DOCUMENTS / INFORMATION REQUIRED FOR GRANT OF DRUG MANUFACTURING LICENSE.

i). Properly filled in application on prescribed **Form-1** along-with pro-forma and all other required documents as per schedule A of the Drugs (Licensing, Registering & Advertising) Rules 1976. The prescribed **FORM-1** see Drugs (Licensing, Registering & Advertising) Rules 1976 is reproduced as below:-

FORM-1

1. I/we …… of ……hereby apply for the grant of a license to manufacture Drugs by way of…….on the premises situated at ……

2. The drug (s) or class (es) of drugs intended to be manufactured: -
   (I) Class (es) of drugs
   (II) Dosage form(s) of drugs.
   (III) Name of drug (s).

3. I enclose: -
   i. Particulars regarding legal status of the applicant (i.e. in case of Proprietorship the name(s) of proprietors and their address(es), in case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).
   ii. Details of the premises including layout plan of the factory.
   iii. Details of the section-wise equipment and machinery for manufacture and quality control.
   iv. Names and qualifications of the Production In-charge and Quality Control In-charge for supervising manufacturing processes and Quality Control Department, and other technical staff working in these departments.

4. The premises and plant will be ready for inspection on …….. or are ready for inspection.

Dated…… Signed……
Place …… Name, Designation & Address……..

ii). **Pro-forma** as per above referred Schedule A.

iii). Copy of Challan of Fee in original duly retained by Statistical Officer DRAP as per following schedule to be deposited under the following head of account

A/C No. 0010008463-100018 Allied Bank Limited

i. Fee of Rs. 100,000/- for Grant of DML by way of Formulation.
ii. Fee of Rs. 30,000/- for Grant of DML by way of Basic and Semi Basic Formulation.
iii. Fee of Rs. 60,000/- for Grant of DML by way of Repacking.
iv. Fee of Rs. 5,000/- per Drugs specified in Schedule D for repacking.

iv). All documents submitted should be duly attested.