, Faculty of Pharmacy, University of Sindh, Jamshoro | Member |
|  | Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar. | Member |
|  | Mr. Muhammad Israr, Law Expert, Mininstry of Law & Justice Division. | Member |
|  | Dr. Muhammad Usmaan, Expert member Manufacturing of Drugs | Member |
|  | Mr. Muhammad Shoaib Ansari, Chief Inspector of Drug, Department of Health, Government of Sindh, Karachi | Member |
|  | Mr. Munawar Hayat,  Chief Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore | Member |
|  | Syed Abdul Saleem, Chief Inspector of Drugs, Department of Health, Government of Balochistan, Quetta | Member |
|  | Dr. Hafsa Karam EllahiRepresentative Director (QA/LT), DRAP, Islamabad | Member |
|  | Zakir Shah, Drug inspector, Department of Health, Govt of Khyber Pakhutonkhuwa. | Member |
|  | Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad. | Secretary/Member |
|  | Mr. Khalid Munir & Mr. Bukhari, Representative of Representative of PPMA. | Observer |
|  | Mr.Nadeem Alamgir aand Rashid Mureed Representative of Pharma Bureau. | 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 (Quality Control), Mr. Zeeshan Nazir Deputy Director (Quality Assurance), Mr. Arslan Taariq, Assistant Director (QC), Dr. Muhammad Yaqoob AD (Lic.), Dr. Muhammad Usman, AD (Lic) and Dr. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

**Item-I CONFIRMATION OF THE MINUTES OF 270thMEETING**

 The Central Licensing Board (CLB) formally confirmed the minutes of its 270thmeeting of the Central Licensing Board (CLB) which was held on **23rd MAY, 2019**.

**A. LICENSING DIVISION**

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

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

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| **S #** | **Name of the firm** | **Date of Inspection / Type of License** | Ranking/ Evaluation | **Inspection Panel Members** |
| 1 | M/s Sami Pharmaceuticals (Pvt) Ltd, Plot No. F-95, S.I.T.E, Karachi(By way of Semi Basic Manufacture) **API (Granules/pellets)**1. Omeprazole (Pellets)- USP
2. Esomeprazole (Pellets) - USP
3. Lansoprazole (Pellets) - USP
4. Tamsulosin (Pellets) - USP
5. Cyclobenzaprine (Pellets)-USP
6. Ciprofloxacin (micro-granules) -USP
7. Itraconazole (Pellets)-BP
8. Dexlansoprazole (Pellets)-MS
9. Mebeverine (Micro-granule)-BP
10. Clarithromycin (Micro-granule)-USP
11. Roxithromycin (Micro-granule)-EP
 |  09-08-2019 | V. Good | 1. Dr. Abdullah Dayo Member Central Licensing Board.
2. Director CDL, DRAP, Karachi
3. Additional Director (E&M) DRAP, Karachi
4. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -**Keeping in view the management commitment for continuous improvement, existing technical staff, facilities, the panel recommends Grant of Drug Manufacturing License (By way of Semi Basic Manufacture) to the firm M/s. Sami Pharmaceuticals (Pvt) Ltd. With reference to DRAP, Islamabad letter No. F.2-4/2019-Lic dated, 8th July, 2019**Decision of the Central Licensing Board in 271st meeting**The Board considered and approved the grant of Drug Manufacturing License by way of Semi Basic manufacture in the name of M/s Sami Pharmaceuticals (Pvt) Ltd, Plot No. F-95, S.I.T.E, Karachi with below mentioned APIs.1. Omeprazole (Pellets)- USP
2. Esomeprazole (Pellets) - USP
3. Lansoprazole (Pellets) - USP
4. Tamsulosin (Pellets) - USP
5. Cyclobenzaprine (Pellets)-USP
6. Ciprofloxacin (micro-granules) -USP
7. Itraconazole (Pellets)-BP
8. Dexlansoprazole (Pellets)-MS
9. Mebeverine (Micro-granule)-BP
10. Clarithromycin (Micro-granule)-USP
11. Roxithromycin (Micro-granule)-EP
 |
| 2 | M/s Aamster Laboratories, Plot No. 18, Street No. SS-2, RCCI, Industrial Estate, Rawat, Rawalpindi.**Sections 04**1. Oral Powder Section–I (Vet) (General).
2. Oral Powder Section–II (Vet) (General).
3. Oral Liquid Section–I (Vet) (General).
4. Oral Liquid Section–II (Vet) (General).
 | 05-09-2019 | **Good** | 1. Prof. Dr. Muhammad Usman, Member, Central Licensing Board.
2. Additional Director (Lic) / Secretary CLB, DRAP, Islamabad.
3. Area Federal Inspector of Drugs, DRAP, Islamabad.
4. Assistant Director (Licensing-III), DRAP, Islamabad.
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| **Recommendations of the panel: -**Keeping in view facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously Recommended M/s Aamster Laboratories, Plot No. 18, Street No. SS-2, RCCI, Industrial Estate, Rawat, Rawalpindi for the grant of Drug Manufacturing Licensee (Formulation) for the following sections namely:1. Oral Powder Section–I (Vet).
2. Oral Powder Section–II (Vet).
3. Oral Liquid Section–I (Vet).
4. Oral Liquid Section–II (Vet).

**Decision of the Central Licensing Board in 271st meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Aamster Laboratories, Plot No. 18, Street No. SS-2, RCCI, Industrial Estate, Rawat, Rawalpindi with following sections:**Section (04)**1. Oral Powder Section–I (Vet).
2. Oral Powder Section–II (Vet).
3. Oral Liquid Section–I (Vet).
4. Oral Liquid Section–II (Vet).
 |
| 3 | M/s Fizi Pharmaceutical & Chemical Laboratories, Bhobattian Sikka Street, 8-Km, Raiwind Road, Lahore.**Name of Sections (02)**1. Oral Liquid (General) (Veterinary) Section
2. Oral Dry Powder (General) (Veterinary) Section
 | **30-05-2019** | **Good****Un- satisfactory (**w.r.t Liquid Injectable section**)** | 1. Dr.Ikram-ul-Haq, Member CLB.
2. Dr. Farzana Chaudhary, Expert Member.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**The Panel of Inspectors **Recommends** the grant of Drug Manufacturing Licensing by way of formulation (Vet) to M/s Fizi Pharmaceutical & Chemical Laboratories in respect of Oral Liquid and Oral Dry Powder sections Only. The Panel of Inspectors **does not recommend** the grant of DML in respect of Liquid Injectable section. **Decision of the Central Licensing Board in 271st meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Fizi Pharmaceutical & Chemical Laboratories, Bhobattian Sikka Street, 8-Km, Raiwind Road, Lahore with following sections:**Section (02)**1. Oral Liquid (General) (Veterinary) Section
2. Oral Dry Powder (General) (Veterinary) Section

However, Board did not approve **Liquid Injectable section** on the recommendations of the panel of experts. |
| 4 | M/s Himark Laboratories (Pvt) Ltd, Plot No. 37-A, Sunder Industrial Estate, Lahore**Name of Sections (06)**1. Tablet (General & General Antibiotics) Section.
2. Capsule (General & General Antibiotics) Section.
3. Dry Powder Suspension (General & General Antibiotics) Section.
4. Sachet (General) Section.
5. Liquid Syrup Oral Section.
6. Cream / Ointment (General) Section..
 | **11-05-2019** | **Good** | 1. Dr. Ikram-ul-Haq, Member CLB.
2. Dr. Farzana Chaudhary, Expert Member.
3. Mr. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore.
4. Maham Misbah, Assistant Director, DRAP, Lahore.
 |
| **Recommendations of the panel: -** Keeping in view the facility like building, HVAC system, Machinery, Equipment, Instruments, Personnel, documentation, Quality Control and Testing Facilities, the panel of inspectors **recommends** the grant of new Drug Manufacturing License to M/s Himark Laboratories (Pvt) Ltd, 37-A, Sunder Industrial Estate, Lahore for the following six sections:1. Tablet (General & General Antibiotics) Section.
2. Capsule (General & General Antibiotics) Section.
3. Dry Powder Suspension (General & General Antibiotics) Section.
4. Sachet (General) Section.
5. Oral Liquid Syrup Section.
6. Cream / Ointment (General) Section.

**Decision of the Central Licensing Board in 271st meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Himark Laboratories (Pvt) Ltd, Plot No. 37-A, Sunder Industrial Estate, Lahore with following sections:**Section (06)**1. Tablet (General & General Antibiotics) Section.
2. Capsule (General & General Antibiotics) Section.
3. Dry Powder Suspension (General & General Antibiotics) Section.
4. Sachet (General) Section.
5. Oral Liquid Syrup Section.
6. Cream / Ointment (General) Section.
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**Item-II**: **GRANT OF ADDITIONAL SECTIONS/ REVISION/AMENDMENTS ETC.**

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

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| **S #** | **Name of the firm** | **Date of Inspection**  | Ranking/ Evaluation | **Inspection Panel Members** |
| 1. | M/s Medisure Laboratories Pakistan (Pvt) Ltd, Plot No. A-115, S.I.T.E, Super Highway, Karachi.DML No. 000503 (by way of Formulation) **Sections.** 1. External preparation section powder (General)
 |  19-07-2019 | Good | 1. Dr. Abdullah Dayo Member Central Licensing Board.
2. Additional Director (E&M) DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -**As per TORs the panel inspected in details the said section in the light of the current GMP guideline. The firm has provided required machines in the area, respective installation documents were checked and found satisfactory level of compliance. Separate AHU is provided to control the inherent chance of contamination and for the safety of product and personnel. A satisfactory level of sanitation was noted during inspection. Other required utilities are also provided at the desired points. All required SOPs were seen in place. Overall section was seen at required level of compliance.Based on the above stated facts the panel unanimously recommends the grant of additional section of Dry Powder External Preparation (G) under the DML No. 000503 by way of Formulation.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following one additional section in the name of M/s Medisure Laboratories Pakistan (Pvt) Ltd, Plot No. A-115, S.I.T.E, Super Highway, Karachi.**Section (01)**1. External preparation section powder (General)
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| 2. | M/s Abbott Laboratories Pakistan Ltd, Plot No. 13, Sector 20, Korangi Industrial area, Karachi.DML No. 000004 (by way of Formulation) **Sections.**Microbiology Laboratory (amendments)  | 21-08-2019 | Good | 1. Dr. Abdullah Dayo Member Central Licensing Board.
2. Director DTL, Sindh
3. Area Federal Inspector of Drugs, DRAP, Karachi.
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| **Recommendations of the panel: -*****Following are the Observation:;****The firm has scientifically modified their Microbiology and QC Labs for attaining better level of compliance. The panel further observed that amendments have made as per DRAP approved Layout plan. With those new changes, the firm will have better controlled environmental conditions suitable for the intended operations. The newly amended separate change rooms are provided with required amenities and found with better personnel flow. Pictorial Instructions for gowning/de-gowning and sanitization are mounted inside the change rooms. HVAC system was seen in place.**Based on the above stated facts the panel unanimously recommends that the current amendments made as per DRAP approved layout plan in their Microbiology & QC Labs for attaining better GMP compliance may be approved for better regulatory compliance.***Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following amendments in facilty/ section in the name of M/s Abbott Laboratories Pakistan Ltd, Plot No. 13, Sector 20, Korangi Industrial area, Karachi.**Facility / Section** 1. Microbiology Laboratory (amendments)
 |
| 3. | M/s Aspin Pharma (Pvt) Ltd, Plot No. 10 &25, Sector 20, Korangi Industrial area, Karachi.DML No. 000045 (by way of Formulation) **Sections.**Dispensing Area (Amendments) | 01-08-2019 | Good | 1. Dr. Ghulam Sarwar Member Drug Registration Board.
2. Additional Director (E&M) DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.
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| **Recommendations of the panel: -****Following are the observations:***The firm has newly designed a well-segregated area for better control of contamination into the material. The designated area is built as per approved layout plan and is provided with authorized entry system. An effective HVAC system with required filters is given in place. Qualification of HVAC system is satisfactory carried out. Devices to monitor differential pressures and temperature are installed for better monitoring. SOPs for environmental monitoring were in place. Emergency and preventive maintenance plans for AHUs were seen in place. The dispensing booth is suitably guarded by buffers and air-locks as per approved design. Dispensed materials will be stored in a separate area adjacent to main room.**Based on the above stated facts the* ***panel unanimously recommends*** *that the current amendments in the stores made for better GMP compliance may be amalgamated with their Layout plan for better regulatory compliance.***Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following amendments in facilty/ section in the name of M/s Aspin Pharma (Pvt) Ltd, Plot No. 10 &25, Sector 20, Korangi Industrial area, Karachi.**Facility Section** 1. Dispensing Area (Amendments)
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| 4. | M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A, Street No. N-5, National Industrial Zone, Rawat, Islamabad.DML No. 680 (Formulation)**Section (06)**1. Bolus Section (General) (Veterinary).
2. Oral Powder Section (General) (Veterinary).
3. Oral Liquid Section (General) (Veterinary)
4. Oral Powder Section (Penicillin) (Veterinary).
5. Dry Powder Injection Section Vials(Penicillin) (Veterinary)
6. Liquid Injection Section Vials (Penicillin) (Veterinary).
 | 25-06-2019 | **Good** | 1. Dr. Muhammad Usman Member CLB.
2. Additional Director (QA/LT) DRAP, Islamabad.
3. Deputy |Director (Lic) – **could not join due to domestic issues**
4. Area Federal Inspector of Drugs, 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 Grand Pharma (Pvt) Ltd, Plot No. 5-A, Street No. N-5, National Industrial Zone, Rawat, Islamabad, for the grant of following additional sections under Drug Manufacturing License No. 000680 as of today;1. Bolus Section (General) (Veterinary).
2. Oral Powder Section (General) (Veterinary).
3. Oral Liquid Section (General) (Veterinary)
4. Oral Powder Section (Penicillin) (Veterinary).
5. Dry Powder Injection Section Vials(Penicillin) (Veterinary)
6. Liquid Injection Section Vials (Penicillin) (Veterinary).

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following six additional sections in the name of M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A, Street No. N-5, National Industrial Zone, Rawat, Islamabad.**Sections (06)**1. Bolus Section (General) (Veterinary).
2. Oral Powder Section (General) (Veterinary).
3. Oral Liquid Section (General) (Veterinary)
4. Oral Powder Section (Penicillin) (Veterinary).
5. Dry Powder Injection Section Vials(Penicillin) (Veterinary)
6. Liquid Injection Section Vials (Penicillin) (Veterinary).
 |
| 5. | M/s Unisa Pharmaceutical Industries Ltd., Main G.T. Road, Adamzai, Akora Khattak, District Nowshera.DML No. 000740 (Formulation)1. Liquid Injectable AmpouleSection (General) - **New**.
2. IPQC and Dispensing -**Amendments**.
3. Finished Goods Store -**Expansion**
 | **29-07-2019** | **Good** | 1. Dr. Jamshed Ali Khan, Member CLB.
2. Director DTL, Peshawar.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
 |
| **Recommendations of the panel: -**Keeping in view the available and newly developed facilities for manufacturing of liquid injectable ampoules (plastic, LDPE), the qualified staff employed in production, quality control quality assurance, the storage facilities provided for the raw materials, LDPE and finished products, the water treatment system installed, the documentation reviewed, testing SOP’s developed and the overall GMP compliance status of the firm, the panel unanimously recommends the grant of following additional section/amendments/expansion to M/s Unisa Pharmaceutical Industries Ltd., Adamzai Main G.T. Road, Akora Khattak, District Nowshera KP vide Drug Manufacturing License (DML) No.000740 by way formulation;

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|  | **Section** |
| **Ground Floor** |
| 1. | Liquid Injectable Ampoule Section (General) - **New** |
| 2. | IPQC and Dispensing – **Amendments** |
| **First Floor** |
| 3. | Finished Goods Store – **Expansion** |

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following three additional sections/ facility in the name of M/s Unisa Pharmaceutical Industries Ltd., Adamzai Main G.T. Road, Akora Khattak, District Nowshera KP.**Sections /facility**

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| **Ground Floor** |
| Liquid Injectable Ampoule Section (General) - **New** |
| IPQC and Dispensing – **Amendments** |
| **First Floor** |
| Finished Goods Store – **Expansion** |

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| 6. | M/s B.J Pharmaceuticals, Mandiali Stop, Bhattianwala Road, 18-Km,Lahore Sheikhupura Road, Lahore.DML No. 000770(Formulation)**Section / Facility(03)**1. Capsule (Cephalosporin) Section.
2. Oral Dry Powder (Suspension) Section.
3. Ware House (Cephalosporin) Section
 | **16-05-2019** | **Good** | 1. Dr. Ikram-ul-Haq, Member CLB.
2. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the observations, the members of the panel are of the opinion to recommend the grant of following new additional section of Capsule (Cephalosporin) Section, Oral Dry Powder (Cephalosporin) Section and Ware House (Cephalosporin) Section to M/s B.J Pharmaceuticals, Mandiali Stop, Bhattianwala Road, 18-Km, Lahore Sheikhupura Road, Lahore as per layout plan approved by DRAP.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following three additional sections/ facility in the name of M/s B.J Pharmaceuticals, Mandiali Stop, Bhattianwala Road, 18-Km, Lahore Sheikhupura Road, Lahore. **Section / Facility(03)**1. Capsule (Cephalosporin) Section.
2. Oral Dry Powder (Suspension) Section.
3. Ware House (Cephalosporin) Section
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| 7. | M/s Surge Laboratories (Pvt) Ltd, 10-Km, Faisalabad Road, Bikhi, District SheikhupuraDML No. 000649 (Semi Basic Manufacture)**Name of API’s(09)**1. Gabapentin Granules (Surge Specs)
2. Mannitol Granules (Surge Specs)
3. Potassium Chloride Granules (Surge Specs)
4. Vitamin-B1 Pellets (Surge Specs)
5. Pregabalin Pellets (Surge Specs)
6. Lansoprazole Pellets (USP 41)
7. Dexlansoprazole Pellets (Surge Specs)
8. Fenovirate Pellets (Surge Specs)
9. Nicotinamide Pellets (Surge Specs)
 | **04-07-2019** | **-** | 1. Dr. Mahmood Ahmad, Ex. Dean IUB.
2. Mr. Shahid Nasir, Member Expert
3. Ms. Majida Mujhahid, Federal Inspector of Drugs, DRAP, Lahore.
4. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
 |
| **Recommendations of the panel: -**The firm has complete set up to manufacture of pilot scale batch of their 09 API’s.Keeping in view the above observations, the infrastructure, machinery, capacity and technical staff and Dissolution Real / Accelerated stability studies were carried out by firm and result of both cases were satisfactory. The panel **recommend** the grant of registration of aforementioned 09 APIs for manufacturing (By way of Semi-Basic Manufacture) under Drug Manufacturing License No. 000649. **Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following APIs in the name of M/s Surge Laboratories (Pvt) Ltd, 10-Km, Faisalabad Road, Bikhi, District Sheikhupura subject to condition that pharmacopoeial reference of API or product would be mentioned against each API which ever would be available in official books. In case no pharmacopoeial reference is available then manufacturers specification would be allowed and mentioned. **Name of API’s(09)**1. Gabapentin Granules
2. Mannitol Granules
3. Potassium Chloride Granules
4. Vitamin-B1 Pellets
5. Pregabalin Pellets
6. Lansoprazole Pellets (USP 41)
7. Dexlansoprazole Pellets
8. Fenovirate Pellets
9. Nicotinamide Pellets
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| 8. | M/s News Pharma, Plot No. 42, Sunder Industrial Estate, Lahore.DML No. 000775 (Formulation)**Name of Section (02)**1. Capsule (Cephalosporin) Section.
2. Dry Powder Suspension (Cephalosporin) Section.
 | **24-07-2019** | **Good** | 1. Dr. Ikram-ul-Haq, Member CLB.
2. Ms. Anam Saeed, Federal Inspector of Drugs, DRAP, Lahore.
3. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.
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| **Recommendations of the panel: -** Keeping in view the facility like building, HVAC system, machinery & equipment, instruments, personnel, documentation, quality control and testing facility, the panel of inspectors **recommends** the grant of aforementioned new sections to News Pharma, Plot No. 42, Sunder Industrial Estate, Lahore.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following two additional sections in the name of M/s News Pharma, Plot No. 42, Sunder Industrial Estate, Lahore.**Name of Section (02)**1. Capsule (Cephalosporin) Section.
2. Dry Powder Suspension (Cephalosporin) Section.
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| 9. | M/s Seatle (Pvt) Ltd, 45-Km, Multan Road, Lahore.DML No. 000481 (Formulation)**Name of Section (02)**1. Tablet (Psychotropic) Section.
2. Capsule (Psychotropic) Section.
 | **24-06-2019** | **Good** | 1. Dr. Farzana Chaudhary, Expert Member.
2. Mr. Shahid Nasir, Expert Member.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**The panel of inspectors **recommends** the grant of additional sections as mentioned above under DML No. 000481 to M/s Seatle (Pvt) Ltd, 45-Km, Multan Road, Lahore.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following two additional sections in the name of M/s Seatle (Pvt) Ltd, 45-Km, Multan Road, Lahore..**Section (02)**1. Tablet (Psychotropic) Section.
2. Capsule (Psychotropic) Section.
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| 10 | M/s Dynatis Pakistan (Pvt) Ltd, Plot No. 710, Sunder Industrial Estate, Lahore.DML No. 000891 (Formulation) **Section (02)**1. Gel (Steroidal) in already approved Cream & Ointment (Steroidal) Section.
2. Gel (General) in already approved Cream & Ointment (General) Section.
 | **01-08-2019** | **-** | 1. Dr. Ikram-ul-Haq, Member CLB.
2. Dr.Zaka-ur-Rehman, Secretary, Pharmacy Council, Punjab.
3. Ms. Anam Saeed, Area Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -** Keeping in view the facility like building, HVAC system, machinery & equipment, instruments, personnel, Quality Control and testing facility, the panel of inspectors **recommends** approval of manufacturing of Gel (General & Steroidal) in already approved Cream & Ointment (General & Steroidal) Section.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following two additional sections in the name of M/s Dynatis Pakistan (Pvt) Ltd, Plot No. 710, Sunder Industrial Estate, Lahore.**Section (02)**1. Gel (Steroidal) in already approved Cream & Ointment (Steroidal) Section.
2. Gel (General) in already approved Cream & Ointment (General) Section.
 |
| 11. | M/s Tabros Pharma (Pvt) Ltd, Plot no. L-20/B, Sector 22, Federal B Industrial area, KarachiDML No. 000106 (Formulation)**Name of Section (02)**1. Tablet (General) Amendments (Granulation Area)
2. Tablet (Steriod) Regularization.
 | **01-08-2019** | **Good** | 1. Dr. Abdullah Dayo Member Central Licensing Board.
2. Additional Director (E&M), Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.
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| **Recommendations of the panel: -***The Panel observed as follows:*1. *The amended Premises / Sections constructed as per DRAP’s authority approved Layout plan.*
2. *An appropriate level of sanitation, cleanliness & worker hygiene was noted.*
3. *The firm has adequate number of processing & testing equipment in respective departments, based on requirements of products.*
4. *The HVAC system was seen installed and observed in operational condition.*
5. *Quality control lab also observed equipped with necessary equipments required for the testing of their registered drugs.*
6. Separate storage areas were noted and noticed well maintained.
7. Personnel met during inspection, observed well conversant with necessary qualification and experience.

Based on the stated observations, the panel recommends the grant of amendment in the layout plan as per following:-1. Tablet (General) Amendments (Granulation Area)
2. Tablet (Steriod) Regularization.

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following two additional sections in the name of M/s Tabros Pharma (Pvt) Ltd, Plot no. L-20/B, Sector 22, Federal B Industrial area, Karachi.**Section (02)**1. Tablet (General) Amendments (Granulation Area)
2. Tablet (Steriod) Regularization.
 |
| 12 | M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore.DML No. 000052 (Formulation)**Name of Section (03)**1. Capsule (General) Section (Revised).
2. Tablet (General) Section (Revised).
3. Capsule (Steroid) Section (New).
 | **21-08-2019** | **-** | 1. Dr. Ikram-ul-Haq, Member CLB.
2. Dr. Mahmood Ahmad, Ex. Dean IUB.
3. Ms. Aisha Irfan, Area Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**  In view of findings, areas, checked, documents reviewed, the panel recommends to grant approval for following sections.1. Capsule (General) Section (Revised).
2. Tablet (General) Section (Revised).
3. Capsule (Steroid) Section (New).

to M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following three additional sections in the name of M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore.**Section (03)**1. Capsule (General) Section (Revised).
2. Tablet (General) Section (Revised).
3. Capsule (Steroid) Section (New).
 |
| 13. | M/s Prix Pharmaceutica (Pvt)Ltd, Plot No. 05, Pharma City, 30-Km, Multan Road, Lahore.DML No. 000587 (Formulation)**Name of Section (01)**1. Liquid Injectable (Vial) (Penicillin) (Veterinary) Section.
 | **26-08-2019** | **Good** | 1. Dr. Ikram-ul-Haq, Member CLB.
2. Dr. Zaka-ur-Rehman, Secretary Pharmacy Council, Punjab.
3. Ms. Uzam Barkat, Area Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**In the light of the inspection conducted by the panel and based on the findings, the panel of inspectors **recommends** grant of additional section i.e. Liquid Injectable (Vial) (Penicillin) (Veterinary) Section to M/s Prix Pharmaceutica (Pvt)Ltd, Plot No. 05, Pharma City, 30-Km, Multan Road, Lahore.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following one additional sections in the name of M/s Prix Pharmaceutica (Pvt)Ltd, Plot No. 05, Pharma City, 30-Km, Multan Road, Lahore.**Section (01)**1. Liquid Injectable (Vial) (Penicillin) (Veterinary) Section.
 |
| 14. | M/s Dew-Max Pharmaceuticals (Pvt) Ltd, Plot No. 6, Street No. SS-4, Main Industrial Area, Rawat, Islamabad.**Section (01)**1. Dry Vial Injection Section (Carbapenem).
 | **06-09-2019** | **Good** | 1. Prof. Dr. Gul Majeed Khan, Professor of Pharmacy, Quaid-e-Azam University, Islamabad.
2. Additional Director (Lic), DRAP, Islamabad.
3. Area, FID, DRAP, Islamabad.
 |
| “Keeping in view the manufacturing and testing facility in place, the panel unanimously **recommends** the Grant of Additional Section i.e. **Dry Vial Injection Section (Carbapenem)** of M/s Dew-Max Pharmaceuticals (Pvt) Ltd, Plot No. 6, Street No. SS-4, Main Industrial Area, Rawat, Islamabad (Formulation). **Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the grant of following one additional sections in the name of M/s Dew-Max Pharmaceuticals (Pvt) Ltd, Plot No. 6, Street No. SS-4, Main Industrial Area, Rawat, Islamabad.**Section (01)**1. Dry Vial Injection Section (Carbapenem).
 |

**Item-III**: **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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S #** | **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| 1. | M/s Cibex (Pvt) Ltd, Plot No. F-405, S.I.T.E, KarachiDML No. 000784 (by way of Formulation) **Period:** commencing on 03.02.2019and ending on02.02.2024**Sections**1. Tablet General
2. Capsule General
3. Liquid Syrup Manufacturing
4. Ointment (Non Steroid)
5. Tablet (General Antibiotic)
6. Capsule (General Antibiotic)
7. Ointment (Steroid)
8. Dry Syrup (General Antibiotic
9. Sachet General
 | 21-05-2019 | 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 Cibex (Pvt) Ltd situated Plot No. F-405, S.I.T.E, Karachi was inspected by the panel as per instruction contained in DRAP, Islamabad letter No. F.2-5/2008-Lic (vol-I) dated 8th March 2019 & 3rd May, 2019 in connection with the renewal of DML by way of formulation following are the observations:Firm has maintained the premises as per layout plan approved by the DRAP authorities. Basic machinery and equipment required for the purpose of production and test/analysis was installed in the relevant sections. Records of the production, testing and warehousing seen in place. Relevant technical personnel seen available, observed well conversant with the requirements of the GMP/cGMP.Keeping in view the management’s commitment for continuous improvement, existing technical staff and facilities, the **panel recommends renewal** of Drug Manufacturing License No. 000784 (by way of formulation**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000784 (Formulation) in the name of M/s Cibex (Pvt) Ltd, Plot No. F-405, S.I.T.E, Karachi,on the recommendations of the panel of experts for the further period of five years commencing on 03.02.2019 and ending on 02.02.2024 for following sections:**Sections**1. Tablet General
2. Capsule General
3. Liquid Syrup Manufacturing
4. Ointment (Non Steroid)
5. Tablet (General Antibiotic)
6. Capsule (General Antibiotic)
7. Ointment (Steroid)
8. Dry Syrup (General Antibiotic
9. Sachet General
 |
| 2. | M/s Espoir Pharmaceuticals PCSIR Klc, PCSIR Laboratories Complex, Shahrah-e-doctor Salim-uz-zaman, Siddiqui off university Road, KarachiDML No. 000754 (by way of Formulation) **Period:** commencing on 05.10.2017and ending on 04.10.2022**Sections**1. Tablet General
2. Capsule General
3. Liquid Syrup
4. Dry Powder Suspension (General)
5. Sachet (General)
 | 21-05-2019 | **Unsatisfactory**  | 1. Dr. Ghulam Sarwar, Member DRB.
2. Director CDL, DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -**Keeping in view the above critical observations with a number of other observations the panel is of opinion to conclude as under:1. The firm must immediately stop all production and quality control activities as manufacturing of any products under the current facilities and controls cannot be rated quality, safe and effective and compliant to cGMP.
2. The firm should be asked to submit comprehensive action plan for improvements to rectify the above critical observations and to comply cGMP if, they want to carry any manufacturing activates in future on this plant.
3. Re-inspection of the firm may be made under the approval of the central licensing board after rectification of all above critical observations and provision of other necessary arrangements to bring the facility to cGMP compliance.
4. Resumption of any manufacturing activity should not be made until re-inspection by the panel under the approval of central licensing board.

In the meanwhile a letter is received from the firm in which firm has stated that office of FID did not issue any correspondence regarding schedule of inspection. Further the firm has intimated that the management is on Hajj and the unit may not be inspected in the absence of management. The panel visited the unit without any intimation which is against the norms and rules of DRAP and the firm is punished without any opportunity of explanation which is against the norms of justice. And this will ruin the business which the firm cannot afford in current situation. Firm has also requested to allow an opportunity to be ready for inspection for which one month time shall be sufficient to meet the standards of DRAP. **Decision by the Central Licensing Board in 271st meeting**The Board considered the report of the panel of experts for renewal of Drug Manufacturing Licence No. 000754 (by way of Formulation) of M/s Espoir Pharmaceuticals PCSIR Klc, PCSIR Laboratories Complex, Shahrah-e-doctor Salim-uz-zaman, Siddiqui off university Road, Karachi and its recommendation for suspension of production and re-inspection of the firm after rectifications. The Board also considered the letter written by M/s Espoir Pharmaceuticals PCSIR Klc, PCSIR Laboratories Complex, Shahrah-e-doctor Salim-uz-zaman, Siddiqui off university Road, Karachi. The Board after delibration decided to suspend the production of M/s Espoir Pharmaceuticals PCSIR Klc, PCSIR Laboratories Complex, Shahrah-e-doctor Salim-uz-zaman, Siddiqui off university Road, Karachi and constituted following panel of experts for re-inspection regarding verification of improvements made. 1. Prof Dr. Abdullah Dayo, Member, Central Licensing Board
2. Additional Director, DRAP, Karachi
3. Federal Inspector of Drugs, Karachi

The panel of experts shall submit detail report to the Central Licensing Board for for fate of the renewal of the firm and resumption of production. The Board shall taking further decision in the light of the recommendations of the panel. Production shall remain suspended till final orders by the Board. |

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| 3. | M/s Semos Pharmaceuticals (pvt) Ltd, Plot No. 11, Sector 12-A, North Karachi Industrial Area, KarachiDML No. 000335 (by way of Formulation) **Period:** commencing on 19.07.2019 and ending on 18.07.2024**Sections**1. Tablet General
2. Capsule General.
3. Capsule (Ceph)
4. Liquid Syrup (General)
5. Dry Powder Suspension (General)
6. Dry Powder Suspension (Ceph)
7. Cream/Ointment/Gel (General)
8. Sterile Dry Powder Injection (Ceph)
 | 27-08-2019 | **Good** | 1. Dr. Abdulah Dayo, Member CLB.
2. Director DTL, Sindh
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -**As per instruction the panel inspected in details Production Section, Quality Control lab, Stores, Utilities and reviewed in details relevant QA documents. Followings are observation and recommendation of the visit.The firm has facilities to manufacture Tablet (G), Capsule (General & Cephalosporin), Dry Powder Suspension (General & Cephalosporin), Liquid Syrup, Cream/Ointment and Sterile Dry Powder injection (cephalosporin).Based on the stated facts and keeping in view the attitude of the management towards continuous improvements, the **panel unanimously recommends the grant of renewal** of their DML No. 000335( Formulation) for the next five years.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000353 (Formulation) in the name of M/s Semos Pharmaceuticals (pvt) Ltd, Plot No. 11, Sector 12-A, North Karachi Industrial Area, Karachi,on the recommendations of the panel of experts for the further period of five years commencing on 19.07.2019 and ending on 18.07.2024for following sections:**Sections**1. Tablet General
2. Capsule General.
3. Capsule (Ceph)
4. Liquid Syrup (General)
5. Dry Powder Suspension (General)
6. Dry Powder Suspension (Ceph)
7. Cream/Ointment/Gel (General)
8. Sterile Dry Powder Injection (Ceph)
 |
| 4. | M/s Winilton Pharmaceuticals (Pvt) Ltd, Plot No. 45, Street No. S-5, National Industrial Zone, Rawat DML No. 721 (Formulation)**Period**: Commencing on 14-06-2016 and ending on 13-06-2021.  | **07-03-2019** | **Good** | 1. Mr. Abdul Sattar Sohrani, Deputy Director, DRAP, Islamabad.
2. Mr. Naveed Anwar, Drug Inspector, Rawalpindi.
3. Dr. Hasan Afzal, FID-III, 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 Winilton Pharmaceuticals (Pvt) Ltd, Plot No. 45, Street No. S-5, National Industrial Zone, Rawat for the renewal of Drug Manufacturing License No. 000721 (Formulation) for the following sections namely;1. Tablet Section (General).
2. Tablet Section (Antibiotic).
3. Capsule Section (General).

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000721 (Formulation) in the name of M/s Winilton Pharmaceuticals (Pvt) Ltd, Plot No. 45, Street No. S-5, National Industrial Zone, Rawat,on the recommendations of the panel of experts for the further period of five years commencing on 14-06-2016 and ending on 13-06-2021for following sections:**Sections*** 1. Tablet Section (General).
	2. Tablet Section (Antibiotic).
	3. Capsule Section (General).
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| 5. | M/s Unimark Pharmaceuticals, Plot No. 7-A, Street No. B-7, National Industrial Zone, Rawat, Islamabad.DML No. 000557 (Formulation)**Period**: 08-12-2014 to 07-12-2019.  | **13-03-2019****28-03-2019****28-06-2019** | **Good** | 1. Mr. Abdul Ghaffar, Deputy Director (H&OTC), DRAP, Islamabad.
2. Dr. Hasan Afzal, FID-III, DRAP, Islamabad.
3. Mr. Muhammad Yaqoob, Assistant Director (Lic-III), Islamabad.
 |
| **Recommendations**Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Unimark Pharmaceuticals, Plot No. 7-A, Street No. B-7, National Industrial Zone, Rawat, Islamabad for approval of Revised Layout Plan and the renewal of Drug Manufacturing License No. 000557 (Formulation) for the following sections as under;1. Tablet Section-I (General).
2. Tablet Section-II (General).
3. Capsule Section (General).
4. Ointment and Creams (General).
5. Dry Powder for Suspension (General).

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000721 (Formulation) in the name of M/s Unimark Pharmaceuticals, Plot No. 7-A, Street No. B-7, National Industrial Zone, Rawat, Islamabad,on the recommendations of the panel of experts for the further period of five years commencing on 08-12-2014 and ending on 07-12-2019for following sections:**Sections**1. Tablet Section-I (General).
2. Tablet Section-II (General).
3. Capsule Section (General).
4. Ointment and Creams (General).
5. Dry Powder for Suspension (General).
 |
| 6. | M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.DML No. 000493(Formulation)**Period**: Commencing on27-02-2017ending on26-02-2022 | **12-06-2019** | **Satisfactory / Average** (w.r.t. Liquid repacking and external preparation sections)**Un- satisfactory (**w.r.t all other sections**)** | 1. Dr. Ikram-ul-Haq, Member CLB.
2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
4. Dr. Akbar Ali, Assistant Director, DRAP, Lahore.
 |
| **Case Background:-**Panel Inspection report dated 26-11-2018 was received from DRAP, Lahore for renewal of Drug Manufacturing License with following recommendations of the panel. **Recommendations of the panel: -**The Panel of inspectors **does Not Recommend** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.**Decision by the Central Licensing Board in 267th meeting**The Board considered the case 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 may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**The Show Cause notice dated 29th January, 2019 was issued to M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.The firm has replied to show cause notice and the firm has requested to provide sufficient time to explain their position in writing.**A letter of Personal hearing has been issued on 19-02-2019****Decision by the Central Licensing Board in 269th meeting**Mr . Arjumand Bhutta, Director of the company appeared before the Board and contended that almost most of the shortcomings have been rectified as advised during the panel inspection and report recived with Showcause Notice. He further contended that period of one month is required to rectify rest of the shortcomings as reported in the report. The Board after hearing the representative of the firm decided to give one month period to the firm. The company shall submit request for re-inspection of the unit once rectification are made and accordingly a panel would be constituted to conduct inspection for consideration of the Board. Meanwhile Licence of the company shall remain suspended.**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**The Licensing Division issued Drug Manufacturing License suspension letter dated 13-03-2019. The firm submitted compliance report and request for re-inspection. Following panel of experts were constituted dated 06-05-2019. 1. Dr. Ikram-ul-Haq, Member CLB.
2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore.
3. Area Federal Inspector of Drugs, DRAP, Lahore.
4. Area Assistant Director, DRAP, Lahore.

Inspection report has been received from DRAP, Lahore with following recommendations of the panel. **Recommendations of the panel: -**The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd in respect of Liquid repacking and external preparation sections only. The Panel of Inspectors **does not recommend** the renewal in respect of all other sections. The Panel further recommends suspension of production in all the section which are not recommended for renewal till the rectification of shortcoming and GMP compliance. **Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**In the meanwhile the firm has informed that they improved of working of HVAC system as per instruction by Panel of inspectors which conducted firms inspection on 12-06-2019. The firm has requested for re-inspection.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000493 (Formulation) in the name of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore,on the recommendations of the panel of experts for the further period of five years commencing on 08-12-2014 and ending on 07-12-2019 for following sections:**Sections**1. Liquid Repacking
2. External Preparation Sections

Moreover, the Board did not approve rest of sections on the recommendation of the panel of experts; |
| 7. | M/s Intervac (Pvt) Ltd, 18-Km, Lahore Sheikhupura Road, Sheikhupura.DML No. 000623(Formulation)**Period**: Commencing on 18-07-2017 ending on 17-07-2022 | **22-02-2019** | **Good** | 1. Dr. Ikram Ul Haq, Member CLB.
2. Dr. Qurban Ali, Member. Drug Registration Board.
3. Dr. Zaka-ur-Rehman, Secretary Pharmacy Council, Punjab.
4. Mr. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the above improvements made by the firm, the members of the panel are of the opinion to **recommend** the grant of renewal of Drug Manufacturing License No. 000623 (Formulation) of M/s Intervac (Pvt) Ltd, 18-Km, Lahore Sheikhupura Road, Sheikhupura for the following section by the way of formulation only:-1. Liquid (General) Section.
2. Liquid (Antibiotic) Section.
3. Powder (General) Section.
4. Powder (Antibiotic) Section.
5. Injectable (General) Section.
6. Bolus Section.
7. Vaccine Section.
8. Hormone Injectable (Veterinary) Section.
9. Oral Powder (Penicillin) (Veterinary) Section.
10. Dry Powder Injection (Penicillin) (Veterinary) Section.
11. Liquid Injectable (Penicillin) (Veterinary) Section.
12. Re-Packing Section (Liquid / Powder Re-packing).

However, as per available record of Licensing Division the firm possess following sections:- 1. Liquid (General) Section.
2. Liquid (**General** Antibiotic) Section.
3. Powder (General) Section.
4. Powder (**General** Antibiotic) Section.
5. **Liquid** Injectable (General) **(Veterinary)**. Section.
6. Bolus Section.
7. Vaccine Section **(Veterinary)**.
8. Hormone Injectable **(Vial)** (Veterinary) Section.
9. Oral Powder **Suspension** (Penicillin) (Veterinary) Section.
10. Dry Powder Injection (Penicillin) (Veterinary) Section.
11. Liquid Injectable (Penicillin) (Veterinary) Section.
12. **Re-Packing Section (Powder Re-packing).**
13. **Re-Packing Section (Liquid).**

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000623 (Formulation) in the name of M/s Intervac (Pvt) Ltd, 18-Km, Lahore Sheikhupura Road, Sheikhupura, on the recommendations of the panel of experts for the further period of five years Commencing on 18-07-2017 ending on 17-07-2022 for following sections:**Sections**1. Liquid (General) Section.
2. Liquid (**General** Antibiotic) Section.
3. Powder (General) Section.
4. Powder (**General** Antibiotic) Section.
5. **Liquid** Injectable (General) **(Veterinary)**. Section.
6. Bolus Section.
7. Vaccine Section **(Veterinary)**.
8. Hormone Injectable **(Vial)** (Veterinary) Section.
9. Oral Powder **Suspension** (Penicillin) (Veterinary) Section.
10. Dry Powder Injection (Penicillin) (Veterinary) Section.
11. Liquid Injectable (Penicillin) (Veterinary) Section.
12. **Re-Packing Section (Powder Re-packing).**
13. **Re-Packing Section (Liquid).**
 |
| 8 | M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore.DML No. 000555 (Formulation)**Period**: Commencing on 01-11-2014ending on 31-10-2019 | 14-11-2018 | **Good** | 1. Dr. Ikram Ul Haq, Member CLB.
2. Mr. Asim Rauf, Additional Director (E&M), Lahore. (Not available due to official work but they allowed the panel to conduct the inspection accordingly)
3. Ms. Nusrat Rehman, Provincial Drug Inspector Industries, Lahore.
4. Ms. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view, the above improvements made by the firm, the member of the panel **recommends** the renewal of Drug Manufacturing License to M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore of **General Tablet Section and General Capsule Section only.**.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000555 (Formulation) in the name of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore, on the recommendations of the panel of experts for the further period of five years Commencing on 01-11-2014ending on 31-10-2019 for following sections:**Sections**1. General Tablet Section
2. General Capsule Section
 |
| 9 | M/s Fynk Pharmaceuticals (Pvt) Ltd, 19-Km, G.T Road, Kalashah Kaku, Tehsil Ferozewala,District Sheikhupura.DML No. 000494 (Formulation)**Period**: Commencing on 11-10-2018 ending on 10-10-2023 | **14-06-2019&****16-07-2019** | **-** | 1. Dr. Farzana Chaudhary, Expert Member.
2. Mr. Shahid Nasir, Expert Member.
3. Ms. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -** Keeping in view the improvements made by the firm, the members of the panel are of the opinion to **recommend** the grant of Renewal of Drug Manufacturing License. 000494 formulation of M/s Fynk Pharmaceuticals (Pvt) Ltd, 19-Km, G.T Road, Kalashah Kaku, Tehsil Ferozewala, District Sheikhupura for the following section by the way of formulation only:-1. Liquid Syrup / Suspension Section.
2. Liquid Injectable (General) Section.
3. Narcotic / Psychotropic Liquid Injection Section.
4. Dry Powder Injection (Cephalosporin) Section.
5. Dry Powder Suspension (Cephalosporin) Section.
6. Capsule (Cephalosporin) Section.
7. Cream / Ointment (General) Section.
8. Cream / Ointment (Steroidal) Section.
9. Tablet (General) Section.
10. Capsule (General) Section.
11. Dry Powder Oral Suspension (General) Section.
12. Sachet (General) Section.
13. Dry Powder Injection (General) Section

However, as per available record of Licensing Division the firm possess following sections:- 1. Liquid Syrup / Suspension Section.
2. Liquid Injectable **(Ampoule)** (General) Section.
3. Liquid Injection**(Ampoule)** (**Narcotic** / Psychotropic) Section.
4. Dry Powder Injection (Cephalosporin) Section.
5. Dry Powder Suspension (Cephalosporin) Section.
6. Capsule (Cephalosporin) Section.
7. Cream /Ointment (General) Section.
8. Cream / Ointment (Steroidal) Section.
9. Tablet (General) Section.
10. Capsule (General) Section.
11. Dry Powder Oral Suspension (General) Section.
12. Sachet (General) Section.
13. Dry Powder Injection (General) Section.

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000494 (Formulation) in the name of M/s Fynk Pharmaceuticals (Pvt) Ltd, 19-Km, G.T Road, Kalashah Kaku, Tehsil Ferozewala, District Sheikhupura, on the recommendations of the panel of experts for the further period of five years Commencing on 11-10-2018 ending on 10-10-2023for following sections:**Sections**1. Liquid Syrup / Suspension Section.
2. Liquid Injectable **(Ampoule)** (General) Section.
3. Liquid Injection**(Ampoule)** (**Narcotic** / Psychotropic) Section.
4. Dry Powder Injection (Cephalosporin) Section.
5. Dry Powder Suspension (Cephalosporin) Section.
6. Capsule (Cephalosporin) Section.
7. Cream /Ointment (General) Section.
8. Cream / Ointment (Steroidal) Section.
9. Tablet (General) Section.
10. Capsule (General) Section.
11. Dry Powder Oral Suspension (General) Section.
12. Sachet (General) Section.
13. Dry Powder Injection (General) Section.
 |
| 10 | M/s A.H Pharmaceuticals (Pvt) Ltd, 865-A, Small Industrial Estate, Sargodha Road, FaisalabadDML No. 000630(Formulation)**Period**: Commencing on 19-06-2018 ending on 18-06-2023. | **27-06-2019** | **Good** | 1. Dr. Farzana Chaudhary, Expert Member.
2. Dr. Zaka-ur-Rehman, Secretary Punjab Pharmacy Council, Punjab.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**The panel of inspectors **recommends** the renewal of Drug Manufacturing License bearing No. 000630issued in favour of M/s A.H Pharmaceuticals, situated at 865-A, Small Industrial Estate, Sargodha Road, Faisalabad.1. Oral Liquid (General) Section.
2. Liquid / Powder (Re-Packing) Section.

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000630 (Formulation) in the name of M/s A.H Pharmaceuticals, situated at 865-A, Small Industrial Estate, Sargodha Road, Faisalabad, on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 ending on 18-06-2023 for following sections:**Sections**1. Oral Liquid (General) Section.
2. Liquid / Powder (Re-Packing) Section.
 |
| 11 | M/s Surge Laboratories (Pvt) Ltd, 10-Km, Faisalabad Road, Bikhi, District SheikhupuraDML No. 000649 (Semi Basic Manufacture)**Period**: Commencing on 12-12-2018 ending on 11-12-2023 | **04-07-2019** | **-** | 1. Dr. Mahmood Ahmad, Ex. Dean IUB.
2. Mr. Shahid Nasir, Member Expert
3. Ms. Majida Mujhahid, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the above observations during the panel inspection of M/s Surge Laboratories (Pvt) Ltd, 10-Km, Faisalabad Road, Bikhi, District Sheikhupura, the panel recommends:The grant of renewal of rug Manufacturing License No. 000649 Semi Basic Manufacturing and allowed the production in the newly extended Semi basic Manufacturing Area of 600Kg.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000649 (by way of semi basic manufacture) in the name of M/s Surge Laboratories (Pvt) Ltd, 10-Km, Faisalabad Road, Bikhi, District Sheikhupura, on the recommendations of the panel of experts for the further period of five years Commencing on 12-12-2018 ending on 11-12-2023. |
| 12. | M/s Getz Pharma (Pvt) Ltd, Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi DML No. 000284 (Formulation)**Period**: Commencing on30-10-2019 ending on 29-10-2024 | **04-09-2019** | **Good** | 1. Dr. Abdullah Dayo Member Central Licensing Board.
2. Additional Director (E&M), Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -**M/s Getz Pharma (Pvt) LTd., situated at Plot No.29-30, Sector-27, Korangi Industrial Area, Karachi was inspected in compliance to the instructions contained in DRAP Islamabad letter No.F.2-5/86-Lic (Vol-II) dated 23rd July, 2019 in connection with the renewal of Drug Manufacturing License No.000284 for the following sections;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** |  **Name of Sections**  | **Sr. No** |  **Name of Sections**  |
|  | Injectable Ampoule (General) |  | Tablet (General) |
|  | Capsule (General) |  | Sachet (General) |
|  | Liquid Injection Vial (General) |  | Dry Powder Injection Vial (General) |
|  | Oral Dry Powder Suspension (General Antibiotic) |  | **Metered Dose Inhalers (MDI)** |
|  | **Dry Powder Inhaler (DPI)** |  | QC Laboratory |
|  | Warehouse (General) |  | Primary & Secondary Packaging Section  |

**Following are the observations;**M/s Getz Pharma (Pvt) Ltd., was inspected in detail and it was observed that necessary production, quality control facilities and storage facilities. Equipment were seen calibrated and qualified, in general. Adequate technical personnel were seen available and observed well conversant with the requirements of the GMP, M/s Getz Pharma has an efficient HVAC system operating through dedicated AHUs (Air Handling Units system) for each sections of production facility with filtration process according to classification of area. Key people has good qualification, experience and skill according to the position and job description for employees. Training program was designed and implemented to cover GMP / GSP trainings, training on SOPs, training for continual improvement; training evaluation for personal was available in respective areas.Based on the people met and the documents reviewed and considering the findings of the inspection M/s Getz Pharma (Pvt) Ltd., situated at Plot No.29-30, Sector-27, Korangi Industrial Area, Karachi is considered to be operating at an acceptable level of compliance of GMP requirements. Therefore, the opinion of the panel is to **recommend the approval for the renewal** of the Drug Manufacturing License (DML#000284) for the above named sections.**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000284 (Formulation) in the name of M/s Getz Pharma (Pvt) Ltd., Plot No.29-30, Sector-27, Korangi Industrial Area, Karachi, on the recommendations of the panel of experts for the further period of five years Commencing on30-10-2019 ending on 29-10-2024 for following sections:**Sections**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** |  **Name of Sections**  | **Sr. No** |  **Name of Sections**  |
|  | Injectable Ampoule (General) |  | Tablet (General) |
|  | Capsule (General) |  | Sachet (General) |
|  | Liquid Injection Vial (General) |  | Dry Powder Injection Vial (General) |
|  | Oral Dry Powder Suspension (General Antibiotic) |  | **Metered Dose Inhalers (MDI)** |
|  | **Dry Powder Inhaler (DPI)** |  | QC Laboratory |
|  | Warehouse (General) |  | Primary & Secondary Packaging Section  |

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 13. | M/s Avant Pharmaceuticals (Pvt) Ltd., Plot M-28, H.I.T.E., BalochistanDML No. 000786 (Formulation)**Period**: Commencing on 03-02-2019 ending on 01-02-2024. | **N/A** | **N/A** | 1. Dr. Abdullah Dayo Member Central Licensing Board.
2. Additional Director (E&M), Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Letter of FID: -**The firm, M/s Avant Pharmaceuticals (Pvt) Ltd., Baluchistan, vide their letter (copy enclosed) has informed that they are doing some renovation work at their facility and not ready for panel inspection.It is therefore kindly requested to your good office that the necessary directions may kindly be passed to the undersigned in the light of Drugs (Licensing, Registering and Advertising) Rules, 1976, for further necessary action in this regard. **Decision by the Central Licensing Board in 271st meeting**The Board considered the letter of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Kararchi and attached letter of the firm M/s Avant Pharmaceuticals (Pvt) Ltd., Plot M-28, H.I.T.E., Balochistan wherein firm was doing renovation work with intimation of the Board and avoiding inspection for renewal of Drug Manufacturing Licence. The Board decided to suspend the production of drugs in manucaturing facility till renovation is made by the firm. The firm shall inform the Board for its readiness for inspection. The Board shall pass orders for inspection accordingly. The production shall remain suspend till final orders by the Board on the recommendations of the panel of experts. |
| 14 | M/s Pakistan Pharmaceutical Products (Pvt) Ltd, D-122, SITE, Karachi DML No. 000091 (Formulation)**Period**: Commencing on 05-07-2019 ending on 04-07-2024 | **27-08-2019** | **Good** | 1. Dr. Ghulam Sarwar Member Drug Registration Board.
2. Additional Director (E&M) DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -**Based on the people met, areas visited and competent of the management for continuous improvement the panel recommends the renewal of DML No. 000091 (Formulation) of M/s PAKISTAN PHARMACEUTICAL PRODUCTS (Pvt) Ltd, D-122, SITE, Karachi for following sections:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** |  **Name of Sections**  | **Sr. No** |  **Name of Sections**  |
|  | Injectable Ampoule (General) |  | Tablet (General) |
|  | Capsule (General) |  | Cream/Ointment/Gel (General) |
|  | Oral Liquid (general) |  | Ear / Eye Drops (General) |
|  | Capsule (Cephalosporin) |  | Oral Dry Powder Suspension (Cephalosporin) |
|  | Oral Dry Suspension (Penicillin) |  | Dry Powder vials Injectable (Cephalosporin) |
|  | Capsule (Penicillin) |  | Tablet (Penicillin)  |
|  |  |  |  |

**Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000091 (Formulation) in the name of M/s Pakistan Pharmaceutical Products (Pvt) Ltd, D-122, SITE, Karachi , on the recommendations of the panel of experts for the further period of five years Commencing on : Commencing on 05-07-2019 ending on 04-07-2024 for following sections:**Sections**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** |  **Name of Sections**  | **Sr. No** |  **Name of Sections**  |
|  | Injectable Ampoule (General) |  | Tablet (General) |
|  | Capsule (General) |  | Cream/Ointment/Gel (General) |
|  | Oral Liquid (general) |  | Ear / Eye Drops (General) |
|  | Capsule (Cephalosporin) |  | Oral Dry Powder Suspension (Cephalosporin) |
|  | Oral Dry Suspension (Penicillin) |  | Dry Powder vials Injectable (Cephalosporin) |
|  | Capsule (Penicillin) |  | Tablet (Penicillin)  |

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| --- | --- | --- | --- | --- |
| 15 | M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road west wharf Karachi DML No. 000017 (Formulation)**Period**: Commencing on 31-03-2015 ending on 30-03-2020 | **05-09-2019** | **V.Good** | 1. Dr. Abdullah Dayo Member CLB.
2. Additional Director (E&M) DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -**Keeping in view the people met, areas visited and commitment of the firm, the panel recommends the renewal of DML No. 000017 (Formulation) for following approved sections:-

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No** | **Name** | **S. No** | **Name** |
|  | Ointment(General) |  | Oral Powder – ENO section |
|  | Ear Drops  |  | Non Pariel Seeds(NPS)- (In house use only) |
|  | Capsule/spansules (General) |  | Eye Ointment |

The renewal of Aerosol section as per submission of the firm is not recommended. The liquid injectable products are all transferred from west wharf to korangi site. Therefore this section is not recommended as the same does not exist at this premises and lying as vacant space. **Decision by the Central Licensing Board in 271st meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000017 (Formulation) in the name of M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road west wharf Karachi , on the recommendations of the panel of experts for the further period of five years Commencing on 31-03-2015 ending on 30-03-2020 for following sections:**Sections**

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No** | **Name** | **S. No** | **Name** |
|  | Ointment(General) |  | Oral Powder – ENO section |
|  | Ear Drops  |  | Non Pariel Seeds(NPS)- (In house use only) |
|  | Capsule/spansules (General) |  | Eye Ointment |

 |

**ITEM – IV MISC CASES**

**Case No. 1. CHANGE OF MANAGEMENT OF M/S SEMOS PHARMACEUTICALS (PVT) LIMITED, PLOT NO 11 SECTOR 12-A NORTH KARACHI INDUSTRIAL AREA, KARACHI.**

M/s Semos Pharmaceuticals (Pvt) Limited, Plot No.11, Sector 12-A North Karachi Industrial area, Karachi, under DML No. 000335 (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:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management** |
| 1. | Mr. Abdullah Shamim S/o Abdul Manan CNIC NO. 42201-7682945-5  | Ms. Aliya Shamim W/O Mr. Abdullah Shamim CNIC NO. 42000-1102009-0 | Mr. Abdullah Shamim S/o Abdul Manan CNIC NO. 42201-7682945-5  |
| 2. | Mr. Muti-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-5543772-5  | \*\*\*\*\*\*\*\* | Mr. Muti-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-5543772-5  |
| 3. | Mr. Fazal-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-3678476-7 | \*\*\*\*\*\*\*\* | Mr. Fazal-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-3678476-7 |
| 4. | Mr. Tanzil-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42201-0801029-7 | \*\*\*\*\*\*\*\* | Mr. Tanzil-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42201-0801029-7 |
| 5. | Ms. Aliya Shamim W/O Mr. Abdullah Shamim CNIC NO. 42000-1102009-0 | \*\*\*\*\*\*\*\* | Mr. asfi-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-1994725-9 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Semos Pharmaceuticals (Pvt) Limited, Plot No.11, Sector 12-A North Karachi Industrial area, Karachi under DML No. 000335 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management** |
| 1. | Mr. Abdullah Shamim S/o Abdul Manan CNIC NO. 42201-7682945-5  | Ms. Aliya Shamim W/O Mr. Abdullah Shamim CNIC NO. 42000-1102009-0 | Mr. Abdullah Shamim S/o Abdul Manan CNIC NO. 42201-7682945-5  |
| 2. | Mr. Muti-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-5543772-5  | \*\*\*\*\*\*\*\* | Mr. Muti-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-5543772-5  |
| 3. | Mr. Fazal-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-3678476-7 | \*\*\*\*\*\*\*\* | Mr. Fazal-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-3678476-7 |
| 4. | Mr. Tanzil-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42201-0801029-7 | \*\*\*\*\*\*\*\* | Mr. Tanzil-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42201-0801029-7 |
| 5. | Ms. Aliya Shamim W/O Mr. Abdullah Shamim CNIC NO. 42000-1102009-0 | \*\*\*\*\*\*\*\* | Mr. asfi-ur-rehman S/O Mr. Abdullah Shamim CNIC NO. 42000-1994725-9 |

**Case No. 2 CHANGE OF MANAGEMENT OF M/S INDUS PHARMA (PVT) LIMITED, PLOT NO. 26, 27, 63, 64, 65, 66 & 67 SECTOR 27 KORANGI INDUSTRIAL AREA KARACHI**

M/s Indus Pharma (Pvt) Limited, Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi. under DML No. 000124 (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:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Khalid Saeed S/O Saeed Ismail CNIC NO. 42201-7292832-3  | Mr. Anwar Saeed | Mr. Khalid Saeed S/O Saeed Ismail CNIC NO. 42201-7292832-3  |
| 2. | Mr. Zahid Saeed S/O Saeed Ismail CNIC NO. 42201-4791181-1  | \*\*\*\*\*\*\*\* | Mr. Zahid Saeed S/O Saeed Ismail CNIC NO. 42201-4791181-1  |
| 3. | Mr. Saeed Ismail S/O Muhammad Ismail CNIC NO. 42201-6916191-5 | \*\*\*\*\*\*\*\* | Mr. Saeed Ismail S/O Muhammad Ismail CNIC NO. 42201-6916191-5 |
| 4. | Mr. Anwar Saeed | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Indus Pharma (Pvt) Limited, Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi under DML No. 000124 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Khalid Saeed S/O Saeed Ismail CNIC NO. 42201-7292832-3  | Mr. Anwar Saeed | Mr. Khalid Saeed S/O Saeed Ismail CNIC NO. 42201-7292832-3  |
| 2. | Mr. Zahid Saeed S/O Saeed Ismail CNIC NO. 42201-4791181-1  | \*\*\*\*\*\*\*\* | Mr. Zahid Saeed S/O Saeed Ismail CNIC NO. 42201-4791181-1  |
| 3. | Mr. Saeed Ismail S/O Muhammad Ismail CNIC NO. 42201-6916191-5 | \*\*\*\*\*\*\*\* | Mr. Saeed Ismail S/O Muhammad Ismail CNIC NO. 42201-6916191-5 |
| 4. | Mr. Anwar Saeed | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |

**Case No. 3. CHANGE OF MANAGEMENT OF M/S MEDIMARKER’S LABORATORIES (PVT) LTD, A-104, SITE, HYDERABAD**

M/s Medimarkes’s Laboratories (Pvt) Limited, A-104, SITE, Hyderabad under DML No. 000615 (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:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management as per Form 29 (year 2016)**  | **Retiring Management**  | **New Management as per Form 29 (year 2019)**  |
| 1. | Mr Abdullah Sheikh S/o Bashir Ahmed Sheikh CNIC No. 42301-2960391-9  | Mr Abdullah Sheikh S/o Bashir Ahmed Sheikh CNIC No. 42301-2960391-9 | Mr. Jai Paldas S/o Parcho Mal CNIC No. 42201-0299960-9  |
| 2. | Ms. Ayesha Abdullah W/O Abdullah Sheikh CNIC No. 42301-7863442-8  | \*\*\*\*\*\*\*\* | Ms. Ayesha Abdullah W/O Abdullah Sheikh CNIC No. 42301-7863442-8 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Medimarkes’s Laboratories (Pvt) Limited, A-104, SITE, Hyderabad under DML No. 000615 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management as per Form 29 (year 2016)**  | **Retiring Management**  | **New Management as per Form 29 (year 2019)**  |
| 1. | Mr Abdullah Sheikh S/o Bashir Ahmed Sheikh CNIC No. 42301-2960391-9  | Mr Abdullah Sheikh S/o Bashir Ahmed Sheikh CNIC No. 42301-2960391-9 | Mr. Jai Paldas S/o Parcho Mal CNIC No. 42201-0299960-9  |
| 2. | Ms. Ayesha Abdullah W/O Abdullah Sheikh CNIC No. 42301-7863442-8  | \*\*\*\*\*\*\*\* | Ms. Ayesha Abdullah W/O Abdullah Sheikh CNIC No. 42301-7863442-8 |

**Case No. 4. CHANGE OF MANAGEMENT OF M/S NABIQASIM INDUSTRIES (PVT) LTD, 17 SECTOR 24 KORANGI INDUSTRIAL AREA KARACHI**

M/s NabiQasim Industries (Pvt) Limited, Plot No. 17 Sector 24 Korangi Industrial Area Karachi under DML No. 000105 (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:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management** |
| 1. | Ms. Humera Jawad W/o Jawad Saeed CNIC NO. 42301-8539616-8  | Mr. Abdul Majid S/O Ch Ghulam Nabi CNIC NO. 42301-0969191-7 | Ms. Humera Jawad W/o Jawad Saeed CNIC NO. 42301-8539616-8  |
| 2. | Mr. Muhammad Abdullah Majeed S/O Abdul Majeed CNIC NO. 42301-1356206-7  | MS. Sajida Sultana W/O Noor Ellahe CNIC NO. 42201-1710479-8 | Mr. Muhammad Abdullah Majeed S/O Abdul Majeed CNIC NO. 42301-1356206-7  |
| 3. | Ms. Saleha Sultana W/O Mr. Abdul Majeed Nabi CNIC NO. 42301-0512065-8 | \*\*\*\*\*\*\*\* | Ms. Saleha Sultana W/O Mr. Abdul Majeed Nabi CNIC NO. 42301-0512065-8 |
| 4. | Mr. Faqir Muhammad S/O Shar Muhammad CNIC NO. 42301-1310425-9 | \*\*\*\*\*\*\*\* | Mr. Faqir Muhammad S/O Shar Muhammad CNIC NO. 42301-1310425-9 |
| 5. | Mr. Muhammad Ali Majid S/O Mr. Abdul Majid CNIC NO. 42301-5590648-9 | \*\*\*\*\*\*\*\* | Mr. Muhammad Ali Majid S/O Mr. Abdul Majid CNIC NO. 42301-5590648-9 |
| 6. | Mr Saad Noor S/O Noor Ellahe CNIC NO. 42201-4748804-5 | \*\*\*\*\*\*\*\* | Mr Saad Noor S/O Noor Ellahe CNIC NO. 42201-4748804-5 |
| 7. | Mr. Abdul Majid S/O Ch Ghulam Nabi CNIC NO. 42301-0969191-7 | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |
| 8. | MS. Sajida Sultana W/O Noor Ellahe CNIC NO. 42201-1710479-8 | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Nabi Qasim Industries (Pvt) Limited, Plot No. 17 Sector 24 Korangi Industrial Area Karachi under DML No. 000105 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management** |
| 1. | Ms. Humera Jawad W/o Jawad Saeed CNIC NO. 42301-8539616-8  | Mr. Abdul Majid S/O Ch Ghulam Nabi CNIC NO. 42301-0969191-7 | Ms. Humera Jawad W/o Jawad Saeed CNIC NO. 42301-8539616-8  |
| 2. | Mr. Muhammad Abdullah Majeed S/O Abdul Majeed CNIC NO. 42301-1356206-7  | MS. Sajida Sultana W/O Noor Ellahe CNIC NO. 42201-1710479-8 | Mr. Muhammad Abdullah Majeed S/O Abdul Majeed CNIC NO. 42301-1356206-7  |
| 3. | Ms. Saleha Sultana W/O Mr. Abdul Majeed Nabi CNIC NO. 42301-0512065-8 | \*\*\*\*\*\*\*\* | Ms. Saleha Sultana W/O Mr. Abdul Majeed Nabi CNIC NO. 42301-0512065-8 |
| 4. | Mr. Faqir Muhammad S/O Shar Muhammad CNIC NO. 42301-1310425-9 | \*\*\*\*\*\*\*\* | Mr. Faqir Muhammad S/O Shar Muhammad CNIC NO. 42301-1310425-9 |
| 5. | Mr. Muhammad Ali Majid S/O Mr. Abdul Majid CNIC NO. 42301-5590648-9 | \*\*\*\*\*\*\*\* | Mr. Muhammad Ali Majid S/O Mr. Abdul Majid CNIC NO. 42301-5590648-9 |
| 6. | Mr Saad Noor S/O Noor Ellahe CNIC NO. 42201-4748804-5 | \*\*\*\*\*\*\*\* | Mr Saad Noor S/O Noor Ellahe CNIC NO. 42201-4748804-5 |
| 7. | Mr. Abdul Majid S/O Ch Ghulam Nabi CNIC NO. 42301-0969191-7 | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |
| 8. | MS. Sajida Sultana W/O Noor Ellahe CNIC NO. 42201-1710479-8 | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |

**Case No.5. CHANGE OF MANAGEMENT OF M/S LINZ PHARMACEUTICALS (PVT) LTD, PLOT NO. 31-4/II, SECTOR-15, KORANGI INDUSTRIAL AREA, KARACHI**

M/s Linz Pharmaceuticals (Pvt) Ltd, Plot No. 31-4/II, Sector-15, Korangi Industrial Area, Karachi, under DML No. 000540 (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:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management** |
| 1. | Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7  | Ms. Kehkashan Adil | Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7  |
| 2. | Ms. Farzana Faisal  | Ms. Farzana Faisal  | Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1  |
| 3. | Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3 | \*\*\*\*\*\*\*\* | Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3 |
| 4. | Ms. Kehkashan Adil  | \*\*\*\*\*\*\*\* | Mr. Zakraria Nasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Linz Pharmaceuticals (Pvt) Ltd, Plot No. 31-4/II, Sector-15, Korangi Industrial Area, Karachi under DML No. 000540 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management** |
| 1. | Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7  | Ms. Kehkashan Adil | Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7  |
| 2. | Ms. Farzana Faisal  | Ms. Farzana Faisal  | Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1  |
| 3. | Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3 | \*\*\*\*\*\*\*\* | Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3 |
| 4. | Ms. Kehkashan Adil  | \*\*\*\*\*\*\*\* | Mr. Zakraria Nasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3 |

**CASE NO.6 CHANGE OF MANAGEMENT OF M/S MCOLSON RESEARCH LABORATORIES (PVT) LTD, SHEIKHUPURA**

M/s McOLSON Research Laboratories (Pvt) Ltd, Plot No. 2, M-2, Pharma Zone, 26-Km, Lahore Sharikpur Road, Sheikhupura under DML No. 000664 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-A** | **Retiring Management**  | **Current Management as per Form-29**  |
| 1. Mr. Muhammad Faisal Mushtaq S/o Mushtaq Ahmad CNIC No. 35202-7491903-9.2. Dr. Zafar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 35202-1546650-7.3. Mr. Faysal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3.4. Mr. Qaisar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-6554673-1.5. Mr. Ghulam Mustafa Jajjah S/o Muhammad Sadiq CNIC No. 34101-2601504-3.6. Ms. Tahira Khatoon W/o Mian Muhammad Sharif CNIC No. 35202-2574072-0.7. Ms. Nadia Shoukat CNIC No. 35202-3209761-0 | 1. Ms. Nadia Shoukat CNIC No. 35202-3209761-0 | 1. Mr. Muhammad Faisal Mushtaq S/o Mushtaq Ahmad CNIC No. 35202-7491903-9.2. Dr. Zafar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 35202-1546650-7.3. Mr. Faysal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3.4. Mr. Qaisar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-6554673-1.5. Mr. Ghulam Mustafa Jajjah S/o Muhammad Sadiq CNIC No. 34101-2601504-3.6. Ms. Tahira Khatoon W/o Mian Muhammad Sharif CNIC No. 35202-2574072-0. |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s McOLSON Research Laboratories (Pvt) Ltd, Plot No. 2, M-2, Pharma Zone, 26-Km, Lahore Sharikpur Road, Sheikhupura under DML No. 000664 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-A** | **Retiring Management**  | **Current Management as per Form-29**  |
| 1. Mr. Muhammad Faisal Mushtaq S/o Mushtaq Ahmad CNIC No. 35202-7491903-9.2. Dr. Zafar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 35202-1546650-7.3. Mr. Faysal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3.4. Mr. Qaisar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-6554673-1.5. Mr. Ghulam Mustafa Jajjah S/o Muhammad Sadiq CNIC No. 34101-2601504-3.6. Ms. Tahira Khatoon W/o Mian Muhammad Sharif CNIC No. 35202-2574072-0.7. Ms. Nadia Shoukat CNIC No. 35202-3209761-0 | 1. Ms. Nadia Shoukat CNIC No. 35202-3209761-0 | 1. Mr. Muhammad Faisal Mushtaq S/o Mushtaq Ahmad CNIC No. 35202-7491903-9.2. Dr. Zafar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 35202-1546650-7.3. Mr. Faysal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3.4. Mr. Qaisar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-6554673-1.5. Mr. Ghulam Mustafa Jajjah S/o Muhammad Sadiq CNIC No. 34101-2601504-3.6. Ms. Tahira Khatoon W/o Mian Muhammad Sharif CNIC No. 35202-2574072-0. |

**CASE NO. 7 CHANGE OF MANAGEMENT OF M/S TITLIS PHARMA, LAHORE.**

M/s Titlis Pharma, Plot No. 528-A, Sunder Industrial Estate, Raiwind Road, Lahoreunder DML No. 000799 by way of formulation has submitted request for change in management of the firm as per Partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Partnership** | **Retiring Management**  | **Current Management as per Partnership deed**  |
| 1. Mr. Syed Faisal Zaman S/o Syed Qamar Zaman CNIC No. 35202-7196906-1.2. Mr. Kamran Malik S/o Abdul Rauf Malik CNIC No. 35202-2475273-3.3. Mr. Saleem Akhtar S/o Ch. Faiz Muhammad CNIC No. 35202-1426086-3. | 1. Mr. Kamran Malik S/o Abdul Rauf Malik CNIC No. 35202-2475273-3.2. Mr. Saleem Akhtar S/o Ch. Faiz Muhammad CNIC No. 35202-1426086-3. | 1. Mr. Syed Faisal Zaman S/o Syed Qamar Zaman CNIC No. 35202-7196906-1.2. Mr. Syed Fahd Zaman S/o Syed Faisal Zaman CNIC No. 35202-2513242-1. |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Titlis Pharma, Plot No. 528-A, Sunder Industrial Estate, Raiwind Road, Lahoreunder DML No. 000799 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Partnership** | **Retiring Management**  | **Current Management as per Partnership deed**  |
| 1. Mr. Syed Faisal Zaman S/o Syed Qamar Zaman CNIC No. 35202-7196906-1.2. Mr. Kamran Malik S/o Abdul Rauf Malik CNIC No. 35202-2475273-3.3. Mr. Saleem Akhtar S/o Ch. Faiz Muhammad CNIC No. 35202-1426086-3. | 1. Mr. Kamran Malik S/o Abdul Rauf Malik CNIC No. 35202-2475273-3.2. Mr. Saleem Akhtar S/o Ch. Faiz Muhammad CNIC No. 35202-1426086-3. | 1. Mr. Syed Faisal Zaman S/o Syed Qamar Zaman CNIC No. 35202-7196906-1.2. Mr. Syed Fahd Zaman S/o Syed Faisal Zaman CNIC No. 35202-2513242-1. |

**Case No.8. CHANGE OF MANAGEMENT OF M/S MEDICON PHARMACEUTICAL INDUSTRIES (PVT) LTD, PESHAWAR.**

M/s Medicon Pharmaceutical Industries (Pvt) Ltd, B-1/11, Industrial Estate, Hayatabad, Peshawar. under DML No. 000215 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-29 of SECP dated 22-11-2011** | **Incoming Management as per Form-A of SECP dated 16-06-2017** | **New Management as per Form-A of SECP dated 16-06-2017** |
| 1. Mr. Maqbool Khan S/o Lal Mir Khan

CNIC No.17301-2252149-91. Mrs. Shakila Bukhari W/o Maqbool Khan

CNIC No. 17301-4904731-0 | 1. Mr. Farjad Maqbool S/o Maqbool Khan

CNIC No.17301-9112974-7 | 1. Mr. Maqbool Khan S/o Lal Mir Khan

CNIC No.17301-2252149-91. Mrs. Shakila Bukhari W/o Maqbool Khan

CNIC No. 17301-4904731-01. Mr. Farjad Maqbool S/o Maqbool Khan

CNIC No.17301-9112974-7 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Medicon Pharmaceutical Industries (Pvt) Ltd, B-1/11, Industrial Estate, Hayatabad, Peshawar under DML No. 000215 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-29 of SECP dated 22-11-2011** | **Incoming Management as per Form-A of SECP dated 16-06-2017** | **New Management as per Form-A of SECP dated 16-06-2017** |
| 1. Mr. Maqbool Khan S/o Lal Mir Khan

CNIC No.17301-2252149-91. Mrs. Shakila Bukhari W/o Maqbool Khan

CNIC No. 17301-4904731-0 | 1. Mr. Farjad Maqbool S/o Maqbool Khan

CNIC No.17301-9112974-7 | 1. Mr. Maqbool Khan S/o Lal Mir Khan

CNIC No.17301-2252149-91. Mrs. Shakila Bukhari W/o Maqbool Khan

CNIC No. 17301-4904731-01. Mr. Farjad Maqbool S/o Maqbool Khan

CNIC No.17301-9112974-7 |

**Case No.9. CHANGE OF MANAGEMENT OF M/S TREAT PHARMACEUTICAL INDUSTRY (PVT) LTD, BANNU.**

M/s Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannu under DML No. 000352 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Memorandum and Article of Association dated 24-05-2011** | **Interim Management as per Form-29 of SECPdated 27-11-2015** | **Current Management as per Form-29 of SECP dated 30-05-2017** |
| 1. Mr. Saifullah Khan S/o Sardar Ali Khan
2. Mr. Mir Shah Zar Khan S/o Sardar Ali Khan
3. Mr. Sanaullah Khan S/o Sardar Ali Khan
 | 1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9
2. Mr. Azmat Ullah Khan Khattak S/o Sadiq Ullah, CNIC No. 17301-1326922-9
 | 1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9
2. Mr. Maqbool Khan S/o Lal Mir, CNIC No. 17301-2252149-9
 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannu under DML No. 000352 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Memorandum and Article of Association dated 24-05-2011** | **Interim Management as per Form-29 of SECPdated 27-11-2015** | **Current Management as per Form-29 of SECP dated 30-05-2017** |
| 1. Mr. Saifullah Khan S/o Sardar Ali Khan
2. Mr. Mir Shah Zar Khan S/o Sardar Ali Khan
3. Mr. Sanaullah Khan S/o Sardar Ali Khan
 | 1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9
2. Mr. Azmat Ullah Khan Khattak S/o Sadiq Ullah, CNIC No. 17301-1326922-9
 | 1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9
2. Mr. Maqbool Khan S/o Lal Mir, CNIC No. 17301-2252149-9
 |

**Case No.10. CHANGE OF MANAGEMENT OF M/S HISUN PHARMACEUTICAL INDUSTRIES, DISTRICT SWABI.**

M/s Hisun Pharmaceutical Industries,37-A, R-02, Industrial Estate Gadoon Amazai, District Swabi under DML No. 000617 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |
| --- | --- | --- |
| **Current Management as per Form-H & Partnership Deed**  | **Retiring management as per Partnership Deed**  | **Previous Management as per Form-H & Partnership Deed**  |
| 1. Mr. Muhammad Nawaz S/o Rana Muhammad Aslam CNIC No. 34601-9588618-1
2. Mr. Shafiq Ur Rehman S/o Abdul Wadood CNIC No.16101-8654128-5.
3. Mr. Muhammad Burhan-ud-Din S/o Haji Yousaf Shah CNIC No.15602-8203622-9
 | 1. Mr. Shafiq Ur Rehman S/o Abdul Wadood CNIC No.16101-8654128-5
2. Mr. Muhammad Burhan-ud-Din S/o Haji Yousaf Shah CNIC No.15602-8203622-9
 | 1. Mr. Rana Munawar Hussain S/o Rana Muhammad Ramzan CNIC No.34601-4783864-1
2. Mr. Rana Muhammad Sarwar S/o Rana Muhammad Ramzan CNIC No.34601-8623941-3
3. Mr. Muhammad Nawaz S/o Rana Muhammad Aslam CNIC No. 34601-9588618-1
 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Hisun Pharmaceutical Industries,37-A, R-02, Industrial Estate Gadoon Amazai, District Swabi under DML No. 000617 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Current Management as per Form-H & Partnership Deed**  | **Retiring management as per Partnership Deed**  | **Previous Management as per Form-H & Partnership Deed**  |
| 1. Mr. Muhammad Nawaz S/o Rana Muhammad Aslam CNIC No. 34601-9588618-1
2. Mr. Shafiq Ur Rehman S/o Abdul Wadood CNIC No.16101-8654128-5.
3. Mr. Muhammad Burhan-ud-Din S/o Haji Yousaf Shah CNIC No.15602-8203622-9
 | 1. Mr. Shafiq Ur Rehman S/o Abdul Wadood CNIC No.16101-8654128-5
2. Mr. Muhammad Burhan-ud-Din S/o Haji Yousaf Shah CNIC No.15602-8203622-9
 | 1. Mr. Rana Munawar Hussain S/o Rana Muhammad Ramzan CNIC No.34601-4783864-1
2. Mr. Rana Muhammad Sarwar S/o Rana Muhammad Ramzan CNIC No.34601-8623941-3
3. Mr. Muhammad Nawaz S/o Rana Muhammad Aslam CNIC No. 34601-9588618-1
 |

**Case No.11. CHANGE OF MANAGEMENT OF M/S MACTER INTERNATIONAL LIMITED, KARACHI.**

M/s Macter International Limited, Plot No. E-40A, SITE, Karachi under DML No. 000641 by way of formulation has submitted request for change in management of the firm as per Form 29 and Form 1A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3  | Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9 | Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3  |
| 2. | Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5  | Syed Salman Ahmed CNIC No.42000-1954567-7 | Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5  |
| 3. | Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 | Mr. Zubeid Qureshi CNIC No. 42301-1491744-1 | Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 |
| 4. | Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 | Mr. Muhammad Asif CNIC No.42301-5182030-1 | Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5 |
| 5. | Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9 | Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1 | Mr. Sohaib Umer S/O Muhammad Umer CNIC No. 42200-16581898-9 |
| 6. | Syed Salman Ahmed CNIC No.42000-1954567-7 | \*\*\*\*\*\*\*\* | Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 |
| 7. | Mr. Zubeid Qureshi CNIC No. 42301-1491744-1 | \*\*\*\*\*\*\*\* | Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 |
| 8. | Mr. Muhammad Asif CNIC No.42301-5182030-1 | \*\*\*\*\*\*\*\* | Miss Masarrat Misbah D/o Misbahuddin CNIC No. 42301-0983750-0 |
| 9. | Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1 | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Macter International Limited, Plot No. E-40A, SITE, Karachi under DML No. 000641 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3  | Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9 | Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3  |
| 2. | Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5  | Syed Salman Ahmed CNIC No.42000-1954567-7 | Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5  |
| 3. | Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 | Mr. Zubeid Qureshi CNIC No. 42301-1491744-1 | Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 |
| 4. | Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 | Mr. Muhammad Asif CNIC No.42301-5182030-1 | Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5 |
| 5. | Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9 | Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1 | Mr. Sohaib Umer S/O Muhammad Umer CNIC No. 42200-16581898-9 |
| 6. | Syed Salman Ahmed CNIC No.42000-1954567-7 | \*\*\*\*\*\*\*\* | Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 |
| 7. | Mr. Zubeid Qureshi CNIC No. 42301-1491744-1 | \*\*\*\*\*\*\*\* | Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 |
| 8. | Mr. Muhammad Asif CNIC No.42301-5182030-1 | \*\*\*\*\*\*\*\* | Miss Masarrat Misbah D/o Misbahuddin CNIC No. 42301-0983750-0 |
| 9. | Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1 | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |

**Case No.12. CHANGE OF MANAGEMENT OF M/S AGP LIMITED, KARACHI.**

M/s AGP Limited, Plot No. D-109, SITE, Karachi under DML No. 000044by way of formulation has submitted request for change in management of the firm as per Form 29 and Form 1A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Tariq Moinuddin Khan S/O K.A-Moinuddin Khan CNIC No. 42301-0755070-1  | Ms. Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2 | Mr. Mahmud Yar Hiraj S/o Sardar Allah yar Hiraj CNIC No. 35200-2240100-7  |
| 2. | Ms. Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2 | Syed Zeeshan Mobin S/o Mobin Shaukat CNIC No. 42301-6467474-3 | Mr. Tariq Moinuddin Khan S/O K.A-Moinuddin Khan CNIC No. 42301-0755070-1  |
| 3. | Syed Zeeshan Mobin S/o Mobin Shaukat CNIC No. 42301-6467474-3 | \*\*\*\*\*\*\*\* | Mr. Kamran Nishat S/O Shaikh Nishat Ahmed CNIC No. 42301-3817237-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Nusrat Munshi S/O Alauddin Munshi CNIC No. 42301-7644816-8 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Naved Abid Khan S/O Muhammad Abid Khan CNIC No. 42301-1101720-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Muhammad Kamran Mirza S/o Muhammad Jameel Mirza CNIC No.42301-9154917-3 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s AGP Limited, Plot No. D-109, SITE, Karachi under DML No. 000044 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Tariq Moinuddin Khan S/O K.A-Moinuddin Khan CNIC No. 42301-0755070-1  | Ms. Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2 | Mr. Mahmud Yar Hiraj S/o Sardar Allah yar Hiraj CNIC No. 35200-2240100-7  |
| 2. | Ms. Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2 | Syed Zeeshan Mobin S/o Mobin Shaukat CNIC No. 42301-6467474-3 | Mr. Tariq Moinuddin Khan S/O K.A-Moinuddin Khan CNIC No. 42301-0755070-1  |
| 3. | Syed Zeeshan Mobin S/o Mobin Shaukat CNIC No. 42301-6467474-3 | \*\*\*\*\*\*\*\* | Mr. Kamran Nishat S/O Shaikh Nishat Ahmed CNIC No. 42301-3817237-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Nusrat Munshi S/O Alauddin Munshi CNIC No. 42301-7644816-8 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Naved Abid Khan S/O Muhammad Abid Khan CNIC No. 42301-1101720-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Muhammad Kamran Mirza S/o Muhammad Jameel Mirza CNIC No.42301-9154917-3 |

**Case No.13. CHANGE OF MANAGEMENT OF M/S AGP LIMITED, KARACHI.**

M/s AGP Limited, Plot No. B-23-C, SITE, Karachi under DML No. 000348by way of formulation has submitted request for change in management of the firm as per Form 29 and Form 1A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Tariq Moinuddin Khan S/O K.A-Moinuddin Khan CNIC No. 42301-0755070-1  | Ms. Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2 | Mr. Mahmud Yar Hiraj S/o Sardar Allah yar Hiraj CNIC No. 35200-2240100-7  |
| 2. | Ms. Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2 | Syed Zeeshan Mobin S/o Mobin Shaukat CNIC No. 42301-6467474-3 | Mr. Tariq Moinuddin Khan S/O K.A-Moinuddin Khan CNIC No. 42301-0755070-1  |
| 3. | Syed Zeeshan Mobin S/o Mobin Shaukat CNIC No. 42301-6467474-3 | \*\*\*\*\*\*\*\* | Mr. Kamran Nishat S/O Shaikh Nishat Ahmed CNIC No. 42301-3817237-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Nusrat Munshi S/O Alauddin Munshi CNIC No. 42301-7644816-8 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Naved Abid Khan S/O Muhammad Abid Khan CNIC No. 42301-1101720-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Muhammad Kamran Mirza S/o Muhammad Jameel Mirza CNIC No.42301-9154917-3 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s AGP Limited, Plot No. B-23-C, SITE, Karachi under DML No. 000348 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Tariq Moinuddin Khan S/O K.A-Moinuddin Khan CNIC No. 42301-0755070-1  | Ms. Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2 | Mr. Mahmud Yar Hiraj S/o Sardar Allah yar Hiraj CNIC No. 35200-2240100-7  |
| 2. | Ms. Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2 | Syed Zeeshan Mobin S/o Mobin Shaukat CNIC No. 42301-6467474-3 | Mr. Tariq Moinuddin Khan S/O K.A-Moinuddin Khan CNIC No. 42301-0755070-1  |
| 3. | Syed Zeeshan Mobin S/o Mobin Shaukat CNIC No. 42301-6467474-3 | \*\*\*\*\*\*\*\* | Mr. Kamran Nishat S/O Shaikh Nishat Ahmed CNIC No. 42301-3817237-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Nusrat Munshi S/O Alauddin Munshi CNIC No. 42301-7644816-8 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Naved Abid Khan S/O Muhammad Abid Khan CNIC No. 42301-1101720-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5 |
|  | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Muhammad Kamran Mirza S/o Muhammad Jameel Mirza CNIC No.42301-9154917-3 |

**Case No.14. CHANGE OF MANAGEMENT OF M/S MACTER INTERNATIONAL LIMITED, KARACHI.**

M/s Macter International Limited, Plot No. F/216, SITE, Karachi under DML No. 000141by way of formulation has submitted request for change in management of the firm as per Form 29 and Form 1A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3  | Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9 | Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3  |
| 2. | Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5  | Syed Salman Ahmed CNIC No.42000-1954567-7 | Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5  |
| 3. | Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 | Mr. Zubeid Qureshi CNIC No. 42301-1491744-1 | Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 |
| 4. | Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 | Mr. Muhammad Asif CNIC No.42301-5182030-1 | Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5 |
| 5. | Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9 | Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1 | Mr. Sohaib Umer S/O Muhammad Umer CNIC No. 42200-16581898-9 |
| 6. | Syed Salman Ahmed CNIC No.42000-1954567-7 | \*\*\*\*\*\*\*\* | Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 |
| 7. | Mr. Zubeid Qureshi CNIC No. 42301-1491744-1 | \*\*\*\*\*\*\*\* | Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 |
| 8. | Mr. Muhammad Asif CNIC No.42301-5182030-1 | \*\*\*\*\*\*\*\* | Miss Masarrat Misbah D/o Misbahuddin CNIC No. 42301-0983750-0 |
| 9. | Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1 | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Macter International Limited, Plot No. F/216, SITE, Karachi under DML No. 000141 by way of formulation as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management**  |
| 1. | Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3  | Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9 | Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3  |
| 2. | Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5  | Syed Salman Ahmed CNIC No.42000-1954567-7 | Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5  |
| 3. | Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 | Mr. Zubeid Qureshi CNIC No. 42301-1491744-1 | Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 |
| 4. | Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 | Mr. Muhammad Asif CNIC No.42301-5182030-1 | Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5 |
| 5. | Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9 | Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1 | Mr. Sohaib Umer S/O Muhammad Umer CNIC No. 42200-16581898-9 |
| 6. | Syed Salman Ahmed CNIC No.42000-1954567-7 | \*\*\*\*\*\*\*\* | Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 |
| 7. | Mr. Zubeid Qureshi CNIC No. 42301-1491744-1 | \*\*\*\*\*\*\*\* | Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 |
| 8. | Mr. Muhammad Asif CNIC No.42301-5182030-1 | \*\*\*\*\*\*\*\* | Miss Masarrat Misbah D/o Misbahuddin CNIC No. 42301-0983750-0 |
| 9. | Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1 | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* |

**Case No.15. CHANGE OF MANAGEMENT OF M/S CHERWEL PHARMACEUTICALS (PVT) LTD., HATTAR.**

M/s Cherwel Pharmaceuticals (Pvt) Ltd, Plot No.20, Phase-4, Hattar Industrial Estate, Hattar under DML No. 000606 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-29 of SECP dated 24-11-2015** | **Retiring/Incoming Management as per Form-29 of SECP dated 27-12-2016** | **New Management as per Form-29 of SECP dated 16-06-2017** |
| 1. Mr. Tahir Ahmed S/o Nisar Ahmad

CNIC No.16101-6321648-51. Mr. Abdul Wahab S/o Zar Muhammad

P. No. 001220131. Shabir Ahmad S/o Kashf-Ud-Dija

CNIC No. 16101-6456368-3 | **Retiring**1. Shabir Ahmad S/o Kashf-Ud-Dija

CNIC No. 16101-6456368-3**Incoming**1. Mr. Kashf-Ud-Duja S/o Badr-Ud-Duja

CNIC No. 16101-1635177-9 | 1. Mr. Tahir Ahmed S/o Nisar Ahmad

CNIC No.16101-6321648-51. Mr. Abdul Wahab S/o Zar Muhammad

P. No. 001220131. Mr. Kashf-Ud-Duja S/o Badr-Ud-Duja

CNIC No. 16101-1635177-9 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Cherwel Pharmaceuticals (Pvt) Ltd, Plot No.20, Phase-4, Hattar Industrial Estate, Hattar under DML No. 000606 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-29 of SECP dated 24-11-2015** | **Retiring/Incoming Management as per Form-29 of SECP dated 27-12-2016** | **New Management as per Form-29 of SECP dated 16-06-2017** |
| 1. Mr. Tahir Ahmed S/o Nisar Ahmad

CNIC No.16101-6321648-51. Mr. Abdul Wahab S/o Zar Muhammad

P. No. 001220131. Shabir Ahmad S/o Kashf-Ud-Dija

CNIC No. 16101-6456368-3 | **Retiring**1. Shabir Ahmad S/o Kashf-Ud-Dija

CNIC No. 16101-6456368-3**Incoming**1. Mr. Kashf-Ud-Duja S/o Badr-Ud-Duja

CNIC No. 16101-1635177-9 | 1. Mr. Tahir Ahmed S/o Nisar Ahmad

CNIC No.16101-6321648-51. Mr. Abdul Wahab S/o Zar Muhammad

P. No. 001220131. Mr. Kashf-Ud-Duja S/o Badr-Ud-Duja

CNIC No. 16101-1635177-9 |

**CASE NO. 16. CHANGE OF MANAGEMENT OF M/S BIO FINE PHARMACEUTICALS (PVT) LTD, MULTAN**

M/s Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multanunder DML No. 000334 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-1A** | **Added Management**  | **Current Management as per Form-29**  |
| 1. Mr. Saadat Ali Ghauri S/o Allaudin CNIC No. 36302-8717595-3. | 2. Ms. Nusrat Jabeen Ghauri W/o Saadat Ali Ghauri CNIC No. 36302-5251045-8.3. Mr. Muhammad Haseeb Ullah Ghauri S/o Saadat Ali Ghauri CNIC No. 36302-7818002-1. | 1. Mr. Saadat Ali Ghauri S/o Allaudin CNIC No. 36302-8717595-3.2. Ms. Nusrat Jabeen Ghauri W/o Saadat Ali Ghauri CNIC No. 36302-5251045-8.3. Mr. Muhammad Haseeb Ullah Ghauri S/o Saadat Ali Ghauri CNIC No. 36302-7818002-1. |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multan under DML No. 000606 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-1A** | **Added Management**  | **Current Management as per Form-29**  |
| 1. Mr. Saadat Ali Ghauri S/o Allaudin CNIC No. 36302-8717595-3. | 2. Ms. Nusrat Jabeen Ghauri W/o Saadat Ali Ghauri CNIC No. 36302-5251045-8.3. Mr. Muhammad Haseeb Ullah Ghauri S/o Saadat Ali Ghauri CNIC No. 36302-7818002-1. | 1. Mr. Saadat Ali Ghauri S/o Allaudin CNIC No. 36302-8717595-3.2. Ms. Nusrat Jabeen Ghauri W/o Saadat Ali Ghauri CNIC No. 36302-5251045-8.3. Mr. Muhammad Haseeb Ullah Ghauri S/o Saadat Ali Ghauri CNIC No. 36302-7818002-1. |

**CaseNo.17. CHANGE OF MANAGEMENT OF M/S AKSON PHARMACEUTICALS (PVT) LTD., PLOT NO. 9-B / 1&2, STREET NO. D-1, OLD INDUSTRIAL ESTATE, MIRPUR, AZAD KASHMIR**

M/s Akson Pharmaceuticals (Pvt) Ltd., Plot No. 9-B / 1&2, Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir, under DML No. 000486 (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 as per Form-29 from S.E.C.P | Incoming management as per Form-29 from S.E.C.P | New Management as per Form-29 from S.E.C.P |
| 1. Siraj Ud Din S/o Syed Ghulam Bacha. CNIC NO. 17301-1302453-3
2. Muhammad Rafique Ch. S/o Peer Muhammad. CNIC NO. 81102-0247964-7.
3. Muhammad Tahir S/o Ch. Lal Din. CNIC NO.81302-1675959-7.
 | 1. Mr. Khalid Saeed S/o Abdul Wadood, CNIC No. 17301-5639125-7.
 | 1. Siraj Ud Din S/o Syed Ghulam Bacha. CNIC NO. 17301-1302453-3
2. Muhammad Rafique Ch. S/o Peer Muhammad. CNIC NO. 81102-0247964-7.
3. Muhammad Tahir S/o Ch. Lal Din. CNIC NO.81302-1675959-7.
4. Mr. Khalid Saeed S/o Abdul Wadood, CNIC No. 17301-5639125-7.
 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Akson Pharmaceuticals (Pvt) Ltd., Plot No. 9-B / 1&2, Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir under DML No. 000486 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| Existing Management as per Form-29 from S.E.C.P | Incoming management as per Form-29 from S.E.C.P | New Management as per Form-29 from S.E.C.P |
| 1. Siraj Ud Din S/o Syed Ghulam Bacha. CNIC NO. 17301-1302453-3
2. Muhammad Rafique Ch. S/o Peer Muhammad. CNIC NO. 81102-0247964-7.
3. Muhammad Tahir S/o Ch. Lal Din. CNIC NO.81302-1675959-7.
 | 1. Mr. Khalid Saeed S/o Abdul Wadood, CNIC No. 17301-5639125-7.
 | 1. Siraj Ud Din S/o Syed Ghulam Bacha. CNIC NO. 17301-1302453-3
2. Muhammad Rafique Ch. S/o Peer Muhammad. CNIC NO. 81102-0247964-7.
3. Muhammad Tahir S/o Ch. Lal Din. CNIC NO.81302-1675959-7.
4. Mr. Khalid Saeed S/o Abdul Wadood, CNIC No. 17301-5639125-7.
 |

**CASE NO. 18. CHANGE OF MANAGEMENT OF M/S BF BIOSCIENCE LTD, LAHORE**

M/s BF Bioscience Ltd, 5-Km, Sunder Raiwind Road, Raiwind, Lahore under DML No. 000655 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-1A** | **Restring Management**  | **Current Management as per Form-29**  |
| 1. Mrs. Akhter Khalid Waheed 2. Mr. Osman Khalid Waheed 3. Mr. Farooq Mazhar 4. Mr. Rallys Eduardo Pilauzer  | 1. Mr. Farooq Mazhar  | 1. Mrs. Akhter Khalid Waheed W/o Khalid Waheed CNIC No. 37405-0348706-0.2. Mr. Osman Khalid Waheed S/o Khalid Waheed CNIC No. 37405-0384955-7.3. Ms. Munize Azhar Peracha W/o Azhar Mehmood Peracha CNIC No. 35202-2778956-0.4. Mr. Rallys Eduardo Pilauzer S/o Rallys Angel Demetrio Pilauzer Passport No. AAF596341. |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s BF Bioscience Ltd, 5-Km, Sunder Raiwind Road, Raiwind, Lahore under DML No. 000655 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-1A** | **Restring Management**  | **Current Management as per Form-29**  |
| 1. Mrs. Akhter Khalid Waheed 2. Mr. Osman Khalid Waheed 3. Mr. Farooq Mazhar 4. Mr. Rallys Eduardo Pilauzer  | 1. Mr. Farooq Mazhar  | 1. Mrs. Akhter Khalid Waheed W/o Khalid Waheed CNIC No. 37405-0348706-0.2. Mr. Osman Khalid Waheed S/o Khalid Waheed CNIC No. 37405-0384955-7.3. Ms. Munize Azhar Peracha W/o Azhar Mehmood Peracha CNIC No. 35202-2778956-0.4. Mr. Rallys Eduardo Pilauzer S/o Rallys Angel Demetrio Pilauzer Passport No. AAF596341. |

**CASE NO. 19. CHANGE OF MANAGEMENT OF M/S JAENS PHARMACEUTICAL INDUSTRIES (PVT) LTD, LAHORE**

M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000352 by way of formulation has submitted request for change in management of the firm as per Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;-

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-1A** | **Restring Management**  | **Current Management as per Form-A**  |
| 1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5.2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7.3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5.4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9.5. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7. | 1. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7. | 1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5.2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7.3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5.4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9. |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000352 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous Management as per Form-1A** | **Restring Management**  | **Current Management as per Form-A**  |
| 1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5.2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7.3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5.4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9.5. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7. | 1. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7. | 1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5.2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7.3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5.4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9. |

**Case No. 20. CHANGE OF MANAGEMENT OF M/S SAMI PHARMACEUTICALS (PVT) LTD, F-129, SITE, KARACHI**

M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 (By way of Re-packing) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management** |
| 1. | Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7  | Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6 | Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7  |
| 2. | Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3  | \*\*\*\*\*\*\*\* | Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3  |
| 3. | Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6 | \*\*\*\*\*\*\*\* | Mr. Abdul Salam S/O Zikr-ur-Rehman CNIC No. 42201-6555398-5 |
| 4. | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Shohaib Shamim S/O Shamim Ahmed CNIC No. 42201-0709871-7 |
| 5. | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Owais Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-5 |
| 6. | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7 |
| 7. | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-07079872-3 |

**Decision by the Central Licensing Board in 271st meeting:**

The Board considered and endorsed the change of management of M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 (By way of Re-packing) as under ;

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Existing Management**  | **Retiring Management**  | **New Management** |
| 1. | Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7  | Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6 | Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7  |
| 2. | Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3  | \*\*\*\*\*\*\*\* | Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3  |
| 3. | Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6 | \*\*\*\*\*\*\*\* | Mr. Abdul Salam S/O Zikr-ur-Rehman CNIC No. 42201-6555398-5 |
| 4. | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Shohaib Shamim S/O Shamim Ahmed CNIC No. 42201-0709871-7 |
| 5. | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Owais Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-5 |
| 6. | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7 |
| 7. | \*\*\*\*\*\*\*\* | \*\*\*\*\*\*\*\* | Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-07079872-3 |

**Case No. 21 CHANGE OF PANEL OF EXPERTS FOR RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S REIGN PHARMACEUTICALS, KARACHI**

M/s. Reign Pharmaceuticals, PCSIR Klc, (Pvt) Ltd, Karachi applied for renewal of DML no. 000757 (Formulation) for the tenure 28.11.2017 to 27.11.2022. After completion of the application a panel of experts consisting of following members was constituted for the said purpose vide letter dated, 02nd March, 2018.

1. Mr. Syed Muied Ahmed, Member Central Licensing Board.
2. Director CDL, DRAP, Karachi
3. Additional Director (E&M) DRAP, Karachi
4. Area Federal Inspector of Drugs, DRAP, Karachi.

The panel inspection report is not received yet and now firm has submitted request for change of panel of experts due to non availability of Mr. Syed Muied Ahmed, and also stated that firm is not comfortable with the panel members due to conflict of interest.

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considered the request of M/s. Reign Pharmaceuticals, PCSIR Klc, (Pvt) Ltd, Karachi and observed that this is unfortunate that “conflict of interest” is being invoked by the applicants against members of the panel. The Board also discussed various options and lacking on part of the applicants as well. To avoid any future litigation, the Board decided to constitute new panel and if observations are also raised on new panel the Board would not spare and would initiate legal proceedings against the firm. The Board also reconstituted panel of experts as under:

* + - 1. Prof. Dr. Abdullah Dayo, Member Centtral Licensing Board
			2. Chief Inspector of Drugs, Government of Sindh, Karachi
			3. Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Karachi
			4. Assistant Director, Drug Regulatory Authority of Pakistan, Karachi

**Case No. 22 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MYRTLE PHARMA, KARACHI**

M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone, Bin Qasim Karachi, had applied for renewal of DML No. 000722 by way of formulation for the period of 22-06-2016 to 21-06-2021.

 The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 15-12-2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form-1A duly attested and signed by owner/ Director of firm alongwith all attested enclosures.
2. Detail of management on firm’s letter head alongwith attested CNIC copies of Partners or Sole proprietor at present renewal and at the time of previous renewal of DML.
3. Approval Complete set of duly attested documents for proposed Production Incharge and Quality Control Incharge as (per check list)..

 The firm submitted their reply on 02nd March 2018. After evaluation of the submitted documents, Final reminder was issued on 17th May 2018. to the firm to submit following shortcomings: -

1. Undertaking on stamp paper of Proposed Quality Incharge & Production Incharge
2. Attested copy of CNIC and academic degree along with Registration Certificate issued from Pharmacy Council of proposed Production Incharge Mr. Rana Akram (dully attested).
3. Experience certificates of proposed Production Incharge.
4. Relevant experience certificates in testing of drugs of 10 years of Proposed Quality Incharge.
5. **All documents should be duly attested.**

 No reply is received from the firm till date and application for renewal of DML is still incomplete as of today.

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone, Bin Qasim Karachi, Drug Manufacturing Licence No 000722 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Case No. 23 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S NAWAN LABORATORIES (PVT) LTD, KARACHI**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 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 .

**The Show cause notice dated 15th July, 2019 was issued to the firm but no reply is received. The firm is called for the personal hearing vide letter dated, 04th September, 2019.** The firm has submitted reply of show cause notice sting that liquid inectable section (General) is an old approved section but the firm never held registrations and was not active since long. In year 2017 and 20189 firm registered three products but decided not to manufacture and with draw the section.The firm has decided to with draw the section and not continuing the registrations and would like to convert into another section for which a separate application shall be submitted. Therefore you are requested that the show cause notice may be cancelled.  |

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considered the facts on record and reply of the Showcause Notice by the firm decided to cancel the liquid inectable section (General) in the name of M/s Nawan Laboratories (Pvt) Ltd, Plot No. 136, sector 15, Korangi Industrial Area, Karachi DML No. 000442 (Formulation) under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The Firm shall submit utility of section within 60 days. Manufacturing of drugs in the section is prohibited and punishable offence under Section 23 and Section 27 of the Drugs Act, 1976 and rules framed thereunder.

**Case No. 24 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AJM PHARMA (PVT) LTD, KARACHI**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | M/s AJM Pharma (Pvt) Ltd, Plot No. 44, sector 27, korangi Industrial Area, KarachiDML 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 License No. 000234 (Formulation) in the name of M/s AJM Pharma (Pvt) Ltd, Plot No. 44, sector 27, korangi Industrial Area, Karachi on the recommendations of the panel of experts for the further period of five years commencing on 10.07.2015to 09.07.2020 for following sections

|  |
| --- |
| 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 The Show cause notice dated 11thJuly, 2019 was issued to the firm and in reply firm has stated that firm does not possess the Ointment /cream section on ground and same was not present & not approved in Regularization of the layout .Firm has also stated that in future if firm plan to add this section it will apply and submit the same in revised layout plan.**The firm is called for the personal hearing vide letter dated, 04th September, 2019.** **Submitted for consideration of the Board** |

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

Col (Retd) Tariq appeared before the Board and contended that they have never applied and while revision of Lay Out Plan they also not got the section regularized. Therefore, company is not interested in section. It was informed to the Board that M/s AJM Pharma (Pvt) Ltd, Plot No. 44, sector 27, korangi Industrial Area, Karachi has purchased pant from M/s Meredoa Compnay Ltd who had mentioned the section while filing of application for renewal of Drug Manufacturing Licence. It was therefore, legal procedure has been adopted to address the matter in hand. The Board considered the facts on record and reply of the Showcause Notice by the firm and after hearing the representative of the firm decided to cancel the Ointment /cream section in the name of M/s AJM Pharma (Pvt) Ltd, Plot No. 44, sector 27, korangi Industrial Area, Karachi DML No. 000234 (Formulation) under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

**Case No. 25 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S. KALIGON AGRO INDUSTRIES (PVT) LTD, BALUCHISTAN**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, BaluchistanDML 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. **The Show cause notice dated 18thJuly, 2019 was issued to the firm but no reply is received. The firm is called for the personal hearing vide letter dated, 04th September, 2019.**  |

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

No person appeared on behalf of the firm the Board decided to seek clarification from the Fedeeral Inspector of Drugs, Drug Regulatory Authority, Quetta @ Karachi and to serve final opportunity to firm before taking final decision.

**Case No. 26 APPROVAL OF LAYOUT PLAN FOR REGULARIZATION UNDER DRUG MANUFACTURING LICENSE NO.000557 (FORMULATION) OF M/S UNIMARK PHARMACEUTICALS, PLOT NO. 7-A, STREET NO. B-7, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD.**

M/s Unimark Pharmaceuticals, Plot No. 7-A, Street No. B-7, National Industrial Zone, Rawat, Islamabad, DML No. 000557 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections: -

1. Tablet Section-I (General).
2. Tablet Section-II (General).
3. Capsule Section (General).
4. Ointment and Creams (General).
5. Dry Powder for Suspension (General).

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. Mr. Abdul Ghaffar, Deputy Director (H&OTC), DRAP, Islamabad.
		2. Dr. Hasan Afzal, FID-III, DRAP, Islamabad.
		3. Mr. Muhammad Yaqoob, Assistant Director (Lic-III), Islamabad.

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

**Recommendations:-**

**The Panel of inspectors endorsed the regularization** of the above mentioned sections to M/s Unimark Pharmaceuticals, Plot No. 7-A, Street No. B-7, National Industrial Zone, Rawat, Islamabad.

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considered and approved regularization of of Lay out plan in the name of M/s Unimark Pharmaceuticals, Plot No. 7-A, Street No. B-7, National Industrial Zone, Rawat, Islamabad. On the recommendation of the panel of experts for the following sections:-

1. Tablet Section-I (General).
2. Tablet Section-II (General).
3. Capsule Section (General).
4. Ointment and Creams (General).
5. Dry Powder for Suspension (General).

**Case No. 27 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 premises 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 clarification on the subject matter.

Accordingly, a personal hearing letter has been issued to the firm on 03-09-2019.

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

Col (Retd) Munawar, owner of M/s Oerlikon Pharmaceutical Industries, Gadoon Amazai appeared before the Board and contended that as per recommendations of the panel of experts they have got structural strength certificate from the Engineer of Malik Associate. The Board considered the facts and perused Certificate presented by the owner of the firm decided approve the site subject to Certificate of registration of the M/s Malik Associates from Pakistan Engineering Council.

**Case No.28 M/S LAWARI INTERNATIONAL, VALLEY ROAD, GULKADA, SWAT – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

M/s Lawari International, Valley Road, Gulkada, Swat submitted the application for renewal of DML No. 000658 by way of formulation on 27-01-2014 for the period of 30-01-2014 to 29-01-2019, which was well on time.After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued advising the firm to submit complete application on prescribed Form-1A with its all enclosures.

2. With reference to above letter, the firm has submitted DML renewal application on Form-1A with some attachments. Upon evaluation, Licensing Division issued letter for completion of application with following shortcomings;

1. Classes of Drugs.
2. Name of drugs.
3. Copy of approved layout plan with sections letters issued by Central Licensing Board (CLB)
4. Approval letters of technical persons i.e. Production Incharge and Quality Control Incharge or provide documents as per checklist (enclosed).
5. Updated nothing due certificate (CRF) from STO (R&D) DRAP Islamabad.
6. Legal status of the firm with the names of directors, owners or partners.

3. With reference to above letter, as per record of Licensing Division no response has been received from the firm and a final reminder was issued on 16th February, 2017 advising again to the firm to rectify following shortcomings;

1. Attested copy of classes of drugs to be manufactured.
2. Attested copy of name of drugs to be manufactured.
3. Attested copy of approved layout plan with approval letter(s) of all approved sections.
4. Approval letter of Production and QC Incharge and if technical persons have been changed then provide attested documents as per enclosed checklist.
5. Up-to-date nothing due certificate (CFR) from STO, DRAP.
6. Legal status of the firm with the names of directors / owners / partners.

4. With reference to above final reminder, as per record of Licensing Division no response has been received from the firm till to date.

**Proceedings and Decision of Central Licensing Board in 255th meeting.**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000658 by way of formulation of M/s Lawari International, Valley Road, Gulkada, Swat may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

Accordingly showcasue notice to the firm was issued to the firm and firm did not submit reply. The firm has also been called for personal hearing. Mr. WAseem Javaid, Propriter of the firm appeared before the Board. He presented before the Board ddocuements mentioned below:

1. Attested copy of name of drugs to be manufactured.
2. Attested copy of approval letter(s) of all approved sections.
3. Attested documents of proposed QC Incharge (Deficient)
4. Legal status of the firm with the names of directors / owners / partners.

He further contended that all formalities are complete and showcasue may be withdrawn. The Board after hearing representative of the firm and perusal of the documents observed that firm has been manufacturing and selling medicines without approval of qualified approved staff since long time and application for renewal of Drug Manufacturing Licence is still short of documents. The Board, therefore, decided to suspend the Drug manufacturing Licence No. 000658 by way of formulation of M/s Lawari International, Valley Road, Gulkada, Swat with immediate effect for a period of six months 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.

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

The firm was issued suspension letter dated 21-12-2017 and the firm was advised to complete the shortcomings of application for renewal of DML. However, the firm was failed to complete shortcomings in application for grant of renewal of DML during this period. Meanwhile, an application is received from the firm for grant of renewal of DML for the period 30-01-2019 to 29-01-2024 which is evaluated and found complete. The case is placed before the Board for constitution of panel of experts / inspectors for grant of renewal of DML for the period of 30-01-2019 to 29-01-2024 and the same panel may be given mandate to resume the production activity which was suspended in its 256th meeting of CLB.

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considered that facts onrecord and decided to constitute following panel of experts for the purpose of renewal of Drug Manufacturing Licence and resumption of production of the manufacturing facility:

* + - 1. Prof. Dr. Muhammad Jamshaid, Member Centrral Licensing Board
			2. Chief Inspector of Drugs, Government of KhyberPakhtunkwa, Peshawar
			3. Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Peshawar.

**Case No.29 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.

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

The Show Cause notice dated 23rd August, 2019 was issued to the of M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Road, Lahore

The firm has replied to Show Cause notice on 05-09-2019 and stated that the management of firm has been changed and few important documents are yet to be provided by the previous management of the company. Therefore they are unable to file a replied to Show Cause notice within given time. The firm has requested to extend the due date of filling replied to Show Cause notice.

A letter of personal hearing has been issued to the firm on 03rd September, 2019.

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

Mr. Uzair Nagra, Chief Executive of the company appeared before the Board and contended that case in the Drug Court, Bahawalpur pertains to year 2007-08 and the old management has resigned in 2010. Case has come to the knowledge of new management due to show cause notice issued by this Board. They have approached the Drug Court, Bahawalpur. The duty judge has given next date on 17th September, 2019 for hearing. As the recommendations of the Chairman Drug Court, Balwalpur for cancellation of Drug Manufacturing Licence was due to non appearance of the accused before the Court. Since, the company has suurndered before the Court, therefore, Show Cause Notice may be dropped. The Board discussed the matter in detail and decided to submit the above facts before the Court.

**CASE NO.30.** **M/S ASTLE MEDICAL DEVICES PAKISTAN (PVT) LTD, PLOT NO. 545-B, SUNDER INDUSTRIAL ESTATE, LAHORE.**

 Drug Manufacturing License No. 000743 (Formulation) was issued to M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *“if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application”.* But, in this case the application for renewal of DML for the period 11-10-2017 to 10-10-2022 has not been received till date. Therefore, DML No. 000743 (Formulation) M/s Astle Medical Devices Pakistan (Pvt) Ltd, Lahore is no more valid.

**Proceedings and Decision of Central Licensing Board in 268th meeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000743 by way of formulation M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, Lahore may not be declared cancelled.

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

The Show Cause notice dated 23rd January, 2019 was issued to M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, Lahore.

No reply of the show cause notice is received from the firm.

**A letter of Personal hearing has been issued on 19-02-2019.**

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

No person appeared on behalf of the firm. However, Secretariat of the Licensing Division informed that a call is recived form Mr. Kashif ( Cell. 03008450930). He introduced himself as MD of the company and informed that he had recived letter of personal hearing on the date of meeting therefore time may be give to appear in the next meeting of the Board. The Board after considering the facts decided to defer the case to give final opportunity to the firm to plead his case.

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

A letter of personal hearing has been issued to the firm on 03rd September, 2019.

**Proceedings and Decision of Central Licensing Board in 271st meeting**

No person appeared on behalf of the firm . The Board considering the facts on the record and after thread bare deliberation decided to declare the Drug Manufacturing Licence 000743 by way of formulation M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, Lahore invalid and cancelled under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The Drug Manufacturing Licence stands cancelled. Manufacturing of drugs is prohibited and punishable offence under Section 23 and Section 27 and rules framed thereunder.

**CASE NO.31.** **M/S KAKASIAN PHARMACEUTICALS (PVT) LTD,29th KM FEROZEPUR ROAD, LAHORE.**

 Drug Manufacturing License No. 000353 (Formulation) was issued to M/s Kakasian Pharmaceuticals (Pvt) Ltd,29th Km Ferozepur Road, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *“if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application”.* But, in this case the application for renewal of DML for the period 02-03-2015 to 01-03-2020 has not been received till date. Therefore, DML No. 000353 (Formulation) M/s Kakasian Pharmaceuticals (Pvt) Ltd, Lahore is no more valid.

**Proceedings and Decision of Central Licensing Board in 268th meeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000353 by way of formulation M/s Kakasian Pharmaceuticals (Pvt) Ltd,29th Km Ferozepur Road, Lahore may not be declared cancelled.

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

The Show Cause notice dated 23rd January, 2019 was issued to M/s Kakasian Pharmaceuticals (Pvt) Ltd,29-Km Ferozepur Road, Lahore.

No reply of the show cause notice is received from the firm.

**A letter of Personal hearing has been issued on 19-02-2019.**

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

No person appeared on behalf of the firm. The Board after considering the facts decided to defer the case to give final opportunity to the firm to plead his case.

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

A letter of personal hearing has been issued to the firm on 03rd September, 2019.

**Proceedings and Decision of Central Licensing Board in 271st meeting**

No person appeared on behalf of the firm . The Board considering the facts on the record and after thread bare deliberation decided to declare the Drug Manufacturing Licence 000353 by way of formulation M/s Kakasian Pharmaceuticals (Pvt) Ltd, 29-Km Ferozepur Road, Lahore invalid and cancelled under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The Drug Manufacturing Licence stands cancelled. Manufacturing of drugs is prohibited and punishable offence under Section 23 and Section 27 and rules framed thereunder.

**CASE NO.32.** **M/S SPECTRUM LABORATORIES (PVT) LTD, 8-KM, RAIWIND ROAD, LAHORE.**

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| **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| 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.
 |

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

The Show Cause notice dated 15th July, 2019 was issued to M/s Spectrum Laboratories (Pvt) Ltd, 8-Km, Raiwind Road, Lahore

The firm has replied to show cause notice and requested to re-constitute panel of experts as they have rectified the shortcoming in tablet and oral liquid sections.

A letter of personal hearing has been issued to the firm on 03rd September, 2019.

**Proceedings and Decision of Central Licensing Board in 271st meeting**

Mian Shafiq ur Rehman, Director of the Company appeared before the Board. He contended that all rectifications are made as pointed out by the panel of experts therefore . The Board after hearing the representative of the firm decided to re-inspect the premises by the following panel:-

1. Dr. Mehmood Ahmad, Ex-Dean, University of Bahawalpur
2. Chief Drug Controller, Government of Punjab, Lahore
3. Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Lahore.

However, production shall remain suspended production will remain stopped/suspended in Tablet and Oral Liquid sections till decision by CLB.

**Case No. 33 APPROVAL OF PRODUCTION INCHARGE OF M/S GMP PHARMACEUTICALS, LAHORE.**

 M/s GMP Pharmaceuticals, 28-Km, Sheikhupura Road, Lahore had applied for approval of Mr. Muhammad Iqbal as Production Incharge on 03rd January, 2019. The application for the was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on
27th February, 2019.

1. Appointment letter
2. Job acceptance letter by the appointee.
3. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of Production Incharge (Not less than 10 years in relevant experience).
4. Resignation / retirement of earlier Production Incharge.
5. Undertaking as whole time employee on stamp paper duly signed by management and appointee.
6. **Documents should be duly attested.**

 The firm submitted their reply on 15th March, 2019. After evaluation of the submitted documents, final reminder was issued on 17th May, 2019 to the firm with following shortcomings: -

1. CNIC copy of Production Incharge.
2. Undertaking as whole time employee on stamp paper duly signed by management and appointee.
3. **Documents should be duly attested / notarized.**

The firm has replied to Final reminder on 12th June, 2019with following shortcomings: -

1. Undertaking as whole time employee on stamp paper duly signed by management and appointee.
2. **Documents should be duly attested / notarized.**

In the meanwhile the firm appointed Mr. Dilawar Hussain as Production Incharge and applied on 18th July, 2019. The application is short of following documents:

* + 1. Resignation / retirement of earlier Production Incharge (Mr. Muhammad Iqbal).
1. Resignation or termination letter of appointee from the previous firm /

 promotion letter / transfer letter from the same firm.

1. Undertaking as whole time employee on stamp paper.
2. **Documents should be duly attested.**

**Proceedings and Decision of Central Licensing Board in 271st meeting.**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule, 19 Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the DML No. 000815 by way of formulation of M/s GMP Pharmaceuticals, 28-Km, Sheikhupura Road, Lahore may not be suspended or cancelled by Central Licensing Board.

**Case No. 34 GRANT OF DRUGS FOR RE-PACKING:**

M/s International Pharma Labs, Raiwind Road, Bhobatian Chowk, Defence Road, 1Km towards Kahna Lahore, under Drug Manufacturing Licence No. 000582 by way of formulation has submitted Application for Grant of Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Drug** | **Schedule-D** |
| 01 | Aluminum Hydroxide Gel Dried | Yes |
| 02 | Ammonium Chloride | Yes |
| 03 | Benzoic Acid | Yes |
| 04 | Bismuth subnitrate | Yes |
| 05 | Borax | Yes |
| 06 | Calamine | Yes |
| 07 | Calcium Lactate | Yes |
| 08 | Calcium Hydroxide | Yes |
| 09 | Cetrimide Powder | Yes |
| 10 | Ferrous Sulphate | Yes |
| 11 | Gentian Violet | Yes |
| 12 | Iodine | Yes |
| 13 | Kaolin | Yes |
| 14 | Magnesium Carbonate  | Yes |
| 15 | Magnesium Sulphate | Yes |
| 16 | Magnesium Trisilicate | Yes |
| 17 | Phenothlazine (B. VET.C) | Yes |
| 18 | Potassium Acetate  | Yes |
| 19 | Potassium Bicarb | Yes |
| 20 | Potassium lodine | Yes |
| 21 | Pulv Gentian | Yes |
| 22 | Salicylic Acid | Yes |
| 23 | Sena  | Yes |
| 24 | Sodium Bicarbonate | Yes |
| 25 | Sodium Bromide  | Yes |
| 26 | Sodium Citrate | Yes |
| 27 | Sodium Metabisulphite | Yes |
| 28 | Sodium Potassium Tartrate  | Yes |
| 29 | Sodium Thiosulphate | Yes |
| 30 | Sulphonilamide Powder (B. VET.C.) | Yes |
| 31 | Sulphur Sublime | Yes |
| 32 | Zinc Oxide | Yes |
| 33 | Ammonium Bicarbonate | Yes |
| 34 | Ammonium Carbonate | Yes |
| 35 | Bismuth Carbonate | Yes |
| 36 | Boric Acid | Yes |
| 38 | Calcium Carbonate  | Yes |
| 39 | Calcium Gluconate | Yes |
| 40 | Castor Oil | Yes |
| 41 | Chloral Hydrate | Yes |
| 42 | Ferric Ammonium Citrate | Yes |
| 43 | Glycerin | Yes |
| 44 | Ichthammol | Yes |
| 45 | Liquid Paraffin Heavy | Yes |
| 46 | Magnesium Hydroxide | Yes |
| 47 | Methylene Blue | Yes |
| 48 | Methyl Salicylate | Yes |
| 49 | Pix Carb | Yes |
| 50 | Potassium Bromide | Yes |
| 51 | Potassium Citrate | Yes |
| 52 | Procaine Hydrochloride | Yes |
| 53 | Resorcin | Yes |
| 54 | Sentonin | Yes |
| 55 | Sodium Benzoate  | Yes |
| 56 | Sodium Chloride  | Yes |
| 57 | Sodium Carbonate | Yes |
| 58 | Sodium Iodide | Yes |
| 59 | Sodium Salicylate | Yes |
| 60 | Sodium Sulphate | Yes |
| 61 | Soft Yellow Paraffin | Yes |
| 62 | Sulphur Precipitated  | Yes |
| 63 | Tannic Acid | Yes |
| 64 | Zinc Sulphate | Yes |

**Proceedings and Decision of Central Licensing Board in 266th meeting**

The Central Licensing Board decided to defer the case till next meeting of the board for further deliberation and justification for all items

**Proceedings and Decision of Central Licensing Board in 271st meeting.**

The Board considered and approved following repacking drugs in the name of M/s International Pharma Labs, Raiwind Road, Bhobatian Chowk, Defence Road, 1 Km towards Kahna Lahore, under Drug Manufacturing Licence No. 000582 by way of formulation.

|  |  |
| --- | --- |
| **Sr. No.** | **Drug** |
| 01 | Aluminum Hydroxide Gel Dried |
| 02 | Benzoic Acid |
| 03 | Bismuth subnitrate |
| 04 | Borax |
| 05 | Calamine |
| 06 | Calcium Lactate |
| 07 | Calcium Hydroxide |
| 08 | Cetrimide Powder |
| 09 | Gentian Violet |
| 10 | Iodine |
| 11 | Kaolin |
| 12 | Magnesium Carbonate  |
| 13 | Magnesium Sulphate |
| 14 | Magnesium Trisilicate |
| 15 | Potassium Acetate  |
| 16 | Potassium Bicarb |
| 17 | Potassium lodine |
| 18 | Pulv Gentian |
| 19 | Salicylic Acid |
| 20 | Sodium Bicarbonate |
| 21 | Sodium Bromide  |
| 22 | Sodium Citrate |
| 23 | Sodium Metabisulphite |
| 24 | Sodium Potassium Tartrate  |
| 25 | Sodium Thiosulphate |
| 26 | Sulphur Sublime |
| 27 | Zinc Oxide |
| 28 | Ammonium Bicarbonate |
| 29 | Ammonium Carbonate |
| 30 | Bismuth Carbonate |
| 31 | Boric Acid |
| 32 | Calcium Carbonate  |
| 33 | Calcium Gluconate |
| 34 | Castor Oil |
| 35 | Ferric Ammonium Citrate |
| 36 | Glycerin |
| 37 | Ichthammol |
| 38 | Liquid Paraffin Heavy |
| 39 | Magnesium Hydroxide |
| 40 | Methyl Salicylate |
| 41 | Potassium Bromide |
| 42 | Potassium Citrate |
| 43 | Procaine Hydrochloride |
| 44 | Resorcin |
| 45 | Sodium Benzoate  |
| 46 | Sodium Carbonate |
| 47 | Sodium Iodide |
| 48 | Sodium Salicylate |
| 49 | Sodium Sulphate |
| 50 | Soft Yellow Paraffin |
| 51 | Sulphur Precipitated  |
| 52 | Tannic Acid |

The Board also considered and deffered following drugs by way of repacking for further clarification / working

|  |  |
| --- | --- |
| **Sr. No.** | **Drug** |
| 1 | Ammonium Chloride |
| 2 | Ferrous Sulphate |
| 3 | Phenothlazine (B. VET.C) |
| 4 | Sena  |
| 5 | Sulphonilamide Powder (B. VET.C.) |
| 6 | Chloral Hydrate |
| 7 | Methylene Blue |
| 8 | Pix Carb |
| 9 | Sentonin |
| 10 | Sodium Chloride  |
| 11 | Zinc Sulphate |

**Case No. 35 CHANGE OF LICENSED SECTION NAME OF M/s MAXITECH PHARMA PVT) LIMITED, KARACHI.**

 M/s Maxitech Pharma (Pvt) Ltd, Karachi has submitted requested for change of licensed section name from Eye Drops (General) section to Ear, Eye & Nasal Drops Section (General).

**Proceedings and Decision of Central Licensing Board in 271st meeting.**

The Board considered and approved change in terminology of the following section in the name of M/s Maxitech Pharma (Pvt) Ltd, Karachi

1. Sterile Ear, Eye & Nasal Drops Section (General) .

**Case No. 36. GRANT OF RENEWAL OF DML NO. 000581 OF M/S. HANSEL PHARMACEUTICAL (PVT) LTD, LAHORE**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore.DML No. 000581 (Formulation)**Period**: Commencing on 24-06-2015 ending on 23-06-2020 | **27-11-2018 &****11-12-2018 & 24-12-2018** | **-** | 1. Dr. Farzana Chowdhary, Director IPS, UVAS, Lahore.
2. Mr. Asim Rauf, Additional Director (E&M), Lahore.
3. Ms. Uzma Barkat, Federal Inspector of Drugs, Lahore.
 |
| **OBSERVATIONS** **Raw Material Store (Main)**1. Firm was storing raw material and Alu-PVC rolls in the same store. To overcome this shortcoming, firm converted the room for released inactive material storage in to room for storage of Aluminum foil and PVC rolls.
2. **Firm had shifted the bulk inactive material and some packing material which was previously placed in main RM store, to the basement. Firm had not taken approval from DRAP for use of this storage area in the basement. It was also seen that there was no temp/humidity maintenance and monitoring system in that area. Separate dispensing room HVAC yet to be provided.**
3. Civil work of new dispensing area was in process. Area was yet to be painted and HVAC system was yet to be installed

**General Capsule Section**1. Manometer of mixing room was not functional.

**General Tablet Section**1. Differential pressure in drying room was positive.
2. Differential pressure in compression cubicles was positive.
3. Air conditioners were installed in all three blistering rooms. Firm was advised to remove AC and provide HVAC system. **26.2˚C/47% RH** seen in Blistering 3 at the time of inspection. **24.1˚C/58% RH** seen in Blistering 1 at the time of inspection.

**General Tablet Section (Amended)**1. Differential pressure was found to be positive in granulation room.
2. Manometer of coating room 2 was not functional.
3. Humidity of granulation area was not maintained.

 **Temp/ humidity observed on 27/11/2018 = 21.2˚C/73% RH** **Temp/ humidity observed on 11/12/2018 = 17.8˚C/70% RH** **Temp/humidity observed on 24-12-2018= 15.8˚C/72% RH** 1. Firm had provided an emergency exit in the granulation area which was not present in the approved layout. This emergency exit was not safe and appropriate in the given location.
2. **Eye Drop Section**
3. RM store was very congested. Firm was using some analytical grade raw materials. The firm was advised to use pharmaceutical grade raw materials in manufacturing.
4. A window had been provided in the Solution preparation area for transfer of material to autoclave room which was opening in main corridor. Advised to provide proper pass through hatch.
5. The filling machine was installed directly under the HVAC diffuser blocking the HVAC supply. Moreover filling nozzles were directly under dead patch of LFC.

**Cream/Ointment Section** 1. Section was not operational
2. HVAC system of the area was under maintenance as informed by the firm’s management.

**Liquid Injectable Section (General)**1. Firm had provided two solution preparation rooms and two filling areas.
2. The firm was advised to provide HVAC system in the buffer of ampoule washing area.
3. Firm was advised to provide flushed lights and windows in solution preparation and filling areas.
4. In material transfer room I, there was no HVAC return duct. Manometer was not installed.
5. In material transfer room II, there was neither HVAC supply nor return. Manometer was not installed.
6. The firm was advised to remove AC from Autoclave room and provide HVAC system.
7. The firm was advised to provide HVAC system in the whole corridor providing access to sterile areas.
8. De-cartoning area was just a closed room. There was no air treatment mechanism in de-cartoning area. The firm was advised to provide HVAC system in this area.

**Dry Powder Injection Section (Cephalosporin)**1. Firm was advised to replace rusted hooks in vial washing area, provide GMP compliant drains throughout the unit and provide flushed lights and windows. Open tube lights and dead spaces were present in LFC.
2. Firm was advised to provide continuous LFC on filling machine without any dead patch.

**Dry Powder Suspension and Capsule Section (Cephalosporin)**1. Firm was advised to provide physical partitioning between bottle filling and sealing operations.
2. Differential pressure was positive inside mixing and filling room.
3. Firm was advised to provide pressure gauges and suction in bottle blowing machine.
4. Dispensing hood room opens in to main corridor. There is a risk of cross contamination.

**Hormone Tablet Section**1. No ventilation or temp/humidity maintenance and monitoring system was provided in quarantine area.
2. In the dispensing room and raw material released area, HVAC system was not functional.
3. Firm was advised to provide proper transfer hatch in dispensing area.
4. Humidity in granulation area : **23.3˚C/ 60% RH (area at rest)**
5. Humidity in mixing room area : **17.5˚C/ 66% RH (area at rest)**
6. Humidity in drying room area : **17.7˚C/ 64% RH (area at rest)**
7. Humidity in blistering area: **19.9˚C/ 69% RH (area at rest)**
8. **Packing hall had been provided an access to the basement where the finished goods will be stored as informed by the firm’s management. Firm had not obtained approval for this FG store from DRAP. It was also seen that there was no temp/humidity maintenance and monitoring system in that area.**

**Hormone Injection Section**1. Dispensing hood was provided. However, firm was advised to provide proper enclosed dispensing room.
2. Sampling booth/area was not provided.
3. Calibration of gauges/equipment/machine parts in this section was yet to be completed.
4. Open tube lights had been installed in LFCs of both solution preparation areas and filling machines. The firm was advised to provide flushed lights.
5. The firm was advised to provide magnehelic gauge for pressure monitoring in buffers for material transfer.
6. Physical partitioning required between vial filling and sealing operation.
7. Water, compressed air, nitrogen gas filters were yet to be installed.
8. No LFC trolley for ampoule cooling/transfer was not provided.

**Quality Control Laboratory:**1. Firm was advised to provide TOC analyzer.

The firm has submitted plan vide letter No. 271218/HP/DRAP/18 dated 27-12-2018 wherein they have given a timeline for rectification/compliance of the observations made during the inspections.**Decision by the Central Licensing Board in 268th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License (No. 000581(Formulation) ) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**The Show Cause notice dated 29th January, 2019was issued to M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore.The firm has replied to show cause notice and submitted compliance report with the request to verify the rectification before taking any action against the firm.**A letter of Personal hearing has been issued on 19-02-2019****Decision by the Central Licensing Board in 269th meeting**Mr. Muhammad Hanif, Managing Director of M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore appeared before the Board. He contended that most of the rectifications have been made as pointed out by the panel and they are ready for re-inspection.The Board after hearing the representative of the company decided to inspect the premises by the same panel. Meanwhile production of the company shall remain suspended for the said period. The Chairman shall pass orders on the report of the panel if panel recommends resumption of production and case would be placed in the next meeting of the Board for ratification. |

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

Panel Inspection report for grant of additional section and renewal of DML of M/s Hansel Pharmaceutical (Pvt) Ltd, Plot No. 02, Pharma City, 30-Km, Multan Road, Lahore under DML No. 000581 (formulation) was received on 01-07-2019 which is as under:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore.DML No. 000581 (Formulation)**Period**: Commencing on 24-06-2015 ending on 23-06-2020 | **15-05-2019** | **Good** | 1. Dr. Farzana Chowdhary, Expert Member.
2. Dr. Mehmood, Ex-Dean IUB.
3. Ms. Uzma Barkat, Federal Inspector of Drugs, DRAP, Lahore.
4. Ms. Anam Saeed, Assistant Director, DRAP, Lahore.
 |
| **Recommendations of the panel: -**In the light of the inspection conducted by the panel and based on the findings, the panel of inspectors recommends resumption of production and grant of renewal of Drug Manufacturing License by way of formulation of M/s Hansel Pharmaceutical (Pvt) Ltd, Plot No. 02, Pharma City, 30-Km, Multan Road, Lahore, for the following sections. 1. Capsule (General).
2. Liquid Injectable (General).
3. Eye drops (General).
4. Cream / Ointment (General).
5. Capsules (Cephalosporin).
6. Oral Dry Powder for Suspension (Cephalosporin).
7. Dry Powder for Injection (Cephalosporin).

The Panel of inspectors also recommends approval / renewal of DML of the following revised / reallocated sections:1. Tablet (General) (Revised / Amended).
2. Tablets (Hormone) (Revised / Amended).
3. Liquid Injectable (Hormone) (Reallocated from list floor to ground floor)
 |

Licensing Division issued production resumption letter on 5th July, 2019 in following Seven (07) Sections in the light of decision of Central Licensing Board in its 269th meeting held on 26th February, 2019.

|  |  |
| --- | --- |
| **Sr. No** | **Name of Section** |
|  | Capsule (General). |
|  | Eye drops (General). |
|  | Cream / Ointment (General). |
|  | Capsules (Cephalosporin). |
|  | Oral Dry Powder for Suspension (Cephalosporin). |
|  | Dry Powder for Injection (Cephalosporin). |
|  | Liquid Injectable (General). |

**Proceedings and Decision by the Central Licensing Board in 271 meeting**

The Board ratified the decision taken by the Chairman, Central Licensing Board for resumption of production. The Board also allowed renewal of following Sections of M/s Hansel Pharmaceutical (Pvt) Ltd, Plot No. 02, Pharma City, 30-Km, Multan Road, Lahore, for the following sections.

1. Capsule (General).
2. Liquid Injectable (General).
3. Eye drops (General).
4. Cream / Ointment (General).
5. Capsules (Cephalosporin).
6. Oral Dry Powder for Suspension (Cephalosporin).
7. Dry Powder for Injection (Cephalosporin).

The Board also approved following revised sections of M/s Hansel Pharmaceutical (Pvt) Ltd, Plot No. 02, Pharma City, 30-Km, Multan Road, Lahore

1. Tablet (General) (Revised / Amended).
2. Tablets (Hormone) (Revised / Amended).
3. Liquid Injectable (Hormone) (Reallocated from list floor to ground floor)

**Case No.37 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AVENTEK PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000660 by way of formulation for the period of 27-03-2019 to 26-03-2024 on 27-02-2019

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th March, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.
2. Nothing due certificate regarding CRF from STO (Updated).
3. Section approval letters of all sections issued by Central Licensing Board, if not available, apply for regularization of layout plan along with prescribe fee of Rs. 5,000/- per each section.
4. Latest certified true copy of Form-29 (Attestation by SECP).
5. CNIC copies of all Directors.
6. Jab acceptance letter of proposed Quality Control Incharge.
7. Undertaking as whole time employee on stamp paper signed by appointee and management. (Quality Control Incharge).
8. Experience certificate from M/s Pulse Pharmaceuticals (Pvt) Ltd, Lahore of proposed Quality Control Incharge.
9. Resignation / retirement of earlier Quality Control Incharge.
10. The proposed Production Incharge completed the degree of Pharm-D on 17th March, 2009 and her total post qualification experience is less than 10 years which does not fulfill the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) rules 1976 in term of relevant experience. You are, therefore, directed to submit complete set of duly attested documents of new proposed Production Incharge who fulfills the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) rules 1976 in terms of Qualification and relevant experience (as per Checklist).
11. **Documents should be duly attested.**

The firm replied to this letter on 18th March, 2019. A Reminder letter was issued on 14th May, 2019 of following shortcomings.

1. Nothing due certificate regarding CRF from STO (Updated).
2. Prescribed fee of Rs. 50,000/- for change of management as there seems to be change in management of the firm.
3. Latest certified true copy of Form-29 (Attestation by SECP).
4. Undertaking as whole time employee on stamp paper duly signed by appointee and management. (Quality Control Incharge and Production Incharge).
5. Appointment letter, academic degree of B. Pharm (Production Incharge).
6. Registration certificate from Pharmacy council (Production Incharge).
7. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of Production Incharge (Not less than 10 years).
8. Resignation / retirement of earlier (Production Incharge)..
9. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge).
10. **Documents should be duly attested.**

The firm did not reply to Final Reminder and application for renewal of DML is still incomplete.

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore, Drug Manufacturing Licence No 000660 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Case No. 38 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ALLMED (PVT) LTD, LAHORE.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| M/s Allmed (Pvt) Ltd, Plot No. 590, Sunder Industrial Estate, Lahore. DML No. 000645 (Formulation)**Period**: Commencing on 21-08-2018 ending on 20-08-2023 | 12-11-2018 | **Good** | 1. Dr. Zaka-ur-Rehman, Secretary, Punjab Pharmacy Council, Punjab.
2. Mr. Asim Rauf, Additional Director, DRA, Lahore.
3. Ms. Ufaq Tanveer, Asif, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the facilities like building HVAC system, Equipment, instrument, personnel, documentation, SOP availability, Quality Control and Testing facilities Panel of inspectors recommends the renewal of Drug Manufacturing License No. 000645 of M/s Allmed (Pvt) Ltd, Plot No. 590, Sunder Industrial Estate, Lahore for the following sections:1. Tablet and Capsule Section (General).
2. Tablet and Capsule Section (Psychotropic).
3. Liquid Syrup and Suspension.
4. Liquid Injectable Section (Ampoules).
5. Liquid Vial Infusion Section

It is pertinent to mention here as per available record of Licensing Division the firm possess following section.1. Tablet and Capsule Section (General).
2. Tablet (Psychotropic).
3. Capsule Section (**General Antibiotic**).
4. Liquid Syrup (**General**).
5. Liquid Injectable Section (**General**) (Ampoules).
6. Liquid Vial Section (**General Antibiotic**).

**Decision by the Central Licensing Board in 267th meeting**The Board considered and differed the case of renewal of Drug Manufacturing Licence No. 000645(Formulation) in the name of M/s Allmed (Pvt) Ltd, Plot No. 590, Sunder Industrial Estate, Lahore for clarification regarding sections from DRAP Lahore. |

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

Licensing Division Issued the letter to DRAP, Lahore on 29th January, 2019 for clarification of sections. Ms. Ufaq Tanveer, Area Federal Inspector of Drugs, DRAP, Lahore submitted report on 13th June, 2019 and clarified that firm possess following sections:-

1. Liquid Injectable Section (General) (Ampoules).
2. Liquid Vial Section (General Antibiotic).
3. Tablet and Capsule Section (General).
4. Capsule Section (General Antibiotic).
5. Liquid Syrup (General).
6. Tablet (Psychotropic).

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to allow renewal of Drug Manufacturing Licence renewal of Drug Manufacturing Licence No. 000645(Formulation) in the name of M/s Allmed (Pvt) Ltd, Plot No. 590, Sunder Industrial Estate, Lahore with following sections:

1. Liquid Injectable Section (General) (Ampoules).
2. Liquid Vial Section (General Antibiotic).
3. Tablet and Capsule Section (General).
4. Capsule Section (General Antibiotic).
5. Liquid Syrup (General).
6. Tablet (Psychotropic).

**CASE NO.39.** **M/S SAFINA PHARMACEUTICALS (PVT) LTD, LAHORE.**

 Drug Manufacturing License No. 000654 (Formulation) was issued to M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *“if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application”.* But, in this case the application for renewal of DML for the period 30-01-2019 to 29-01-2024 has not been received till date. Therefore, DML No. 000654 (Formulation) M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore is no more valid.

**Proceedings and Decision of Central Licensing Board in 271st meeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000654 by way of formulation M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore may not be declared cancelled.

**Case No.40. RESTORATION OF DRUG MANUFACTURING LICENSE NO.000158 (FORMULATION) OF M/S QAMAR COTTON INDUSTRIES, DIPALPUR CHOWK OKARA.**

**Summary of the Case:-**

* Drug Manufacturing License (DML) of M/s Qamar Cotton, Dipalpur Chowk, Okara was cancelled by the Central Licensing Board on 10-07-1999 due to continuous non-compliance of Good Manufacturing Practices (GMP) by the firm.
* The firm filed an appeal against the decision of cancellation of DML which was heard on 06-10-1999 in the 98th sitting of the Appellate Board where the decision of the Central Licensing Board was upheld and the order of the Appellate Board was conveyed to the Appellant on 15-11-1999.
* The firm filed a writ petition in the Lahore High Court, Lahore on 06-12-1999 against the decision of Appellant Board.
* The Hon’rable Lahore High Court set aside the decision of the Appellate Board with its orders dated 08-02-2000 and directed that the appeal filed by the petitioner shall be deemed pending with the Appellant Board which shall be considered and decided afresh by affording a reasonable opportunity of hearing to the petitioner in accordance with law with in a period of one month.
* Accordingly, the Appellant was called for personal hearing in the 100th sitting of the Appellant Board held on 08-04-2000. Mr. Manzoor Hussain, Mr. Ahsan and Mr. Bashir Ahmad appeared on behalf of the firm. During proceedings of the Board, it was transpired that Mr. Qamar-ud-din, the sole proprietor of the firm, had expired on 06-12-1999.
* The Appeal was deferred for legal opinion on the matter from Ministry of Law and Justice and Human Rights, Which opined as under:

“*Mr. Qamar-ud-din was the sole proprietor of the firm as is evident from proforma”A” on the record by Qarmar-ud-din himself. On his death the firm stood automatically dissolved. The drug-manufacturing license was issued to Mr. Qamar-ud-din and with the death of licensee the said license seized [sic] to exist. The license to a sole partnership was a personal and permissive right which was neither assignable nor heritable”.*

* Based on the opinion of Ministry of Law Division, the Appellant Board dismissed the Appeal in its 101st sitting held on 28-06-2000.
* The firm again filed the writ petition in the said Court against the decision of Appellate Board, where the Hon’rable Court directed the Board to hear and decide the Appeal afresh by affording personal hearing to the firm.
* Accordingly, the Appellate Board in its 126th sitting held on 01-06-2006 heard the Appellant, where the Appellant informed that they were already carrying on manufacturing activates assuming that the Lahore Court vide its orders dated 20-11-2000 had suspended the orders of Central Licensing Board dated 10-07-1999 meaning, thereby, that their DML was valid whereas the Appellant Board was of opinion that firm should have not start the manufacturing activities till final decision by the Appellant Board as per orders of the Hon’rable Court dated 06-02-2006.
* The case was accordingly, referred for legal opinion to the Law Division in view of Appellate Boards observation. *The Law Division opined that the firm should stop manufacturing of drugs and apply afresh for grant of MDL and registration of drugs if so desired.*
* The case was again taken up in the 130th sitting of the appellate Board held on 22-11-2006. After deliberation on the matter and taking into account the orders of the Hon’rable Lahore High Court, Lahore the Board decided to accept the Appeal subject to verification of compliance of the firm towards cGMP by the following panel of inspector within a period of one month:
	+ Pro. Mumtaz Hassan (Member, Appellate Board)
	+ Mr. Faqeer Muhammad Sheikh (Chairman, Quality Control)
	+ Mr. HyderBuxBozdar DDG (E&M), Lahore
	+ Mr. Obaid Ali Assistant Drugs Controller Karachi
* The Appellant later informed, vide its letter dated 25-01-2007, that it was not ready for inspection and requested that the said inspection be deferred for a period of 15 days.
* The matter could not be taken up due to the 18th Constitutional Amendment and remained pending. After the reconstitution of the Appellate Board a letter was received from the Appellant dated 19-06-2013 and 19-09-2013 requested for reconstitution of panel of inspectors for appellate re-inspection of their manufacturing unit in light of the decision of the Appellate Board taken in its 130th sitting held on 22-11-2006.
* Consequently, the following panel was reconstituted by the Chairman, Appellate Board:
* Dr. Farzama Chaudhary (Member Appellate Board).
* DDG-E&M, Lahore.
* Area Federal Inspector of Drugs, Lahore.
* Chief Drugs Inspector, Punjab or his nominee
* The reconstituted panel conducted the inspection on 8th May, 2014 and has informed that:

“*An inspection was ordered by the Appellate Board which was conducted on 04-03-2007 by the panel comprising Mr. Khadim Hussain Drugs Controller (QA) / CQCA, Islamabad, Prof Dr. Shabbir Ali Bhatti, Head Department of Pharmacology, King Edward Medical University , Lahore, Mr. Hyder Bux Bozdar, Deputy Director General (E&M), Lahore and Mr. Obaid Ali, Assistant Drugs Controller, Karachi. The Panel did not recommended the restoration of DML at that time”.*

* The Panel has passed the following recommendations:

“ *In view of the observation noted during the inspection, the panel recommended restoration / re-grant of the Drug Manufacturing License of M/s Qamar Cotton Dipalpur Chowk subject to the fulfillment of codal requirements”.*

* However, one member of the panel i.e. Mr. Hafiz Faisal (Nominee of CDI, Punjab) has submitted that the DML of the said firm may be renewed subject to fulfilling the minimum area requirements as per SRO 470 (I) / 98 dated 15-05-1998. However, the management of the firm, as mentioned in the report, informed that their unit had been granted the DML when this condition was not imposed. Many other old units, granted license at that time, were constructed on area less than 04 Kanals and were also working presently.

**Appellant Represented By:**

* Mr. Muhammad Aslam Javed, Advocate.
* Mr. Muhammad Qamar Ilyas, Manager.
* Mr. Muhammad Irfan Qamar, Proprietor.

**Decision of the 142nd Sitting of Appellate Board held on 24th June, 2014:-**

The Appellate Board in light of the recommendation of the panel and the clarification that the license was granted before the notified of S.R.O 470 (I) / 98 dated 15-05-1998, after detailed discussion, decided by majority vote that the Central Licensing Board restore the license of the firm after fulfillment of codal formalities including submission of legal papers regarding ownership of the firm.

Accordingly matter was placed before the Central Licensing Board in its 252nd meeting.

**Decision in 252nd meeting of CLB.**

The Board after detailed discussion, making deliberations, taking into account all pros and cons and considering facts on record decided to call the representative of the firm for personal hearing before next meeting of the Board to ascertain the facts regarding codal formalities specially plot size of the unit as well as location of the firm as per prevailing laws.

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

The firm has been called for personal hearing vide Licensing Division letter date 08-05-2017. Mr. Aslam Javed Advocate and Mr. Muhammad Irfan, Owner of the M/s Qamar Cotton, Dipalpur Chowk, Okara appeared before the Board and admitted that area of the plot on which short of 2000 sq.yards and unit is located in commercial area. They also apprised that Board that they made efforts to purchase land adjacent to the unit but could not be successful.

**Decision of the Central Licensing Board in 253rd meeting**

The Board after hearing the representative of the firm and perusal of facts observed that “codal formalities” includes size and location of the plot under Rule 16 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The firm has submitted application afresh which is subject to codal formalities. The Board, therefore, decided to decline grant of Drug Manufacturing Licence being not in accordance with law.

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

Licensing Division issued the letter on 04-01-2019 in the light of decision of Central Licensing Board. The firm filled a Writ Petition No. 57037/2017 in Lahore High Court, Lahore. A copy of Court Order dated 27-06-2019 was received from Assistant Registrar (Writ) with following directions:-

*“In the view of the above, this petition is* ***disposed of*** *with a direction to the Board/respondent No.1 to complete the hearing of the petitioner’s case within a period of two months. The petitioner shall in meanwhile take all necessary steps to respond to the queries raised by the Board with regard to the preconditions for the restoration of Drug Manufacturing License in favour of the petitioner.”*

Licensing Division forwarded the case to Legal Division, DRAP, Islamabad for seeking their opinion **whether** the case may be sent to MD&MC Division as now the subject matter falls under their domain in the light of SRO No. 824(1)2018 dated 26-06-2018 **or** the case may be placed in agenda of upcoming meeting of CLB for consideration of the Board **or** the applicant may be informed regarding the shortcomings for fulfillment of legal/codal formalities.

**Remarks of Legal Division.**

The direction in Court Order dated 27-06-2019 in Writ Petition No. 57037/2017 is for Central Licensing Board (CLB). Now the subject matter in the Writ Petition comes under the jurisdiction of MD&MC Division after promulgation of DRAP Act, 2012 and medical device rules 2017. Therefore, CLB may consider the case, and stated the reasonable grounds for sending the matter to medical device Board to decide the issue as per direction of the Court. Furthermore, CLB may intimate the action / proceeding of the meeting in the case to Registrar Lahore High Court to avoid any contempt proceeding in the said petition in future.

**Proceeedings and Decision of the Central Licensing Board in 271st meeting**

The Board considered the opinion of Legal Affairs Division in the light of Orders of the Court and SRO. 842 (I)/ 2018 dated 28-6-2018 and decided to refer the case to Division of Medical Devices and Medicated Cosmetics with relevant file record as the subject matter now falls under their domain and Central Licensing Board can not further proceed on the subject matter. The Honourable Lahore High Court, Lahore shall be informed accordingly.

**Case No. 41. INSPECTION REPORT OF M/S REKO PHARMACAL, LAHORE.**

A panel inspection report pertaining to M/s M/s Reko Pharmacal (Pvt) Ltd., 13-KM, Multan Road, Lahore forwarded vide letter No. F. No. 1-21/2012-FID (F)dated 12thJune, 2017, on the subject cited above. The panel observed that Liquid Injectable (General) Section was neat and clean. HVAC system was installed and functional. However, it was noted that firm has not provided appropriate vial filling machine and hence did not possess proper vial manufacturing facility. The firm has provided the necessary equipment and instrument for test / analysis of products except the liquid injectable dosage forms. It was noted the firm has not provided TOC and liquid particle analyzer, required for conducting test / analysis of liquid injectable dosage forms. Hence the firm did not possess the Quality Control facility for liquid injectable.**The case was accordingly placed before the Central Licensing Board in its 254th meeting held on 15thJune, 2017.**

**The Central Licensing Board considered the facts of the case, legal provisions and decided as under;**

 *“The Board decided to issue 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 / cancellation of Liquid Injectable Section on the recommendations of the Panel of Inspectors till the provision of proper manufacturing and testing facilities”.*

The Show Cause notice dated 26thOctober, 2017 was issued to the M/s Reko Pharmacal (Pvt) Ltd., 13 KM, Multan Road, Lahore.

 Now the firm has replied to Show Cause notice the observations of panel and reply of the firm is as under:

|  |  |
| --- | --- |
| **Observations of panel** | **Reply of the firm** |
| Liquid Injectable (General) Section was neat and clean. HVAC system was installed and functional. However, **it was noted that firm has not provided appropriate vial filling machine and hence did not possess proper vial manufacturing facility** | In respect to the specific observation of the panel regarding manual vial machine in the vial filling section, we are in the process of upgrading the vial section and have ordered the new automatic vial filling machine (quotation is attached) which will replace the manual vial filling machine.  |
| The firm has provided the necessary equipment and instrument for test / analysis of products except the liquid injectable dosage forms. **It was noted the firm has not provided TOC and liquid particle analyzer, required for conducting test / analysis of liquid injectable dosage forms. Hence the firm did not possess the Quality Control facility for liquid injectable.**  | As per instruction / observations of panel inspection report pertaining to M/s Reko Pharmacal (Pvt) Ltd, we have upgraded our testing facilities of liquid injectable dosage forms. We have purchased and installed the TOC analyzer and liquid particle counter and all tests for injectable dosage form are being conducted on these instruments (copies of invoices of TOC analyzer and liquid particle counter attached ) |

 Furthermore, the firm has requested that they would highly appreciate if the CLB note the required change and withdraw the whole cause and renew their injectable section.

The firm has been called for personal hearing vide Licensing Division letter dated 17th January, 2018.

**Proceedings and Decision of Central Licensing Board in 257th meeting.**

Ms. Seemal Khalid, Director and Mr. Sameer Iftikhar appeared before the Board and contended that all rectifications have been made as per advice of the panel of experts. She further requested that panel of experts may be constituted for verification of the improvements made in Liquid Injectable Section. The Board after hearing the representative of the firm decided to constitute same panel for verification of improvements made and installation of liquid injectable filling machine..

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

Licensing Division issued a letter on 27-02-2018 in the light of decision of CLB in its 257th meeting held on 24th & 25thJanuary, 2018.

Panel inspection report was received from DRAP, Lahore on 06-09-2019. The conclusion of the report is as under:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| M/s Reko Pharmacal (Pvt) Ltd., 13-Km, Multan Road, Lahore.DML No. 000037(Formulation)**Period**: Commencing on 30-04-2015 ending on 29-04-2020 | **15-03-2019 &****13-05-2019** | **Good** | 1. Dr. Ikram-Ul-Haq, Member CLB.
2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. (Could not joined due to other official assigment).
3. Dr. Shafiq ur Rehman, Director, DTL, Lahore.
4. Ms. Uzma Barkat, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**In the light of the inspection conducted by the panel and based on the findings, the panel of inspector **recommends**to grant renewal of DML by way of formulation of General Liquid Injectable Section (Ampoule) only to M/s Reko Pharmacal (Pvt) Ltd., 13-Km, Multan Road, Lahore |

**Proceeedings and Decision of the Central Licensing Board in 271st meeting**

The Board after considering the report of the panel of experts decided to allow resumption of production and grant renewal of following section in the name of M/s Reko Pharmacal (Pvt) Ltd., 13-Km, Multan Road, Lahore

1. General Liquid Injectable Section (Ampoule)

**Case No. 42 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.

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

The firm was issued show cause notice as per decision of Central Licensing Board on 03rd July, 2019.

**Reply of the firm.**

The firm has replied vide their letter dated 19-07-2019, wherein the firm has forwarded copy of court orders of High Court of Balochistan, Quetta. The detail of Court order is as under;

*“In the meanwhile, the implementation of the impugned order dated 18th June, 2019 and the impugned Murasla dated 10th May, 2019, passed by the Chairman Drug Court, Balochistan, Quetta are hereby suspended till the next date of hearing.”*

**Proceeedings and Decision of the Central Licensing Board in 271st meeting**

The Board after perusal of facts on record decided to seek further confirmation of stay order as mentioned in the Order of the Hnourable High Court dated 18th June, 2019 from the firm as well as area Federal Inspector of Drugs and deffered the case till next date of meeting.

**Case No.43 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEGA PHARMACEUTICALS LTD LAHORE.**

M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore had applied for renewal of DML No. 000537 by way of formulation for the period of 17-04-2019 to 16-04-2024 on 19-02-2019

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 06th March, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.
2. Latest certified true copy of Form-29 (Attestation by SECP).
3. Duly attested CNIC copies of all Directors.

The firm replied to this letter on 29th March, 2019. A Reminder letter was issued on 03thJuly, 2019 of following shortcomings.

1. Latest certified true copy of Form-29 having complete detail of CEO/Directors of the firm (duly attested by SECP).
2. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.

The firm has replied to Final Reminder on 23rd July, 2019 but the application for renewal of DML is still incomplete with following shortcoming:

1. Prescribed fee of Rs. 50,000/- for change of management.
2. Latest certified true copy of Form-29 or Form-A mentioning detail of Directors (Attestation by SECP).

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore, Drug Manufacturing Licence No 000537 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Case No.44. M/s REHMAT PHARMA, LAHORE.**

A copy of letter is received from Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has considered the case of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore in its 206th meeting held on 23rd May, 2019 and Provincial Quality Control Board decided to recommend the **cancellation** of the Drug Manufacturing License of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore to Central Licensing Board, DRAP, Islamabad due to violation of non-compliance / violation of Schedule B-II (GMPs) of Drug (L, R & A) Rule 1976 and manufacturing for sale of Drugs under unhygienic conditions. Orders of the Provincial Quality Control Board, Punjab marked as **Annex-I**.

**Proceedings and Decision by the Central Licensing Board in 271st meeting:**

The Board considering the facts and report of PQCB Punjab 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing Licence No 000537 of M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore, may not be cancelled by Central Licensing Board on the recommendation of Punjab Quuality Control Board.

**Case No. 44 GRANT OF DRUGS FOR RE-PACKING:**

M/s Health Care Pharmaceuticals, 40-Km, Lahore Road, Multan, under Drug Manufacturing Licence No. 000905 by way of formulation has submitted Application for Grant of Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Drug** | **Schedule-D** |
| 01 | Liquid Paraffin | Yes |
| 02 | Castor Oil | Yes |
| 03 | Calamine | Yes |
| 04 | Glycerin | Yes |
| 05 | Ichthammol | Yes |

**Proceedings and Decision of Central Licensing Board in 271st meeting.**

The Board considered and approved following repacking drugs in the name of M/s Health Care Pharmaceuticals, 40-Km, Lahore Road, Multan, under Drug Manufacturing Licence No. 000905 by way of formulation.

|  |  |
| --- | --- |
| **Sr. No.** | **Drug** |
| 01 | Liquid Paraffin |
| 02 | Castor Oil |
| 03 | Calamine |
| 04 | Glycerin |
| 05 | Ichthammol |

**QUALITY ASURANCE CASES**

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

**Case No. i: M/S. NIMRALL LABORATORIES, RAWAT.**

**Background:**

 Mr. Hasan Afzaal and Hafiz Muhammad Umair, Assistant Director (I&E) conducted inspection of the firm M/s. M/s. Nimrall Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate, Rawat on 30-05-2019.

2. The panel during inspection noted the following critical observations:-

1. No improvement has been observed in the pest control in the general sections as the undersigned observed a lizard in the dry suspension section (General), a wasp in the liquid Ampoule (General) washing area and Ants in liquid Syrup (General) Area. No production was seen in the DS (General) and liquid Ampoule (General), however batch # S-671 of Product Do-One Suspension was in filling stage, hence the undersigned has taken samples to assess whether or not the presence of pest have a direct impact on the quality of product, irrespective of the fact that the presence of pests itself is a gross violation of GMP.
2. QA Person has still not been hired, along with 05 production pharmacist required under law as the firm has total of 10sections, yet 05 pharmacists are present in the production section.
3. Record for temp/ humidity control was not found in the production section as well as the warehouse (FGS).
4. Main corridor does not have HVAC installed, and since no buffer (with ++ve pressure) is provided in general sections (DS, ) there are evidence /prominent chances of adulteration from particles from the corridor; as seen in tablet coating section, due to high –ve pressure (regulation) as small particles were sucked into the coating section.
5. Cleaning validation is not in production in oral solid dosage form i.e. tablet/capsule despite the fact that the mixer is shared.
6. In the QC section the following equipment are not provided as required for compendial testing;
	1. Liquid Particle Counter
	2. TOC analyzer
	3. FTIR
	4. Gradient HPLC
7. Currently 04 out of approximately 170 products are tested on the available isocratic HPLC.
8. Stability chamber for long term testing was out of order.
9. Stability testing for accelerated results was done on 37°C/75%RH.
10. Testing record for water and area maintenance was seen and found maintained.
11. Calibration of sterilizers i.e. Autoclave and Dry Heat Oven was seen; however validation of same has been advised.

**Action taken by DRAP:**

The firm M/s. Nimrall Laboratories, Rawat was served Show Cause Notice and suspension of production activities order No.F.4-17/2006-QA on 17.06.2019.

**Reply of the firm:**

The firm M/s. Nimrall Laboratories, Rawat vide letter dated 27.06.2019 submitted compliance report of the observations noted by the panel and requested for the resumption of production.

**Updated Status:**

Request of the firm was placed before Director QA & LT. The Director QA & LT constituted following panel of experts for the purpose of verifications of observations.

1. Additional. Director (QA), Islamabad
2. Area FID, Islamabad
3. Ishtiaq AD I&E

The panel conducted inspection of the firm M/s. Nimrall Laboratories, Rawat on 24.07.2019 and recommend the resumption of the firm. Recommendation of the panel of experts were placed before the Director QA&LT. The Director QA&LT allowed resumption of production. Letter for resumption of production was issued on 31.07.2019.

**Proceedings of 271st meeting:-**

Quality Assurance Division place the case before the Board for ratification of the decision of Director (QA&LT). The Board raised query regarding the powers delegated to Director (QA&LT) by the Central Licensing Board. The Addl. Director (QA&LT) informed the board that the Central Licensing Board in its 237th meeting delegated some powers of the Board to Director (QA&LT) under Rule 8 (10) of the Drugs (LR,A) Rules, 1976, in order to dispose of day to day business of Board.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to defer the case for next meeting. The Board advised the Quality Assurance Section to place the case of power delegation to Director (QA&LT) as agenda item, in the next meeting of CLB.

**Case No. ii: M/S. TG PHARMA, KARACHI.**

**Background:**

Inspection of the firm M/s. T.G. Pharma (Pvt) Ltd, Plot No. E-30, Sector 15, Korangi Industrial Area, Karachi was conducted on 17.05.2019 by the following panel of experts. The inspection was carried out on complaint through email.

1. Mrs. Muneeza Khan, FID-II, Karachi
2. Mr. Abdul Rasool Shaikh, FID-IV, Karachi
3. Dr. Shoaib Ahmed, FID-IX, Karachi
4. Dr. Kirshan, Assistant Director, Karachi

2. The panel during inspection noted the following critical observations:-

1. *Very poor hygienic conditions.*
2. *Non availability of HVAC system.*
3. *Manufacturing was carried without qualified/technical staff.*
4. *Lack of GMP compliant equipment/machinery for test/analysis in QC.*
5. *Lack of GMP compliant equipment/machinery for manufacturing in production area.*
6. *Non availability of SOPs, Validation, Qualification, Calibration and Documents/records.*
7. *Severe non GMP compliance was observed in all sections from change room till final production.*

**Action taken by DRAP:**

The firm M/s. T.G. Pharma (Pvt) Ltd, Karachi was served Show Cause Notice and suspension of production activities order No. F.4-16/2009-QA on 21.05.2019.

**Reply of the firm:**

The firm M/s. TG Pharma, Karachi vide letter dated 18.07.2019 submitted reply of Show Cause Notice and informed that they have proposal for the state of the art building with GMP compliance.

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board. No representative of the firm appeared before the Board to defend the case.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to provide final opportunity of personal hearing to the firm, under Section 41 of the Drugs Act, 1976 and rules made there under.

**Case No. iii: M/S. WELL CARE PHARMACEUTICALS, SARGODHA.**

**Background:**

Mrs. Majida Mujahid, FID, DRAP, Lahore conducted inspection of the firm M/s. Well Care Pharmaceuticals, Sargodha, conducted on 13.03.2019.

2. The FID during inspection noted the following observations which need attention and rectifications:-

**Entrance of General Production Area:-**

1. Provide executive / workers entries which were not met as per GMP requirements.
2. Remove all stay places.
3. Give air supply in entries.
4. Improve hygiene condition of area and implement all SOPs regarding to hygiene and sanitations.
5. Remove small holes / gutters in above said areas.
6. Covered all necked electric wires in production corridors.

**Ware House (Raw Material Store, Packing Material Store, Finished Goods Store):-**

1. No de-dusting area and Quarantine area were provided.
2. No temperature / humidity record was maintained.
3. Identification labels regarding to Quarantine, Release was not properly pasted on Raw Material.
4. No GSP was seen in their ware house.
5. No proper dispensing / sampling booth was installed. They were directed to develop proper sampling / dispensing area with sampling / dispensing booths.

**Production Area:-**

1. Validate HVAC system.
2. Unilateral flow of manufacturing was not seen.
3. They were directed to remove bottle blowing machine in filling area.
4. Production area needed civil work regarding to paint on walls / corridor.
5. All their machineries / equipment installed in production area needed polish / buffing.
6. No In-processes Quality Control Laboratory was provided by firm.

**Quality Control Laboratory:-**

1. To installed FTIR, Automatic Polarimeter.

**Quality Assurance Department:-**

1. No Quality Assurance Department or personal was hired as Quality Assurance Manager.

**Reference Standard:-**

1. No reference standards were available.
2. It was observed that firm had not doing their test / analysis on their Raw Material and on finished products. They were releasing products without doing any test / analysis which was alarming / serious.
3. No proper format was developed for BMR which seemed poor traceability of product.

**Documentations:-**

1. Poor documentation related to production / Quality control was seen.

**Stability:-**

1. No Stability chamber or SOPs were available regarding to stability.

**Vendor Validation:-**

1. Firm did not do any vendor validation of their Raw Material.

**Process Vendor:-**

1. Firm did not do processes validation of their critical steps of manufacturing of their any products.

**Complaint / Recall System:-**

1. No SOPS was developed for complaint / recall system.

**Medical Record:-**

1. No Medical record was maintained.

**Water Treatment Plant:-**

1. No validation of water treatment was carried by the firm.
2. No flow diagram was available.
3. No identification of their Colum was mentioned.

**Conclusions:-**

 *“Condition of firm was unsatisfactory regarding to premises, Production area, Quality Control laboratory, documentation and SOPs related to Production / Quality Control and Quality Assurance Laboratory.”*

**Action taken by DRAP:**

The firm M/s Well Care Pharmaceutical, Sargodha was served Show Cause Notice and suspension of production activities order No.F.4-11/2001-QA on 10.05.2019.

**Reply of the firm:**

The firm M/s Well Care Pharmaceutical, Sargodha vide letter dated 13.05.2019 submitted reply of Show Cause Notice and submitted compliance report. The firm stated that they have improved in all aspects and they want to be presented in person.

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board. Mr. Malik Saeed Akhtar, MD of the firm M/s Well Care Pharmaceutical, Sargodha appeared before the Board. He informed that improvements have been done, as mentioned by the FID. He further stated that the firm is ready for inspection.

**Decision of the 271st 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 13.03.2019 before resumption of production:-
2. Dr. Mehmood Ahmad, Ex-Dean, Faculty of Pharmacy, Islamia University Bahawalpur
3. Dr. Hafsa Karam Elahi, Addl. Director (QA&LT), 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 13.03.2019, with clear and candid recommendations.
6. Production of the firm M/s Well Care Pharmaceutical, Sargodha shall remain suspended till recommendation by panel and subsequent approval by the CLB.

**Case No. iv: M/S. UNI-TIECH PHARMACEUTICALS, KARACHI.**

**Background:**

Mrs. Muneeza Khan, FID-II, Karachi conducted inspection of the firm M/s. Uni-tiech Pharmaceuticals (Pvt) Limited, Plot No. 4/116, Sector 21 Korangi Industrial Area Karachi on 29.04.2019.

2. The FID during inspection noted the following critical observations which need attention and rectifications:-

**3rd Floor: Warehouse, Retention Samples room and printing room;**

1. No Sampling and dispensing booths are available for dispensing purpose.
2. Dispensing area is provided but no HVAC installed. It is advised to redesign the dispensing area, the personal and material flow with air locks and efficient HVAC as per cGMP Guidelines.
3. No concept of change room with HVAC and basic amenities for the personals to change clean cloths was observed.
4. Change rooms should be redesigned with effective HVAC system.
5. Cephalosporin active raw material is also placed general raw material store in separate room.
6. The printing area is also present at 3rd floor where no exhaust / safety system was observed with the laser/inkjet printing machines for the hazardous fumes generated during the printing process.

**2nd Floor: QC Laboratory/ Quality Assurance;**

1. New HPLC was purchased and found under installation at the time of inspection.
2. It is recommended to provide Liquid Particle Counter, TLC, FTIR and Velocity meter for the test analysis purpose.
3. BP/USP reference standards not available and it is advised to provide lab with required reference standards.
4. Stability chamber with printer is advised to carry on stability studies for manufactured products.
5. All SOPs should be revised with documentation control and should be implemented.
6. It is advised to perform self-audit by QA and actions to be taken as required by self-inspection report.
7. It is suggested to make R&D section for research and analysis purpose.
8. Quality Assurance system should be strengthened, implemented and maintained to ensure process performance and products quality. All product manufacturing orders processing from QA department should be reviewed and checked. Calibrations and validations to be carried out by QA
9. This unit doesn’t possess a well-developed micro lab including well-qualified and experienced technical person. The firm has facility to manufacture sterile products so it is necessary for the manufacturer to establish a well-equipped micro lab to carry out required micro testing at the premises including environmental monitoring and water testing.

**Cephalosporin Located at 2nd Floor;**

1. Secondary change rooms/ Double change is required in Ceph manufacturing area.
2. No magnehallic gauges are installed to monitor the HVAC air balancing in the Cephalosporin manufacturing area.

**First Floor/ Production Areas;**

1. Secondary change rooms required in each and every manufacturing area.
2. The psychotropic area found empty, without any manufacturing equipment/ machinery, hence found closed.

**Ground Floor/ Liquid Inj. Sterile Production Area;**

1. Sterile liq. infusion area found closed with no machinery and equipment.
2. HVAC is to be installed in the said area therefore has shut down the area till the installation of HVAC.
3. In liq. inj. sterile area WFI and UNIZBO was under filling, under laminar and HEPA. HVAC found operational.

**SITE Plan;**

1. The firm has no approved site validation master plan (SVMP) to define in detail the company’s validation & qualification policy. It is recommended to make VMP and to execute for the critical process equipment, areas and analytical test methods to be validated as per requirement of site validation master plan.
2. Qualification of all instruments, equipment/ machinery and procedures is advised to be done.
3. Cleaning validation need to be revise and implement as per SOPs.

**Training Schedule;**

1. Extensive Training of All Staff/ Officers engaged in ware housing, manufacturing and QC areas are recommended.
2. It is advised to hire more experienced, qualified and technical persons in all operations to achieve cGMP, cGLP, Communication & Coordination and EHS compliance.

**Action taken by DRAP:**

The firm M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd, Karachi was served Show Cause Notice and suspension of production activities order No.F.4-6/2009-QA on 21.05.2019.

**Reply of the firm:**

The firm M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd, Karachi vide letter dated 10.06.2019 submitted reply of Show Cause Notice and requested time for improvements.

**Updated Status:**

A panel comprising of Dr. Najam us Saquib, Addl. Director (QA), DRAP, Karachi and Ms. Muneeza Khan, FID re-inspected the firm on 08.07.2019 and inform that some of the observations are yet to be addressed. Accordingly the area FID was advised to revisit the firm and inform the updated status of the observations noted on 08.07.2019.

Mr. Abdul Rasool Sheikh, Area FID re-inspected the firm on 04.09.2019 and recommended as under:-

 *“During the inspection it was observed that the desired level of compliance has been achieved and all the raised NCs have satisfactorily been addressed in all the sections except Sterile Liquid Infusion section, hence it is recommended that the firm may be given an opportunity to resume their production activities in all the sections except Sterile Liquid Infusion with the periodic monitoring of this office”.*

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board keeping in view the recommendations of FID in its report dated 04.09.2019. The Board raised query regarding the inspection dated 04.09.2019. It was informed to the Board that the inspection was carried out by Mr. Abdul Rasool Shaikh, FID, Karachi.

**Decision of the 271st Meeting of CLB**

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

1. Re-Inspect the firm by following panel of experts:-
2. Dr. Abdullah Dayo, Member, CLB.
3. Chief Drug Inspector, Sindh
4. Area FID, Karachi
5. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 29.04.2019 & 08.07.2019, with clear and candid recommendations.
6. Production of the firm M/s Uni-Tiech Pharmaceuticals (pvt) Limited, Karachi shall remain suspended till recommendation by panel and subsequent approval by the CLB.

**Case No. v: M/S. GULF PHARMACEUTICALS, RAWAT**

**Background:**

Mr. Hasan Afzaal, FID, Islamabad conducted inspection of the firm M/s. Gulf Pharmaceuticals, Plot No 49, St. No. S-5, National Industrial Zone, Rawat (DML No. 000750) on 12.07.2019.

2. The FID during inspection noted following critical observations:-

1. The rodent/pest control appeared compromised as litter of same was seen in the ware house, including the dispensing area/ dispensing room.
2. Lignocaine HCL, batch unknown, consignee info: unknown was present, the firm could not provide import documents of API.
3. Sampling booth has not been provided.
4. Foil segregation not seen.
5. HVAC validation requires to be done as pressure differential were not maintained.
6. Cleaning validation not in practice.
7. Micro lab was under maintenance.
8. The Good Storage Practices of the firm are not as per standard which puts effect on the whole manufacturing process

**Action taken by DRAP:**

The firm M/s Gulf Pharmaceuticals, Rawat was served Show Cause Notice and suspension of production activities order No.F.4-57/2012-QA on 26.07.2019.

**Reply of the firm:**

The firm M/s Gulf Pharmaceuticals, Rawat vide letter dated 08.08.2019 submitted reply of Show Cause Notice and requested that they want to avail opportunity of statutory of personal hearing before the competent authorities. The firm vide letter dated 09.08.2019 requested for constitution of independent panel of experts for inspection.

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board. Dr. Khawaja Tahir Mehmood, Legal Advisor and Mr. Waqar Alam, QCM of the firm M/s Gulf Pharmaceuticals, Rawat appeared before the Board. Legal Advisor of the firm informed that improvements have been done, as noticed by the FID. He further stated that the firm is ready for inspection.

**Decision of the 271st 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 12.07.2019 before resumption of production:-
2. Dr. Munawar Hayat, Chief Drugs Controller, Punjab.
3. Dr. Hafsa Karam Elahi, Addl. Director (QA&LT), DRAP, Islamabad
4. Area Federal Inspector of Drugs, Islamabad.
5. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 12.07.2019, with clear and candid recommendations.
6. Production of the firm M/s Gulf Pharmaceuticals, Rawat shall remain suspended till recommendation by panel and subsequent approval by the CLB.

**Item No. II PERSONAL HEARING IN COMPLIANCE 270TH MEETING OF CLB**

**Case No. i 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.

5. The case was placed in 270th Meeting of CLB. Wherein the Board after detailed discussion decided as under:-

**Decision of the 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

**Action Taken by DRAP**: - Keeping in view decision of 270th Meeting of CLB. Show Cause Notice in compliance to decision of 270th meeting was issued to the following accused persons on 24.06.2019.

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
3. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
4. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3
5. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9
6. Mr Jamshaid Ghani, Production Incharge S/o Abdul Ghani, CNIC No. 54400-0548981-5

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board. The Board was informed that the Show Cause Notices were sent through official dak and FID was also directed to convey the directions of personal hearing before the Board. Mr. Hasan Javed, Regulatory Affairs Executive appeared before the Board. He requested for the adjournment of the case due to some emergency.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to provide final opportunity of personal hearing to the following accused, under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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. III RESUMPTION OF PRODUCTION**

**Case No. i M/s. Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur-KP**

**Background of the case:-**

Mr. Zia Ullah, AD/FID-III, DRAP, Peshawar conducted inspection of firm M/s. Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur-KP on 02.08.2018. The FID noticed a number of observations, which need urgent attention and rectification.

**Action taken by DRAP:**

The firm M/s Iceberg Pharma, Risalpur was issued Show Cause Notice/ Suspension of production order on 28.08.2018.

2. The case was placed before the 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 Q.C. Manager and Production Manager, the Central Licensing Board decided to:-

1. Constitution of following panel of experts for verification of the observations before resumption of production:-
2. Prof. Dr. Jamshaid Ali Khan, Member, CLB
3. Additional Director, DRAP, Peshawar
4. 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 to CLB including rectification status of the observations noted by the FID in its report dated 02.08.2018, with clear and candid recommendations.

**Updated Status:-**

In the light of decision of 266th meeting of CLB. The panel conducted inspection of the firm on 27.03.2019. The panel gave updated status of observations noted by the FID in its report dated 28.08.2018. The panel concluded as under:-

*“Keeping in view the preceding observations, the production, quality control and environmental facilities provided, the improvements and rectifications made by the firm in light of the last routine GMP inspection, commitment of the firm’s management to remain strictly adhere to the cGMP guidelines, the technical staff employed, the panel therefore, unanimously recommends the resumption of production activities in all sections of M/s. Iceberg Pharmaceuticals (Pvt0 Ltd. 144-Nowshera Industrial Estate, Risalpur KP.”*

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board. Panel Inspection report of the firm M/s Iceberg Pharmaceuticals (pvt) Limited, Risalpur-KP dated 27.03.2019 was discussed in detail.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations and keeping in view the panel inspection of the firm dated 27.03.2019 and its recommendations, the Central Licensing Board decided to:-

1. Resume production activities of the firm M/s. Iceberg Pharmaceuticals (pvt) Limited, Risalpur-KP, from the date of issuance of decision of the 271st meeting of CLB.
2. Cease the operation of show cause notice dated 28.08.2018, from the date of issuance of decision of the 271st meeting of CLB.

**Case No. II M/S. PARADISE PAHRMA, LAHORE.**

The following panel of experts conduced inspection of the firm M/s. Paradise Pharma, Lahore on 19.11.2018 to check the compliance of GMP.

1. Mrs. Majida Mujahid, FID, DRAP, Lahore
2. Ms. Maham Misbah, Assistant Director, DRAP, Lahore

 2. The Panel has noticed critical observations.

**Action taken by DRAP:**

The firm M/s. Paradise Pharmaceutical, Lahore was issued Show Cause Notice and suspension of production orders on 01.01.2019.

3. The case was placed before the 269th meeting of CLB. Wherein the board 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. Mr. Munawar Hayat, Chief Drug Controller, Punjab
4. Area Federal Inspector of Drugs, Lahore
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 FID in its report dated 19.11.2018, with clear and candid recommendations.

**Updated Status:-**

In the light of decision of 269th meeting of CLB. The panel conducted inspection of the firm on 27.03.2019. The panel recommended as under:-

*“Firm inquired about the improvements required to be made in Syrup and Sachet Section. They submitted an undertaking that both sections are not ready for inspection and they needed time to remove their shortcomings / observations which were pointed out in panel inspection. (Copy of undertaking is attached with report).*

*Keeping in view improvements made by the firm in Liquid Repacking Section and External Preparation Section with respect to civic work, working of HVAC system and up gradations of SOPs the panel of inspectors was of the opinion to recommend the resumption of production in Liquid Repacking Section and External Preparation Section only of M/s. Paradise Pharma, 23-KM, Sheikhupura Road, Lahore.”*

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board. Panel Inspection report of the firm M/s Paradise Pharmaceuticals, Lahore dated 27.03.2019 was discussed in detail.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations and recommendation of the panel of experts dated 27.03.2019, the Central Licensing Board decided to:-

1. Resume production activities in the following section, from the date of issuance of decision of 271st meeting of CLB.
2. Liquid Re-packing Section
3. External Preparation Section
4. However production will remain suspended in the following sections, till the improvements made and reported by the firm, verification by the panel of experts and subsequent approval by the CLB.
5. Oral Liquid Syrup Section
6. Sachet Section

**Case No. III: 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.

5. The case was placed in 270th meeting of Central Licensing Board. The Board decided as under:-

**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.

**Updated Status:-**

The panel conducted inspection of the firm M/s. Sarco Chemical Industry, 17-KM, Peerwala More, Qadir Pur Ran, Khenewal Road, District Multan on 30.08.2019 and submitted compliance report in tabulated form indicating the previous observations noted on 15.10.2018 and updated status on 30.08.2019. The panel concluded as under:-

*“Based on the finding of inspection, it is concluded that the firm has rectified and removed most of the shortcomings pointed out during last inspection. Keeping in view the above, the panel of insepctors is of the opinion to recommend the resumption of production and restoration of the DML of the firm M/s. Sarco Chemical Industry, 17-KM, Peerwala More, Qadir Pur Ran, Khanewal Road, District Multan”.*

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board. Panel Inspection report of the firm M/s Sarco Chemical Industry, Khanewal Road, Multan dated 30.08.2019 was discussed in detail.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations and keeping in view the panel inspection of the firm dated 30.08.2019 and its recommendations, the Central Licensing Board decided to:-

1. Restore the Drug Manufacturing License of the firm M/s Sarco Chemical Industry, Khanewal Road, Multan from the date of issuance of decision of the 271st meeting of CLB.
2. Resume the production activities of the firm M/s. Sarco Chemical Industry, Khanewal Road, Multan, from the date of issuance of decision of the 271st meeting of CLB.
3. Cease the operation of show cause notice dated 19.11.2018, from the date of issuance of decision of the 271st meeting of CLB.

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

**Case No. i M/S. HEALER LABORATORIES, PESHAWAR.**

**Background:-**

Mr. Atiq-Ul-Bari, FID-II, DRAP, Peshawar, on 04.09.2018 conducted inspection of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar.

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

**Action taken by DRAP:**

The firm M/s Healer Laboratories, Peshawar was served Show Cause Notice on 23.10.2018.

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
4. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 25.10.2018, with clear and candid recommendations.

4. The panel conducted inspection of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar on 26.03.2019 and concluded as under:-

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

The panel further recommended the firm to:-

1. Provide an Air conditioner in Raw Material Quarantine area.
2. Calibrate balances from external sources and provide digital balances in process QC and Capsule filling Section.
3. Provide room for retention samples.

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board, keeping in view the recommendations of panel in its report dated 26.03.2019. The Board raised query regarding the further recommendations made by the firm.

**Decision of the 271st Meeting of CLB**

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

1. Re-Inspect the firm by same panel of experts, constituted in 267th meeting of CLB, to verify the following improvements suggested by the panel in its report dated 26.03.2019:-
2. Provide an Air conditioner in Raw Material Quarantine area.
3. Calibrate balances from external sources and provide digital balances in process QC and Capsule filling Section.
4. Provide room for retention samples.
5. The panel shall submit detailed inspection report including rectification status of the observations with clear and candid recommendations.
6. Production of the firm M/s Healer Laboratories, Peshawar shall remain suspended till recommendation by panel and subsequent approval by the CLB.

**ITEM NO. V INSPECTION REPORT IN COMPLIANCE TO 259TH & 270TH MEETING OF CLB**

**Case No. i M/s Rex Pharmaceutical Pakistan, Karachi**

**Background of the case**

Mr. Abdul Rasool Sheikh, FID, Karachi conducted inspection of the firm M/s Rex Pharmaceutical Pakistan, Karachi on 06.03.2013. During inspection the FID pointed out number of serious/critical shortcomings in all sections. Accordingly showcause notice/stop production order was issued on 23.04.2013. The case was presented before CLB in its 232nd meeting held on 29&30th July 2013. The Board had decided as under:-

1. *The case was deferred by Central Licensing Board till its next meeting as per your request that the Director of the firm had gone to Saudi Arabia for performing Umrah and requested to defer the case till next meeting of CLB.*
2. *The production will remain stopped / suspended till the final approval for resumption of production by the Central Licensing Board.*

2. The case was presented before the 233rd Meeting of CLB, wherein the CLB had decided as under:-

**Decision of 233rd Meeting of CLB:**

After thorough discussion and deliberations, considering the background of the case and facts on record, Board unanimously decided to suspend the DML of the firm for period of three months under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976. The Board further decided to issue show cause notice and personal hearing to the firm and advised for market survey of production manufactured by firm.

3. Decision of the CLB was conveyed to the firm on 24.02.2014.The firm vide letter No. Nil dated 02.04.2014 replied that they have removed all the shortcomings and ready for inspection. The Area FID visited the firm on 18.11.2014 and recommended for cancellation of DML. The case was placed before the CLB in its 245th Meeting held on 30.12.2015.

4. The case was again presented before the 245th Meeting of CLB, wherein the CLB had decided as under:-

**Decision of 245th Meeting of CLB:**

The Board after thorough discussion, keeping in view the available record, observations of the FID in its inspection conducted on 06.03.2013, track record and non-serious attitude of the firm, and report of the FID dated 18.11.2014 which categorically stated that “The DML of the firm may be cancelled in larger public interest”, has decided to suspend the DML of the firm M/s Rex Pharmaceuticals Pakistan, Karachi for a period of 06 months, under Rule 12 of the Drugs (LR&A) Rules, 1976.

5. The decision of the CLB was conveyed to the firm on 09.02.2016.

**Recommendations of FID**

Mr. Abdul Rasool Shaikh, FID, Karachi vide letter dated 24.01.2017 informed that the firm was inspected on 06.01.2017 and found non-operational, no one was there except watchman who told that factory is closed since 2011 and owners are reported to be living in USA now days. Based on the current conditions of the firm it is recommended that their DML by way of formulation may be cancelled in larger public interest.

6. The recommendations of FID were presented before the 252nd Meeting of CLB, wherein the CLB had decided as under:-

**Decision of the 252nd Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the Federal Inspector of Drugs in its letter dated 24.01.2017, in which the FID recommended to cancel the DML of the firm in the larger public interest, casual attitude of the firm towards GMP compliance, track record of the firm and nonappearance of representatives of the firm before the Board to defend the case, the Board decided to *cancel the Drug Manufacturing License of the firm M/s Rex Pharmaceutical Pakistan, Karachi*, 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 252nd meeting of CLB.

7. The firm file appeal in Appellate Board under section 9th of the Drugs Act, 1976 147th. The Board decided as under:-

**Decision of Appellate Board in its 147th Meeting**

M/s Rex Pharmaceutical Pakistan, Karachi filed an appeal against the decision of the CLB regarding cancellation of DML. The case was considered in 147th meeting of the Appellate Board held on 28.08.2017, wherein the appellate board decided to suspend the operation of impugned order of CLB dated 15.03.2017 communicated on 24.04.2017 and remand the appeal back to the CLB. The appellate board constituted a panel of following panel to inspect the premises of the appellant who shall submit its report within 30 days from the date of communication:-

1. Dr. Kifayat Ullah, CDC, Gilgit, Baltistan
2. Prof. Dr. Maqsood Ahmed, Ripah International University, Lahore
3. Syed Muied Ahmed, Expert in Manufacturing, Karachi

The report of the panel will be placed before the CLB in its forthcoming meeting. Meanwhile the production of the firm will remain suspended till recommendations by the panel for the resumption of production and approval thereof by the CLB.

8. The panel inspected the firm on 12.12.2017 and noticed observation which still needs rectification:-

**The panel further concluded and recommended that:-**

 The panel observed a number of shortcomings in building, production machinery, HVAC system, documentation etc. Therefore, based on the areas inspected, the people met and documents reviewed and considering the findings of inspection the panel recommends that the Drug Manufacturing License may be granted to M/s Rex Pharmaceuticals Pakistan, Karachi, for two sections only namely Oral Liquids and Tablet (after addressing the observations in this report).

9. The panel inspection report was placed before 257th meeting of CLB. Wherein the Board decided as under:-

**Decision of 257th Meeting of CLB:-**

The case was placed before the Central Licensing Board in its 257th Meeting held on 24-25 Jan, 2018 and decided as under:-

*“After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in its report dated 12.12.2017 decided to*

*i. Re-inspect the firm M/s Rex Pharmaceutical Pakistan, Karachi by following panel of experts, constituted by the Appellate Board in its 147th Meeting:-*

1. *Dr. Kifayat Ullah, CDC, Gilgit, Baltistan*
2. *Prof. Dr. Maqsood Ahmed, Ripah International University, Lahore*
3. *Syed Muied Ahmed, Expert in Manufacturing, Karachi*

ii. The panel shall submit the detailed report alongwith rectification status of the observations in the Tablet Section and Liquid Syrup Section noted by the panel in the report dated 12.12.2017. Furthermore the panel will also submit detailed report regarding the quality control laboratory and storage facilities of the firm. The report shall be placed in the forthcoming meeting of Central Licensing Board for consideration.

10. The Decision of the 257th meeting of CLB was conveyed to the firm and quarters concerned on 06.03.2018.

11. The firm vide letter No. Nil dated 20.03.2018 received on 27.03.2018 informed that they have rectified the observations recommended by the panel. In the meanwhile one of the respected panel member Dr. Kifayat Ullah, CDC, Gilgit passed away.

12. The case was placed before 259th meeting of CLB. The Board decided as under:-

**Decision of the 259th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case and intimation of the firm regarding death of the worthy panel member Dr. Kifayatullah, Chief Drug Controller, Gilgit Baltistan, the Central Licensing Board decided to replace name of deceased member Dr. Kifayatullah, Chief Drug Controller, Gilgit Baltistan with Additional Director, Karachi, other members of the panel shall remain same.

13. 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.

14. Request of Mr. Syed Muied Ahmad, Member, CLB was placed before 270th meeting of CLB. The Board decided as under:-

**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.

15. Decision of 270th meeting was conveyed to the quarters concerned. The panel conducted inspection of the firm on 12.07.2019 submitted comparison of observations noted on 12.12.2017 and 12.07.2019. The panel concluded as under:-

 *“Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, it was noticed that no technical person (in Quality Control laboratory, Production sections and ware house) was available in the firm to represent and answer, technically, the observations of the panel. The firm was being represented by Mr. Muhammad Amin along with his son and daughter. Moreover, Quality Control Laboratory required to be upgraded in terms of equipment and testing procedures. Management also couldn’t display the equipment in working condition as no power supply was seen in the QC Laboratory and re-calibration was also due for available equipments. HVAC system, in general, requires to be commissioned and qualified and air balancing to be performed to avoid any chance of contamination and cross-contamination. Power supply was also seen inadequate and insufficient to run the production operations smoothly including HVAC system. The management of M/s. Rex Pharmaceutical Pakistan couldn’t improve / upgrade the production and testing facility as identified by the panel during inspection on dated 12.12.2017.*

*Keeping in view the above stated facts, Panel does not recommend the commencement of the production in these sections in larger public interest.”*

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board keeping in view the recommendations of panel in its report dated 12.07.2019. The board discussed the case in detail including decision of 252nd meeting of CLB, wherein the Board decided to cancel the DML of the firm. The Board also go through the decision of 147th meeting of Appellate Board and subsequent recommendations of the panel in its report dated 12.07.2019, in compliance to 270th meeting of CLB.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations, the Board considered the report of the panel of experts dated 12.07.2019 and recommendations of the panel of experts. The Board also considered the background history of the case and failure on the part of the firm for complying the conditions of Licence as enumerated under Rule, 16 of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 and Schedule B framed under the Drugs Act, 1976. The Board, therefore decided to serve Show Cause Notice under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 to the firm M/s Rex Pharmaceuticals Pakistan, DP-3, Sector 12-D, North Karachi Industrial Area, Karachi as to why their Drug Manufacturing Licence No. 000536 by way of formulation may not be suspended or cancelled for failure to maintain conditions of Licence as enumerated under Rule, 16 of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 and Schedule B framed under the Drugs Act, 1976 and reported by the panel of experts in their inspection report dated 12.07.2019.

**ITEM NO. VI INSPECTION REPORT IN COMPLIANCE TO 255TH MEETING OF CLB**

**Case No. i M/s Medipak Limited Lahore**

**Case Background**

Mr. Abdul Rashid Shaikh, FID, Lahore conducted inspection of M/s Medipak (Pvt) Ltd, Lahore on 13.04.2016 to verify the GMP compliance and production activities. The FID noticed number of observations.

2. Accordingly, show cause notice was served to the firm on 25.05.2016. The firm vide letter No. Nil dated 03.06.2016 submitted detailed reply of showcause notice including compliance status.

3. The case was placed before the 248th meeting of CLB held on 13.07.2016. The Board decided as under:-

**Decision of the 248th Meeting of CLB**

A. 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. Abdur Rashid, Chairman, Quality Control
2. Dr. Zaka ur Rehman, CDC, Punjab
3. Mr. Abdul Rashid Shaikh, Area FID, Lahore

B. The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status.

4. The panel conducted inspection of the firm on 17-01-2017. The panel concluded as under:-

“In view of all the above, it is observed that the management has addressed most of the shortcomings, which were pointed out during the last inspection, which leads the panel of inspectors to the conclusions that the firm is presently operating at the good level of GMP compliance, hence it is advised to the management to continue their efforts to further upgrade their systems.”

5. The case was placed in 255th meeting of CLB. Wherein the Board decided as under:-

1. To defer the case and constituted new panel comprising following members who will conduct cGMP inspection of the firm on approved format under Schedule B-II of Drugs (Licensing, Registration and Advertising) Rules, 1976.
2. Dr. Ikram Ul Haq, Member CLB
3. The Chief Drugs Controller, Government of Punjab, Lahore
4. The Area FID, DRAP, Lahore
5. The Board also decided to direct the panel to submit brief report in tabulated form identify the previous observations and the current status.
6. The Board further directed that, the inspection of the firm will be conducted within one month of the communication of the decision of CLB and report of the firm shall be placed before the board in next meeting.

6. The panel conducted inspection of the firm on 11.07.2019 submitted comparison of observations noted on 13.04.2016. The panel concluded as under:-

*“The panel observed that the firm had rectified most of the deficiencies pointed out in the inspection dated 213.04.2016. Further improvements suggested would be verified in the next inspection due for renewal of Drug Manufacturing License.”*

**Proceedings of 271st meeting:-**

Quality Assurance Division presented the case before the Board. Panel Inspection report of the firm M/s Medipak (Pvt) Ltd, Lahore dated 11.07.2019 was discussed in detail.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations and keeping in view the panel inspection of the firm dated 11.07.2019, the Central Licensing Board decided to cease the operation of show cause notice dated 25.05.2016, from the date of issuance of decision of the 271st meeting of CLB.

**QUALITY CONTROL CASES**

 **ITEM NO. 2**

**OLD CASES RELATED TO DRAP OFFICE, QUETTA REFERRED BY HONORABLE DRUG COURT QUETTA.**

It is submitted that the FID, Q@K vide letter vide letter 3-1/2009-FID(Q)K dated 28.01.2019 stated that the Honorable Drug Court, Quetta has passed the orders during proceedings on 3rd December, 2018 in the case titled “Surat Khan Medical Store and others” to provide the list of pending cases of DRAP, Quetta. Moreover, the FID Quetta requested vide letter No.3-1/2019-FID(Q) K dated 05th August 2019 “the old pending cases may kindly be discussed in the Boards concerned on priority basis and necessary decisions may kindly be passed in order to submit the status/copies of decisions in the Honorable Drug Court, Quetta”.

In the light of directions of the Honorable Drug Court Quetta, a list of cases was handed over to the DRAP representative for necessary proceedings under the law. The Court has highlighted its serious concerns on the state of affairs about the cases pended in the DRAP without any reason. The record of the QA&LT Division was thrashed out and it was found that the list of cases forwarded by the court contained following categories of cases:

* + 1. Some of the cases were decided by the CLB but prosecutions not launched.
		2. Some of the cases were decided but name of the accused persons were not given in the prosecution permission letters.
		3. Some of the cases of un-registered were disposed of by the Registration Board.
		4. Some of the cases of un-registered/spurious drugs were disposed of by giving warning.
		5. Some of the cases are pended being incomplete on the part of FID and/or stuck during the shifting of the records after devolution of
		de-funct Ministry of health under the 18th CONSTITUTIONAL AMENDMENT.

The record of the QA&LT Division was sorted out and it was matched with the copies of record from FID, Quetta. In light of both records and keeping in view the request from FID Quetta, the agenda of cases have been prepared according to records available in the section and the records shared by DRAP Office Quetta, for the consideration of Board please. The details of the cases are as under:-

**Case No.I**

Case No. I-A **MANUFACTURING AND SALE OF UN-REGISTERED DRUG NAMELY TRISH ZEE BATCH NO.TZ001**

That Syed Abdul Saleem, FID Quetta forwarded vide letter No.F.SAS-122-124/2009-FID(Q)/195 dated 08th March 2010. The FID Quetta stated that during visit some un-registered drugs were found available without having Drug Sale license. The FID ordered Not to dispose of all available stocks of said drugs.The same was reported the Chairman CLB for extension of time of said orders vide this office letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 and subsequent request vide No.F.12-1/DCA-QTA/M survey dated 12.12.2009 a sample of drug namely Trish Zee Tabs B.No. ZT001 claimed to be manufactured by M/s Starix Nutraceuticals Karachi was also taken along with other samples of drugs for the purpose of test/analysis.

02. The-then FID Quetta submitted that the sealed sample of Trish Zee B.No.TZ001 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID (Q) -16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Starix Nutraceutical Karachi vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.202/2009 dated 09-12-2009 **declared the sample of Trish Zee Tablets B.No.ZT001 and Un-registered.**

04. The FID, Quetta also informed that M/s Starix Nutraceuticals Karachi was called to show cause and explain for its position for manufacturing and selling un-registered drug vide this office show-cause notice No.SAS-122-124/2009-FID (Q)/87dated 15-12-2009 but same was also received back undelivered.

05. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey -30 dated 21-11-2009. M/s Kozak submitted copies of invoices of invoices for drugs that were ordered not to dispose off on receipt of test report from CDL Karachi M/s Kozak Traders Quetta again called to show cause notice and explain its position vide this office letter No. SAS-122-124/2009-FID(Q)/86 dated 15-12-2009 but no response is received as yet.

06. The FID Quetta submitted the above mentioned facts and revealed that M/s Kozak Traders Quetta involved in manufacturing and selling of un-registered drug namely tablets Trish Zee with a fake name M/s Starix Nutraceuticals Karachi and violated the section 23(1)(a)(x), 23(1)(b),23(1)(c) and 27(3) of the Drugs Act 1976.

07. The FID Quetta is submitted for placement before CLB for its **consideration and permission of prosecution against Mr. Muhammad Ashraf proprietor of M/s Kozak Traders Quetta along with M/s Starix Nutraceuticals Karachi.**

08. The case was put up for approval of show cause notice to the accused persons on 13-05-2010 in Quality Control Section vide F.No.3-37/2009-DDC(QC). A**show cause notice was issued** to the M/s Kozak Traders Archer Road Quetta and M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi dated 04th August 2010**on behalf of Drug Registration Board with approval of Chairman, DRB**. Personal hearing letter was also issued to the M/s Kozak Traders Archer Road Quetta and M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi on 21st June 2011 **to appear before the Drug Registration Board** for personal hearing on 25th June 2011 at 11:00 am in committee Room of Ministry of Health Islamabad.

09. That the-then DDC(QC-I) vide letter no. F.03-37/2009-DDC(QC-I) dated 2nd April, 2014 requested for appraisal of the latest position of the case on priority basis to the-then FID-Quetta for which no reply is available in the record.***The matter was wrongly processed for DRB.***

***Permission for Show cause Notice to prosecute.***

10. It is therefore submitted that ***Muhammad Ashraf proprietorM/s Kozak Traders Archer Road Quetta through and M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi*** may be served with show cause notice for selling of unregistered and manufacturing of drugs without manufacturing license.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

11. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Kozak Traders Archer Road Quetta through its proprietor Muhammad Ashraf
2. Muhammad Ashraf proprietor M/s Kozak Traders Archer Road Quetta
3. M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi through its owner/ proprietor / CEO/ MD

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

12. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No.I-B: MANUFACTURING AND SELLING OF UN-REGISTERED DRUG NAMELY BELT LIQUID B.NO.BS03.**

That Mr. Syed Abdul Saleem, FID Quetta forwarded case vide letter No.F.SAS-122-124/2009-FID(Q)/194 dated 08thMarch 2010. The FID Quetta stated that he visited the M/s Kozak Traders Archer Road Quetta on 05-11-2009, during the visit some un registered drugs were found available without having Drug Sale License. The FID ordered Not to dispose of all available stocks of said drugs. The same was reported the Chairman CLB for extension of time of said orders vide this office letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 (copy Annex B) and subsequent request vide No.F.12-1/DCA-QTA/M survey75 dated 12.12.2009 (copy annex C) a sample of drug namely Belt Liquid B.No. BS.03 claimed to be manufactured by M/s Starix Nutraceuticals Karachi was also taken along with other samples of drugs for the purpose of test/analysis.

02. The FID Quetta submitted that the sealed sample of Belt Liquid B.No. BS.03 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID (Q) -16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Starix Nutraceutical Karachi vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.202/2009 dated 31-12-2009 **declared the sample of Beld Liquid B.No.BS03 Un-registered.**

04. FID, Quetta informed that M/s Starix Nutraceuticals Karachi was called to show cause and explain for its position for manufacturing and selling un-registered drug vide this office show-cause notice No.SAS-122-124/2009-FID (Q)/121 dated 06-1-2010 but same was also received back undelivered.

05. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey-30 dated 21-11-2009.
M/s Kozak submitted copies of invoices for drugs that were ordered not to dispose off on receipt of test report from CDL Karachi. M/s Kozak Traders Quetta again called to show cause notice and explain its position vide this office letter No. SAS-122-124/2009-FID(Q)/86 dated 15-12-2009 but no response is received as yet.

06. The FID Quetta submitted the above mentioned facts and revealed that M/s Kozak Traders Quetta involved in manufacturing and selling of un-registered drug namely **Belt Liquid B.No.BS03** with a fake name M/s Starix Nutraceuticals Karachi and violated the section 23(1)(a)(x), 23(1)(b),23(1)(c) and 27(3) of the Drugs Act 1976

07. The FID Quetta is submitted for placement before CLB for its consideration and **permission of prosecution against Mr. Muhammad Ashraf proprietor of M/s Kozak Traders Quetta along with M/s Starix Nutraceuticals Karachi**.

***Permission for Show cause Notice to prosecute.***

8. It is therefore submitted that ***Muhammad Ashraf proprietorM/s Kozak Traders Archer Road Quetta through and M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi*** may be served with show cause notice for selling of unregistered and manufacturing of drugs without manufacturing license.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

9. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Kozak Traders Archer Road Quetta through its proprietor Muhammad Ashraf
2. Muhammad Ashraf proprietor M/s Kozak Traders Archer Road Quetta
3. M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi through its owner/ proprietor / CEO/ MD

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

10. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No. I-C: MANUFACTURING AND SALE OF UN REGISTERED DRUG NAMELY SYP IRO-C B.NO. 123**

Syed Abdul Saleem, FID Quetta forwarded vide letter No.F.SAS-122-124/2009-FID(Q)/195 dated 08th March 2010. The FID Quetta stated that during visit some un-registered drugs were found available without having Drug Sale license. The FID ordered Not to dispose of all available stocks of said drugs (Copy of Form-I Annex A) the same was reported the Chairman CLB for extension of time of said orders vide this office letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 (copy Annex B) and subsequent request vide No.F.12-1/DCA-QTA/M survey 75 dated 12.12.2009 (copy annex C) a sample of drug namely IRO-C, B.No.123 claimed to be manufactured by M/s Welldone Pharma Nutraceuticals Division Multan was also taken along with other samples of drugs for the purpose of test/analysis

02. The FID Quetta submitted that the sealed sample of IRO-C, B.No. 123 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID (Q) -16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Welldone Pharma Multan vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.203/2009 dated 31-12-2009 **declared the sample of IRO-C B.No.123 Un-registered.**

04. M/s Welldone Pharma Multan was called to show cause and explain for its position for manufacturing and selling un-registered drug vide his office show-cause notice No.SAS-122-124/2009-FID (Q)/122 dated 06-01-2010 but same was also received back undelivered.

05. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey -30 dated 21-11-2009. M/s Kozak submitted copies of invoices of invoices for drugs that were ordered not to dispose off on receipt of test report from CDL Karachi M/s Kozak Traders Quetta again called to show cause notice and explain its position vide this office letter No. SAS-122-124/2009-FID(Q)/86 dated 15-12-2009 but no response is received as yet.

06. The FID Quetta submit the above mentioned facts and revealed that M/s Kozak Traders Quetta submitted invoices bearing No.282 dated 02-11-2009 of M/s Allah Waley Food Products Trading Town Hall Multan in respect of said drug. M/s Allah Waley Food Products Trading Multan was asked to verify its invoice with warrantee and provide further invoice with warranty and provide further invoice with warrantee vide his office letter No. SAS.122-124/2009-FID(Q)/100 dated 21.12.2009 but same was received back un delivered.

The FID Quetta stated that on the basis of facts it is reveled that M/s Kozak Traders Quetta involved in manufacturing and selling of un registered drug namely Syp IRO-C with a fake name M/s Welldone Pharma Multan and violated the section 23(1)(a)(x), 23(1)(b),23(1)(c) and 27(3) of the Drugs Act 1976

07. The FID Quetta is submitted for placement before CLB for its consideration and permission of **prosecution against Mr. Muhammad Ashraf proprietor of M/s Kozak Traders Quetta along with M/s Allah Waley Food Products Trading Town Hall Multan and M/s Welldone Pharma Multan.**

***Permission for Show cause Notice to prosecute.***

8. It is therefore submitted that ***Muhammad Ashraf (CNIC No.: 54400-4016531-7) proprietorM/s Kozak Traders Archer Road Quetta through along with M/s Allah Waley Food Products Trading Town Hall Multan and M/s Welldone Pharma Multan*** may be served with show cause notice for selling of unregistered and manufacturing of drugs without manufacturing license.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

09. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Kozak Traders Archer Road Quetta through its proprietor Muhammad Ashraf
2. Muhammad Ashraf proprietor M/s Kozak Traders Archer Road Quetta
3. M/s Allah Waley Food Products, Trading Town Hall, Multan
4. M/s Welldone Pharma (Nutraceutical Division), Multan

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

10. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No. II: MANUFACTURING AND SELLING OF SPURIOUS AND UN-REGISTERED DRUG NAMELY INJ. EXIR 1 GM B.NO. A0001.**

**That** Mr. Syed Abdul Saleem, FID Quetta forwarded vide letter No.F.SAS-140-141/2009-FID(Q)/198 dated 10thMarch 2010. The FID Quetta stated that during visit M/s Malik & Sons Dr. Bano Road Quetta on 10-11-2009 during the visit sample of drug namely Inj. Exir 1gm B.No. A0001 claimed to be manufactured by M/s Winner Pharmaceuticals Pvt Ltd Korangi Industrial area Karachi was taken along with other samples of the drugs for the purpose of test analysis.

02. The FID Quetta submitted that the sealed sample of Inj. Exir 1gm B.No. A0001 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID (Q) -12 dated 11-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009 with advise to rpvide the copy of registration along with acknowledgment of its receipt but no response from your side is received as yet.

03. The Federal Government Analyst CDL karachi vide issued test report bearing No. SCD.479/2009 dated 21-12-2009 without final opinion but with remarks as Since registration number of Drug Product is not available therefore laboratory is unable to decide the quality and regulatory compliance .

04 M/s Malik and Sons Quetta submitted copy of invoice bearing No. 1170 dated 18.10.2009 M/s Winner Pharmaceuticals Pvt Ltd Karachi was served with a show cause notice bearing No. SAS-140-141/2009-FID(Q)/23 dated 20-11-2009 to explain its position for selling said un registered drug but same is received back undelivered. The copy of said notice was also endorsed to the Deputy Director General (E&M) Karachi with request address of said manufacturer may kindly be verified and inspection of premises may be inspected through are FID Karachi but no response is received as yet. On receipt of test report of CDL Karachi show cause notice again issued to M/s Winner Pharmaceuticals Pvt Ltd Karachi vide No. F.SAS-140-141/2009-FID(Q)/131 dated 08-01-2010 but same again received back un delivered M/s Malik & Sons Quetta was also served with a show cause notice vide letter No.F.SAS-140-141/2009-FID (Q)/132 dated 08.01.2010 but no response in this regard is received as yet.

05. The FID Quetta stated of above mentioned facts of the case it reveled that M/s Malik &Sons Quetta is involved in manufacturing and selling spurious and un-registered drug namely Inj.Exir 1gm in name of M/s Winner Pharmaceuticals Pvt Ltd Karachi which is fake firm and violated section 23(1)(a)(x) 23(1)(c) and 27(3) of Drug Act 1976 it is added that before considering the case against M/s Malik & Sons Quetta the existence of manufacturer i.e. M/s Winner Pharmaceuticals Karachi may kindly be verified through are FID Karachi as same is still awaited which is also mentioned above.

06. The FID Quetta submitted the above mentioned facts and requested to the CLB and CLB for its consideration and **permission of prosecution against M/s Malik & Sons Quetta for above mentioned violation.**

***Permission for Show cause Notice to prosecute.***

07. It is therefore submitted that ***Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor* M/s Malik & Sons,Dr. Bano Road, Quetta**may be served with show cause notice for selling of unregistered and manufacturing of drugs without manufacturing license.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

08. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Kozak Traders Archer Road Quetta through its proprietor Muhammad Ashraf
2. Muhammad Ashraf proprietor M/s Kozak Traders Archer Road Quetta
3. M/s Allah Waley Food Products, Trading Town Hall, Multan
4. M/s Welldone Pharma (Nutraceutical Division), Multan

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

09. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No. III** **MANUFACTURING STOCKING FOR SALE AND SELLING OF UN-REGISTERED DRUG NAMELY SYP ZING B.NO.RP799 MFG BY REIGN NUTRO PHARMA PVT LTD KARACHI.**

That Mr. Syed Abdul Saleem, FID Quetta forwarded vide letter No.SAS-21-2010-FID(Q)/344 dated 12th May 2010. The FID Quetta stated that during visit AMN Traders Quetta on 18.03.2010 and a sample of drug namely Syp Zing B.No. RP799 claimed to be manufactured by M/s Reign Nutro Pharma Pvt Ltd Karachi marketed by M/s Nexsus Pharma Pvt Ltd karachi was drawn along with other samples of drug on Form -3.

02. The FID Quetta submitted that the sealed sample of Syp Zing B.No.RP799 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-21-22/2010-FID (Q) -222 dated 19-03-2010 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-21-22/2010-FID(Q)/222 dated 19-03-2010.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi declared said sample of drug as un-registered vide his test report No. R.281/2010 dated 07.04.2010.

04. M/s Reign Nutro Pharma Pvt Ltd karachi was served with a show cause notice vide his letter No. SAS-21/2010-FID(Q)/273 dated 12.04.2010 to explain its position for manufacturing and sale of un-registered drug namely Syp Zing B.No.RP799.

05. M/s Reign Nutro Pharma Pvt Ltd Karachi submitted its reply vide its letter dated 19.04.2010 wherein stating that they stopped further manufacturing of said unregistered drug and applied to the Ministry of Health for Drug Manufacturing License The firm also submitted the site verification report beraring No. F.3-3/2010-FID(K)-III dated 30.03.2010 of proposed site of the said manufacturing unit issued by Mr. Abdul Rasool Sahikh FID Karachi. The firm further added that the site plan of the manufacturing unit has also been sent to the Ministry of Health

In light of the test report No. R.281/2010 dated 07.04.2010 of FGA, M/s Reign Nutro Pharma Pvt Ltd Karachi had violated the section 23(1)(a)(x) 23(1)(a)(x) 23(1)(c) of Drug Act 1976

06. The FID submitted the case for placement before the CLB &CLB for its consideration and further guidance on the matter as firm had stopped further manufacturing of said un registered drug and applied for Drug manufacturing License under Drug Act 1976.

07. The M/s Reign Nutro Pharma Pvt ltd 213, Block-A SMCHS karachi served a show cause notice vide letter No.3-58/2010-DDC(QC-I) dated 20th September 2010 and the firm was called for personal hearing before the Drug Registration Board on 13.10.2010 at 10:00am in Ministry of Health. The firm had replied and stated that they already attended a personal hearing in the 227 registration board meeting regarding this type of matter dated August 27th August 2010 at Ministry of Health the firm informed that they have stopped manufacturing since February 25th, 2010.

08. ***The matter was wrongly placed before the DRB and the said Board in its 228th meeting decided to issue warning to the accused persons.***

***Permission for Show cause***

09. It is therefore submitted that M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui through its Chief Executive, Farhan Khan may be show caused for manufacturing and selling of **unregistered** and drugs without manufacturing license.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

10. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui through its Chief Executive, Farhan Khan
2. Farhan Khan, Chief Executive, M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

12. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

Case No IV:- **MANUFACTURING Stocking for sale and selling of UN-REGISTERED DRUG NAMELY Prozinc B.No.RP796 Mfg by Reign Nutro Pharma Pvt Ltd Karachi**

 That Mr. Syed Abdul Saleem, FID Quetta forwarded vide letter No.SAS-158/2009-FID(Q)/206 dated 16thMarch 2010. The FID Quetta stated that during visit M/s Fine Enterprises Quetta on 12.11.2009 and a sample of drug namely Syp Prozinc B.No. RP796 claimed to be manufactured by M/s Reign Nutro Pharma Pvt Ltd Karachi was drawn along with other samples of drug on Form -3.

02. The FID Quetta submitted that the samples was sent to the Government Analyst, Central Drug Laboratory, Karachi on Form-4 vide his office memorandum No. SAS-157-158/2009-FID (Q) -16 dated 12-11-2009 a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-157-158/2009-FID(Q)/222 dated 12-09-2010.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi declared said sample of drug as **un-registered and substandard**vide his test report No. RSCD.497/2009 dated 31.12.2009.

04. M/s Reign Nutro Pharma Pvt Ltd Karachi was served with a show cause notice vide his letter No. SAS-158/2009-FID(Q)/127 dated 06.01.2010 to explain its position for manufacturing and sale of **un-registered and substandard**drug namely Syp Prozinc B.No.RP96.

05. M/s Reign Nutro Pharma Pvt Ltd Karachi submitted its reply vide its letter dated 14.01.2010 wherein stating that the said product is food supplement and being manufactured in collaboration with PCSIR Laboratories Karachi The firm also submitted references from FDA USP etc along with its reply but it revealed that the certification and interpretation of the firm has contradiction and mis-represented by calming false statement/ references on label as FDA approved and USP specification and alo offer for treatment as drug for cure of disease without establishment of official references for growth retardation in children prevention of Diarrhea attention disorder delayed wound healing anoxia and hair loss. This is clear violation of Drug Act 1976.

06. M/s Reign Nutro Pharma Pvt Ltd Karachi again asked vide office letter No. SAS-158/2009-FID(Q) /173 dated 11.02.2010 for clarification of some points and required information/documents but no response is received as yet.

07. Keeping in view of above stated facts it revealed that M/s Reign Nutro Pharma Karachi involved in manufacturing and selling of Unregistered and substandard drug namely Prozinc syrup and violated the section 23(1)(a)(vii) 23(1)(a)(v) 23(1)(a)(x) 23(1)(b) 23(1)(c) 23(1)(h) and 27 (3) of Drug Act 1976. ***The matter was wrongly placed before the DRB and the said Board decided to issue warning to the accused persons in its 227th Meeting held on 27th August, 2010.***

***Permission for Show cause Notice.***

08. It is therefore submitted that M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui through its Chief Executive, Farhan Khan may be show cause notice for manufacturing and selling of unregistered and substandard drugs without manufacturing license.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

09. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui through its Chief Executive, Farhan Khan
2. Farhan Khan, Chief Executive, M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

10. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No.V: Import and sale of un-registered Drug Namely Caps Flexeze. B,No. 901121 Mfg by M/s Gold Shield Crooxt, UK Marketed by M/s Biogenics Pakistan Pvt Ltd Karachi.**

That Mr. Syed Abdul Saleem, FID Quetta forwarded vide letter No.F.SAS-86/2009-FID(Q)/201 dated 11thMarch 2010. The FID Quetta stated that during visit Haji Nizamuddin & Sons Quetta on 01.10.2009 during the visit sample of drug namely Caps Flexeze Batch No. 021121 claimed to be manufactured by M/s Gold Shield Crooxt UK marketed by M/s Biogenics Pakistan Pvt Ltd Karachi was taken along with other samples of drugs on Form-3.

02. The FID Quetta submitted that the sealed sample of Caps Flexeze B.No.021121 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-84-93/2009-FID (Q) dated 05-10-2009 a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-86/2009-FID(Q)/3036 dated 09-10-2009 with advise to provide the copy of registration along with acknowledgment of its receipt but not response is received as yet.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report bearing No.729/2009 dated 30-12-2009 **declared the Un-registered.**

04. M/s Biogenics Pvt Ltd Karachi was served with a show cause notice bearing No. SAS-86/2009-FID (Q)/116 dated 04.01.2010 to explain its position for selling said unregistered drug M/s Biogenics Pakistan Pvt Ltd Karachi submitted its reply without required documents/information vide its letter dated 18.01.2010 stating that said drug is nutritional supplements and quoted references but not any documentary evidence was found attached with its reply it is further added that the same formulation i.e. AscoCLBic Acid and Glucosamine is being manufactured and registered with different manufactures in different brand names but said firm imported it as nutritional supplement without having registration.

FID stated that the firm also submitted copy of letter No.PQCB/Rp.179-11/2009 dated 25-22-2006 of Secretary PQCB Punjab through which the District QCB was directed not to launch prosecution against the firm in Drug Court M/s Biogenics Pakistan Pvt Ltd Karachi was again asked to provide information/ documents and also current status of the case with Provincial Quality Control Board Punjab vide this office letter No. SAS-86/2009-|FID(Q)/116 dated 06.02.2009 but not reply response is received as yet.

05. The FID Quetta submit the above mentioned facts and revealed that the firm has violated the section 23(1)(a)(vii), 23(1)(e),23(1)(f) and 27(3) of the Drugs Act 1976

06. The FID Quetta is submitted for placement before CLB for its consideration and **permission of prosecution against M/s Biogenics Pakistan Pvt Ltd Karachi**.

***Permission for Show cause***

07. It is therefore submitted that **NasirMehmood, GM Technical Operations of M/s Biogenics Pakistan Pvt Ltd Karachi**and M/s **Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital through it owner/proprietor i.e. Fawad Mehmood**may be served show caused for manufacturing and selling of **unregistered** and drugs without manufacturing license.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

08. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

* + - 1. M/s Biogenics Pakistan Pvt Ltd Karachi through Nasir Mehmood, GM Technical Operations
			2. NasirMehmood, GM Technical Operations of M/s Biogenics Pakistan Pvt Ltd Karachi
			3. M/s Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital through it owner/proprietor Fawad Mehmood
			4. Fawad Mehmood, owner/ proprietor M/s Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

09. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No. VI:- Stocking for sale and selling of un-registered drugs by M/s. Al-Hamd, medical store, Kuchlak, Quetta.**

**01 Proceeding and Decision of 227th Meeting of CLB:**

That F.I.D, Quetta alongwith F.I.A raided Al-Hamd Medical Store, situated by pass road Kuchlak, Quetta from and recovered/ seized un-registered medicines (Hi Tulsi containing Sildenafil Citrate, Vega 100 tablets containing Sildenafil Citrate, Deuroran-50 tablets containing Diclofenac Sodium, Voren Tablet containing Diclofenac Sodium etc). Occupant of the premises Ham-Ullah s/o Muhammad Shah failed to provide any drug sale license, warranty etc for the seized stock. Sample sent to Central Drugs Laboratory, Karachi has been declared Un-Registered by the Federal Government Analyst. F.I.R was launched by the F.I.A against Hamd-Ullah and Shafi-Ullah. F.I.A has recently submitted the Challan to F.I.D, Quetta. Which was faxed by the F.I.D just a day before meeting. The Board was informed that on receipt of complete case from F.I.D, as per procedure, show cause notices will be issued to the accused and they will be offered opportunity of personnel hearing before a decision by the Board.

**Decision of 227th Meeting of CLB:-**

The Board instructed the F.I.D to submit complete case immediately so that show cause notices be issued to the accused. The Board further authorized its Chairman to grant personnel hearing to the accused and take appropriate decision on behalf of the Central Licensing Board.

02. That Mr. Syed Abdul Saleem, FID Quetta forwarded the case vide letter No.12-7/DCA-QTA/Al-Hamd Medical Store-580 dated 08th June 2011. The FID Quetta stated that during visit some un-registered drugs were found available without having Drug Sale license. The FID ordered Not to dispose of all available stocks of said drugs the same was reported the Chairman CLB for extension of time of said orders vide this office letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 (copy Annex B) and subsequent request vide No.F.12-1/DCA-QTA/M survey 75 dated 12.12.2009 (copy annex C) a sample of drug namely IRO-C, B.No.123 claimed to be manufactured by M/s Welldone Pharma Nutraceuticals Division Multan was also taken along with other samples of drugs for the purpose of test/analysis

03. Challan is submitted by Investigation officer FIA on 19-03-2011 registered the case was registered against accused Hamdullah S/o Muhammad Shah was arrested and transfer to judicial lock up however another accused Shafiullah S/o Muhammad Shah still not arrested and FIA has strong efforts for arrest him.

On 19-03-2011 as per information Hamdullah and Shafiullah S/o Muhammad Shah cast Sulemankhail resident of Kuckhlak owner of Alhamd Medicine Agency Kuchlak trade illegally un registered spurious, substandard medicines business so under the supervision of Mr. Habibullah Naran Assistant Director ACW, FIA Quetta along with inspector Muhammad Hashim, Inspector Hukum Dad, ASI Bahadur Khan Bazai, Muhammad Zaman HC, Muhammad Sidique FC and Muhammad Hanif, Kuckhlak Bye Pass, and FID Quetta Mr. Syed Abdul Saleem. The person present at Alhamd medicine Agency informed that his name is Hamdullah S/o Muhammad Shah and stated that he along with his brother Shafiullah are linked with business of medicines and for this they hold license by way of whole sale in the name of Shafiullah but he could not furnish any permit or license regarding presence of foreign medicines in his shop. That the Federal Drug Inspector Syed Abdul Saleem cheked all available medicines in the shop who declared all the medicines as unregistered and foreign origin and stated that these medicines does not belong to any registered company in Pakistan hence he took samples for the purpose of test/analysis from all medicines individually and as prescribed handed over other medicines to the custody of FIA. As prescribed the accused Hamdullah was arrested and after completion of investigation has been transferred to Judicial Lockup. Accused Shafiullah who ran off to avoid arrest, whose arrest warrant was obtained from the court of competent jurisdiction. The mentioned accused got arrested on 04-06-2011 after cancellation of interim bail as prescribed and after completion of investigation has been transferred to Judicial Lockup on 18-06-2011. Many evidences are available on record against the accused shafiullah. The Challan against the accused Hamdullah along with all relevant record has been handed over to Federal Inspector of Drugs on 09-04-2011. Hence, it is prayed vide this letter along with sent record that this initial report against accused Hamdullah and this report against accused Shafiullah, the Challan is prepared to be sent to the Court of Competent Jurisdiction for the purpose of prosecution/hearing.

04. Show cause notice was issued to the accused vide letter no. 13-20/2019-QC dated 22.03.2019. The copy of the same was forwarded to Officer In-Charge Quetta @ Karachi with request to ensure the delivery of this letter to the accused and acknowledge the receipt. The acknowledgement receipt was forwarded by AD, DRAP, Quetta vide letter NO.
12-7/DCA-QTA/Al-Hamd Medical Store-72 dated 17.06.2019.

**Submitted for show cause notice to prosecute:**

05. It is therefore submitted that **Hamdullah S/o Muhammad Shah R/o Killi New Khoratabad, District Quetta, Shafiullah S/o Muhammad Shah R/o Killi New Khoratabad, District Quetta and Al-hamd medical Store, Quetta through its owner/proprietor**may be served show caused for violations conveyed to the accused persons vide show cause notice dated 22.03.2019.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

06. Request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @Karachi vide letter No.3-1/2019-FID (Q) K dated 5th August, 2019, the case was placed before the Central Licensing Board. Furthermore, the matter was also referred by the Honourable Chairman, Drug Court Balochistan, Quetta. The Board deliberated the matter in depth, considered the facts of the case and perused the available record. It was revealed that a showcause notice for prosecution has been issued vide letter No. 13-20/2019-QC dated 22.3.2019 for which acknowledgement receipt has been forwarded by Assistant Director, DRAP, Quetta vide letter No. 12-7/DCA-QTA/Al\_Hamd Medical Store-72 dated 17.06.2019. Keeping view the facts the Board decided that all the accused persons may be given final opportunity of personal hearing either in person or through authorized counsel may be afforded in the forthcoming meeting of the Board.

**Case No. VII:- STOCKING FOR SALE AND SELLING UN REGISTERED DRUGS SEIZURE ON FORM-2 – M/S ZARGHOON VETERINARY QUARRY ROAD QUETTA.**

 Mr. Syed Abdul Saleem, FID Quetta forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 180 dated 16th February 2010. The FID Quetta visited along with FIA to **M/s Zarghoon Veterinary Quarry Road Quetta** 04.11.2009 during the visit some unregistered drugs were found placed in its godown located at Room No.2 ACLBab Plaza Road Quetta The FID seized the all available stocks of unregistered drugs on Form-2 it is further added that stocking for sale and sale of unregistered drugs is violation of provisions of Drug Act 1976 and Rules made there under. The details of the seized stock as under:-

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| S.No. | Name of Drug  | B.No. | Quantity  | Mfg date  | Exp date  | Purported by Mfg by |
| 01. | Albendazole 150mg  | 090310 | 50 botles 1x500 | 03-2009 | 03-2012 | Made in China |
| 02. | Sulphadimiciline 600 | 090310 | 50 bottles x1x400 | 03-2009 | 3-2012 | Made in China |
| 03. | Niclosemide 125mg | 090309 | 50 bottles x1x370 | 03-2009 | 3-2012 | Made in China |
| 04. | Niclosam 125mg  | 090320 | 100 bottles x1x100 | 03-2009 | 3-2012 | Made in China |
| 05. | Deyletsrcyeline 50mg/ml | 090770 | 50mlx1x190 | 07-2009 | 7-2012 | Made in China |
| 06. | Noromcetine Injection | 090773 | 50mlx1x80 | 07-2009 | 7-2012 | Made in China |
| 07. | Alamycine-LA | 090771 | 50mlx1x320 | 07-2009 | 7-2012 | Made in China |

02. The same was reported for further instructions/guidance on the matter and permission of safe custody of seized stocks of unregistered drugs vide office letter No.F.12-1/DCA-QTA/M.Survey dated 05.11.2009 and subsequent request vide letter No.12-1/DCA-QTA/M Survey/80 dated 12.12.2009

03. M/s Zarghoon veterinary Quetta was called to explain its position for stocking for sale and selling unregistered drugs vide letter No.F.12-1/DCA-QTA/M.Survey-44 dated 15.11.2009 but no response is received as yet.

04. The FID Quetta is submitted the case for placement before CLB for its consideration and permission of **prosecution against Khushhal Khan Proprietor Mr.Rahat Ahmed Qualified person and Mr. Khuda-e-Noor persons present of M/s Zarghoon Veterinary Quarray Road Quetta for stocking for sale and selling unregistered drugs.**

**Submitted for show cause notice to prosecute:**

05. It is therefore submitted that **Khushhal Khan Proprietor, Rahat Ahmed Qualified person and Khuda-e-Noor persons present of M/s Zarghoon Veterinary, Quarray Road, Quetta** may be served show caused **for stocking for sale and selling unregistered drugs**.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

06. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

* + - 1. M/s Zarghoon Veterinary, Quarray Road, Quetta through Khushhal Khan Proprietor
			2. Khushhal Khan Proprietor, M/s Zarghoon Veterinary, Quarray Road, Quetta
			3. Rahat Ahmed Qualified person M/s Zarghoon Veterinary, Quarray Road, Quetta
			4. Khuda-e-Noor persons present of M/s Zarghoon Veterinary, Quarray Road, Quetta

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

07. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No. VIII:** **MANUFACTURING DRUGS WITHOUT HAVING DRUG MANUFACTURING LICENSE STOCKING FOR SALE SELLING UN-REGISTERED DRUGS IN SHAPE OF NUTRITIONAL SUPLIMENT AND KEEPING PHYSICIAN SAMPLE OF REGISTERED DRUGS \_- RANA TRADERS, QUETTA.**

That Mr. Syed Abdul Saleem Shah forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 179 dated 16th February 2010. The FID Quetta informed that during visited along with FIA team to M/s Rana Traders Flat No.1, 1st Floor Saleem Medical Complex Jinnah Road Quetta 11.11.2009 during the visit some unregistered drugs were found available with claimed to have nutritional/food supplements but suspected to have allopathic ingredients along with labels of registered drugs and physician samples of registered drugs were found placed in ready shelves for sale with other registered drugs. The FID Quetta ordered seized all available stocks of said un-registered drugs and labels on Form-2. The FID Quetta further informed that stocking for sale and sale of unregistered drugs and keeping labels of registered drugs is violation provision of Drugs Act 1976 and rules frame there under. The details of the seized products as under

|  |  |  |
| --- | --- | --- |
| 1. Ronil Tabs
 | M/s Bio Naturo Lahore  | Unregistered |
| 1. Calcid D3 Cap
 | M/s SPC Ltd Lahore  | Unregistered |
| 1. Lakostat Cap
 | M/s Sehafi Natural Lab Lahore  | Unregistered |
| 1. Semen Tab
 | M/s BiocareNeturo Kraft Lahore  | Unregistered |
| 1. Rebion Tab
 | M/s Muwadat Pharma Lahore  | Unregistered |
| 1. Iromums Tab
 | -do- | Unregistered |
| 1. IsonimsSyp
 | -do- | Unregistered |
| 1. Irocal-M Tab
 | M/s Mason Lahore  | Unregistered |
| 1. Irocal-M tab
 | -do- | Unregistered |
| 1. Irocal-M tab
 | M/s Naturo Kraft Lahore  | Unregistered |
| 1. Iro C sachet
 | -do- | Unregistered |
| 1. Oro-C Sachet
 | M/s Cosmo Pharma Karachi | Unregistered |
| 1. RonilSyp
 | M/s Muwadat Pharma Lahore  | Unregistered |
| 1. RemaltSyp
 | -do- | Unregistered |
| Details of Printed empty carton/Label of registered/ unregistered drugs along with quantity seized is as under |
| 1. Canpril tab 10mg
 |  | M/s convell labs Swat  |
| 1. ConrineTabl
 |  | M/s convell labs Swat |
| 1. Veldox Tab
 |  | M/s convell labs Swat |
| 1. Olamsaf tab
 |  | M/s Saaf Pharmaceutical Risalpur |
| 1. Mina Inj 2ml
 |  | M/s Vision Pharmaceutical Islamabad  |
| 1. Bactil 250mg cap
 |  | M/s convell labs Swat |
| 1. Conflox tab 200mg
 |  | M/s convell labs Swat |
| 1. Meprawin cap 20mg
 |  | M/s WNS field Pharmaceutical Hattar |
| 1. Sajd Inj.2ml
 |  | M/s vision Pharmaceuticals Islamabad  |

02. The FID Quetta stated that the same was reported for further instructions/guidance on the matter and permission of safe custody of said seized unregistered drugs and labels of registered drugs vide letter No.F.12-1/DCA-QTA/M. survey dated 13.11.2009 and subsequent request letter No. F.12-1/DCA-QTA/M. survey 81 dated 12.12.2009. The FID informed that the M/s Rana Traders Quetta was called to explain its position for stocking for sale and selling unregistered drugs and keeping labels of registered drugs vide ltter No. F.12-1/DCA-QTA/M. survey-34 dated 21.11.2009 and on not response a reminder vide letter No. F.12-1/DCA-QTA/M. survey 92 dated 16.02.2009 M/s Rana Traders Quetta submitted its reply vide letter No.RTQ/Drugs/12/2009 dated 18.12.2009. it is mention that the invoice submitted by M/s Rana Traders Quetta for said unregistered drugs were also not verified from the supplier/manufacturers are received back un delivered.

03. The FID Quetta is submitted the case for placement before Central Registration Board for its consideration and permission of prosecution against Mr. Rana Sarwer Shad. Proprietor & Mr. Saleem Mansoor, Qualified persons of M/s Rana Traders Quetta and Mr. Imran Saeed and Rana Anwer Saeed persons present for stocking of sale and selling unregistered drugs and keeping labels of registered drugs at your earliest possible

**Submitted for show cause notice to prosecute:**

04. It is therefore submitted **that Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor & Saleem Mansoor S/o Nazeer Ahmed, Qualified persons of M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta and Imran Saeed and Rana Anwer Saeed persons present**may be served show causedfor stocking of sale and selling unregistered drugs and keeping labels of registered drugs.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

05. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for stocking for sale and selling of unregistered drugs and keeping labels of registered drugs against the following accused

* + - 1. M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta through Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor
			2. Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta
			3. Saleem Mansoor S/o Nazeer Ahmed, Qualified persons of M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta
			4. Imran Saeed persons present M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta
			5. Rana Anwer Saeed persons present M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

06. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No. IX.** **STOCKING FOR SALE AND SELLING UNREGISTERED DRUGS ALONG WITH REGISTERED DRUG WITHOUT HAVING DRUG SALE LICENSE – M/S BILAL VETERINARY, QUETTA**

 Mr. Syed Abdul Saleem Shah forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 181 dated 16th February 2010. The FID Quetta informed that during visited along with FIA team to M/s Bilal Veterinary Mecongy Road Quetta 04.11.2009 during the visit some unregistered drugs were found placed in ready shelves for sale with other registered drugs as well as in its godown adjacent to it during visit Mr. Ali Khan claimed proprietor failed to produce in his Drug Sale License The unregistered seized the all stocks of unregistered drugs on Form-2 The FID Quetta further added that socking for sale and ale of unregistered drugs is violation of provisions of Drug Act 1976 and rules framed there under. The details of the seized drugs as under:-

|  |
| --- |
| 1. **M/s Bilal Veterinary Mecongy Road, Quetta.**
 |
| 1. Ivectin 1% inj
 | Unregistered  | M/s Razak Lab Tehran Iran |
| 1. Ivectin 3% Inj.
 | Unregistered | -do- |
| 1. Ivectin 5% Inj
 | Unregistered | -do- |
| 1. Ivectin 5%
 | Unregistered | -do- |
| 1. OxyteracycleneInje. 50mg/5ml
 | Unregistered  | M/s Shanghai Medicine china  |
| 1. Dehorning Paste
 | Unregistered | M/s is not readable  |
| 1. Oxytetracycline Injection 50mg
 | Unregistered | M/s Shanghai Medicine china |
| 1. Albandazole Oral susp2.5%wv
 | Unregistered | M/s Cipla Ltd Mumbai India  |
| 1. Albandazole Oral susp2.5%wv
 | Unregistered |  |
| 1. Loramisole Granules
 | Unregistered | Made in Iran  |
| 1. Calciject-40 solution for injection
 | Unregistered | M/s NooCLBook Lab Ltd Northern Irelan |
| 1. Ciprofloxacin Powder 20mg
 | Unregistered | M/s Made in Iran  |
| 1. Multivitamin Sacet
 | Unregistered | M/s Made in Iran  |
| 1. Pen & Strep suspension for Injection
 | Unregistered | NooCLBook Labs Ltd Carlisle  |
| 1. Triclaz 250 Bouls
 | Unregistered | M/s Razak Lab Tehran Iran  |
| 1. Sulphadimine 2.5gm
 | Unregistered | Made in Iran |
| 1. Albandazole 152 mg
 | Unregistered | M/s Domlgran Pharma |
| 1. Mac tac 125%
 | Unregistered | M/s Made in Iran  |

02. The FID Quetta stated that the same was reported for further instructions/guidance on the matter and permission of safe custody of said seized unregistered drugs and labels of registered drugs vide letter No.F.12-1/DCA-QTA/M. survey dated 06.11.2009 and subsequent request letter No. F.12-1/DCA-QTA/M. survey 78 dated 12.12.2009. The FID informed that the M/s Bilal Veterinary and poultry Services Quetta was called to explain its position for stocking for sale and selling unregistered drugs and keeping labels of registered drugs vide ltter No. F.12-1/DCA-QTA/M. survey-36 dated 23.11.2009. M/s Bilal Veterinary Quetta submitted its reply through Mr. Muhammad Akram Sales man informed that proprietor went to Karachi for treatment of his child and requested for grant of time of one month period for proper reply on the matter vide letter No. Nil dated 03.12.2009 and no further reply is received as yet

03. The FID Quetta is submitted the case for placement before Central Registration Board for its consideration and **permission of prosecution against Mr. Ali Khan Proprietor of M/s Bilal Veterinary Mecongy road Quetta for stocking of sale and selling unregistered drug without having Drug Sale License at your earliest possible**

**Submitted for show cause notice to prosecute:**

04. It is therefore submitted that **Ali Khan Proprietor of M/s Bilal Veterinary Mecongy Road Quetta** may be served show caused **for stocking of sale and selling unregistered drug without having Drug Sale License**.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

5. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for stocking for sale and selling of unregistered drugs without having Drug Sale Licence against the following accused

* + - 1. M/s Bilal Veterinary Mecongy Road Quetta through Ali Khan S/o Sarfroz Khan , Proprietor
			2. Ali Khan S/o Sarfroz Khan (CNIC No. 54400-034418-5) R/o H. No. 10, Ghora (Veterinary ) Hospital Colony, Quetta Proprietor of M/s Bilal Veterinary Mecongy Road Quetta

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

06. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No.X:- MANUFACTURE AND SALE OF SUBSTANDARD UNREGISTERED AND MISBRAND DRUG NAMELY CM 1000 TABS B.NO.001**

Mr. Usman Hameed FID Quetta, submitted that then FID Mr Muhammad Adnan Faisal Saim visited the premises of M/s Seema Marketing 201-2nd Floor Universal Complex Quetta on 03-08-2005 and took samples of CM 1000 Tablets labeled to be manufactured by M/s Painex Pharma Germany along with the others samples for the purpose of test analysis on prescribed Form-3 along with copy of CNIC No.38403-3018079-4.

02. As per information of FID Quetta the sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide office memorandum No.F/5/DCA-QTA/Sample-3332A dated 05-08-2005 on form-4 under Section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB and CLB Islamabad vide letter No.F.5/DCA-QTA/Sample-3334 dated 05-08-2005 under section 19(3)(ii) of Drug Act 1976. The firm M/s Seema marketing Quetta was sent various reminders to provide the invoices bill warranties for the said drugs vide letter No.F.5/DCA-QTA/Sample-3362 dated 12-08-2005, .F.5/DCA-QTA/Sample-3577 dated 07-10-2005 and .F.5/DCA-QTA/Sample-4031 dated 24-12-2005 under Section 23(1)(j) of Drug Act 1976 but the firm failed to provide the requisite information.

03. That the Government Analyst CDL Karachi declared the sample C.M1000 Tablet B.No.001 mfg by M/s Painex Pharma Germany as Substandard un registered and Misbranded drug vide test report No.R1899/2005 dated 25-09-2006 copy of test analysis certificate is enclosed as required under section 22(3)© of Drug Act 1976.

04. In light of Government Analyst, CDL, Karachi a show cause notice was issued vide letter No.F.12-21/2006 DCA Sample-1106 dated 13-03-2007 was accordingly issued to M/s Seema Marketing Quetta for explaining the position in the matter of manufacturing and selling of the above mentioned Misbranded and substandard Drug and not providing the invoices bill warranty in respect of said drug.

05. The FID informed that the above referred letter is returned back by Pakistan Post on 03-04-2007 with remarks that the office of Seema Marketing has been shifted from the 201 Phase No.2ndFloor Universal Complex Quetta The firm have violated section 23(1)(a)(iii)(V) and (vii) and section 23(1)(h)(i) of Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi

**Submitted for show cause notice to prosecute:**

06. It is therefore submitted that **Mudassir Rafique& Chaudhary Rabina Warraich (NSM/Proprietor), M/s** Seema Marketing, Phase No.2, 2ndFloor Universal Complex Quetta may be served show caused **for stocking of sale and selling unregistered, Misbranded and Substandard drug**.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

07. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for stocking for sale and selling of unregistered, misbranded and substandard against the following accused

1. M/s Seema Marketing, Phase No.2, 2ndFloor Universal Complex Quetta through Mudassir Rafique, Proprietor
2. Mudassir Rafique, Proprietor M/s Seema Marketing, Phase No.2, 2ndFloor Universal Complex Quetta
3. Chaudhary Rabina Warraich NSM, M/s Seema Marketing, Phase No.2, 2ndFloor Universal Complex Quetta

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

08. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No. XI:- STOCKING FOR SALE AND SELLING COUNTERFEIT DRUGS IN SHAPE OF HOMOEO MEDICINES SEIZURE ON FORM-2 – M/S UNIQUE TRADERS, QUETTA**

Mr. Syed Abdul Saleem, FID, Quetta informed that during visit M/s Unique Traders, Bolan Medicine Plaza, Dr. Bano Raod, Quetta on 10.11.2009 un-registered/counterfeit drugs claimed to be homoeo medicines suspected to have allopathic ingredients were found placed in ready shelves for sale with other registered drugs The said counterfeit drugs deceive general public by presenting and offering for treatment and regulatory authorities by placing as homoeo medicines it was also observed that the names color scheme font shape of tablets and blisters are very much resembled with well known registered drugs the unregistered seized all available stocks of said counterfeit drugs on Form 2. The M/s Unique traders Quetta called for show the cause and explain the position for stocking for sale and selling counterfeit drugs with claimed to have homoeo medicines

02. The FID Quetta requested to Chairman CLB that necessary guidance and permission of safe custody of said seized drugs

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of Drug** | **B.No.** | **Quantity**  | **Mfg date** | **Exp date** | **Purported to be mfg by**  |
| Mintodine tablet  | Fc No. MP/203 | 1x45 | 10-2010 | 5 years  | M/s S.H Pharmacy Hyderabad |
| Homzole Tablet | 001 | 500 tabletx1x13 | 7-2009 | 5 years  | M/s Home Homeo Lab Karachi |
| Becofen 400 | KBF-002 | 250 tabletsx1x13 | 04-2009 | 04-2014 | M/s KB Pharmacy Hyderabad  |
| Kamdex-N Cream | FC.No.KN033 | 15gmx1x100 | 10-08 | 05 years  | M/s S.H Pharmacy Hyderabad  |
| Basopan Tablet | B.No.DA/013 | 100 tabletsx1x6 | 07-07 | 3 years  | M/s Rana Pharma karachi |

03. Submitted for the grant of safe custody of the seized drugs.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

04. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to grant permission for safe custody of seized stock till decision of the case. The Board further directed area Federal Inspector of Drugs, Quetta to complete investigation on priority and submit his report for consideration in forthcoming meeting of the Central Licensing Board.

**Case No. XII:- IMPORT AND SALE OF UNREGISTERED DRUGS IN SHAPE OF NUTRITIONAL SUPLIMENT ORDERED NOT TO DISPOSE OFF – SHAHEEN MEDICINE AGENCY.**

Mr. Syed Abdul Saleem FID Quetta informed that during visit M/s Shaheen Medicine Agency Flat No. 1,2nd Floor Rana Plaza Archer Road Quetta 07.11.2009 during the visit some unregistered drugs namely Q-Role Soft Gel b.No.364658 claimed to be manufactured by M/s NHK Labs Sante FE Springs USA Imported by M/s MPC and Tabs. Vivit B.No.82081020 claimed to be imported and re-packed by M/s RSA Faisalabad were found placed in ready shelves for sale with other registered drugs The FID Quetta orderee Not to dispose of all available stocks of said unregistered drugs on Form-1 for a period of 14 days it is further added that stocking for sale and sale of unregistered drugs is violation of provisions of Drugs Act 1976 and Rules made there under. The details of the seized products as under:-

|  |
| --- |
| 1. **M/s Shaheen Medicine Agency Archer Road, Quetta**
 |
| 1. Vivit tablet Batch No.820081020
 | Imported & Repacked by M/s RSA Faisalabad  | Unregistered |  |  | As per available record in the Quality Control Section i.e Diary dispatch/register record, files record and Computerized record have not shown this case record after checking available record of the section  |
| 1. Q-Role Softgel
 | M/s NHK Lab Santa USA | Unregistered  |  |  | -do- |

The same was reported for further instructions/guidance on the matter and extension of said orders of unregistered drugs vide letter No.F.12-1/DCA-QTA/M. Survey dated 09-11.2009 and subsequent request vide letter No. No.F.12-1/DCA-QTA/M. Survey/73 dated 12-12.2009. M/s Shaheen Medicine Agency Quetta was called to explain its position for stocking for sale and selling unregistered drugs vide letter No. No.F.12-1/DCA-QTA/M. Survey 31 dated 21-11.2009 and on not response a reminder vide letter No. No.F.12-1/DCA-QTA/M. Survey/94 dated 17-12.2009 was also issued but not reply is received as yet

The FID Quetta submitted the case for placement before Central Registration Board for its consideration and permission of **Prosecution against Mr. Qaiser Riaz Proprietor and Mr. Qaser Khan Qualified persons of M/s Shaheen Medicine Agency Archer Road Quetta for stocking of sale and selling unregistered drugs at your earliest possible**

**Submitted for show cause notice to prosecute:**

02. It is therefore submitted that**Qaiser Riaz Proprietor and Qaser Khan Qualified persons of M/s Shaheen Medicine Agency Dr. Bano Roada Quetta** may be served show caused**for stocking of sale and selling unregistered drugs**.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

03. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for stocking for sale and selling of unregistered, drugs against the following accused

1. M/s Shaheen Medicine Agency Archer Road Quetta Mr. Qaiser Riaz Proprietor
2. Mr. Qaiser Riaz Proprietor M/s Shaheen Medicine Agency Archer Road Quetta
3. Mr. Qaser Khan Qualified persons of M/s Shaheen Medicine Agency Archer Road Quetta

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

04. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No. XIII: MANUFACTURING AND SELLING OF UNREGISTERED DRUG NAMELY TABS. KALPHOMEX POWDER (FOR VET. USE ONLY) B.NO. ARX-3459**

Mr. Abdul Saleem the then FID Quetta forwarded the case vide letter No.SAS-94-102/2009-FID(Q)/229 dated 25th March 2010 wherein informed that the FID Quetta visited to M/s Chiltan Veterinary Quarry Road Quetta on 06-10-2009 and a sample of drug namely Kalphomex Powder (For Vet Use only) B.No.ARX-3459 claimed to be manufactured by M/s Afrasco laboratories Lahore was taken for the purpose of test/analysis.

02. The sealed sample of above drug with other samples of drugs was sent to the Federal Government Analyst Central Drug Laboratory karachi for the purpose of test analysis vide office letter No.SAS-94-102/2009-FID(Q)-3024 dated 07-10-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing & Registration Board Islamabad vide letter No.SAS-94-102/2009-FID(Q)-3028 dated 07-10-2009 a portion of said sample was also sent to the manufacturer vide letter No.SAS-94-95/2009-FID(Q)-3047 dated 09-10-2009 with advise to provide the copy of registration along with acknowledgment of its receipt.

03. It is to inform that M/s Chiltan Veterinary Quetta submitted invoice No.402 dated 07-08-2009 of M/s Afrasco Laboratories Lahore.

04. That the Federal Government Analyst Central Drugs Laboratory Karachi vide test report No.737/2009 dated 19-11-2009 declared the sample of Kalphomex powder (For Vet use only) as **Unregistered** A copy of test analysis certificate is sent here with under section 22(3) (c ) of drugs Act 1976

05. The firm M/s Afrasco Laboratories Lahore was served with a show cause notice was issued vide letter No.SAS-94-102/2009-FID(Q)-59 dated 05-12-2009 to explain its position for manufacturing and selling the said unregistered drug M/s Afrasco Lab Lahore submitted its reply through its legal advisor Mr. Ahson Mehmood claiming that the said drug contains 100% indigenous sources but no documentary evidence submitted in support of its reply. He further challenged the powers of FID and quoted references The firm was again asked to provide required information/documents as asked vide letter dated 05-12-2009 vide letter No. SAS-94-102/2009-FID(Q)-172 dated 10-02-2010 but again no response is received as yet.

06. In the light of test report of Federal Government Analyst Central Drug Laboratories Karachi the firm M/s Afrasco Lab Lahore violated the section 23(1)(a)(vii) 23(1)(a)(x) 23(1)(b) 23(1)( c) and 27(3) of Drug Act 1976.

07. Keeping in view of above stated facts the case is being submitted for placement before Central Licensing & Registration Board for its consideration and **permission of prosecution against M/s Afrasco Lab Lahore.**

**Submitted for show cause notice to prosecute:**

08. It is therefore submitted that**M/s Afrasco Laboratories, Umar Khan Road,Manawan,Lahoreand Tariq Mehmood S/o Nasarullah Kahn (CNICNo. 54400-9743364-1) address r/o 8-18/4, Kansi Road, Teen Town, Quetta, proprietor chiltan Veterinary, Quarry Raod, Quetta** may be served show caused**for manufacturing and selling of unregistered drugs**.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

09. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for manufacturing and selling of unregistered, drugs against the following accused

1. M/s Afrasco Laboratories, Umar Khan Road,Manawan, Lahore through owner / proprietor
2. M/s chiltan Veterinary, Quarry Raod, Quetta through Tariq Mehmood S/o Nasarullah Kahn proprietor
3. Tariq Mehmood S/o Nasarullah Kahn (CNICNo. 54400-9743364-1) address r/o 8-18/4, Kansi Road, Teen Town, Quetta, proprietor chiltan Veterinary, Quarry Raod, Quetta

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

12. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No.XIV:** **MANUFACTURING AND SELLING OF COUNTERFEIT DRUGS NAMELY BECOFEN 400MG BATCH NO. BKF-002**

FID, Quetta inspected the Business premises of M/s Unique Traders, Dr. Bano Road, Quetta on 10-11-2009, and took the sample of said product on Form-3 in the presence of Proprietor Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta.

The said sample was sent to Federal Government Analyst for the purpose of test/analysis.

The Government Analyst declared the sample as “**Counterfeit**” vide test report No. R.SCD.476/2009 dated 09-12-2009.

That M/s Unique Traders, Dr. Bano Raod Quetta, Submitted invoice/ cash memo No. FM0286 dated 10-10-2009 signed and issued by FM Traders Lajpat Road, Hyderabad.

That M/s FM Traders Lajpal Road, Hyderabad failed to produce invoice warranty of said drug.

That M/s Unique Traders failed to produce warranted invoice and is also responsible for the offence

The case was processed for Registration Board. The due process of law was completed and the accused were served with Show Cause Notice and given chance of personal hearing. The Registration Board in its 228th Meeting decided to prosecute the accused in the Drug Court of competent jurisdiction. Prosecution permission was communicated vide letter no. 03-38/2009-DDC(QC-I) dated 26.01.2011.

**It is therefore requested that permission may be granted to issue show cause notice to the following accused persons for manufacturing and selling of counterfeit product (imitation product of Brufen 400mg of M/s Abbott Laboratories, Karachi):**

1. Proprietor –Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta – M/s Unique Traders, Dr. Bano Road, Quetta.
2. M/s FM Traders, Lajpal Road, Hyderabad through its owner/proprietor

**Proceedings and Decision of 271st meeting of Central Licensing Board**

02. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for manufacturing and selling of counterfeit drugs against the following accused

1. M/s Unique Traders, Dr. Bano Road, Quetta Proprietor –Muhammad S/o Umair
2. Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta – Proprietor – M/s Unique Traders, Dr. Bano Road, Quetta.
3. M/s FM Traders, Lajpal Road, Hyderabad through its owner/proprietor

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

12. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

**Case No.XV: MANUFACTURING AND SELLING OF UN-REGISTERED AND SPURIUOS DRUGS NAMELY SUN-C TABLETS BATCH NO. SP-101 MANUFACTUERD BY SIMILE NUTRITION, PVT LTD, LAHORE**

01 ThatMr. Syed Abdul Saleem, FID, Quetta inspected the Business premises of M/s Malik & Sons, Dr. Bano Road,46 Ahmed Complex,Quetta on 10-11-2009, and took the sample of said product on Form-3 in the presence of Proprietor Zahoor Ahmed S/o Malik Abdul Ghani (CNIC No. 54400-8436784-5).

The said sample was sent to Federal Government Analyst for the purpose of test/analysis vide No.F.SAS-140-141/2009-FID(Q)-12 dated 11-11-2009.

The Government Analyst declared the sample as “**Spurious and Un-registerd**” vide test report No. R.SCD.480/2009 dated 11-12-2009.

That FID issued show cause notice to the M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahroe to explain their position, wherein the firm (M/s Simile Nutition)in their reply,claimed that Vitamin-C is drived from Rose hip and Embilica officinalis, Zinc is derived from wheat germ and calcium carbonate was purchased from bakery stuff vandors which is of food grade.

The case was properly processed forCenteral Licensing Board. The due process of law was completed and the accused were served with Show Cause Notice and given chance of personal hearing. The CLB in its 227th Meeting decided to prosecute the accused in the Drug Court of competent jurisdiction. Prosecution permission was communicated vide letter no. 03-40/2009-DDC(QC-I) dated 28.06.2011.

As the prosecution permission doesn’t contain the names of the accused persons therefore the case is re-submitted for issuance of show cause notices to prosecute the following accused persons:

* + - 1. ***Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor*M/s Malik & Sons,Dr. Bano Road, Quetta**
			2. Wasim Ahmed, M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore
			3. M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore through its Chief executive/MD.

**Proceedings and Decision of 271st meeting of Central Licensing Board**

02. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising ) Rules, 1976 for manufacturing and sale of spurious and unregistered drugs against the following accused

1. M/s Malik & Sons,Dr. Bano Road, Quetta through Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor
2. Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor M/s Malik & Sons,Dr. Bano Road, Quetta
3. Wasim Ahmed, M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore
4. M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore through its Chief executive/MD.

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

* 1. Prosecution in the Court of competent jurisdiction
	2. Any other action the Board may deem fit under the law.

03. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

Meeting ended with the vote of thanks to and by the chair