**“FORM-1**

[See rule 5(1)]

**APPLICATION FORM FOR GRANT OF A LICENSE TO MANUFACTURE DRUGS BY WAY OF FORMULATION / BASIC MANUFACTURE / SEMI-BASIC MANUFACTURE/RE-PACKING.**

 I/We of  hereby apply for the grant of a license to manufacture by way of  on 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 the 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.

Date………………………………….. Signed……………………………………………..

Place …………………………………. Name, designation and address of the signatory

 ………………………………………………..