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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 | TestPerformed | 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 | TestPerformed | 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** |  |  |  |  |

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| **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
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| **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.
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