FORM 24

(*See* rule 69)

Application for the grant of or renewal of a [1][*licence to manufacture for sale or for distribution] of drugs other than those specified in* [2][*Schedules C and C (1) and X*]

1 . I / We .....of. ..... hereby apply for the grant / renewal of a licence to manufacture on the premises situated at ..... the following drugs being drugs other than those specified in [2][Schedules C and C (1) and X] of the Drugs and Cosmetics Rules, 1945.

2. Names of drugs categorized according to Schedule M.

3. Names, qualifications and experience of technical staff employed for manufacture and testing.

4. A fee of rupees ..... has been credited to Government under the head of account .....

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

Note: The application should be accompanied by a plan of the premises.

1. 1. Subs. by. G.S.R. 788(E), dt. 10.10.1985.
2. Subs. by G.S.R. 462(E), dt. 22.6.1982.

FORM 24A

(*See* rule 69A)

***Application for grant or renewal of a loan* [1][*licence to manufacture for sale or for distribution*] *of drugs other than those specified in* [2][*Schedules C and C (I) and X*]**

1 . I /We*.....of# .....hereby apply for the grant/renewal of a loan licence to manufacture on the premises situated at..... C/o§ ..... the under- mentioned drugs, other than those specified in [2] [Schedules C and C(1) and X] to the Drugs and Cosmetics Rules, 1945.

Names of drugs (each substance to be separately specified).

2. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in manufacturing premises.

3. I/We enclose–

(a) A t ru e c o p y of a let t e r fr om m e /u s to the m a nufac t u r i n g c o nce r n wh os e manufacturing capacity is intended to be utilized by me/us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me/us and that they will analyse every batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately in this behalf.

(c) Specimens of labels, cartons of the products proposed to be manufactured.

4. A fee of rupees.....has been credited to Government under the head of account .....

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

* *Enter here the name of the proprietor, partners of Managing Director as the case may be.*

Enter here the name of the applicant firm and the address of the principal place of business.

§ *Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the Licence number under which the latter operates.*

1. Subs. by G.S.R. 788(E), dt. 10.10.1985.
2. Subs. by G.S.R. 462(E), dt. 22.6.1982.

[1] **[FORM 24F**

(*See* rule 69)

Application for the grant or renewal of a[2] [licence to manufacture for sale or for distribution of] drugs specified in Schedule X and not specified in Schedules C and C(1)

1. I/We ..... of .....hereby apply for the grant/renewal of licence to manufacture on premises situated at ..... the undermentioned drugs, specified in Schedule X to the Drugs and Cosmetics Rules, 1945.
2. Names of drugs.
3. Names, qualifications and experience of technical staff employed for manufacture and testing.
4. A fee of rupees..... has been credited to Government account under the head of account.....

Signature ..... ……..

Date:..... *Designation ..... ……..]*

1. Subs. by .G.S.R. 462(E) ,dt. 22.6.1982.
2. Subs. by G.S.R. 788(E) dt. 10.10.1985.

FORM 27

Application for grant or renewal of a[1] [licence to manufacture for sale or for distribution] of drugs specified in Schedules C and C (1)[2] [excluding those specified in[3] [Part XB and] Schedule X]

1 . I / We ..... hereby apply for the grant / renewal of a licence to manufacture on the premises situated at the undermentioned drugs, being drugs specified in Schedules C and C (1) [2][excluding those specified in [3][Part XB and] Schedule X] to the Drugs and Cosmetics Rules, 1945.

Names of drugs……..……(each item to be separately specified).

2. The names, qualifications and experience of the expert staff responsible for the manufacture and testing of the above mentioned drugs.

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

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

4. A fee of rupees ..... and an inspection fee of rupees ……has been credited to Government under the head of account…….

Date ..... *Signature…….*

Designation…...

Note-The application shall be accompanied by a plan of premises.

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1. Ins. by. G.S.R. 788(E), dt. 10.10.1985. 3. Ins. by G.S.R. 28(E), dt. 22.1.1993.
2. Subs. by G.S.R. 462(E), dt. 22.6.1982.

FORM 27A

(*See* rule 75A)

Application for grant or renewal of a loan[1] [licence to manufacture for sale or for distribution of] drugs specified in Schedules C and C(1)[2] [excluding those specified in Part XB and Schedule X]

1. I / We* .....of# ..... …..hereby apply for the grant/ renewal of Loan Licence to manufacture on the premises situated at C/o$……. the undermentioned drugs, being drugs specified in Schedules C and C (1) [2][excluding those specified in Part XB and Schedule X] to the Drugs and Cosmetics Rules.

Names of drugs (each substance to be separately specified).

2. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.

(a) Name (s) of expert staff responsible for manufacture .....

(b) Name (s) of the expert staff responsible for testing .....

3. I /We enclose:

(a) A true copy of a letter from me / us to manufacturing concern whose manufacturing capacity is intended to be utilized by me / us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me / us and that they shall will analyse every batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf.

(c) Specimens of labels, cartons of the drugs proposed to be manufactured.

4. A fee of Rs ..... has been credited to Government under the head of account ..... ……

Date ..... *Signature* ..... ……

Designation……..

** Enter here name of the proprietor, partners or Managing Director, as the case may be.*

 # Enter here name of the applicant firm and the address of the principal place of business.

$ Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the latter operates.

1. Subs. by G.S.R. 788(E) ,dt. 10.10.1985.
2. Ins. By G.S.R. 462(E), dt: 22.6.1982.

[1][FORM 27B

Application for grant or renewal of a[2] [licence to manufacture for sale or for distribution of] drugs specified in Schedules C, C(I) and X

1. I/We ..... of ..... hereby apply for the grant/renewal of a licence to manufacture on the premises situated at…… the undermentioned drugs, specified in Schedules C, C(I) and X to the Drugs and Cosmetics Rules, 1945.

2. Names of drugs.

3. The names, qualifications and experience of the expert staff responsible for the manufacture and testing of the abovementioned 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 .....

Date..... *Signature*……

Note: The application shall be accompanied by a plan of the premises.]

** Delete whichever is not applicable.*

1. Subs. by G.S.R. 462(E) dt. 22.6.1982.
2. Subs. by G.S.R. 788(E) ,dt. 10.10.1985.

[1][FORM 27D

(See rule 75)

Application for grant or renewal of a licence to manufacture for sale or for distribution of [2] [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/renewal of a licence to manufacture for sale or distribution on the premises situated at……..…the undermentioned[2] [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. Ins. by. G.S.R.119(E), dt. 11-3-1996.
2. Subs. By G.S.R.26 (E) dt: 19.1.2006.

[1][FORM 27DA

(See rule 75A)

Application for grant or renewal of a loan 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/renewal of a loan licence to manufacture on the premises situated at c/o @……..…the undermentioned drugs being Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs specified in Schedules C, C(1) excluding those specified in Schedule X 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 competent technical staff responsible for testing .....
(b) Name(s) of competent technical staff responsible for manufacturing .....
4. I /We enclose:
(a) A true copy of a letter from me / us to manufacturing concern whose manufacturing capacity is intended to be utilized by me / us.
(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me / us and that they shall will analyse every batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf.
(c) Specimens of labels, cartons of the drugs proposed to be manufactured.
5. A fee of rupees .....has been credited to the Government under the Head of Account.....]

Date: .....

Signature .....
Designation.....

* Enter here name of the proprietor, prtners or managing director, as may be.
# Enter here nam of the applicant firm and the address of the principal place of business.
@ Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the license number under which the latter operates.

1. Ins. by. G.S.R. 574 (E), dt.07-7-2012.

FORM 30

(*See* rule 90)

Application for licence to manufacture drugs for purposes of examination, test or analysis

1. ……of ..... ……by occupation ..... hereby apply for licence to manufacture the drugs specified below for purposes of examination, test or analysis at and I undertake to comply with the conditions applicable to the licence.

Names of Drugs

Date..... *Signature*……..