

**942| FORM 27D**

(See rule 75)

**APPLICATION FOR GRANT <sup>943</sup>\*\*\*] OF A LICENCE TO  
MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF <sup>944</sup>[LARGE  
VOLUME PARENTERALS/ SERA AND VACCINE/RECOMBINANT  
DNA (R-DNA) DERIVED DRUGS] EXCLUDING THOSE SPECIFIED  
IN SCHEDULE X**

1. I/We,..... of..... hereby apply for the <sup>945</sup>[grant] of  
a licence to manufacture for sale or distribution on the premises situated at  
....., the undermentioned \* [Large Volume Parenterals/Sera and  
Vaccine/Recombinant DNA (r-DNA) derived drugs], specified in Schedules C  
and C(I) to the Drugs Rules, 1945.

2. Name(s) of drug(s)..... (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 staff responsible for testing.....

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

4. The premises and plant are ready for inspection/will be ready for inspection  
on.....:

5. A fee of rupees..... and an inspection fee of  
rupees..... has been credited to the Government under the Head of  
Account.....

Signature.....

Date..... Designation.....

**Notes 1.** The application is to be accompanied by a plan of the premises; list of  
equipments and machinery to be employed for manufacture and testing;

memorandum of association/constitution of the firm; copies of qualification and experience of competent technical staff and documents relating to ownership or tenancy of the premises.

**Notes 2.** A copy of the application together with relevant enclosure shall also be sent each to Central Licence Approving Authority and concerned Zonal/Sub-Zonal Officers of Central Drugs Standard Control Organisation.]