FORM 27-D

[See Rule 75]

*Application for the grant of a licence to manufacture for sale or for distribution of Large Volume Parenterals / Sera and Vaccines excluding those specified in Schedule X*

1. I/We ………………….. of………………………… hereby apply for the grant of licence to manufacture for sale or distribution on the premises situated at ……………… the under mentioned Large Volume Parenterals/Sera and Vaccines, specified in Schedule C and C(1) to the Drugs & Cosmetics Rules, 1945.

2. Name(s) of drugs(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 manufacturing …………………….

4. The premises and plan are ready for inspection/ will be ready for inspection on … .

5. A fee of Rs. ……………………... and an inspection fee of Rs. ………….. has been credited to the Govt. Account under the head of Account :

Date ………….. Signature

Note:

1. The application is to be accompanied by a plan of the premises, list of equipment and machinery to be employed for manufacturing and testing; memorandum of association/ constitution of the firm; copies of qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the premises.

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