

LOCAL MANUFACTURER CHECKLIST

Subject: - CHECKLIST FOR SCREENING THE DOCUMENTS FOR ENLISTMENT OF COMPANY OR FIRM

S.NO.	PARAMETER	YES	NO
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 equipments (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		

Remarks: - Application is not complete as identified herein above. Photocopies of original documents shall be backed up with attestation. Every page of documents submitted to this Division in connection with this correspondence shall be signed and stamped by the applicant