[1][FORM 27D

(See rule 75)

Application for grant [1][***] of a licence to manufacture for sale or for distribution of[Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs]excluding those specified in Schedule X

1. I/We ..... of .....hereby apply for grant [1][***] of a licence to manufacture for sale or distribution on the premises situated at..... the undermentioned Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs, specified in Schedules 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), 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 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.....

Date: ..... *Signature*.....

Designation.....

Notes:

1. The application is to be accompanied by a plan of the premises, list of machinery and equipment 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 the relevant enclosures shall also be sent each to the Central Licence Approving Authority and concerned Zonal/Sub-Zonal Officers of Central Drugs Standard Control Organization].

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1. The words “or renewal” omitted by GSR 1337(E) dt. 27-10-2017 (w.e.f. 27-10-2017)