

946 | **FORM 27DA**

(See rule 75A)

APPLICATION FOR GRANT ⁹⁴⁷*1 OF A LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF LARGE VOLUME PARENTERALS/SERA AND VACCINE/ RECOMBINANT DNA (R-DNA) DERIVED DRUGS EXCLUDING THOSE SPECIFIED UNDER SCHEDULE X**

1. I/We*, of # hereby apply for the ⁹⁴⁸[grant] of a loan licence to manufacture on the premises situated at c/o @ the under-mentioned drugs being Large Volume Parenterals/Sera and Vaccine/ Recombinant DNA (r-DNA) derived drugs specified in Schedules C, C(D), excluding those specified in Schedule X to the Drugs Rules, 1945.

2. Name(s) of drugs (each item to be separately specified).

3. The name(s), qualifications and experience of the competent technical staff responsible for the manufacture of the above-mentioned drugs.

(a) Name(s) of competent technical staff responsible for testing.....

(b) Name(s) of competent technical staff responsible for manufacture.....

4. I/we enclose:

(a) A true copy of a letter from me/us to manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and they will analyse every batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf.

(c) Specimens of labels, cartons of the drugs proposed to be manufactured.

5. A fee of rupees.....has been credited to Government under the head of account.....]

Date.....

Signature.....

Designation.....

* Enter here name of the proprietor, partners or Managing Director, as may be.

Enter here name of the applicant firm and the address of the principal place of business.

@ Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the latter operates".

