

Form 27-D
[See Rule 75]

Application for 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 a 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 and Cosmetics Rules,1945.

2. Name(s) of Drug(s)
.....
.....
.....

(each item to be separately specified).

3. The name(s), qualification 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 plant are ready for inspection/will be ready for
inspection on

5. A fee of rupees and an
inspection of rupeeshas been credited to Government under the
head of account

Date:.....

Signature.....
Designation

Notes:

1.The application is to be accompanied by a plan of the premises, list of equipment 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.

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