Form 27-D

[See Rule 75]

Application for grant or renewal 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/renewal of licence to manufacture for sale or distribution on premises

situated at _____the

undermentioned Large Volume Parenterals / Sera and Vaccines, specified in Schedules C

and C (1) to the Drugs and Cosmetics Rules, 1945.

2. Name (s) of drugs (s) _____

_____ (each item to be separately specified)

3. The Name (s), qualifications and experience of 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 rupees _____ and an inspection fee of

rupees _____ has been credited to Government under the head of

account _____

Date _____ Signature _____

Designation_____

_____

Note :

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.

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 Central Drugs Standard Control Organisation.

Information Data Submitted with the Application for Grant of Drug Manufacturing Licence Regarding Items to be Approved

1. Name & Address of the Firm : _____

2. Licence No. and Date : New Licence Case

3. Categories of items permitted under the licence : Not applicable (New Licence Case)

4. For Pharmacopoeial Drugs : Not applicable

(a) Name of the Product : _____

(b) Pharmacopoeial Reference (Indicate the edition and page of Pharmacopoeia) : _____

5. Patent and Proprietory Drugs

(a) Name of the drug : _____

(b) Complete formula : Kindly see overleaf.

(c) If the product is a combination, the the data of the rationals, efficacy and safety of each of the ingredient singally or in combination. : Not applicable as similar product exists in market

(d) Whether a similar product is being manufactured by any other firm in India. : Yes

If so, details thereof. : Mfd. By M/s. _____
_____
_____
_____

(e) Proposed Dosage : _____

(f) The therapeutic claims proposed to to made on the label/carton and insert literature. : NIL

(g) Certificate that the proposed name : It is certified that the proposed name does

does not infringe the Trade Mark Act for the time being in force.	not infringe the Trade Mark Act for the time being in force. An affidavit in this regard, is enclosed with the application.