F.No.14-1/2024/DMC
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
Division of Pharmaceutical Evaluation & Registration

Islamabad, 24th January, 2024

Subject: **PROCEDURE FOR CAPACITY ASSESSMENT OF THE CONTRACT ACCEPTER**

Registration Board in its 333rd meeting held on 19th – 20th December, 2023 discussed the subject mentioned case and decided as under: -

1. Inspection of contract accepter for manufacturing / testing capacity assessment shall be conducted for all those contract manufacturers, who has not been inspected for such purpose with in the last 3 years. The panel shall verify capacity assessment of all those sections, which are approved by the Licensing Division.

2. Capacity assessment of newly applied facility (Section) shall not be carried out, if any section of that manufacturing facility has already been assessed within last three years.

3. Following shall be prerequisites for submission of application for contract manufacturing under Rule 20(A) of Contract Manufacturing Policy.

   a. Affidavit on stamp paper (Showing name, designation, CNIC Number of contract giver) stating installed capacity of the contract accepter for contract manufacturing. This affidavit shall only be signed by the CEO / MD of the firm. i.e. contract accepter.

   b. Copy of DML of both firms. i.e. contract giver and contract accepter along with Section (s) approval from Licensing Division.

   c. Valid GMP certificate or GMP inspection report of the contract accepter, conducted within last three years.

   d. Copy of legalized contract between contract giver and contract accepter on stamp paper presenting the capacities of the contract accepter for the manufacturing sections for whom the products have been applied, and

4. Affidavits submitted by the contract accepter, showing manufacturing / testing capacity, will be verified in the subsequent inspections conducted for GMP / renewal of DML and will be reported accordingly. Chairman, Registration Board may constitute panel of experts to verify capacity assessment, if required.

5. The capacity verification report will be valid for 3 years.

Above mentioned decision is being circulated for compliance.

24-01-2024

(H.M. Asif Iqbal)
Deputy Director (PE&R)

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