SCHEDULE A

FORM 1

(*See* rule 4)

Memorandum to the Central Drugs Laboratory

Serial Number .....

To the Director, Central Drugs Laboratory .....

From.....

I send herewith, under the provisions of section 25 (4) of the Drugs and Cosmetics Act, 1940, sample(s) of a drug purporting to be .....for test or analysis and request that a report of the result of the test or analysis may be supplied to this Court.

(2) The distinguishing number on the packet is .....

(3) Particulars of offence alleged .....

(4) Matter on which opinion is required .....

(5) A fee of Rs ..... has been deposited in Court.

Date .....

... .
Magistrate

[1][FORM 1

(*See* rule 163C)

Memorandum to the Pharmacopoeial Laboratory for Indian Medicine (PLIM)

From .....

(Full name, Designation and Postal address of the sender)

Serial No.....

To the Director,

Pharmacopoeial Laboratory for Indian Medicine,

I send herewith, under the provisions of section 11(2)/section 25(4) and section 33H of the Drugs and Cosmetics Act, 1940, sample(s) of a drug purporting to be .....for test or analysis and request that a report of the result of the test or analysis may be supplied to this Court.

(2) The distinguishing number on the packet is .....

(3) Particulars of offence alleged .....

(4) Matter on which opinion is required .....

(5) A fee of Rs ..... has been deposited in Court.

Date .....

……. .....
Magistrate/Authorized Signatory]

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1. Ins. by G.S.R. 352(E) , dt. 1.6.2006.

FORM 2

(*See* rule 6)

Certificate of test or analysis by the Central Drugs Laboratory

Certified that the sample bearing number ..... ……..
purporting to be a sample of. ..... received on ..... with memorandum No ..... dated..... from ..... has been tested/analysed and that the result of such test / analysis is as stated below.

2. The condition of the seals on the packet on receipt was as follows: —

*3. In the opinion of the undersigned the sample is of standard quality is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder for the reasons given below:–

Director

Date…… Central Drugs Laboratory or other authorised officer
Details of results of test or analysis with protocols of test applied

Director

Date.....Central Drugs Laboratory or other authorised officer
* *If opinion is required on any other matter, the paragraph should be suitably amended.*

[1][FORM 2A

(*See* rule 163E)

Certificate of test or analysis from the Pharmacopoeial Laboratory for Indian Medicine or Governmen Analyst

Certified that the sample bearing number ..... ……..
purporting to be a sample of. ..... received on ..... with memorandum No ..... dated..... from ..... has been tested/analysed and that the result of such test / analysis is as stated below.

2. The condition of the seals on the packet on receipt was as follows: —

*3. In the opinion of the undersigned the sample is of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder for the reasons given below.

Or

In the opinion of the undersigned the sample is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder for the reasons given below.

"**Note**: *delete whichever is not applicable."

(Signature of the Analyst Person-in-Charge of testing)

Date…….
Place…….

Name & Designation and Seal…….
Name and Address of the laboratory ……]

1. Ins. by G.S.R. 352(E) , dt. 1.6.2006.

[1]FORMS 3-7 (*Omitted*)

[2][FORM 8

(*See* rule 24)

***Application for licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules*, 1945**

I/We* ..... (full address with telephone number, fax number and e-mail address) hereby apply for a licence to import drugs specified below manufactured by M/s ..... (full address with telephone no, fax and e- mail no.).

2. Names of the drugs to be imported:

(1)

(2)

(3)

3. I/We* ..... enclose herewith an undertaking in Form 9 dated ……signed by the manufacturer as required by rule 24 of the Drugs and Cosmetics Rules, 1945.

4. I/We* ..... enclose herewith a copy of Registration Certificate concerning the drugs to be imported in India, issued under Form 41 of the rules, vide Registration Certificate No .....dated ..... issued through M/s. .....(name and full address) .....valid up to .....

5 I/We* ..... hold a valid wholesale licence for sale or distribution of drugs or valid licence to manufacture drugs, under the provisions of the Act and rules made thereunder. A copy of the said licence is enclosed.

6. A fee of .....has been credited to Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945 - Central vide Challan No ..... dated .....(attached in original)

Signature .....

Name.....

Designation .....

Seal/Stamp of Manufacturer's agent in India.

Place: .....

Date: .....

**Delete whichever is not applicable.*]

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1. Forms 3 to 7 omitted by Notfn. No. F. 1-16/57-D, dt. 15-6-1957.
2. Subs. by G.S.R. 604(E) , dt. 24.8.2001.

[1][FORM 8A

(*See* rule 24)

***Application for licence to import drugs specified in Schedule X to the Drugs and Cosmetics Rules,* 1945**

I/We* ..... (full address with telephone number, fax number and e-mail address) hereby apply for a licence to import drugs specified below manufactured by M/s ..... (full address with telephone no, fax and e-mail no.).

2. Name of the drugs to be imported:

(1)

(2)

(3)

3. I/We* ..... enclose herewith an undertaking in Form 9 dated……signed by the manufacturer as required by rule 24 of the Drugs and Cosmetics Rules, 1945.

4. I/We* ..... enclose herewith a copy of Registration Certificate concerning the drugs to be imported in India, issued under Form 41 of the rules, vide Registration Certificate No dated issued through M/s. ..... (name and full address) ..... …… valid upto……

5. I/We* ..... hold a valid wholesale licence for sale or distribution of drug or licence to manufacture drugs, under the provisions of the Act and rules made thereunder. A copy of the said licence is enclosed.

6. A fee of .....has been credited to Government under the Head of Account "0210 - Medical and Public Health, 04- Public Health, 104- Fees and Fines" under the Drugs and Cosmetics Rules 1945 - Central vide Challan No ..... dated ..... (attached in original).

Signature .....

Name .....

Designation .....

Seal/Stamp of Manufacturer's agent in India.]

Place: .....

Date: .....

**Delete whichever is not applicable.*

1. Subs. by G.S.R. 604(E), dt.24.8.2001.

FORM 9

(*See* rule 24)

Form of undertaking to accompany an application for an import licence

Whereas ..... of..... intends to apply for a licence under the Drugs and Cosmetics Rules, 1945, for the import into India, of the drugs specified below manufactured by us, we……of……..hereby give this undertaking that for the duration of the said licence—

(1) the said applicant shall be our agent for the import of drugs into India;

(2) we shall comply with the conditions imposed on a licence by [1][rules 74 and 78] of the Drugs and Cosmetics Rules, 1945;

(3)we declare that we are carrying on the manufacture of the drugs mentioned in this undertaking at the premises specified below, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories;

(4) we shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945;

(5) every drug manufactured by us for import under licence into India shall as regards strength, quality and purity conform with the provisions of Chapter III of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945;

(6) we shall comply with such further requirements, if any, as may be specified by Rules, by the Central Government under the Act and of which the licensing authority has given to the licensee not less than four months' notice.

Names of drugs and classes of drugs

Particulars of premises where manufacture is carried on.

Date.....

[2][*Signature, Name, Designation Seal/Stamp of manufacturer or on behalf of the manufacturer*.]

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1. Subs. by. G.S.R. 462(E), dt. 22.6.1982.
2. Subs. by G.S.R. 604(E), dt. 24.8.2001

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[1][FORM 10

(*See* rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic Rules, 1945

Licence Number..... Date... ……..

1. ..... (Name and full address of the importer) is hereby licensed to import into India during the period for which the licence is in force, the drugs specified below, manufactured by M/s ..... (name and full address) and any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from ..... to ..... unless it is sooner suspended or cancelled under the said rules.

3. Names of drugs to be imported.

Place : ……..

Date : ……..

Licensing Authority

Seal/Stamp

Conditions of Licence.

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and the date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

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1. Subs. by G.S.R. 604(E) ,dt. 24.8.2001.

[1][FORM 10A

(*See* rules 23 and 27)

Licence to import drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945

Licence Number ..... Date…….

.....(Name and full address of the importer) is hereby licensed to import into India during the period for which the licence is in force, the drugs specified below, manufactured by M/s ..... (name and full address) and any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from..... to ..... unless it is sooner suspended or cancelled under the said rules.

3. Names of drugs to be imported.

Place:.....

Date: .....

Licensing Authority

Seal/Stamp.

**Delete whichever is not applicable.*

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and the date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

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1. Subs. by G.S.R. 604(E), dt. 24.8.2001.

FORM 11

(*See* rule 33)

Licence to import drugs for the purposes of examination, test or analysis

1 ……of..... is hereby licensed to import from ..... the drugs specified below for the purposes of examination, test or analysis at .....or in such other places as the licensing authority may from time to time authorise.

2. This licence is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date specified below:–

Name of drugs	*Quantities which may be imported*

Date..... *Licensing Authority*
Seal/Stamp

[1]**[FORM 11A**

(*See* rule 33A)

Licence to import drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patients

Licence No ……. Date…….
Dr. ..... ……Designation ……..of ……
(Name of College/Hospital/Autonomous Institution)

is hereby licenced to import from M/s .....(name and full address) the drugs specified below for the purpose of treatment of patients for the disease (name of the disease) ..... at ..... or in such other places as the licensing authority may from time to time authorise.

2. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date of issue specified above.

3. Names of drugs to be imported:

Name of drugs	*Quantities which may be imported*

Place :
Date :.....

Licensing Authority
Seal / Stamp

Conditions of Licence

1. The licence shall be displayed in the Office of the Medical Superintendent of Government Hospital / Head of Institution of Autonomous Medical Institution.

2. The licensee shall store the drugs imported under this licence under proper storage conditions.

3. The drugs imported under this licence shall be exclusively used for the treatment of patients, and a record shall be maintained in this regard, by a registered pharmacist giving the full name(s) and address(es) of the patients, diagnosis, dosage schedule, total quantity of drugs imported and issued, and shall be countersigned by the Medical Superintendent of the Government Hospital or Head of the Autonomous Medical Institution which shall be produced, on demand by an Inspector appointed under the Act.]

1. Subs. by G.S.R.. 604(E), dt. 24.8.2001.

FORM 12

(*See* rule 34)

Application for licence to import drugs for purpose of examination, test or analysis

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

[1][A fee of rupees ..... has been credited to Government under the head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945—Central vide Challan No…….dated……(attached in original).]

Name of drugs	*Quantities which may be imported*

Place……..

Date…….. *Licensing Authority*

1. Subs. by G.S.R. .604(E), dt. 24.8.2001.

[1][FORM 12A

(*See* rule 36, Second Proviso)

Application for the issue of a permit to import small quantities of drugs for personal use

I, ...resident of .....by occupation..... hereby apply for a permit to import the drugs specified below for personal use from .....

I attach a prescription from a registered medical practitioner in regard to the need for the said drugs.

Name of drugs	*Quantities which may be imported*

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

1. Added by Notifn No. F.1-36/54-DS, dt: 3.3.1955.

[1][FORM 12AA

(*See* rule 34A)

Application for licence to import small quantities of new drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patients.

I, ... (name and designation) ..... of …… (name of the Hospital/Autonomous Medical Institution) hereby apply for a licence to import small quantities of new drugs specified below for the purpose of treatment of patients for the disease ..... (name of the disease)…… … …… at…….(name and place of the hospital) and I undertake to comply with the conditions applicable to the licence and other provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder, from time to time.

1. A fee of rupees ..... has been credited to Government under the Head of Account "0210-Medical and Public Health, 04- Medical and Public Health, 104- Fees and Fines" under the Drugs and Cosmetics Rules, 1945 - Central vide Challan No……..dated ..... (attached in original).

2. Name of new drugs to be imported:

Name of drugs	Quantities which may be imported

Place: ……..

Date: ……..

Signature……..

Name……

Seal/Stamp……

Certificate

Certified that the drugs specified above for import are urgently required for the treatment of patients suffering from and that the said drug(s) is/are not available in India.

Place……..

Date .....

Signature ..... ……

Medical Superintendent of the Government Hospital / Head of Autonomous Medical Institution

*Seal / Stam*p.]

1. Subs. by. G.S.R. 604(E), dt. 24.8.2001.

[1][FORM 12B

(*See* rule 36, Second Proviso)

Permit for the import of small quantities of drugs for personal use

……of ..... is hereby permitted to import from..... the drugs specified below for personal use.

2. This permit is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This permit shall, unless previously suspended or revoked, be in force for a period of six months from date specified below.

Name of drugs	Quantities which may be imported

Date…….. *Licensing Authority]*

FORM 13

(*See* rule 46)

***Certificate of test or analysis by Government Analyst under section 25 (1) of the Drugs and Cosmetics Act,* 1940**

1. Name of Inspector from whom received .....
2. Serial No. and date of Inspector's memorandum.....
3. Number of sample .....
4. Date of receipt .....
5. Name of drugs purporting to be contained in the sample .....
6. Condition of seals on the [2][packet or on portion of sample or container] .....
7. Result of test or analysis with protocols of test or analysis applied .....

In the opinion of the undersigned the sample referred to above (is of standard/is not of standard) quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder for the reasons given below.

for the reasons given below:-

Date..... *Government Analyst.*

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1. Subs. by. G.S.R. 753(E), dt. 4.11.1999.
2. Subs. by G.S.R. 59(E), dt. 7.2.1995.

[1][FORM 13A

[*See* rule 163 (5)]

Certificates of tests or analysis by Government Analyst under section 33H of the Drugs and Cosmetics Act, 1940

1. Names of Inspector from whom received .....
2. Serial No. and date of Inspector's memorandum.....
3. Number of sample.....
4. Date of receipt .....
5. Names of ingredients purporting to have been used in the preparation of the sample…..
6. Condition of seals on the package.....
7. Results of test or analysis ……..

[2][In the opinion of the undersigned the sample referred to above is of standard/is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and the rules made thereunder for the reasons given below]

Date..... *Government Analyst..]*

FORM 14A

(*See* rule 47)

Application from a purchaser for test or analysis of a drug under Section 26 of the Drugs and Cosmetics Act, 1940

1. Full name and address of the applicant .....
2. Occupation.....
3. Name of drug purporting to be contained in the sample .....
4. Name and full address of the pharmacy or concern where the drug was purchased…….
5. Date on which purchased.....
6. Reasons why the drug is being submitted for test or analysis…….

[3][7. A fee of rupees ..... *vide* Schedule B of the Drugs and Cosmetics Rules, 1945, has been credited to Government under the head of account "080—Medical—Miscellaneous—Fees under the Drugs and Cosmetics Rules, 1945—Central/State"—*vide* treasury receipt attached.]

I hereby declare that the drug being submitted for test was purchased by or for me. I further declare that the sample of the drug being sent for test or analysis is exactly as it was purchased and has not been tampered with in any way to reduce its potency.

Date..... *Signed*.... …..

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1. Added by Notfn. No. F 1-23/67-D (S.O. 642), dt. 2.2.1970.
2. Ins. By G.S.R. 376(E), dt: 3..5.2010.
3. Added by Notfn. No. F. 1-3/51-D.S., dt. 15-10-1954

FORM 14-B

(*See* rule 47)

Certificate of test or analysis by Government Analyst under Section 26 of the Drugs and Cosmetics Act, 1940

1. Name of person from whom sample received.....
2. Date of receipt .....
3. Name of drug purporting to be contained in the sample .....
4. *Opinion of the Government Analyst*—The sample referred to above is/is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder.

Date..... *Government Analyst*……..

[1][**FORM 15**

(*See* rules 54 and 145C)

Order under section 22 (1)(c) of the Drugs and Cosmetics Act, 1940 requiring a person not to dispose of stock in his possession

Whereas, I have reasons to believe that the stocks of drugs/cosmetics in your possession, detailed below contravene the provisions of section 18 of the Drugs and Cosmetics Act, 1940;

Now, therefore, I hereby require you under clause (c) of sub-section (1) of section 22 of the said Act not to dispose of the said stock for a period of ..... days from the date of this order.

Date..... *Inspector*……

Details of stock of drugs/ cosmetics

Date..... *Inspector*.....]

[2][**FORM 16**

(*See* rules 55 and 145-B)

Receipt for stock of drugs or cosmetics for record, register, document or material object seized under section 22 (1) (c) or (cc) of the Drugs and Cosmetics Act, 1940.

The stock of drugs or cosmetics for records, registers, documents or material objects detailed below has / have this day been seized by me under the provisions of clause (c) or clause (cc) of sub-section (1) of section 22 of the Drugs and Cosmetics Act. 1940 (23 of 1940) from the premises of ..... situated at.....

Date..... *Inspector*. .....

Details of drugs, cosmetics, records, registers, documents or material objects seized.

Date..... *Inspector*. .....]

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1. Subs. by G.S.R. 1594, dt. 28.10.1976.
2. Subs. by. G.S.R. 926 , dt. 24-6-1977.

[1] **[FORM 17**

(*See* rules 56 and 145A)

Intimation to person from whom sample is taken

I have this day taken from the premises of …….situated at..... samples of the drugs / cosmetics specified below for the purpose of test or analysis.

Date..... *Inspector*.....

Details of samples taken

Date..... *Inspector*.....]

[2]**[FORM 17A**

(See rules 56A and 145AA)

Receipt for samples of drugs or cosmetics taken where fair price tendered thereof under sub- section (I) of Section 23 of the Drugs and Cosmetics Act, 1940 is refused

To.....

Whereas I, this..... day of ..... [3][20].....,have taken from the premises of…….. situated at..... samples of drugs/cosmetics as specified below:-

Details of Samples……

And whereas I had offered to pay you rupees..... as the fair price of the samples of drugs/cosmetics taken:

And whereas, you have refused to accept the fair price tendered thereof.

Now, therefore, I give you the receipt as the fair price tendered for the samples of the drugs/cosmetics taken by me.

Date: ..... *Inspector* ….. …..]

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1. Subs. by S.O. 2139, dt. 5.6.1972.
2. Ins. by G.S.R. 292(E) , dt. 29.5.1997.
3. Subs. by G.S.R. 592(E) , dt. 13.8.2008.

FORM 18

(*See* Rule 57)

Memorandum to Government Analyst

Serial No. of Memorandum.....

From:

To

The Government Analyst

……

……

The portion of sample / container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (4) of Section 23 of the Drugs and Cosmetics Act, 1940.

The portion of sample/container has been marked by me with the following mark.

Details of portion of sample or container with [1][name of drug/cosmetic] which it purports to contain—

Date..... *Inspector*.....

[2][FORM 18A

(*See* Rule 163 (1))

Memorandum to Government Analyst

Serial No……..

From

To

The Government Analyst

……

……

The portion of sample / container described below is sent herewith for test or analysis under the provisions of Section 33H of the Drugs and Cosmetics Act, 1940.

The portion of sample / container has been marked by me with the following mark.

Details of portion of sample or container with name of ingredients from which it is claimed to be made.

Date..... *Inspector*.....

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1. Subs. by G.S.R. 370(E), dt. 7.4.1994.
2. Added by Notfn. No. F 1-23/67-D, dt. 2-2-1970.

[1][FORM 19

[*See* rule 59 (2)]

Application for grant or renewal of a [2][licence to sell, stock or exhibit or offer for sale, or distribute] of drugs other than those specified in Schedule

1. I/ We*.....hereby apply for licence to sell by wholsesale/retail drugs specified in Schedules C and C(1) excluding those specified in Schedule X *and/or drugs other than those specified in Schedules C, C(1) and X to the Drugs and Cosmetics Rules, 1945 *and also to operate a pharmacy on the premises situated at.....

2. ** The sale and dispensing of drugs will be made under the personal supervision of the registered pharmacists namely:-

(Name) ..... (Qualification)……

(Name) .....(Qualification)……

3. Categories of drugs to be sold .....

4.*** Particulars of special storage accommodation .....

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

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

* *Delete whichever is not applicable.*
** *To be deleted if drugs will be sold only by wholesale.*
****Required only if products requiring special storage are to be sold.*

---

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 19A

[*See* rule 59 (2)]

Application for the grant or renewal of a restricted [1][licence to sell, stock or exhibit or offer for sale, or distribute] drugs by retail by [2][***] dealers who do not engage the services of a registered pharmacist

1. I/We ..... of. .....hereby apply for a licence to sell by retail

(i) [3][Drugs other than those specified in Schedule C, C1 and X] on the premises situated at……/[2][***]

or (ii) [4][Drugs specified in Schedule C(1)] on the premises situated at ……/ [4][Drugs specified in Schedule C(1)] as vendor in the area……

2. Sales shall be restricted to such drugs as can be sold without the supervision of a registered pharmacist under the Drugs and Cosmetics Rules.

3. Names or classes of drugs proposed to be sold.....

*4. Particulars of the storage accommodation for the storage of [5][Schedule C(1)] on the premises referred to above.

**5. The drugs for sale will be purchased from the following dealers and such other dealers as may be endorsed on the licence by the Licensing Authority from time to time.

Name of the dealers.....Licence No.....

6. A fee of rupees [2][***]/#twenty has been credited to Government under the head of account.....

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

**Delete whichever is not required.*

**Applies only to an itinerant vendor.

Rupees five for itinerant vendors and applicant from a village or town having a population of 5000 or less, and rupees twenty for other restricted licence.

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1. Subs. by G.S.R. 788(E) ,dt. 10.10.1985.
2. Omitted by. G. S. R. 231(E) , dt. 4.6.1996.
3. Subs. by G.S.R. 462(E), dt. 22.6.1982.
4. Subs. by.G.S.R. 487(E) , dt. 2.7.1984.

[1]**[FORM 19AA**

(*See* rule 62C)

Application for grant or renewal of a [2][licence to sell, stock or exhibit or offer for sale by wholesale, or distribute] drugs from a motor vehicle

I/We* _____ of _____hereby apply for [2][licence to sell, stock or exhibit or offer for sale by wholesale, or distribute] drugs specified in Schedules C and C (1) and /or drugs other than those specified in Schedules C and C (1) from the vehicle bearing registration no._____assigned under the Motor Vehicles Act, 1939.

2. Categories of drugs to be sold / distributed _____

3. A fee of rupees _____has been credited to Government under the head of account _____

*4.Particulars of the storage accommodation for the storage of drugs specified in Schedules C and C (1) on the vehicle referred to above.

Date _____ *Signature* _____

**Delete* if not required.

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1. Ins. by. G.S.R. 42 (E), dt. 25.1.1979.
2. Subs. by.G.S.R. 788(E), dt. 10.10.1985.

FORM 19B

(*See* rule 67A)

Application for [1][licence to sell, stock or exhibit or offer for sale, or distribute] Homoeopathic medicines

1 . I / We* .....of..... hereby apply for a licence to sell by *wholesale/*retail Homoeopathic medicines on the premises situated at .....

**2. The sale and dispensing of Homoeopathic medicines shall be made under the personal supervision of the following competent person in -charge.

Name .....

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

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

**Delete whichever is not required.*

** To be deleted if Homoeopathic medicines will be sold by wholesale.

---

1. Subs. By G.S.R. 788(E), dt.10.10.1985.

[1][**FORM 19C**

[*See* rule 59(2)]

Application for grant or renewal of a [2][licence to sell, stock, exhibit or offer for sale, or distribute] of drugs specified in Schedule .

1. I/We* ..... of.....hereby apply for a licence to sell by *wholesale/*retail drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945. We operate a pharmacy on the premises, situated at .....

2. ** The sale and dispensing of drugs will be made under the personal supervision of the registered pharmacists mentioned below:-

(Name) ..... (Qualification)

(Name) .....(Qualification)

3. Name of drugs to be sold.

4. *** Particulars of storage accommodation.

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

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

** Delete whichever is not applicable.*

** To be deleted if drugs will be sold only by wholesale.

***Required only if products requiring special storage are to be sold.]

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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 20

[*See* rule 61(1)]

[1][*Licence to sell, stock or exhibit or offer for sale, or distribute*] *drugs by retail other than those specified in* [2][*Schedules C, C(1) and X*]

1. ..... is hereby [1][licensed to sell, stock or exhibit or offer for sale, or distribute] by retail drugs other than those specified in [2][Schedules C, C (1) and X] of the Drugs and Cosmetics Rules 1945, *and to operate a pharmacy on the premises situated at..... subject to the conditions specified below and to provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.

2 The licence shall be in force from..... to .....

3. Name (s) of qualified person (s) in charge .....

4. Categories of drugs.....

Name of the dealer……Licence No……

Date..... *Licensing Authority* ..... ……

** Delete whichever is applicable*

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.
3. The licensee shall report to the Licensing Authority any change in the qualified staff in charge within one month of such change.

4. No drug shall be sold unless such drug is purchased under cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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 20A

[*See* rule 61 (1)]

Restricted [1][Licence to sell, stock or exhibit or offer for sale, or distribute] drugs by retail other than those specified in [2] [Schedules C, C (1) and X] for [3][***] dealers who do not engage the services of a registered pharmacist

1. .....is hereby [1][licensed to sell, stock or exhibit or offer for sale, or Distribute] on the premises situated at [3][***] .....the following drugs being drugs other than those specified in [2][Schedules C, C (1) and X] of the Drugs and Cosmetics Rules, 1945, subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from..... to .....

3 The licensee can deal only in such drugs as can be sold without the supervision of qualified person under the Drugs and Cosmetics Rules, 1945.

[4] [***]

Name of the dealer ..... *Licence No* .....

Date..... *Licensing Authority*

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public. [3][***].
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.
3. No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

1. Subs. by.G.S.R. 788(E), dt. 10.10.1985
2. Subs. by G.S.R. 462(E), dt. 22.6.1982.
3. Omitted by G.S.R. 231 (E) , dt. 4.6.1996
4 Sl. No. 4 omitted by G.S.R. 504(E) dt. 18.7.2002.

FORM 20B

[*See* rule 61 (1)]

[1]*[Licence to sell, stock or exhibit or offer for sale, or distribute] by wholesale, drugs other than those specified in* [2][*Schedules C, C(I) and X*]

1 ..... is hereby [1][licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale drugs other than those specified in [2][Schedules C, C(1) and X] on the premises situated at ..... subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940, and the Rules thereunder.

2. The licence shall be in force from .....to .....

Date..... *Licence No*……

Licensing Authority.

Conditions of Licence

1. This licence shall be displayed in a prominent place in part of the premises open to the public.

2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.

[3][3 (i) No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

(ii) No sale of any drug shall be made to a person not holding the requisite [1][licence to sell, stock or exhibit for sale, or distribute] the drug. Provided that this condition shall not apply to the sale of any drug to—

(a) an officer or authority purchasing on behalf of Government, or

(b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or

[4][(c) a manufacturer of beverages, confectionery biscuits and other non-medicinal products, where such drugs are required for processing these products.]

[5][***]

5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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1. Subs. by.G.S.R. 788(E), dt. 10.10.1985.
2. Subs. by G.S.R. 462(E) , dt. 22.6.1982.
3. Subs. by Notfn. No. F. 1/63/61-D, dt. 17.7.1963.
4.Ins. by S.O.23, dt:23.12.1969.
5.Clause 4 ommited by S.O. 289, dt:20.12.1992. Earlier clause 4 added by Notfn. F. No. 1-113/69-D, dt. 23.12.1969.

[1][FORM 20BB

(*See* rule 62-D)

[2]*[Licence to sell, stock or exhibit or offer for sale by wholesale, or distribute] drugs other than those specified in Schedule C and Schedule C (1) to the Drugs and Cosmetics Rules, 1945 from a motor vehicle*

1. …… is hereby [2][licensed to sell, stock or exhibit or offer for sale by wholesale, or distribute] drugs other than those specified in Schedule C and Schedule C(1) from the vehicle bearing registration no._____ assigned under under Motor Vehicles Act, 1939, subject to the conditions specified below and to the

provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from _____ to _____

3. Categories of drugs.....

Date:…….. *Licence No……..*

Licensing Authority.

Conditions of Licence

1. This licence shall be displayed in a prominent place on the vehicle.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.
3. (i) No drugs shall be sold by wholesale or distributed unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

(ii) No sale by wholesale or distribution of any drug shall be made to a person not holding the requisite [2][licensed to sell, stock or exhibit or offer for sale by wholesale, or distribute] the drug:

Provided that this condition shall not apply to the sale of any drug to—

(a) an officer or authority purchasing on behalf of the Government, or

(b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or

(c) a manufacturer of beverages, confectionery, biscuits and other non-medical products, where such drugs are required for processing these products.

4. The licensee shall inform the Licensing Authority in writing in the event of change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.
5. The licensee shall inform the Licensing Authority in writing in the event of any change in ownership of the vehicle specified in this licence within seven days of such change.

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1. Added by Notfn. No. X. 11013/7/76-D&MS (G.S.R. 42(E)), dt. 25.1.1979.
2. Subs. by G.S.R .788(E), dt.10.10.1985

[1]**[FORM 20-C**

(*See* rule 67-C)

[2]***[Licence to sell, stock or exhibit or offer for sale, or distribute] Homoeopathic medicines by retail***

1. ……is hereby [2][licensed to sell, stock or exhibit or offer for sale by wholesale, or distribute]by retail Homoeopathic medicines on the premises situated at.....subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from.....to .....

3. Name of the competent person in-charge.

Date..... *Licensing Authority*

Conditions of Licence

1. The licence shall be displayed in a prominent place in a part of the premises open to the public.
2. The licensee shall comply with the provisions applicable to homoeopathic

medicines under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.

3. The licensee shall report to the Licensing Authority any change in the competent staff within one month of such change.

[3][4. This licence authorises the sale of Homoeopathic medicines made from one earlier potency up to a quantity of 30 ml at a time.]

[4][5. Where any change in the constitution of the firm takes place, a licensee shall inform the Licensing Authority in writing about the same and the current licence shall be valid only for a period of three months from the date on which the change takes place unless, in the meantime, name of the firm with the changed constitution.]

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1. Added by Notfn. No. F. 1-35/64-D (G.S.R. 1185), dt. 18.8.1964.
2. Subs. by.G.S.R. 788(E), dt. 10.10.1985.
3. Added by.Notfn. No. F. 1-59/68-D (S.O. 4816), dt. 19.11.1969.
4. Added. G.S.R. 665, dt. 28-5-1977.

[1][FORM 20D

(*See* rule 67C)

[2][*Licence to sell, stock or exhibit or offer for sale, or distribute*] *Homoeopathic medicines by wholesale*

1. .....is hereby [2][licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale Homoeopathic medicines on the premises situated at.....subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act,. 1940 and the Rules made thereunder.

2. The licence shall be in force from.....to……..

Date..... *Licensing Authority.*

Conditions of Licence

1. This licence shall be displayed in a prominent place on the premises.
2. The licensee shall comply with the provisions as applicable to Homoeopathic medicines under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.
3. No sale of any drug shall be made to a person not holding the requisite [2][licensed to sell, stock or exhibit or offer for sale, or distribute] the drug. Provided that this conditions hall not apply to the sale of any drug to (a) an authority purchasing on behalf of Government, or (b) a hospital, medical, educational or research institute or a Homoeopathic medical practitioner for the purpose of supply to his patients.

[3][4 The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence and the current licence shall be valid only for a period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.]

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1. Added by Notfn. No. F.1-35/64-D, dt. 18.8.1964.
2. Subs. by.G.S.R. 788(E), dt. 10.10.1985.
3. Added by G.S.R. 665, date 28.5.1977.

[1][**FORM 20E**

(*See* rule 67 EE)

Certificate of renewal of [2][***Licence to sell, stock or exhibit or offer for sale, or distribute***] ***Homoeopathic medicines***

1. Number of licence and date of issue .....……

Certified that licence no ..... in Form 20C / 20D granted on the ..... to..... for sale of Homoeopathic medicines at the premises situated at .....has been renewed for a period from ..... to.....

2. Name of competent persons in-charge.

Date..... *Licensing Authority.*

1. Added by Notfn. No. F. 1-14/67-D, dt. 3.2.1969.
2. Subs. by G.S.R. 788 (E), dt. 10.10.1985

[1][**FORM 20F**

[*See* rule 61(3)]

Licence to sell, stock or exhibit for sale or distribute by retail drugs specified in Schedule X

1. ……..is hereby licensed to sell, stock or exhibit for sale or distribute by retail drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945 on the premises situated at……..

2. Names of drugs.

3. This licence shall be in force from..... ……to.....……

4. Name(s) of registered pharmacist in-charge.

5. The licence is subject to the conditions stated below and the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

Date:.....
Licence No……..

Licensing Authority……..

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

2. The licensee shall report to the licensing authority any change in the qualified staff in charge within one month of such change.

3. No drug shall be stocked or sold unless such drug has been purchased under cash/credit memo from a duly licensed dealer or a duly licensed manufacturer.

4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

1. Ins. by G.S. R. 462(E) , dt. 22.6.1982 corrected vide corrigendum G.S.R. 373(E) , dt. 2.5.1983.

[1][FORM 20G

[*See* rule 61(3)]

[2][*Licence to sell, stock or exhibit or offer for sale, or distribute*] *by wholesale drugs specified in Schedule X*

1. ……..is hereby [2][licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945 on the premises situated at……..

2. Names of drugs……

3. This licence shall be in force from..... to.....

4. The licence is subject to the conditions stated below and the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

Date:.....

Licence No……..

Licensing Authority……..

Conditions of license

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder.
3. No drug shall be stocked or sold unless such drug has been purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
4. The licensee shall forward to the licensing authority copies of the invoices of sales made to the retail dealers.
5. No sale of any drug by wholesale shall be made to a person not possessing the requisite [2] [licence to sell, stock or exhibit or offer for sale, or distribute] drugs specified in Schedule X :

Provided that this condition shall not apply to the sale of any drug to -

(a) an officer or authority purchasing on behalf of Government;

(b) a hospital, medical, educational or research institution, nursing home, Registered Medical Practitioner for the purpose of supply to its/his patients or manufacturer holding a licence in Form 25-E or 28-B to manufacture the drugs containing drugs included in Schedule X.

[3] [The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence, where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]]

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1. Ins. by. G..S. R. 462(E) , dt. 22.6.1982.
2. Ins. by. G.S..R. 788(E) , dt. 10.10.1985.
3. Ins. by 370(E), dt. 7.4.1994.

FORM 21

[*See* rule 61 (2)]

[1][*Licence to sell, stock or exhibit or offer for sale,or distribute*] *by retail drugs specified in Schedules C and C (1)* [2][*excluding those specified in Schedule X*]

[3][1..... is hereby [1][licensed to sell, stock or exhibit or offer for sale, or distribute] by retail the following categories of drugs specified in Schedules C and C (1) [2][excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 19454 and to operate a pharmacy on the premises situated at ..... subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.]

2. The licence shall be in force from .....to .....

3. Name(s) of registered pharmacists in charge .....

[3][4. Categories of drugs .....]

Date.....
Licence No .....

Licensing Authority

**Delete if not applicable.*

Conditions of License

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

2. The licensee shall report to the Licensing Authority any change in the qualified staff in charge within one month of such change.

[4] [***]

4. If the licensee wants to sell, stock or exhibit for sale, or distribute, during the currency of the licence, additional categories of drugs listed in Schedules C and C(I) [2][excluding those specified in Schedule X] but not included in this licence, he should apply to the Licensing Authority for the necessary permission. This licence will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the licence by the Licensing Authority.

[5][5. No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.]

6. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place, unless in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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1. Subs. by G.S.R.788(E), dt. 10.10.1985.
2. Subs. by G.S.R. 462(E), dt. 22.6.1982
3. Amended by. S.O. 2139 ,dt. 12-8-1972.
4. Omitted by. G.S.R. 17(E) , dt. 7.1.1986.
5. Inerted. by Notfn. No. F. 1-63/61, dt. 17.7.1963

FORM 21A

[*See* rule 61 (2)]

[1][*Licence to sell, stock or exhibit or offer for sale, or distribute] by retail drugs specified in [2][Schedule C (1)] [3][excluding those specified in Schedule X] [4][***] for dealers who do not engage the services of a registered pharmacist*

1. ……is hereby [1][licensed to sell, stock or exhibit or offer for sale, or distribute] by retail on the premises situated at [4][***] the following drugs being drugs specified in [2][Schedule C (1)] [3][excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945, subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.

2. The licence will be in force from…….. .

3. Particulars of [2][Schedule C (1)] [3][excluding those specified in Schedule X] drugs to be sold.

[5] [***]

Name of dealer(s)…… Licence No……..

Date..... *Licensing Authority*

Conditions of Licence.

1. This licence shall be displayed in a prominent and conspicuous place in a part of the premises open to the public [6][***]

[7][***]

3. The licensee shall deal only in such drugs as can be sold without the supervision of a "qualified person" as defined in the Explanation to sub-rule (15) of rule 65 of the Drugs and Cosmetics Rules, 1945.

4. No drug shall be sold unless such drug is purchased under cash or credit memo from duly licensed manufacturer.

5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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1 Subs. by G.S.R.788(E), dt. 10.10.1985.
2 Ins. By S.O. 1458, dt:27.4.1965.
3. Ins. by G.S.R. 462(E), dt. 22.6.1982.
4. Amended. by G.S.R 487(E), dt. 2.7.1984.
5. Item 4 omitted G.S.R. 504(E), dt. 18.7.2002
6. Certain words omitted by G.S.R. 231 (E), dt. 4.6.1996
7. Condition No. 2 omitted by G.S.R. 17 (E), dt:7.1.1986.

FORM 21B

[*See* rule 61(2)]

**[1][*Licence to sell, stock or exhibit or offer for sale, or distribute*] *by wholesale drugs specified in Schedules C and C (1)* [2][*excluding those specified in Schedule X*

1. ……is hereby [1][licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale on the premises situated at the following categories of drugs specified in Schedule. C and C (1) [2][excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Categories of drugs

2. This licence shall be in force from..... to…….

[3][2A. The sale shall be made under the personal supervision of a competent person. (Name of the competent person)].

3. This licence is subject to the conditions stated below and to the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder.

Licence No……..

Date..... *Licensing Authority.*

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

[4][2.***]

3. If the licensee wants to sell, stock or exhibit for sale or distribute during the currency of the licence additional categories of drugs listed in Schedules C and C (1) [2][excluding those specified in Schedule X] but not included in this licence, he should apply to the Licensing Authority for the necessary permission. This licence will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the licence by the Licensing Authority.

[5][4. (i) No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

(ii) No sale of any drug shall be made for purposes of resale to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug:

Provided that this condition shall not apply to the sale of any drug to —

(a) an officer or authority purchasing on behalf of Government, or

(b) a hospital, medical, educational or research institute or a registered medical practitioner for the purpose of supply to his patients, or

[6][(c) a manufacturer of hydrogenated vegetable oils, beverages, confectionary and other non-medicinal products, where such drugs are required for processing these products.]

[7][5.***]

[8][6. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from Licensing Authority in the name of the firm with the changed constitution.

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1. Subs. by. G.S.R.788(E), dt. 10.10.1985.
2. Subs. by.G.S.R.462(E), dt. 22.6.1982
3. Ins. by.G.S.R. 681(E), dt. 6.6.1988.
4. Condition no. 2 omitted by.G.S.R. 17(E), dt. 7.1.1986
5 Added by. Notfn. No. F. 1-63/61 -D, dt. 17.7.1963.
6.Added by Notfn. No. F. 1-113/69-D, dt. 23.12.1969.
7. Condition 5 omitted by S.O. 289, dt 20.12.1973 (w.e.f. 3.2.1973)
8. Ins. By S.O. 1458, dt:27.4.1965.

[1][FORM 21BB

[*See* Rule 62D]

Licence to sell by wholesale or to distribute drugs specified in Schedule C and Schedule C (1) to the Drugs and Cosmetics Rules, 1945 from a motor vehicle.

1. ..... is hereby licensed to sell by wholesale, or to distribute drugs specified in Schedule C and Schedule C(1) from the vehicle bearing registration no. ..... assigned under Motor Vehicles Act, 1939, subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from ..... to .....

3. Categories of drugs .....

Date ..... *Licence No……..*

Licensing Authority……..

Conditions of licence

1. This licence shall be displayed in a prominent place on the vehicle.
2. No drugs to which this licence applies shall be sold by wholesale or distributed unless the precautions as are published by the Licensing Authority from time to time in the Official Gazette have been observed throughout the period during which it has been in the possession of the licensee.
3. If the licensee wants to sell by wholesale or distribute during the currency of the licence, additional categories of drugs listed in Schedules C and C (1) not included in this licence, he shall apply to the Licensing Authority for necessary permission. This licence shall be deemed to extend to the categories of drugs in respect of which such permission is given. This shall be endorsed on the licence by the Licensing Authority.
4. (i) No drugs shall be sold by wholesale or distributed unless such drug is purchased under a cash or credit memo from a duly licensed manufacturer.
   (ii) No sale for wholesale or distribution of any drug shall be made for the purpose of resale to a person, not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug:

Provided that this condition shall not apply to the sale of any drug to—

(a) an officer or authority purchasing on behalf of the Government, or

(b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or

(c) a manufactures of hydrogenated vegetable oils, beverages, confectionery and other non-medical products, where such drugs are required for processing their products.

5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from
the Licensing Authority in the name of the firm with the changed constitution.
6. The licensee shall inform the Licensing Authority in writing in the event of any change in the ownership of the vehicle specified in this licence within seven days of such change.]

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1. Added by Notfn. No. 11013/7/76DSMS (G.S.R. 42(E), dt. 25.1.1979.

FORM 21C

(*See* rule 63A)

Certificate of renewal of* [1][*licence to sell, stock or exhibit or offer for sale, or distribute*] *drugs

Number of licence and date of issue……

1. Certified that licence No ..... in [2][Form 20, 20A, 20B, 20F, 20G, 21, 21A or 21B], granted on the.....to ..... for sale of the following drugs at the premises situated at..... has been renewed for a period from .....to .....

2. Categories or particulars of drugs .....

3. Name (s) of registered pharmacist(s) in-charge.....

Date..... *Licensing Authority.*

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

[1][FORM 21CC

(*See* rule 63B)

Certificate of renewal of* [2][*licence to sell, stock or exhibit or offer for sale by wholesale, or distribute*] *drugs from a motor vehicle

Number of licence and date of issue……..

1. Certified that licence no……in Form 20-BB or Form 21-BB granted on the ……to……..for sale by wholesale or distribution of the following drugs from the vehicle bearing registration No…….. assigned under the Motor Vehicles Act, 1939 has been renewed for a period from……..to ……

2. Categories of the drugs:

……

……

Date…….. *Licensing Authority.*

1. Subs. by G.S.R. 788(E), dt.10.10.1985.
2. Added by Notfn. No. 11013/7/76DSMS (G.S.R. 42(E), dt. 25.1.1979.

FORM 22

(*See* rule 67)

(Omitted by S.O. 289, dt. 20.12.1972)

FORM 23

(*See* rule 67)

(Omitted by S.O. 289, dt. 20.12.1972)

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 true copy of a letter from me/us to the 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 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 24B

(*See* rule 69A)

Application for grant or renewal of licence to repack for sale or distribution of drugs, being drugs other than those specified in Schedules C and C (1) [2][excluding those specified in Schedule X]

1.1/ We ……of……hereby apply for grant/renewal of a licence to repack the following drugs at the premises situated at……...

2. Names of the drugs to be repacked ……

3. Name, qualification and experience of competent staff.....

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

Date..... *Signature of applicant.*

NOTE :—The application shall be accompanied by a plan of the premises.

1. Ins. By S.O. 1196, dt:6.5.1960.
2. Subs. by G.S.R. 462(E), dt. 22.6.1982.

[1][FORM 24C

(*See* rule 85B)

Application for the grant or renewal of a [2][licence to manufacture for sale or for distribution of] Homoeopathic medicines or a licence to manufacture potentised preparations from back potencies by licensees holding licence in Form 20C

[3][1. I / We* ..... of ..... holder of licence no ..... in Form 20-C hereby apply for the grant/renewal of licence to manufacture the undermentioned Homoeopathic mother tinctures/potentised preparations on the premises situated at…… …….

Name of the Homoeopathic preparations ..... ……. ….
(*Each item to be separately specified*)].

2. Names, qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.

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

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

Note 1. Delete whichever portion is not applicable.
2. The application should be accompanied by a plan of the premises.

1. Amended by Notfn. No. F. 1-598-D, dt. 19.11.1969
2. Subs. by. G.S.R.788(E) dt. 10.10.1985.
3. Subs. by. G.S.R. 13(E) dt. 7.1.1983.

[1][FORM 24D

(*See* rule 153)

Application for the grant / renewal of a licence to manufacture for sale of Ayurvedic/ Siddha or Unani drugs

1. I/We .....of.....hereby apply for the grant / renewal of a licence to manufacture Ayurvedic (including Siddha) or Unani drugs on the premises situated at..... …….

2. Names of drugs to be manufactured (with details)

3. Names, qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic (including Siddha) or Unani drugs .....

4. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan is enclosed herewith.

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

(applicant)

Note—The application should be accompanied by a Plan of the premises.]

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1. Added by Notfn. No. 1-23/67-D,dt. 2.2.1970.

[1][FORM 24E

(*See* rule 154A)

Application for grant or renewal of a loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs

1. I / We* .....of**..... hereby apply for the grant / renewal of a loan licence to manufacture Ayurvedic (including Siddha) or Unani Drugs on the premises situated at.....……..

C/o*** .....……

2. Names of drugs to be manufactured (with details).

3. The names, qualifications and experience of technical staff actually connected with the manufacture and testing of Ayurvedic (including Siddha) or Unani drugs in the manufacturing premises.

4. I / We* enclose,

(a) A true copy of a letter from me/us to the 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 maintain the registers of raw materials and finished products separately in this behalf.

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

5. A fee of Rs ..... has been credited to Government under the head of account ..... and the relevant Treasury Challan is enclosed herewith.

Date ..... *Signature* ..... ……]

(applicant)

[*] *Enter here the name of the proprietor, partners or 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 letter operates.*

1. Added by G.S.R. 376 (E), dt. 20.7.1978.

[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 25

(*See* rule 70)

[1]*[Licence to manufacture for sale or for distribution of] drugs other than those specified in [2][Schedules C and C(1) and X]*

Number of Licence and date of issue .....

1 ..... is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in [2][Schedules C and C (1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated at..... under the direction and supervision of the following [3][competent technical staff]:

(a) [3][Competent technical staff]. (Names)……

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

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

3. The licence shall be in force from..... to .....

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date.....

Signature .....

Designation .....

[4][*Licensing Authority/
*Central Licence Appoving Authority.]

**Delete whichever is not applicable.*

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale additional items of drugs not included above he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 69(5). This licence will be deemed to extend to the categories so endorsed.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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1. Subs. by. G.S.R. 788(E) ,dt. 10.10.1985
2. Subs. by G.S.R. 462(E), dt. 22.6.1982.
3. Subs. by G.S.R. 231(E), dt. 4.6..1996.
4 Subs. by G.S.R. 923(E), dt. 14.12.1992.

FORM 25A

(*See* rule 70A)

Loan [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. Number of licence and date of issue .....

2..... of ..... is hereby granted a loan licence to manufacture the following drugs other than those specified in [2][Schedules C and C(1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated at C/o under the direction and supervision of the following [3][competent technical staff]:

(a) [3][competent technical staff] (Names):…….

(c) Names of drugs .....

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date..... *Signature ……..*

Designation.. .....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the [3][competent technical staff] named in the licence shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to undertake during the currency of the licence the manufacture for of sale additional drugs he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in Rule 69-A. This licence will be deemed to extend to the drugs so endorsed.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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1. Subs. by G.S.R. 788(E) , dt.10.10.1985.
2. Subs. by G.S.R. 462(E), dt. 22.6.1982.
3. Subs. by. G.S.R. 231(E) ,dt. 4.6.1996.

[1][FORM 25B

(*See* rule 70)

Licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C (1) [2]***[excluding those specified in Schedule X]***

Number of licence and date of issue.

1. …….. ..... of .....is hereby granted a licence to repack the following drugs for sale or distribution on the premises situated at..... under the supervision of the following competent staff.

(a) Names of drugs to be repacked.

(b) Names of competent staff.

2. The licence shall be in force from ..... to .....

3. The licence authorises the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs repacked under the licence subject to conditions applicable to licences for sale.

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date..... *Signature*... ……..

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to repack for sale or distribution additional items he should apply to the Licensing Authority for the necessary endorsement to this licence. This licence will be deemed to extend to only those items so endorsed.
4. The drugs repacked under this licence shall bear on their label, apart from other particulars required by these Rules, the name and address of the licensee and the number of the licence under which the drug is repacked preceded by the words "Rpg. Lic. No.".
5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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1. Added by Notfn. No. F. 1-22/59-D, dt. 9-4-1960.
2. Subs. by G.S.R. 462(E), dt. 22.6.1992.

[1][FORM 25C

(*See* rule 85D)

[2][*Licence to manufacture for sale or for distribution of*] *Homoeopathic medicines*

Number of Licence and date of issue .....

[3][*1. ……..…….. of..... who holds a licence in Form 20-C is hereby licensed to manufacture undermentioned Homoeopathic Mother Tinctures/ potentised and other preparations on the premises situated at .... under the direction and supervision of the following technical staff:

Names of the Homoeopathic preparations.
(*Each item to be separately specified*).

Names of the Technical Staff.....]

2. The licence shall be in force from ..... to .....

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date..... *Signature*……

Designation….

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.

[4][3. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.]

**Delete* the words "who holds a licence in Form 20C" in case this is not applicable.

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1. Added by Notfn No. F.1-36/64-D, dt:18.8.1964
2. Subs. by.. G.S.R.788(E) , dt. 10.10.1985.
3. Subs. by. G.S.R. 13(E) , dt. 7.1.1983.
4. Added by S.O. 903, dt. 28.2.1976.

[1][FORM 25D

(*See* rule 154)

Licence to manufacture for sale of Ayurvedic (including Siddha) or Unani drugs

No. of Licence……

1. …. .....is / are hereby licensed to manufacture the following Ayurvedic (including Siddha) or Unani drugs on the premises situated at..... under the direction and supervision of the following technical staff: —

(a) Technical staff (Names).

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

2. The licence shall be in force from .....to .....

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of issue: …….. *Signature*.....

Designation .....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the Technical staff named in the licence shall be forthwith reported to the Licensing Authority.

3. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be

deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.]

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1. Added by Notfn. No. 1-23/67 –D (S.O. 642), dt. 2-2-1970.

[1][FORM 25E

(*See* rule 154A)

Loan Licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs

1. Number of Licence……

2 ..... of. ..... is hereby granted a loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani drugs, on the premises situated at ..... C/o..... under the direction and supervision of the following expert technical staff:

(a) Technical staff (Names)…….

(b) Names of drugs (each item to be separately specified)

3. The licence shall be in force from ..... to……

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of Issue.....

Signature .....

Designation.....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced on the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the technical staff named in the licence shall be forthwith reported to the Licensing Authority.
3. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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1. Added by G.S.R. 376 (E), dt. 20.7.1978

[1][FORM 25F

(*See* rule 70)

[2][Licence to manufacture for sale or for distribution of] drugs specified in Schedule X and not specified in Schedules C and C(I)

1. .....of.....is hereby licensed to manufacture at the premises situated at……the following drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

2. Names of drugs.

3. Names of approved [3][competent technical staff]

4. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale.

5. The licence shall be in force ..... to.....

6. The licence is subject to conditions stated below and to other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of issue..... *Signature* .....

Licence No..... *Designation*.....

[4][*Licensing Authority/Central Licence Approving Authority.]

**Delete* whichever portion is not required.

Conditions of Licence

1. The licence and any certificate of renewal in force shall be kept on the licensed premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule X not included above, he should apply to the Licensing Authority for the necessary endorsement of this licence. This licence shall be deemed to extend to only those items so endorsed.

3. Any change in the [3][competent technical staff] shall be forthwith reported to the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

5. The licensee shall furnish to the Licensing Authority copies of the invoices of sales made to dealers.

6. The licensee shall not manufacture drugs covered by this licence for use as 'Physician's Samples'.]

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1. Subs. by G.S.R. 462(E) dt. 22.6.1982.
2. Subs. by G.S.R.788(E) dt. 10.10.1985.
3. Subs. by G.S.R.231(E) dt. 4.6.1996.
4. Subs. by G.S.R. 923(E) dt. 14.2.1992.

[1][FORM 26

(*See* rules 73 and 83)

Certificate of renewal of licence to manufacture for sale of drugs other than those specified in Schedule X

1. Certified that licence No ..... granted on the.....to ..... for the manufacture of the following categories of drugs being *drugs other than those specified in Schedules C, C (1) and X/*drugs specified by Schedules C and C (1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945, at the premises situated at ..... has been renewed from..... to.....

2. Name(s) of approved [2][competent technical staff] .....

[3][3 Names of the drugs (each item to be separately specified) .....

Signature .....

Date..... *Designation*.....

[4][Licensing Authority/ *Central Licence Approving Authority.]

**Delete* whichever portion is not required.]

1. Subs. by G.S.R. 462(E) dt. 22.6.1982.
2. Subs. by G.S.R.231(E) dt. 4.6.1996
3. Ins. By G.S.R. 370(E) dt. 7.4.1994.
4. Subs. by G.S.R. 923(E), dt. 14.12.1992.

[1][FORM 26A

(*See* rules 73A and 83A)

Certificate of renewal of loan licence to manufacture for sale of drugs other than those specified in Schedule X

1. Certified that a loan licence No .....granted on the..... to..... for the manufacture of the *drugs other than those specified in Schedules C, C (1) and X the undermentioned drugs being drugs specified in Schedules C and C (1) excluding those specified in Schedule X, to the Drugs and Cosmetics Rules, 1945, at the premises situated at..... C/o .....has been renewed from ..... to.....

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

3. Names of the approved [2][competent technical staff]

Date.....

Signature……..

Designation……..]

** Delete whichever is not applicable.*

1.Ins. by G.S.R. 462(E), dt. 22.6.1982.

2. Subs. by G.S.R.231(E) dt. 4.6.1996.

[1][FORM 26B

(*See* rule 73B)

Certificate of renewal of licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C (1) [2][***excluding those specified in Schedule X***]

1. Certified that licence No ..... granted on the..... to.....for the repacking of the following drugs at the premises situated at .....has been renewed from ..... to.....Names of drugs to be repacked.....

2. Names of competent staff. .....

Date : .....

Signature……..

Designation……..

[3][*Licensing Authority.
*Central licence Approving Authority.]

* *Delete* whichever is not applicable.]

1 Added by Notfn. No. F.1-22/5 9-D, dt. 9.4.1964.
2 Subs. by G.S.R. 462(E) dt. 22.6.1982.
3. Ins. by G.S.R. 923(E) dt. 14.12.1992

FORM 26C

(*See* rule 85G)

Certificate of renewal of licence to manufacture for sale of Homoeopathic medicines

1. Certified that licence No ..... granted on the……. to…… for the manufacture for sale of the Homoeopathic mother tinctures/potentised preparation at the premises situated at .....has been renewed for a period from the .....to ..... ……

2. Name of the technical staff ..... ……

[1][3. Names of the drugs (*each item to be separately specified*) .....]

Date……..

Signature ..... ……..
Designation.. ……

1. Ins. by G.S.R. 370(E) dt. 7.4.1994.

[1][**FORM 26D**

(*See* rule 155)

Certificate of renewal of licence to manufacture for sale of Ayurvedic / Siddha or Unani drugs

1. Certified that licence No ..... granted on the……to Shri/ Messers ..... for the manufacture of Ayurvedic/Siddha/Unani drugs at the premises situated at……has been renewed from……to .....

2. Names of technical staff .....

[2][3. Names of drugs (each item to be separately specified).]]

Date ……. *Signature*…….
Designation……..

1. Ins. by F. No.1 -23/67-D, dt. 2-2-1970.
2. Ins. by G.S.R 376 (E), dt. 20.7.1978

[1][**FORM 26E**

(*See* rule 155A)

Certificate of renewal of loan licence to manufacture for sale of Ayurvedic / Siddha or Unani Drugs

1. Certified that loan Licence No .....granted on the……to……...…… for the manufacture ofAyurvedic/ Siddha or Unani drugs at the premises situated at..... C/o .....has been renewed from.....to ..... …….

2 Names of technical staff.

Date: …….. *Signature……*
Designation……..

1. Added by G.S.R. 376(E), dt. 20.7.1978.

[1][FORM 26E-I

(*See* rule 157B)

Certificate of Good Manufacturing Practices (GMP) to manufacture of Ayurveda, Siddha or Unani drugs

Certified that manufacturing unit licensee, namely ..... situated at ..... State ..... Licence No..... comply with the requirements of Good Manufacturing Practices of Ayurveda-Siddha-Unani drugs as laid down in Schedule T of the Drugs and Cosmetics Rules, 1945.

This certificate is valid for a [2][period of five years and the Good Manufactruing Practices (GMP) is valid for the various dosage forms or Rasaushadhis, as follows:]

Date :..... *Signature……..*

Place : …. *Designation……*

Licensing Authority for Ayurveda/ Siddha/ Unani Drugs.]

1.subs. by G.S.R.198(E), dt. 7.3.2003. Earlier Ins. by G.S.R. 561(E), dt. 23.6.2000.
2.Subs. by G.S.R. 376(E), dt. 3.5.2010

[1][FORM 26E2-I

(*See* rule 158C)

State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines

Name of the State or Union territory……..

Free Sale Certificate

It is certified that M/s. …….(Name of the company)……..situated at ……. (Address) ..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing License Number..... valid till ……and certificate of Good Manufacturing Practices for the State or Union territory of ……The manufacturer has applied for renewal of license on .....(to be mentioned, if application for renewal of license has not been rejected).

It is also certified that the manufacturing plant siuated at ……..(Address)……..in which the Ayurvedic or Unani or Sidhha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.

The firm has been permitted under License Number……..to manufacture and market the following products (attach list of products, if multiple) freely for sale in India under the provisions of the Drugs and Cosemtics Atc, 1940 and the rules thereunder.

(i)……
(ii)……
(iii)……..

Date :..... *(Seal of issuing Officer)* ... ...

(Signature and Name)

State Drug Controller/Licensing Authority

Address……

Name of State or Union territory……..]

1.Ins. by G.S.R. 153 (E), dt. 5.3.2014.

[1]**[FORM 26E2-II**

(*See* rule 158C)

State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines

Name of the State or Union territory……..

Free Sale Certificate

It is certified that M/s. …….(Name of the company)……..situated at ……. (Address) ..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing Loan License Number..... valid till ……and the valid certificate of Good Manufacturing Practices for the State or Union territory of ……The manufacturer has applied for renewal of loan license on .....(to be mentioned, if application for renewal of license has not been rejected).

It is also certified that the manufacturing plant siuated at ……..(Address)……..in which the Ayurvedic or Unani or Sidhha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected toinspection as per rules.

The firm has been permitted under Loan License Number……..to manufacture and market the following products (attach list of products, if multiple) freely for sale in India under the provisions of the Drugs and Cosemtics Atc, 1940 (23 of 1940) and the rules thereunder.

(i)……
(ii)……
(iii)……..

Date :.....

(Seal of issuing Officer) … … … … … … .

(Signature and Name)

State Drug Controller/Licensing Authority

Address……

Name of State or Union territory……]

1.Ins. by G.S.R. 153 (E), dt. 5.3.2014.

[1]**[FORM 26 E3**

(*See* rule 158C)

State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines

Name of the State or Union territory……..

Non-Conviction Certificate

It is certified that M/s. …….(Name of the company)……..situated at ……. (Registered Address) ..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing License Number..... in Form 25D/25E valid till ……and certificate of Good

Manufacturing Practices/valid Good Manufacturing Practices certificate of principal or original manufacturer for the State or Union territory of ……The manufacturer has applied for renewal of license on .....(date to be mentioned, if application for renewal of license has not been rejected).

As per the records of the State Drug Controller or Licensing Authority, as it may be, and affidavit (Annexure I) given by the company, the firm has not been conicted under the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder in the State or Union territory of …….., during the last three years of the issuing of this certificate.

This certificate shall be valid only for six months from the date of issue.

Date :..... *(Seal of issuing Officer) … … … … … … … … … … … … … … .*

(Signature and Name)
State Drug Controller/Licensing Authority for
Ayurveda, Siddha and Unani Medicines.
Address……
Name of State or Union territory……..]

[1][ANNEXURE-1

(Proforma of Affidavit to be submitted on stamp paper of Rs. 50 attested by Magistrate not below the rank of first class)

I, ……S/O…….age…….working as …….of……..(Name and address of the company)……from ……to……do hereby solemnly affirm and declare as under:

1. That I, in the capacity of Authorized Signnatory of ……(name and address of the company)….,am duly competent to depose and verify the present affidavit.
2. That I apply for Non-conviction Certificate on behalf of M/s. ……..
3. Thar I declare that I am aware of the details of my organization asnd day to day activities from….to….
4. That I hereby undertake that the Non-Conviction Certificate, if issued, will be utilized for the bona fide purpose only.
5. I declare that the aforesaid firm is not convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the last three years.
6. That it is my true statement.

…….
Signatature of Deponent

Verification

Verified at…….(Palce and State)…….today on this……..…..day of…..(month)….(Year)…..that the contents of the above affidavit are true to my knowledge and belief and no part of it is false and nothing has been concealed therefrom.

…….
Signature of Deponent]

Witness with Address
1.
2.

1.Ins. by G.S.R. 153 (E), dt. 5.3.2014.

[1][FORM 26F

(*See* rules 73 and 83)

Certificate of renewal of licence to manufacture for sale of drugs specified in Schedule X

1. Certified that licence No .....granted on the ..... to ..... for the manufacture of drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945, at the premises situated at…….. has been renewed from…… to……

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

3. Names of the approved [2][competent technical staff].

Date:……

Date of issue……

Signature……..

Designation……..

[3]*[*Licensing Authority/Central Licence Approving Authority]*

**Delete whichever is not applicable.*

1. Ins. by. G.S.R. 462(E) ,dt. 22.6.1982.
2. Subs. by G.S.R. 231(E), dt. 4.6.1996.
3. Subs. by G.S.R. 923(E), dt. 14.12.1992.

[1][FORM 26G

(*See* rules 122F)

Certificate of renewal of licence to operate a Blood Bank for processing of whole human blood and/or* for preparation for sale or distribution of its components

1. Certified that Licence No..... . granted on …….. to M/s…… ..... for the operation of a Blood Bank for processing of whole human blood and*/or for preparation of its components at the premises situated at..... is hereby renewed with effect from…….. to .....

2. Name(s) of items :

   1.

   2.

   3.

3. Name(s) of competent Technical Staff:

   1.

   2.

   3.

Dated……..

Signature……..

Designation……..

*[*Licensing Authority/Central Licence Approving Authority]*

* *Delete whichever is not applicable.*

1. Subs. by G.S.R 245(E) dt. 5.4.1999.

[1][**FORM 26H**

(*See* rules 68A, 76, 77, 78)

Certificate of renewal of licence to manufacture for sale of [2][Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA)derived drugs] specified in Schedules C and C(I) excluding those specified in Schedule X

1. Certified that licence No..... granted on the ..... to ..... for the manufacture of following [2][Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs] at the premises situated at..... has been renewed from.....to……

2. Name(s) of drug(s) ..... …….
(each item to be separately specified).

3. Name(s) of competent technical staff:

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.
3.	3.
4.	4.

Date:……

Signature……..

Designation……..

*[*Licensing Authority/Central Licence Approving Authority]*

** Delete whichever is not applicable.*

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 26-I**

(*See* rules 122-I)

Certificate of renewal of licence for manufacture of blood product.

1. Certified that licence no ..... granted on the ..... to M/s. ..... for the manufacture of blood products at the premises situated at.....is hereby renewed with effect from .....…… to……

2. Name(s) of item (s):

1.
2.
3.

3. Name(s) of competent technical staff:

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.
3.	3.
4.	4.

Date:……

Signature……..
Designation……..
*[*Licensing Authority/Central Licence Approving Authority]*

** Delete whichever is not applicable.*

1. Ins. by G.S.R 245(E), dt. 5.4.1999.

[1]**[FORM 26-J**

(*See* rules 122G, 122H, 122I, 122P)

Certificate of renewal of licence for collection, processing, testing, storage, banking and release of umblical cord blood stem cells.

Certified that licence no ..... granted on the ..... to M/s. ..... for collection, processing, testing, storage, banking and release of umblical cord blood stem cells at the premises situated at.....is hereby renewed with effect from .....……..… to……

1. Name(s) of competent technical staff:
   1……..
   2……..
   3……..

Date:……

Signature……..
Designation……..
*[*Licensing Authority/Central Licence Approving Authority]*

** Delete whichever is not applicable.*

1. Ins. by G.S.R 899(E), dt. 27.12.2011.

[1]**[FORM 26J**

(*See* rules 83A and 83AA)

Certificate of renewal of loan licence to manufacture for sale of Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs specified in Schedules C and C(I) excluding those specified in Schedule X

Certified that licence no ..... granted on the ..... to M/s. ..... for the manufacture of following Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs at the premises situated at .....has been renewed from .....……..… to……

2. Name(s) of drug (s)…….(Each item to be separately specified)

3. Name(s) of competent technical staff:

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.
3.	3.
4.	4.

Date:……

Signature……..
Designation……..
*[*Licensing Authority/Central Licence Approving Authority]*

** Delete whichever is not applicable.*

1. Ins. by G.S.R 574(E), dt.17.6.2012.

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.

---

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

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 27C

(*See* rule 122-F)

Application for grant/renewal* of licence for the operation of a Blood Bank for processing of whole blood and/or* preparation of Blood Components

1. I/We, ... of M/s ..... hereby apply for the grant of licence/renewal of licence number ..... dated…….to operate a Blood Bank, for processing of whole blood and/or* for preparation of its components on the premises situated at ……..

2. Name(s) of the item(s)

   1.

   2.

   3.

3. The name(s), qualification and experience of competent Technical Staff are as under:

   (a) Name(s) of Medical Officer.

   (b) Name(s) of Technical Supervisor

   (c) Name(s) of Registered Nurse.

   (d) Name(s) of Blood Bank Technician.

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

5. A licence fee of rupees ..... and an inspection fee of rupees .....has been credited to the Government under the Head of Account..... (receipt enclosed)

Signature .... ……

Dated..... *Name and Designation……..*

* *Delete whichever is not applicable.*

Notes:

1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for collection, processing, storage and testing of whole blood and its components, memorandum of association/constitution of the firm, copies of certificate relating to educational qualifications and experience of the 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 to the Central Licence Approving Authority and to the Zonal/Sub-Zonal Officers concerned of the Central Drugs Standard Control Organization].

---

1. Subs. by G.S.R. 245(E), dt. 5.4.1999.

[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.

[1][**FORM 27E**

(See rule 122F)

Application for grant/renewal* of licence to manufacture blood products for sale or distribution

1. I/We ..... of M/s ..... hereby apply for the grant of licence/renewal of licence number ..... dated…….. to manufacture Blood products on the premises situated at ..... …….

2. Name(s) of the item(s)
   1.
   2.
   3.
   4.

3. The name(s), qualification and experience of competent Technical Staff are as under:

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.
3.	3.

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

5. A licence fee of rupees …… ..... ……..and an inspection fee of rupees ..... has been credited to the Government under the Head of Account..... (receipt enclosed)

Signature .... ……..

Dated..... *Name and Designation*..... ....

* *Delete whichever is not applicable.*

Notes:

1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for manufacture of blood products, memorandum of association/constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the said premises.
2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the Zonal/Sub-Zonal Officers concerned of the Central Drugs Standard Control Organization].

1. Ins. by G.S.R. 245(E), dt. 5-4-1999.

[1][FORM 27F

(See rule 122F)

Application for grant/renewal* of licence for collection, processing, testing, storage, banking and release of umblical cord blood stem cells

1. I/We ..... of M/s ..... hereby apply for the grant of licence/renewal* of licence number ..... dated…….. for collection, processing, testing, storage, banking and release of umblical cord blood stem cells on the premises situated at ..... …….

2. Name(s), qualification and experinec of competent technical staff are as under:
   1. Medical Director
   2.Laboratory In-charge
   3.Technical Supervisor
   4.Cord Blood Bank Technician (s)

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

4. A licence fee of rupees …… ..... …….and an inspection fee of rupees .....has been credited to the Government under the Head of Account..... (receipt enclosed)

Signature .... ……..

Dated..... *Name and Designation..... ....*

** Delete whichever is not applicable.*

Notes:

1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for manufacture of blood products, memorandum of association/constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the said premises.
2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the Zonal/Sub-Zonal Officers concerned of the Central Drugs Standard Control Organization].

---

1. Ins. by G.S.R. 899(E), dt. 27-12-2011.

FORM 28

(*See* rule 76)

[1][Licence to manufacture for sale or for distribution of] drugs specified in Schedules C and C (1) [2][excluding those specified in Schedule X]

Number of Licence and date of issue .....

1. ……. is hereby licensed to manufacture at the premises situated at the following drugs, being drugs specified in Schedules C and C (1) [2][excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Names of drugs .....

2. Names of approved [3][competent technical staff].

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.

4. The licence will be in force from .....to .....

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act,1940.

Date:……

Signature……..

Designation……..

[4]*[*Licensing Authority/Central Licence Approving Authority]*

**Delete whichever is not applicable*

Conditions of Licence

1 This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2 If the licensee wants to undertake during the currency of the licence the manufacture any drug specified in Schedules C and C (1) [2][excluding those specified in Schedule X] not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in rule 75(3). This licence will be deemed to extend to the items so endorsed.

3 Any change in the [3][competent technical staff] shall be forthwith reported to the Licensing Authority.

4 The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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1. Subs. by G.S.R. 788(E), dt. 10.10.1985.
2. Ins. by G.S.R. 462(E), dt. 22.6.1982.
3. Subs. by G.S.R. 231(E), dt. 4.6.1996
4. Subs. by G.S.R. 923(E), dt. 14.12.1992.

FORM 28A

(*See* rule 76-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 Schedule X]

1. Number of licence and date of issue .....

2. ……. of.....…….is hereby granted a loan licence to manufacture on the premises situated at ……... C/o ..... the following drugs being drugs specified in Schedules C and C (1) [2][excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Names of Drugs .....

3. Names of [3][competent technical staff].....

[4][3A. The licence shall be in force from ..... to.....

4. The licence authorises the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale.

5 The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of issue: ……..

Signature……..

Designation .....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence to manufacture any drugs specified in Schedules C and C (1) [2][excluding those specified in Schedule X] not included above, he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in rule 75A. This licence will be deemed to extend to the items so endorsed.

3. Any change in the [3][competenet technical staff] shall be forthwith reported to the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

---

1. Subs. by G.S.R 788(E), dt. 10-10-1985.
2. Ins. by G.S.R. 462(E), dt. 22.6.1982.
3. Subs. by G.S.R.231(E) dt. 4.6.1996.
4. Added by Notfn. F. No. 1-10/62-D, dated 10.4.1964.

[1][FORM 28B

(*See* rule 76)

[2][Licence to manufacture for sale or for distribution of] drugs specified in Schedules C, C(I) and X

No of Licence……

1. ..... is hereby licensed to manufacture at the premises situated at..... the following drugs specified in Schedules C, C(I) and X to the Drugs and Cosmetics Rules, 1945.

Name of drugs……

2. Names of [3][competent technical staff]

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale.

4. The licence will be in force.....to .....

5. The licence is subject to conditions stated below and to other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date:……

Signature……..

Designation……..

*[4][*Licensing Authority/Central Licence Approving Authority]*

**Delete whichever is not applicable*

Conditions of Licence

1. The licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule X not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 75(4). This licence will be deemed to be applicable to the items so endorsed.

3. Any change in the [1][competent technical staff] shall be forthwith reported to the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

5. The licensee shall furnish to the Licensing Authority copies of the invoices of sales made to dealers.

6. The licensee shall not manufacture drugs specified in Schedule X covered by this licence for use as "Physicians Samples".]

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1. Subs. by G.S.R. 462(E) dt. 22.6.1982.
2. Subs. by G.S.R.788(E) dt. 10.10.1985.
3. Subs. by G.S.R.231(E) dt. 4.6.1996.
4. Subs. by G.S.R. 923(E) dt. 14.12.1992.

[1][FORM 28C

(*See* rule 122-G)

Licence to operate a Blood Bank for collection, storage and processing of whole human blood and/or* its components for sale or distribution

1. Number of licence..... date of issue ..... at the premises situated at
…….

2. M/s ..... is hereby licensed to collect, store, process and distribute whole blood and/or its components.

3. Name(s) of the item(s) :
   1.
   2.

4. Name(s) of the Competent Technical Staff:
   1.
   2.
   3.

5. The licence authorises licensee to collect, store, distribute and processing of whole blood and/or blood components subject to the conditions applicable to this licence.

6. The licence shall be in force from ..... …….to.……..

7. The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time to time in the Rules made under Drugs and Cosmetics Act, 1940.

Dated: ……

Signature……

Name and Designation .....

*Licensing Authority/
*Central Licence Approving Authority

** Delete whichever is not applicable*

Conditions of Licence

1. The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components from the blood collected from such a donor.

2. The licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

3. Any change in the technical staff shall be forthwith reported to the Licensing
Authority and/or Central Licence Approving Authority.

4. The licensee shall inform the Licensing Authority and/or Central Licence approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes places, the current licence shall be deemed to be valid for maximum
period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

1.Ins. by G.S.R. 245(E), dt. 5.4.1999.

[1][FORM 28D

(See Rules 76)

Licence to manufacture for saleor for distribution of [2][Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs] specified in Schedules C and C(I) excluding those specified in Schedule X

Number of licence ..... and date of issue…….

1. ..... is hereby licensed to manufacture at the premises situated at..... the following [2][Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs] specified in Schedules C and 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. Name(s) of competent technical staff:

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.

4. The licence authorises the sale by way of wholesale dealing and storage for sale

by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

5. The licence shall be in force from..... to .....

6. The licence shall be subject to the conditions stated below and to such other conditions as shall be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date: ……..

Signature……..

Designation……

*Licensing Authority/*Central Licence Approving Authority

** Delete whichever is not applicable*

Conditions of Licence

1. The licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence to manufacture of any drug specified in Schedule C and/or C(I) excluding those specified in Schedule X not included above, he should apply to the Licensing Authority and or Central Licence Approving Authority for the necessary endorsement as provided in the rules. This licence shall be deemed to extend to the items so endorsed.

3. Any change in the competent technical staff named in the licence shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.

4. The licensee shall inform the licensing authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licnece shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been applied along with prescribed fee and necessary documents to the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

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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 28DA

(See Rules 76A, 78A, 83AA)

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

Number of licence ..... and date of issue…….

1. ..... of……..is hereby granted a loan license to manufacture on the premises situated at.....c/o..... the following drugs being [2][Large Volume Parenterals/Sera and Vaccines/recombinant

DNA (r-DNA) derived drugs] specified in Schedules C and 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. Name(s) of competent technical staff:

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.

4. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

5. The licence shall be in force from..... to .....

6. The licence shall be subject to the conditions stated below and to such other conditions as shall be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date: ……

Signature……..

Designation……

*Licensing Authority/*Central Licence Approving Authority

** Delete whichever is not applicable*

Conditions of Licence

1. The licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence to manufacture of any drug specified in Schedule C and/or C(I) excluding those specified in Schedule X not included above, he should apply to the Licensing Authority and or Central Licence Approving Authority for the necessary endorsement as provided in the rules. This licence shall be deemed to extend to the items so endorsed.

3. Any change in the competent technical staff named in the licence shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.

4. The licensee shall inform the licensing authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licnece shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been applied along with prescribed fee and necessary documents to the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

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1. Ins. by G.S.R. 574(E), dt: 17.7.2012.

[1]**[FORM 28E**

(*See* rule 122 G)

Licence to manufacture and store blood products for sale or distribution.

1. Number of licence ..... date of issue .....at the premises situated at…….....

2. M/s.....is hereby licensed to manufacture, store, sell or distribute the following blood products:-

3. Name(s) of the item(s) :

1.

2.

3.

4. Name(s) of the competent technical staff:

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.
3.	3.

5. The licence authorises licensee to manufacture, store, sell or distribute the blood products, subject to the conditions applicable to this licence.

6. The licence shall be in force from..... to.....

7. The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time to time in the rules made under Drugs and Cosmetics Act, 1940.

Dated.: ..... *Signature*.....

……..

Name and Designation..

……..

*Licensing Authority/ *Central Licence Approving Authority

** Delete whichever is not applicable*

Conditions of License

1. The licensee shall not manufacture blood products from the blood drawn from any professional donor or paid donor.

2. The licence and any certificate of renewal in force shall be displayed on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

3. Any change in the technical staff shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.

4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing any change in the constitution of the firm operating under the licence. In the event of any change in the constitution of the firm, the licence shall be deemed to be valid for a period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

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1. Ins. by G.S.R. 245(E), dt. 5.4.1999.

[1][**FORM 28F**

(*See* rules 122 F to 122-I, 122K, 122P)

Licence To Collect, Process, Test, Store, Banking And Release Of Umbilical Cord Blood Stem Cells.

1. Number of licence ..... date of issue .....at the premises situated at…….....

2. M/s.....is hereby licensed to collect, process, test, store, banking and release of umbilical cord blood stem cells.

3. Name(s) of competent technical staff :

1.

2.

3.

4. The licence authorises licensee to collect, process, test, store, banking and release of umbilical cord blood stem cells.

5. The licence shall be in force from..... to.....

6. The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time to time in the rules made under Drugs and Cosmetics Act, 1940.

Dated.: ..... *Signature*.....

……..

Name and Designation..

……..

*Licensing Authority/ *Central Licence Approving Authority

** Delete whichever is not applicable*

Conditions of License

1. Umbilical cord blood specific for an individual will be collected after signing an agreement with the parent(s), whose child's umbilical cord blood is to be collected, and the cord blood bank.

2. Umbilical cord blood shall be collected from hospitals, nursing homes, birthing centres and from any other place where a consenting mother delivers, under the supervision of the qualified Registered Medical Practitioner responsible for the delivery.

3. The licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an inspector appointed under the Drugs and Cosmetics Act, 1940.

4. Any change in the technical staff shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.

5. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing any change in the constitution of the firm operating under the licence. In the event of any change in the constitution of the firm, the licence shall be deemed to be valid for a period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

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1. Ins. by G.S.R. 889(E), dt. 27.12.2011.

FORM 29

(*See* rule 89)

Licence to manufacture drugs for purposes of examination, test or analysis

1. ….....of…… is hereby licensed to manufacture the drugs specified below for purposes of examination, test or analysis at……

2. This licence is subject to the conditions prescribed in Part VIII of the Drugs and Cosmetics Rules, 1945.

3. This licence shall be in force for one year from date specified below.

Names of drugs

Date : …… *Licensing Authority……*

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……..

[1][FORM 31

(*See* rule 139)

Application for grant or renewal of a [2][*licence to manufacture cosmetics for sale or for Distribution*]

1.1/ We..... of..... hereby apply for grant /renewal of a licence to manufacture on the premises situated at..... the following cosmetics :-

2. Names of Cosmetics .....

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. Added by Notfn No.F.1-36/64-D (G.S.R.1183), dt:17.8.1964.
2. Subs. by G..S.R .788 (E), dt. 10.10.1985.

[1][FORM 31A

(*See* rule138A)

***Application for grant or renewal of loan* [2][*licence to manufacture cosmetics for sale or for distribution*]**

1. I / We .....of. .....hereby apply for grant/renewal of a loan licence to manufacture cosmetics for sale on the premises situated at.....C/o .....the following cosmetics :—

2. Names of Cosmetics.....

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

4. I /We enclose–

(a) A true copy of a letter from me / us to the 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 will analyse every batch of and maintain the registers of raw materials , finished products and reports of analysis separately in this behalf.

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

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

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

**Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also their licence number.*

---

1. Ins. by G.S.R. 444, dt. 28-4-1973.
2. Subs. by G.S.R. 788(E), dt. 10.10.1985.

[1][FORM 32

(*See* rule140)

[2][Licence to manufacture cosmetics for sale or for distribution]

Number of Licence and date of issue

1 .....is hereby licensed to manufacture on the premises situated at

..... the following cosmetics under the supervision of the following technical staff:-

(a) Names of cosmetics.

(b) Names of technical staff

2. The licence shall remain in force from.....to.....(both days inclusives)

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Drugs and Cosmetics Rules, 1945.

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

Designation .....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the technical staff shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale of additional items he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in rule 138 (3). This licence shall be deemed to extend to the cosmetics so endorsed.

[3][4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.]

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1. Added by Notfn No.F.1-36/64-D, dt:17.8.1964.
2. Subs. by G.S.R. 788 (E), dt. 10.10.1985.
3. Added by S.O. 903, dt. 10-2-1976.

[1][**FORM 32A**

(*See* rule 139B)

Loan [2][***licence to manufacture cosmetics for sale or for distribution***]

1. Number of Licence and date of issue……

2 . .....of. ..... is hereby granted a loan licence to manufacture the following cosmetics on the premises situated at.....C/o..... under the direction and personal supervision of the following technical staff:

(a) Names of technical staff.

(b) Names of cosmetics.

3. The licence shall remain in force from .....to .....

4. The licence is subject to the conditions stated below and to such other conditions as are specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

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

Designation.....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the technical staff shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale additional items he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in rule 138A(5).This licence shall be deemed to extend to the cosmetics so endorsed.]

---

1. Ins. by G.S.R. 444, dt. 28-4-1973.
2. Ins. by G.S.R. 788 (E), dt. 10.10.1985.

[1][**FORM 33**

(*See* rule 141)

Certificate of renewal of licence to manufacture cosmetics for sale

1. Certified that licence No……granted on the…….. to……for the manufacture for sale of the following cosmetics at the premises situated at……has been renewed from……and shall expire on……

2. Names of cosmetics.

3. Names of technical staff

Date…….. *Signature……..*
Designation……]

---

1. Ins. by G.S.R. 1183, dt. 17.8.1964.

[1][FORM 33A

(*See* rule 141-A)

Certificate of renewal of loan licence to manufacture cosmetic for sale

1. Certified that loan licence No…….granted on the …….. to……for the manufacture for sale of the following cosmetics at the premises situated at C/o……has been renewed from……to .....

2. Names of cosmetics.

3. Names of technical staff.

Date…… *Signature……..*
Designation……]

---

1. Added by G.S.R. 444, dt. 28-4-1973.

[1][FORM 34
(See rules 131 and 150)

Certificate of test or analysis of cosmetic by the Central Drugs Laboratory or the Government Analyst

1. Name of the officer or Inspector from whom received .....
2. Serial number and date of the Officer's / Inspector's memorandum.....
3. Number of sample .....
4. Date of receipt.....
5. Name of the Cosmetic purporting to be contained in the sample…….
6. Condition of seals on the [2][packet or on portion of sample or container]

7. *Results of test or analysis* :— The sample of cosmetics—

(a) contains a prescribed colour only/does not contain a prescribed colour.

(b) does not contain harmful ingredients/ contains harmful ingredients

(c) conforms/does not conform to claims m,ade on the label as to the nature and quality of the cosmetics.

[3][(d) contains not more than …….parts per million of Lead and ……..parts per million of Arsenic……../contains more than ……parts per million of Lead and ……parts per million of Arsenic.]

Date……

Director……..
Central Drugs Laboratoy/Government Analyst]

1. Added by Notfn No.F.1-36/64-D (G.S.R 1183), dt:17.8.1964.
2. Subs. by G.S.R. 59(E), dt. 7.2.1995.
3. Subs. by G.S.R. 510(E), dt. 26.7.1982.

[1][FORM 35

[2][*See* Rules 65, 67-G, 74, 74A, 74B, 78, 78A, 85H, 122P, 142, 142-B, 150E, 158 and 158A]

Form in which the Inspection Book shall be maintained

(A) The cover of the Inspection Book shall contain the following particulars, namely :—

1. The name and address of the licensee.....
2. Licence number and the date upto which the licence is valid .....

(B) (i) The pages of the Inspection Book shall be serially numbered and duly stamped by the Licensing Authority. The pages, other than the first and the last pages, shall have the following particulars:--

Name and designation of the Inspector who inspects the premises of the licensee:–

Date of Inspection.....

Observations of the Inspector .....

Signature of the Inspector

(ii) The first and last pages of the Inspection Book shall be endorsed by the Licensing Authority with the following words, namely:—

Inspection Book maintained by M/s……

situated at …… for licence number …… in Form …….. under the Drugs and Cosmetics Rules, 1945.

Seal and Signature of the Licensing Authority.

Notes:-

(i) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment.

(ii) The Inspection Book shall be maintained at the premises of the licensee.

(iii) The observations made by the Drug Inspector shall be in triplicate. The original copy shall be retained in the Inspection Book to be maintained in the premises of the licensee. The duplicate copy shall be sent to the Licensing Authority. The triplicate copy shall be taken as record by the Inspector.

1. Added by Notfn. No.F.1-14/68-D (G.S.R. 3869), dt. 26.10.1968.
2. Subs. by G.S.R. 592(E), dt: 13.8.2008.

[1][FORM 36

(*See* rule 150B)

Application for grant or renewal of approval for carrying out tests on drugs/ cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs /cosmetics

(1) *I/We……of……hereby apply for the grant or renewal of approval for carrying out tests of identity, purity, quality and strength on the following categories of drugs / items of cosmetics or

raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs / cosmetics.

(2) *Categories of drugs, items of cosmetics:

(a) Drugs other than those specified in Schedules C and C (1) and also excluding Homoeopathic Drugs:-

1. Crude vegetable drugs.
2. Mechanical contraceptives.
3. Surgical dressings.
4. Drugs requiring the use of ultravoilet / Infra Red. or Chromatography.
5. Disinfectants.
6. Other drugs.

(b) Drugs specified in Schedules C and C (1):—

1. Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages and similar Immunological Products.
2. Antibiotics.
3. Vitamins
4. Parenteral preparations.
5. Sterilized surgical ligature / suture.
6. Drugs requiring the use of animals for their test.
7. Drugs requiring microbiological tests.
8. Drugs requiring the use of Ultravoilet/ Infra Red/ Spectrophotomete or Chromatography.
9. Other drugs.

(c) Homoeopathic drugs.

(d) Cosmetics.

(3) Name, qualifications and experience of expert staff employed for testing and the person-in-charge of testing.

(4) List of testing equipments provided.

(5) *I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.

(6) An inspection fee of rupees .....has been credited to Government under the Head of Account.....

Date..... *Signature……]*

** Delete whichever is not applicable*

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1. Ins. by Notfn. No .X. 11014/7/76-D&MS (G.S.R 1172), dt. 23-8-1977.

[1][FORM 37

(*See* rule 150C)

Approval for carrying out tests on drugs / cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs /cosmetics

Number of approval and date of issue:……

(1) Approval is hereby granted to ..... …….for carrying out tests for identity, purity, quality and strength on the following categories of drugs/items of cosmetics and the raw materials used in the manufacture thereof on the premises situated.....

Categories of drugs / items of cosmetics
……..
……..
……..

(2) Names of [2][competent technical staff] employed for testing and the person-in- charge of testing.

(3) The approval shall be in force from..... to.....

(4) The approval is subject to the conditions stated below and such other conditions as may be specified in the rules for the time being in force under the Act.

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

Designation .....

Conditions of Approval

(1) This approval and any certificate of renewal in Form 38 shall be kept in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.

(2) If the approved institution wishes to undertake during the currency of the approval the testing of any other category of drugs or items of cosmetics it should apply to the approving authority for necessary endorsement as provided in rule 150-B.This approval will be deemed to extend to the item so endorsed.

(3) Any change in the analytical staff or in the person-in-charge of the testing shall be forthwith reported to the approving authority.

[3][(4) The approved institution shall inform the approving authority in writing in the event of any change of the constitution of the institution operating under this Form. Where any change in the constitution of the institution takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh approval has been taken from the approving authority in the name of the institution with the changed constitution.]

1.Ins. by G.S.R.1172, dt:23.8.1977.
2. Subs. by. G.S.R. 231(E), dt. 4.6.1996.
3. Ins. by G.S.R. 681 (E), dt. 5-12-1980.

[1][FORM 38

(*See* rule 150J)

Certificate of renewal of approval for carrying out tests on drugs / cosmetics and raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs / cosmetics

(1) Certified that approval number ..... granted on the ..... for carrying out tests of identity, purity, quality and strength on the following categories of drugs/ items of cosmetics and the raw materials used in the manufacture thereof at the premises situated at……has been renewed from…….to.....

Categories of drugs/items of cosmetics
……..
……

(2) Names of [2][competent technical staff] and person-in-charge of testing.

Date..... *Signature*.....……

Designation……..

---

1. Ins. By G.S.R. 1172, dt:23.8.1977.
2.Subs. by. G.S.R.231(E) ,dt. 4.6.1996.

[1][FORM 39

[*See* rule150E(f)]

Report of test or analysis by approved institution

(1) Name of manufacturer from whom sample received together with his manufacturing licence number under the Act and under the rules made thereunder.

(2) Reference number and date of the letter from the manufacturer under which the sample was forwarded.

(3) Date of receipt of the sample.

(4) Name of drug / cosmetics / raw material purporting to be contained in the sample.

(5) Details of raw material/final product in bulk/final product (in finished pack)* as obtained from the manufacturer:

(a) Original manufacturer's name in the case of raw materials and drugs repacked.

(b) Batch number.

[2][(c) Batch size as represented by sample.]

(d) Date of manufacture, if any.

(e) Date of expiry, if any.

(6) Results of test or analysis with protocols of test or analysis applied.

In the opinion of the undersigned, the sample referred to above is **of standard quality/is not of standard quality* as defined in the Act and the rules made thereunder for the reasons given below.

Date..... .....

Signature of Person-in-charge of testing

Note:- Final product includes repacked material.

**Delete whichever is not applicable*

1. Ins. By G.S.R. 1172, dt:23.8.1977.
2. Subs. by. G.S.R. 681(E), dt. 6.6.1988.

[1][Forms 40 to 43

(Pertaining to Ayurveda, Siddha and Unani drugs replaced by Forms Nos .47 to 50.)

[1. Ins. by G.S.R. 701(E), dt. 27.9.2001]

[1][FORM 40

(See rule 24-A)

Application for issue of Registration Certificate for import of drugs into India under the Drugs and Cosmetics Rules 1945

I/We* ……(Name and full address) hereby apply for the grant of Registration Certificate for the manufacturer, M/s…….. (full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises, and manufactured drugs meant for import into India.

1. Names of drugs for registration.

[2][***]

2. I/We enclose herewith the information and undertakings specified in Schedule D (1) and Schedule D(II) duly signed by the manufacturer for grant of Registration Certificate for the premises stated below.

3. A fee of_____for registration of premises, the particulars of which are given below, of the manufacturer has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945-Central *vide* Challan No._____ dated_____(attached in original).

4. A fee of_____for registration of the drugs for import as specified at Serial No. 2 above has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945-Central vide Challan No._____, dated_____. (attached in original).

5. Particulars of premises to be registered where manufacture is

carried on: Address (es)……..

Telephone No……..

Fax……

E-mail…….

I/We* undertake to comply with all terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.

Place:

Date:

*Signature*_____
*Name*_____
*Designation*_____
Seal/Stamp of manufacturer or his authorised Agent in India.

(**Note**: In case the applicant is an authorised agent of the manufacturer in India, the Power of Attorney is to be enclosed).

**Delete whichever is not applicable.*

1. Ins. by G.S.R. 604(E) dt. 24-8-2001 (w.e.f. 1-1-2003).
2. Figures 1,2,3 omitted by G.S.R. 35(E), dt. 20.1.2005.

[1][FORM 41

(*See* rule 27 A)

Registration

Certificate

Registration Certificate to be issued for import of drugs into India under Drugs and Cosmetics Rules, 1945

Registration Certificate No……. Date……

M/s _____ (Name and full address of registered office) having factory premises at……..(full address) has been registered under rule 27-A as a manufacturer and is hereby issued this Registration Certificate.

2. Name (s) of drugs which may be imported under this Registration Certificate:

[2][***]

3. This Registration Certificate shall be in force from _____ to_unless it is sooner suspended or cancelled under the rules.

4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/s (name and full address)_____ who will be responsible for the business activities of the manufacturer, in India in all respects.

5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Act and the rules, from time to time.

Place…….
Date…….

Licensing Authority
Seal/Stamp

Conditions of the Registration Certificate.

1. The Registration Certificate shall be displayed at a prominent place by the authorised agent.

2. No drug shall be registered unless it has a free sale approval in the country of origin, and/or in other major countries.

3. The manufacturer or his authorised agent in India shall comply with the conditions of the import licence issued under the Drugs and Cosmetics Rules, 1945.

4. The manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorization, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed.

The dispatch and marketing of the drug in such cases shall be stopped immediately, and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of drug shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned drug in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours time period.

5. The manufacturer or his authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the drugs pertaining to this Registration Certificate.

In such cases, where there shall be any major change/modification in manufacturing, or in processing or in testing, or in documentation as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent in

India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub-rule (3) of rule 24-A.

6. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and / or address of the registered office / factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises.]

1. Ins. by G.S.R. No.604(E), dt. 24-8-2001 (w.e.f. 1-1-2003)
2. Figures 1,2,3 omitted by G.S.R. 32, dt. 20.1.2005.

[1][FORM 42

(See rule 129A)

Application for issue of Registration Certificate for import of cosmetics into India under the Drugs and Cosmetics Rules, 1945

I/We* ……(Name and full address) hereby apply for the grant of Registration Certificate for the manufacturer, M/s…….. (full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises, and manufactured cosmetics meant for import into India.

1.Name of cosmetics along with their brand name and pack size(s) and variants for registration.

(1)…… (4)……
(2)…… (5)……
(3)…… (6)……

2. I/We* enclose herewith the information and undertakings specified in Schedule D (III) duly signed by the manufacturer for grant of Registration Certificate for the premises stated below.

3. A fee of_____for registration of cosmetics for import as specified at serial no. 2 above has been credited to the Central Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945-Central *vide* Challan No._____ dated_____(attached in original).

4. Particulars of premises to be registered where manufacture is carried on:

Address (es)……..
Telephone No……..

Fax……..

E-mail…….

I/We* undertake to comply with all terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.

Place:……

Date:……

Signature……
Name……
Designation……
Seal/Stamp of manufacturer or his authorised Agent in India.

(**Note**: In case the applicant is an authorised agent of the manufacturer in India, the Power of Attorney is to be enclosed).

**Delete whichever is not applicable.*

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1. Ins. by G.S.R. 4 2 6 (E) dt. 19-5-2010, read with corrigendum G.S.R263(E) dt:30.3.2011, corrigendum G.S.R. 733(E) dt:29.9.2011, corrigendum G.S.R.270(E) dt:30.3.2012 and corrigendum G.S.R. 733(E) dt:29.9.2012.

[1][FORM 43

(*See* rule 129C)

Registration Certificate

Registration Certificate to be issued for import of cosmetics into India under Drugs and Cosmetics Rules, 1945

Registration Certificate No……. Date……..…

M/s _____ (Name and full address of registered office)…….having factory premises at ……. (full address) has been registered under rule 1 2 9 A as a manufacturer and is hereby issued this Registration Certificate.

2. Name (s) of cosmetics, along with thrir brand names and pack size(s) and variants which may be imported under this Registration Certificate:

(1)……
(2)……
(3)……

3. This Registration Certificate shall be in force from …… to……..unless it is sooner suspended or cancelled under the rules.

4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent or importer in India or by the subsidiary in India authorized by the manufacturer, namely.-M/s (name and full address)_____ who shall be responsible for the business activities of the manufacturer, in India in all respects.

5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Drugs and Cosmetics Act, 1940 and the rules made thereunder, from time to time in this regard..

Place…….
Date…….

Licensing Authority
Seal/Stamp

Conditions of the Registration Certificate.

1. The Registration Certificate shall be produced by the authorised importer/distributor/agent as and when required by the licensing authority/regulatory authority.

2. The manufacturer or his authorised importer/distributor/agent in India shall inform the licensing authority forthwith in the event of any administrative action taken namely, market withdrawal, regulatory restrictions, or cancellation of authorization, and/or not of standard quality report of any cosmetic pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the cosmetic is marketed/sold or distributed.

The dispatch and marketing of the cosmetic in such cases shall be stopped immediately, and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of drug shall be followed as per the

direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned cosmetic in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the cosmetic from Indian market within 48 hours time period.

3. The manufacturer or his authorised agent/importer/distributor or subsidiary in India shall inform the licensing authority within 30 days in writing in the event of additional variants/additional cosmetic category/additional manufacturing location or any change in labeling or in testing, or in documentation of any of the cosmetic pertaining to this Registration Certificate.

In such cases, where there shall be additional variants/additional cosmetic category/additional manufacturing location, as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent/importer/distributor/subsidary in India shall apply for necessary approval within 30 days by submitting a separate application along with the registration fee.

4. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and / or address of the registered office / factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises.]

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1. Ins. by G.S.R. 426 (E) dt. 19-5-2010, read with corrigendum G.S.R263(E) dt:30.3.2011, corrigendum G.S.R. 733(E) dt:29.9.2011, corrigendum G.S.R.270(E) dt:30.3.2012 and corrigendum G.S.R. 733(E) dt:29..2012.

[1][FORM 44

(*See* rules 122A, 122B, 122D and 122 DA)

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

I/We*…… of M/s. ..... ……..
(address) hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information / data is given below :

1. *Particulars of new drug :*
   (1) Name of the drug.
   (2) Dosage form.
   (3) Composition of the formulation :
   (4) Test specification.
      (i) active ingredients.
      (ii) inactive ingredients.
   (5) Pharmacological classification of the drug.
   (6) Indications for which proposed to be used.
   (7) Manufacturer of the raw material (bulk drug substances).
   (8) Patent status of the drug.

2. Data submitted along with the application (as per Schedule Y with indexing and page numbers:)
   A. Permission to market a new drug :

(1) Chemical and Pharmaceutical information.
(2) Animal Pharmacology.
(3) Animal Toxicology.
(4) Human / Clinical Pharmacology (Phase I).
(5) Exploratory Clinical Trials (Phase II).
(6) Confirmatory Clinical Trials (Phase III) (including published review articles)
(7) Bio-availability, dissolution and stability study data.
(8) Regulatory status in other countries.
(9) Marketing information :
(a) Proposed product monograph.
(b) Drafts of labels and cartons.
(10) Application for test licence.
[2][(11) New Chemical Entity and Global Clinical Trial-
(a) Assessment of risk versus benefit to the patients
(b) Innovation vis-à-vis existing therapeutic option
(c) Unmet medical need in the country.]

B. Subsequent approval / permission for manufacture of already approved new drug :

(a) Formulation:
(1) Bio-availability / bio-equivalence protocol.
(2) Name of the investigator/center.
(3) Source of raw material (bulk drug substances) and stability study data.

(b) Raw material (bulk drug substances):
(1) Manufacturing method.
(2) Quality control parameters and/or analytical specification, stability report.
(3) Animal toxicity data.

C. Approval / Permission for fixed dose combination:
(1) Therapeutic Justification.
(authentic literature in [3][pre-reviewed journals]/text books)
(2) Data on pharmacokinetics/pharmacodynamics combination.
(3) Any other data generated by the applicant on the safety and efficacy of the combination.

D. Subsequent Approval or approval for new indication - new dosage form:
(1) Number and date of Approval / permission already granted.
(2) Therapeutic justification for new claim / modified dosage form
(3) Data generated on safety, efficacy and quality parameters.

A total fee of rupees ..... (in words) ..... has been credited to the Government under the Head of Account..... (Photocopy of receipt is enclosed).

Dated : .....

Signature……

Designation……

Note: **Delete whichever is not applicable.*

1. Forms 44 to 46 A ins. by No.G.S.R. 900 (E), dt. 12.12.2001.
2. Ins. By G.S.R. 826 (E), dt. 30.10.2015.
3. Subs by G.S.R. 26(E), dt. 19.1.2006.

[1][FORM 45

(*See* rules 122 A, 122 D and 122 DA)

Permission to import Finished Formulation of a New Drug

Number of the permission and date of issue……..
M/s ..... of…….
(address) is hereby permitted to import the following new drug formulation under rule 122 A /122 D/122 DA of the Drugs and Cosmetics Rules, 1945.

(1) Name of the New Drug :
(2) Dosage form :
(3) Composition :
(4) Indications :

Dated:.....
Signature.....

Name and designation of Licensing Authority

Conditions for Grant of Approval / Permission.

(1) The formulation shall conform to the specifications approved by the Licensing Authority.

(2) The proper name of the drug shall be printed or written in indelible ink and shall appear in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.

(3) The label of the innermost container of the drug and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which shall not be less than 1 mm in width and without disturbing the other conditions printed on the label to depict it as prescription drug.

(4) The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

"WARNING : To be sold by retail on the prescription of a ..... Only."

[2][(5) Post marketing surveillance study shall be conducted during initial period of two years of marketing of the new drug formulation, after getting the protocol and the names of the investigator duly approved by the Licensing Authority.]

(6) All reported adverse reactions related to the drug shall be intimated to the Drugs Controller, India and Licensing Authority and regulatory action resulting from their review should be complied with.

(7) No claims except those mentioned above shall be made for the drug without the prior approval of the Licensing Authority.

(8) Specimen of the carton, labels, package insert that will be adopted for marketing the drug in the country shall be got approved from the Licensing Authority before the drugs is marketed.

(9) Each consignment of imported drug shall be accompanied by a test/analysis report.

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1. Ins. by No.G.S.R. 900 (E), dt. 12.12.2001.
2. Subs by G.S.R. 101(E), dt. 18.2.2011.

[1][FORM 45A

(*See* rules 122A and 122DA)

Permission to import raw material (new bulk drug substance)

Number of the permission and date of issue…….
M/s .....of……(address)
is hereby permitted to import the following raw material (new bulk drug substances) under rule 122 A / 122DA of the Drugs and Cosmetics Rules, 1945, namely :-

Name of the raw material (new bulk drug substances):
(1) .....
(2) .....
(3) .....

Dated ..... *Signature*.....

Name and Designation of the Licensing Authority……

Conditions for Grant of Approval / Permission

(1) The raw material (new bulk drug substance) shall conform to the test specifications as approved by the Licensing Authority.

(2) For manufacture of raw material (new bulk drug substance) or its formulation in the country, separate approval under rule 122-B shall be obtained from the Licensing Authority.

(3) The permission to import shall not be used to convey or imply that the raw material
(new bulk drug) is categorized as "life saving or essential drug."]

1. Ins. By G.S.R. 900 (E), dt. 12.12.2001.

[1][FORM 46

(*See* rules 122 B, 122 D and 122 DA)

Permission / Approval for manufacture of new drug formulation

Number of permission and date of issue ..... ……. M/s of ..... (address) is hereby granted Permission/Approval to manufacture following new drug formulation under rule 122B/122D/122DA of the Drugs and Cosmetics Rules, 1945, namely :-

(1) Name of the formulation:
(2) Dosage form:
(3) Composition:
(4) Indications:

Dated ……..... *Signature*.....

Name and designation of Licensing Athority……..

Conditions for Grant of Approval / Permission.

(1) The formulation shall conform to the specifications approved by the Licensing Authority.

(2) The proper name of the drug shall be printed or written in indelible ink and shall appear in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name on the label of he innermost container of the drug or every other covering in which the container is packed.

(3) The label of the innermost container of the drug and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which shall not be less than 1 mm in width and without disturbing the other conditions printed on the label to depict it as prescription drug.

(4) The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

"WARNING : To be sold by retail on the prescription of a ..... only."

[2][(5) Post marketing surveillance study shall be conducted during initial period of two years of marketing of the new drug formulation, after getting the protocol and the names of the investigator duly approved by the Licensing Authority.]

(6) All reported adverse reactions related to the drug shall be intimated to the Drugs Controller, India and Licensing Authority and regulatory action resulting from their review should be complied with.

(7) No claims except those mentioned above shall be made for the drug without the prior approval of the Licensing Authority.

(8) Specimen of the carton, labels, package insert that will be adopted for marketing the drug in the country shall be got approved from the Licensing Authority before the drug is marketed.

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1. Ins. by G.S.R. 900 (E), dt. 12.12.2001.
2. Subs by G.S.R.101(E), dt. 18.2.2011.

[1][FORM 46A

(*See* rules 122 B and 122 DA)

Permission/ Approval for manufacture of raw material (new bulk drug substance)

Name of the permission/ approval and date of issue.....
M/s ..... of..... (address) is hereby granted Permission/Approval to manufacture the following raw material (new bulk drug substance) under rule 122B / 122DA of the Drugs and Cosmetics Rules, 1945.

Name of the raw material (new bulk drug substance):
(1) .....
(2) .....
(3) ….....

Dated..... *Signature*.....
Name and designation of Licensing Authority.

Conditions for Grant of Permission /Approval

(1) The raw material (new bulk drug substance) shall conform to the specifications approved by the Licensing Authority.

(2) The raw material (new bulk drug substance) can be sold to only those manufacturers who have permission, in writing, from Licensing Authority, either to use the drug for development purpose/clinical trial-bio-equivalence study or to manufacture the formulation.

(3) For manufacture of the formulation in the country, separate approval under rule 122B shall be obtained from the Licensing Authority.]

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1. Ins. by No.G.S.R. 900 (E), dt. 12.12.2001.

[1][FORM 47

(*See* rule 160 A)

Application for grant or renewal of approval for carrying out tests on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs

1. *I/We..... of ..... hereby apply for the grant/renewal of approval for carrying out tests of identity, purity, quality and strength on the following categories of Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensee for manufacture for sale of Ayurvedic, Siddha and Unani drugs.

2. *Categories of Ayurvedic, Siddha and Unani drugs other than those specified in the First Schedule to this Act for which testing will be carried out:

	AYURVEDA AND SIDDHA		UNANI
1.	Asava and Arista	1.	Nabeez, Khal (Sirka)
2.	Arka-Tinir	2.	Majoon and its sub-categories Itrifal, Jawarish, Khameera, Laooq, Halwar
3.	Avaleha and Paka-Ilakam	3.	Sufoof, Zuroor, Sunoon.
4.	Kavatha Curna-Kutinir Curanam	4.	Namak, Khar
5.	Guggulu	5.	Raughan
6.	Ghrita-Ney	6.	Zimad
7	Churna-Curanam	7.	Habb (Pill)
8.	Taila-Tailam	8.	Shiyaf
9.	Dravaka-Tiravakam	9.	Qutoor (drops)
10.	Lavana-Uppu	10.	Kohal (Surma), Kajal
11.	Kshara-Saram	11.	Satt, Usara
12.	Lepa-Pacai	12.	Kushta
13.	Vati, Gutika-Kulikai	13.	Joshanda (Single drugs)
14.	Vartti	14.	Sharbat Sikanjabeen
15.	Netrabindu (Aschyotan)	15.	Sayyal, Arq (Distillates)
16.	Anjana-Kanmai	16.	Qurs (Tablet)
17.	Sattva-Sattu	17.	Marham, Qairooti
18.	Kupipakva Rasayana-Kuppi Centuram	18.	Humool, Furzaja
19.	Parpati	19.	Bakhoor
20.	Pishti	20.	Nabati Advia
21.	Bhasma-Parpam	21.	Maadni Advia
22.	Mandura-Atai kutinir	22.	Asjad Advia
23.	Rasay oga-C entur am	23.	Haiwani Advia
24.	Lauha	24.	Jauhar
25.	Ghana Sattva	25.	Natool
26.	Kvath Pravahi- Kutinir	26.	Nashooq, Naswar
27.	Panak (Syrup)-Manappaku	27.	Shamoom

28. Tablet-Mattirai	28. Saoot (Nasal drops)
29. Capsule	29. Mazoogh
30. Ointment- Kalimapu	30. Tila
31. Phalavarti	31. Lashooq
32. Dhoomravarti/Doopan	32. Gulqand
33. Kshar Sutra/Kshar Varti	33. Fateela
34. Single drugs:	34. Ghaza, Utban, Sasbhh
(a) Plant based	
(b) Mineral based	
(c) Metal based	
(d) Animal based	
(e) Synthetic	
(f) Any other Ayurvedic, Siddha, Unani formulation	
35. Pushp (Phool)	35. Capsule
36. Nasya	36. Huqna
37. Swarasa (Fresh juice)	37. Naurah
38. Karna Bindu (Ear drops)	38. Latookh
39. Any other dosage of Patent and Proprietary and Ayurvedic, Siddha, Unani Drug	39. Vajoor (Throat paint)
	40. Mazmazah (Mouth washer)

(3) Names, qualifications and experience of experts employed for testing and the person in-charge of testing.

(4) List of testing equipment provided.

(5) *I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.

(6) An inspection fee of rupees ..... has been credited to Government under the head of account.....

Dated……

Signature…….

Full address of the Applicant

*Delete which is not applicable.

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1. Ins. by G.S.R. 701(E), dt. 27.9.2001 and subs. by G.S.R. 73(E), dt. 31.1.2003.

[1][FORM 48

(See Rule 160 B)

Approval for carrying out tests or analysis on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs

Number of approval and date of issue……

1. Approval is hereby granted to .....for carrying out tests in identity, purity, quality and strength on the following categories of Ayurvedic, Siddha or Unani drugs and the raw materials used in the manufacture thereof on the premises situated at .....

Categories of Ayurvedic, Siddha and Unani drugs.

……
……
……

2. Name of experts employed for testing and the person-in-charge of testing

……(experts) and…… (person in-charge).

3. The approval shall be in force from ..... to.....

4. The approval is subject to the conditions stated below and such other conditions as may be specified in the rules for the time being in force under the Act.

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

Place ..... *Designation* .....

Seal of State Licensing Authority

Conditions of approval

(1) This approval and any certificate of renewal in Form 49 shall be displayed in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.

(2) If the applicant wishes to undertake during the currency of the approval the testing of any other category of Ayurvedic, Siddha or Unani drugs it should apply to the approving authority for necessary endorsement as provided in Rule 160A. This approval will be deemed to extend to the items so endorsed.

(3) Any change in the experts or in the person in-charge of the testing shall be forthwith reported to the approving authority.

(4) The applicant shall inform the approving authority in writing in the event of any change of the constitution of the laboratory operating under this Form. Where any change in the constitution of the laboratory takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh approval has been taken from the approving authority in the name of the laboratory with the changed constitution.]

1.Ins. by G.S.R. No.702(E) dt. 27-9-2001 and subs.by.G.S.R.73(E), dt.31.01.2003.

[1][**Form 49**

(See rule 160- I)

Certificate of renewal for carrying out tests or analysis on Ayurvedic, Siddha or Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha or Unani drugs

1. Certified that approval number ..... granted on the ..... day of ..... 20…. for carrying out tests of identity, purity, quality and strength on the following categories of Ayurvedic, Siddha or Unani, drugs and the raw materials used in the manufacture thereof at the premises situated at ..... has been renewed from ……to..... (date).

Catagories of Ayurvedic, Siddha or Unani drugs:

……

2. Name of experts and the person-in-charge of testing…….
(experts) and…….(person in charge)

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

Place *:* .....

Designation .....

Seal of State Licensing Authority]

1. Ins. by G.S.R. No.701(E) dt. 27-9-2001 and subs. by G.S.R.73(E) dt. 31.01.2003.

[1][FORM 50

[*See* rule 160 D(f)]

Report of test or analysis by approved Laboratory

(1) Name of manufacturer from whom sample received together with his manufacturing licence number under the Act or the rules made thereunder.

……

(2) Reference number and date of the letter from the manufacturer under which the same was forwarded.

……

(3) Date of receipt of the sample

……

(4) Name of Ayurvedic, Siddha and Unani drug of raw material purporting to be contained in the sample.

……

(5) Details of raw material of final product (in bulk finished pack)* as obtained from the manufacturer:

(a) Original manufacturer's name in the case of raw materials and drugs repacked…… …….

(b) Batch number……

(c) Batch size as represented by sample……..

(d) Date of manufacture, if any .....……

(e) Date of expiry, if any…….

(6) Results of test or analysis with protocols of test or analysis applied or as per Ayurvedic, Siddha or Unani Pharmacopoeial standards.

(7) Other specific tests for identity, purity, quality and strength of Patent and Proprietary drugs.

In the opinion of the undersigned, the sample referred to above is of standard *quality/is not of standard quality as defined in the Act or the rules made thereunder for the reasons given below

……

Date…….

Place…..

(Signature of the person-in-charge of testing)

(F. No……..)

Name and Designation and Seal……

Name and Address of the Laboratory……

License No……..

Note: Final product includes repacked material.

*Delete whichever is not applicable.

1. Ins. by G.S.R. 701(E) dt. 27-9-2001 and subs. by G.S.R.73(E) dt. 31.1.2003