**CHECKLIST FOR SCREENING THE DOCUMENTS FOR ENLISTMENT OF COMPANY OR FIRM**

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| **S.NO.** | **PARAMETER** |
| 01. | Application on Prescribed Form 1 by Manufacturer |
| 02. | Copy of constitution of firm and National Tax Certificate |
| 03. | Site Master File |
| 04. | Plan of the premises along with details of the areas of each section |
| 05. | Name, along with appointment letter, Address, Qualification and Experience of the technical staff responsible for manufacturer and testing. The Qualification and experience should be backed up with attested proof |
| 06. | Name and Address of the Director, Partners, or Proprietor |
| 07. | Proof of Payment of fee (Original Challan) |
| 08. | List of products intended to be manufactured [along with formula, pack size and detail of primary packing material (Glass or Plastic)] |
| 09. | Ownership, Rent or Lease details of the premises in case of grant of enlistment certificate as manufacturer |
| 10. | Layout plan in triplicate with feasibility reports stating surrounding location and environment. |
| 11. | Section wise List of machinery installed and Laboratory equipment |
| 12. | Validation and calibration of essential and critical equipment and instruments. |
| 13. | Validation of HVAC system (applicable for sterile products). |
| 14. | Copies of procurement documents of machinery and equipment (bill etc.) in case of grant of enlistment certificate as manufacturer. |
| 15 | Description and flow chart of manufacturing process for dosage form (in case of grant of enlistment certificate as manufacturer) |
| 16. | List of firms / companies and their products applied for enlistment under the contract manufacturing or testing (applicable for contract manufacturing / testing). |
| 17 | Quality agreement for contractual manufacturing and testing (if applicable) |
| 18. | Letter from Manufacturer being ready for inspection |
| 19. | Signature and Undertaking by the Applicant |