**CAPACITY ASSESSMENT INSPECTION REPORT OF M/S. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **General Information**   |  |  | | --- | --- | | Name of manufacturer | M/s. | | Physical Address |  | | DML No. |  | | Date of inspection |  | | Purpose of inspection | Assessment and confirmation of manufacturing capacity with reference to DRAP, Islamabad letter No. | | Dosage Form/Sections Included |  | | Composition of Panel |  | | Name of Firm’s Representative (s) accompanying during inspection |  |   Manufacturing and testing record/data was evaluated from **January \_\_\_\_\_\_\_\_ to December \_\_\_\_\_\_\_\_\_** for the said purpose. The details of capacity calculations are as under: |
| **SECTION WISE MANUFACTURING CAPACITY**  **1. CAPACITY OF \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ SECTION (name of first section)**  **NUMBER OF PRODUCTS MANUFACTURED BY THE FIRM**   |  |  |  |  | | --- | --- | --- | --- | | **Section** | **No of products registered for self-manufacturing** | **No of products registered for contract manufacturing** | **Total** | |  |  |  |  | |  |  |  |  | |  |  |  |  | | Total products |  |  |  |   **Manufacturer’s Pending applications** *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  **Contract products Pending applications \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**   |  |  |  | | --- | --- | --- | | **Step wise capacity of \_\_\_\_\_\_\_\_\_\_ manufacturing** | **Maximum production Capacity (\_\_\_\_\_)** | | | **Per day**  (\_\_\_ hour working shift) | **Per month**  (\_\_\_\_\_ working days) | |  |  |  | |  |  |  | |  |  |  | |  |  |  |   ***Note: Limiting step in this process is \_\_\_\_\_\_\_\_\_\_ for calculating Utilized Capacity.***   |  |  |  |  | | --- | --- | --- | --- | | **Quarter Wise capacity utilized in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Section** | | | | | **Quarter** | **Actual Production**  **(\_\_\_\_\_\_\_)** | **Capacity**  **(\_\_\_\_\_\_\_)** | **Capacity utilized in (%)** | | **I** (1st Jan – 31st March \_\_\_\_\_\_\_\_\_\_) |  |  |  | | **II** (1st April – 30th June \_\_\_\_\_\_\_\_\_\_) |  |  |  | | **III** (1st July – 30th Sep\_\_\_\_\_\_\_\_\_) |  |  |  | | **IV** (1st Oct – 31st Dec\_\_\_\_\_\_) |  |  |  | | Average Capacity Utilized for January – December \_\_\_\_\_\_\_\_\_\_\_ | | |  |  |  |  | | --- | --- | | **Manufacturing Capacity Utilized (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | **Manufacturing Capacity Available (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| **2. CAPACITY OF \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ SECTION (name of 2nd section)** |
| **CAPACITY OF QUALITY CONTROL DEPARTMENT**   |  |  |  |  | | --- | --- | --- | --- | | **Quality Control Equipment Detail** | | | | | Sr. No | Equipment | Qty. | Capacity per day (tests) | | 1 |  |  |  | | 2 |  |  |  | | 3 |  |  |  | | 4 |  |  |  | | 5 |  |  |  |   The details of the total registered products of the firm with respect to the method of testing is provided below:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Total No of registered Products** | **No of Products with official Monograph**  **(USP/BP/JP)** | **No of Products with In-house/Innovator specs** | **No of product currently on HPLC** | **No of products to be shifted to HPLC** | |  |  |  |  |  |   **In-house / Innovator Specs products:**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **HPLC Capacity Calculation Quarter Wise**  **(Average \_\_\_\_\_\_\_ tests/day/HPLC)**  **TOTAL \_\_\_\_\_\_ HPLC** | | | | | | | | Quarter | Average testing capacity / Quarter | Raw material tests | Product tests | Stability tests | Total tests | Capacity utilized  (%) | | **I** (1st Jan – 31st March \_\_\_\_\_) |  |  |  |  |  |  | | **II** (1st April – 30th June \_\_\_\_\_\_\_) |  |  |  |  |  |  | | **III** (1st July – 30th Sep\_\_\_\_\_) |  |  |  |  |  |  | | **IV** (1st Oct – 31st Dec\_\_\_\_\_\_) |  |  |  |  |  |  | | **Average capacity** | | | | | |  |  |  |  | | --- | --- | | **HPLC Testing Capacity Utilized (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | **HPLC Testing Capacity Available (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **UV Spectrophotometer Capacity Calculation Quarter Wise**  **(Average \_\_\_\_\_\_\_\_\_tests/day)**  **TOTAL \_\_\_\_\_\_\_\_ UV** | | | | | | | | Quarter | Average testing capacity / Quarter | Raw material tests | Product tests (Dissolution) | Stability tests | Total tests | Capacity utilized  (%) | | **I** (1st Jan – 31st March \_\_\_\_\_) |  |  |  |  |  |  | | **II** (1st April – 30th June \_\_\_\_\_\_\_) |  |  |  |  |  |  | | **III** (1st July – 30th Sep\_\_\_\_\_) |  |  |  |  |  |  | | **IV** (1st Oct – 31st Dec\_\_\_\_\_\_) |  |  |  |  |  |  | | **Average capacity** | | | | | |  |  |  |  | | --- | --- | | **UV Testing Capacity Utilized (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | **UV Testing Capacity Available (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Dissolution Capacity Calculation Quarter Wise**  **(Average \_\_\_\_\_ tests/day)**  **TOTAL \_\_\_\_\_\_\_ DISSOLUTION** | | | | | | | | Quarter | Average capacity / Quarter | Raw material tests | Product tests | Stability tests | Total tests | Capacity utilized  (%) | | **I** (1st Jan – 31st March \_\_\_\_\_) |  |  |  |  |  |  | | **II** (1st April – 30th June \_\_\_\_\_\_\_) |  |  |  |  |  |  | | **III** (1st July – 30th Sep\_\_\_\_\_) |  |  |  |  |  |  | | **IV** (1st Oct – 31st Dec\_\_\_\_\_\_) |  |  |  |  |  |  | | **Average capacity** | | | | | |  |  |  |  | | --- | --- | | **Dissolution Testing Capacity Utilized (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_** | | **Dissolution Testing Capacity Available (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |  |  |  |  | | --- | --- | --- | --- | | **Sterility Testing Capacity Calculation Quarter Wise (Average \_\_\_\_\_\_\_\_\_\_ tests/day)** | | | | | Quarter | Average capacity/ Quarter | Test  Performed | Capacity Utilized % | | **I** (1st Jan – 31st March \_\_\_\_\_) |  |  |  | | **II** (1st April – 30th June \_\_\_\_\_\_\_) |  |  |  | | **III** (1st July – 30th Sep\_\_\_\_\_) |  |  |  | | **IV** (1st Oct – 31st Dec\_\_\_\_\_\_) |  |  |  | | **Average capacity available:** | | |  |  |  |  | | --- | --- | | **Sterility Testing Capacity Utilized (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_** | | **Sterility Testing Capacity Available (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |  |  |  |  | | --- | --- | --- | --- | | **Bacterial Endotoxin Test Capacity Calculation Quarter Wise (Average \_\_\_\_\_\_\_\_\_ tests / day)** | | | | | Quarter | Average capacity/ Quarter | Test  Performed | Capacity Utilized % | | **I** (1st Jan – 31st March \_\_\_\_\_) |  |  |  | | **II** (1st April – 30th June \_\_\_\_\_\_\_) |  |  |  | | **III** (1st July – 30th Sep\_\_\_\_\_) |  |  |  | | **IV** (1st Oct – 31st Dec\_\_) |  |  |  | | **Average capacity available:** | | |  |  |  |  | | --- | --- | | **BET Testing Capacity Utilized (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_** | | **BET Testing Capacity Available (average):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_** |   **Hot and Cold Incubator Testing Capacity**  The testing capacity of hot and cold incubators was determined at maximum production load during the study period i.e. January – December \_\_\_\_\_\_\_\_\_\_\_\_.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **HOT INCUBATOR** | | | | | | **Item** | **Media capacity at a time for incubation** | **Media used for testing (Maximum production load)** | **Capacity utilized (%)** | **Capacity Available (%)** | | **Test** | | | | | | **Media bottles** |  |  |  |  | | **Media plates** |  |  |  |  | | **Pre Incubated** | | | | | | **Item** | **Maximum capacity** | **Maximum incubated** | **Capacity utilized (%)** | **Capacity Available (%)** | | **Media bottles** |  |  |  |  | | **Media plates** |  |  |  |  | | **COLD INCUBATOR** | | | | | | **Item** | **Media capacity at a time for incubation** | **Media used for testing (Maximum production load)** | **Capacity utilized (%)** | **Capacity Available (%)** | | **Test** | | | | | | **Media bottles** |  |  |  |  | | **Media plates** |  |  |  |  | | **Pre Incubated** | | | | | | **Item** | **Maximum capacity** | **Maximum incubated** | **Capacity utilized (%)** | **Capacity Available (%)** | | **Media bottles** |  |  |  |  | | **Media plates** |  |  |  |  | |
| **CAPACITY OF STORAGE AREA**   1. Raw Material \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 2. In process quarantine \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3. Finished Goods \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 4. Packing Material \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Observations by the Inspection Panel:**  **CONCLUSION:** |
| **ANNEXURES:**   |  |  | | --- | --- | | **Annexure 1** | * Total number of registered products of the firm, * Total number registered product for each aforementioned section * Existing registered products on contract manufactured by the firm in aforementioned sections | | **Annexure 2** | * List of all quality control equipment along with its testing capacity * Total number of QC, IPQC and stability study tests performed in each quarter | | **Annexure 3** | * List of production equipment along with capacity | | **Annexure 4** | * List of all production batches of each product manufactured in each quarter from January to December \_\_\_\_\_\_\_\_\_\_\_. | | **Annexure 5** | * Specifications and analytical methods for all products with in-house / As per innovator’s specifications. | |