**DOCUMENTS TO BE SUBMITTED TO FOR GRANT OF TEST LICENCE IN FORM-29**

Following documents are required to be submitted for the grant of first test license on the applied premises in the case where the applicant does not hold a manufacturing license as applicable on Form 25 or 28 :

1. Application (Statutory) in Form - 30 (duly signed or counter signed by the Head of the institution/ Director of the firm or company)
2. Partnership deed / List of Directors signed by authorized signatory.
3. Ownership document (Registered sale deed and/or proof of allotment of the site), or Rent / Lease deed in case of Rental premises.
4. Plan and layout of the premises showing the installation of Machinery and Equipment duly signed by the applicant who signed in the statutory form.
5. Self attested Photo copy of Aadhar card/Passport/Electoral card for Id and address Proof of Managing Director / Partners/ Proprietor.
6. Consent from State Pollution Control Board regarding the activities proposed by the applicant.
7. List of Manufacturing and analytical equipment.
8. Affidavit covering the points given in the Annexure.
9. Form CT 11/ Form CT 14/ Form CT 15 from CDSCO for ‘New Drugs’ as per New Drugs & Clinical Trial Rules.

Bulk Drugs/Formulations

1. Brief Manufacturing procedure of each product
2. Flow Chart with structural Formula of reactions (for bulk drugs) per Master Formula record
3. Specifications & analytical procedure of applied products
4. Copies of monographs for drugs with Pharmacopoeial specifications.

Annexure

AFFIDAVIT

The Affidavit should include:

1. That we have applied for license on form 29 to manufacture the following formulations only for the purpose of examination test or analysis in our unit.
2. Details of formulations.
3. The drugs will be manufactured at ……….. (Name and address of premises).
4. We shall ensure that the purpose of the manufacture of the above mentioned drugs is only for examination, test or analysis and will not be used for any clinical study or toxicological study on humans or animals.
5. We will cease to manufacture or export if the drug is prohibited in future in the country and the same will be intimated.

Deponent