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 Cosme tics Act, 1940, sample(s) of a drug purporting to be……for test or analysis and request that a report that a report of the result of the test or analysis may be supplied to this Court.

1. The distinguishing number on the packet is ……
2. Particulars of offence alleged…….
3. Matter on which opinion is required……
4. A fee of Rs……..has been deposited in Court.

Date……. ……

Magistrate

_____

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 separate 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 conditions 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
as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:--

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

Date…….. *Director*
Central Drugs Laboratory or other authorised officer

* If opinion is required on any other matter, the paragraph should be suitably amended.

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[1]Form 3 to 7

([1]Omitted under Government of India Notification No. F. 1-16/57-D, dated 15-6-1957).

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[1]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)

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[1]Subs. by G.O.I. Notification No. GSR 604(E) dt 24.8.2001.

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 ……..

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* delete whichever is not applicable.

FORM 8-A

[See rule 24)

Application for licence to import drugs specified in Schedule X to the Drugs and Cosmetic 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 drugs 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 ……..

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 & 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 & Cosmetics Rules, 1945;

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[1]Subs. by G.O.I. Notification No. GSR 462(E) dt 22.6.1982.

* delete whichever is not applicable.

(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 & 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 & Cosmetics Act, 1940, and the Drugs & 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……..

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

[1][FORM 10
[See rules 23 and 27]

Licence to import drugs (excluding hose specified in Schedule X) to the Drugs and Cosmetic 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 the said manufacturer as may from time to time be endorsed on this licence.

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

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[1] Subs. by G.O.I. Notification No. GSR 604(E) dt 24.8.2001.

(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 authorized 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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FORM 10-A
(See rule 23 and 27)

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

Licence Number …….. Date …….

…….. (Name and full address of the importer) is hereby licenced 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 licencee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorized agent.

4. The licencee 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.]

FORM 11
[See Rule 33]
Licence to import drugs for the purposes of examination, test or analysis

…….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 authorize.

2. This licence is subject to the conditions prescribed in the Rule under the Drugs & 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—

Names of drugs *Quantity which may be imported*

Date……. *Licensing Authority*

———————

[1][FORM 11 – A

(See rule 33-A)

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 authorize.

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

3. Name of drugs to be imported:

Names of drugs	Quantity which may be imported

Place :……..
Date : …….

Licensing Authority
Seal / Stamp

[1] Subs. by G.O.I. Notification No. GSR 604(E) dt 24.8.2001

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.]

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).]

Names of drugs and classes of drugs *Quantities*

Date……

Signature……

[1] Subs. by G.O.I. Notification No. GSR 604(E) dt 24.8.2001

[1]FORM 12-A

[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.

Names of drugs *Quantities*

Date…… *Signature*……

[2] [FORM 12-AA
(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.

A fee of rupees …… has been credited to Government under the Head of Account "0210-Medical and Public Health, 04- Medical and Public Health, 10- 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:

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[1]Added under Government of India Notification No. F. 1-36/54-DS, dated 3-3-1955.
[2]Subs. by G.O.I. Notification No. GSR 604(E) dt 24.8.2001

Names of drugs	Quantity 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.

Signature …….
Place : ……..
Date: ……
Medical Superintendent of the Government of Hospital / Head of Autonomous Medical Institution

Seal / Stamp

FORM 12-B
[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.

Names 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 [1][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 quality as defined in the Drugs and Cosmetics Act, 1940. and Rules thereunder
is not of standard quality as defined in the Drugs and Cosmetics Act 1940 and Rules thereunder
for the reasons given below:-

Date…… *Government Analyst*……..

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[2]FORM 13-A
[See Rule 163 (5)]
Certificates of tests or analyst 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 drugs purporting to be contained in the sample…….
6. Condition of seals on the package……..
7. Result of test or analysis with protocols of test or analysis applied
…….

Date…… *Government Analyst*……..

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[1]Subs. by G.O.I. Notification No. GSR 59(E) dt 7.2.1995.
[2]Added under G.O.I. Notification No. F 1-23/67-D, dated 2-2-1970.

FORM 14-A
[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
   ……..……

[1]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*……

———————

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……..

[1]Added under Government of India Notification No. F. 1-3/51-D.S., dated 15-10-1954.

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 hereunder.

Date…… *Government Analyst*……..

_____

[1]FORM 15

[See Rule 54 and 145 C]

Order under Section 22 (1)(c) of the Drugs and Cosmetics Act, 1940 requiring a person not to dispose of stock in this 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*…….

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[2]FORM 16

[See Rule 55 and 145-B]

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

The stock of drugs or cosmetics or 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 object seized

Date…… *Inspector*……...

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[1]Amended by G.O.I. Notification No. G.S.R.1594, dtd 13-11-1976.

[2]Amended by G.O.I. Notification No. G.S.R. 926 dtd 16-07-1977.

[1]FORM 17

[See Rules 56 and 145-A]

Intimation to person from whom sample is taken

To……..

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 17-A

I[*See* Rules 56-A and 145-AA]

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 …….19 …….. have taken, from the premises of situated at …… samples of drugs/cosmetics as specified below:-

Details of Samples ……..

And where 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]Added under G.O.I.Notification No. F 1-23/67-D, dated 2-2-1970.
[2] Ins. by G.O.I. Notification No. GSR 292(E) dt 29.5.1977.

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*…….

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[2] FORM 18-A
[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.O.I. Notification No. GSR 370(E) dt 7.4.1994.
[2]Amended by G.O.I. Notification No. S.O. 2139 dt 12-8-1972.

[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*] *drugs other than those specified in Schedule X.*

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 qualified persons namely:-

…… (Name) …….. (Qualification)
…… (Name) …….. (Qualification)

3. Categories of drugs to be sold……..
4.O Particulars of special storage accommodation ……..
5. A fee of rupees…….has been credited to Government under the head of account……

Date…… *Signature*……..]

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

FORM 19-A

[See Rule 59 (2)]

Application for the grant or renewal of a restricted [2] *[licence to sell, stock or exhibit for sale, or offer for sale or distribute] drugs by retail by*[3]*[* * *] dealers who do not engage the services of a qualified person*

1. I / We ……..of……..hereby apply for a licence to sell by retail (i) Drugs other than those specified in Schedule C, C1 and X [3][* * *] on the premises situated at……

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[1]Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982.
[2] Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985.
[3]Omitted by G.O.I. Notification No. GSR 231(E) dt 4.6.1996.
.

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

2. Sales shall be restricted to such drugs as can be sold without the supervision of a qualified person 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 [1][Schedules 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 dealers…….Licence No. ……..

[2][* * *]
6. A fee of rupees _____has been credited to Government under the
twenty
head of account……..

Date…… *Signature*…….

*Delete whichever is not required.
**Applies only to an itinerant vendor.

[3]FORM 19-AA
[See Rule 62C]
Application for grant or renewal of a[4][licence to sell, stock or exhibit or offer for sale by wholesale or to distribute] drugs from a motor vehicle

1. I / We _____of _____hereby apply for [4][licence to sell, stock or exhibit or offer for sale by wholesale or to distribute] drugs specified in Schedule C and C (1) and /or drugs other than those specified in Schedule 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_____

[1]Subs. by G.O.I. Notification No.GSR 487(E) dt 2.7.1984.
[2]Omitted by G.O.I. Notification No. GSR 231(E) dt 4.6.1996.
[3]Ins. by G.O.I. Notification No.X.11013/7/76-D&MS dt 25.1.1979.
[4]Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985.

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*_____

FORM 19-B
[See Rule 67-A]
Application for [1][licence to sell, stock or exhibit for sale, 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.

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[2][FORM 19-C
[*See* Rule 59(2)]

Application for grant or renewal of a[1][licence to sell, stock, exhibit or offer for sale, or distribute] drugs specified in Schedule X.

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 …….

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[1] Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985

[2] Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982

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

…… (Name) …….. (Qualification)
…… (Name) …….. (Qualification)

3. Names 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 ……..……..……..]*

* Dele te whichever is not applicable.
** To be deleted if drugs will be sold only by whole.
# Required only if products requiring special storage are to be sold.

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*].

I …….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.

1. The licence shall be in force from……..to……
2. Name (s) of qualified person (s) in charge…….
3. Categories of drugs……

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

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[1] Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985

[2] Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982

3. The licence 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 taken 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.

FORM 20-A

[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 qualified person.*

I ……..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.

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

2. 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.

3. The licence, if he be an itinerant vendor, shall buy drugs only from the following dealers and such other dealers as may be endorsed on the licence by Licensing Authority from time to time.

4. [* * * Omitted as per G.O.I. Notification No. GSR 504(E) dt 18.7.2002.]

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[1]Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985
[2]Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982
[3]Omitted by G.O.I. Notification No. GSR 231(E) dt 4.6.1996

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. [* * * Omitted by G.O.I. Notification No. GSR 231(E) dt 4.6.1996].

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 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.

FORM 20-B
[*See* Rule 61 (1)]

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

1. …… hereby [1][licensed to sell, stock or exhibit or offer for sale or distribute] by wholesale drugs other than those specified in [2][Schedule 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……..

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

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[1]Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985
[2]Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982
[3] Ins. by G.O.I. Notification No. GSR 681(E) dt 6.6.1988.

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.

[1]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 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
(c) a manufacturer of beverages, confectional biscuits and other non-medicinal products, where such drugs are required for processing these products;

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 taken place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the changes 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] Amended by G.O.I. Notification No. F.1/63/61-D, dtd 17.7.1963.

[1][FORM 20-BB
[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] to sell by wholesale, or to distribute drugs other than those specified in Schedule C and Schedule C (1) from the vehicle bearing registration no._____ assigned under Motor Vehicle 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 prominent place on the vehicle.
2. The licence 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 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 manufacturer of beverages, confectionary, biscuits and other non-medical products where such drugs are required for processing these products.

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[1] Added by G.O.I. Notification No. X. 11013/7/76-D&MS, dtd 25.1.1979.
[2] Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985

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 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]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 licensed to sell, stock or exhibit for sale 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 30ml at a time.

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[1]Added under G.O.I. Notification No. F. 1-35/64-D dtd 18.8.1964.
[2] Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985
[3] Added under G.O.I.Notification No. F. 1-59/68-D, dtd 19.11.1969.

[1]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 form with the changed constitution.

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[2]FORM 20-D

[*See* Rule 67-C]

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

1. ……is hereby [3][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……..

Date……. *Licensing Authority*

Conditions of Licence

1. This licence shall be displayed in a prominent place on the premises.

2. The licence 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 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 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.

[1]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 under G.O.I. Notification No. G.S.R. 665, dtd 28-5-1977..
[2]Added under G.O. Notification No. F.1-35/64-D, dtd 18.8.1964.
[3]Subs. by G.O.I. Notification No.GSR 788(E) dt 10.10.1985

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

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[3][FORM 20-F
[*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. Name of drugs
3. This licence shall be in force from ……. to ……...
4. Name(s) of qualified person-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 Authrotity.

Conditions of the licence.

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

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[1]Ins. by G.O.I. Notification No. F.1-14/67-D dt 3.2.1969.
[2] Subs, by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.

[3] Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982

2. The licencee shall report to the licensing authority any change in the qualified staff incharge 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.

FORM 20-G

[*See* Rule 61(3)]

[1] *[Licence to sell, stock or exhibit or offer for sale, or distribute*] *by wholesale 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. Name 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.

Conditions of the 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 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 licence to sell, stock or exhibit for sale or distribute drugs specified in Schedule X :

[1]Subs, by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.

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 drug included in Schedule X.]

[1][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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FORM 21

[See Rule 61 (2)]

[1][*Licence to sell, stock or exhibit or offer for sale 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, 1945* 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 qualified persons in charge…….

[3]4. Categories of drugs……..

Date…… *Licensing Authority*

Licence No.……

*Delete if not applicable.

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[1]Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.

[2] Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982

[3] Amended by G.O.I. Notification No. S.O. 2139 dt 12-8-1972.

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. [* * * Omitted by G.O.I.Notification No. GSR 17(E) dt 7.1.1986.]

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 (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.

[1]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 licence 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.

FORM 21-A
[See Rule 61 (2)]

[3]*Licence to sell, stock or exhibit or offer for sale distribute*] *by retail drugs specified in* [5]*[Schedules C (1)]*[4][* * *] *dealers who do not engage the services of a qualified person.*

1. ……..is hereby [licensed to sell, stock or exhibit or offer for sale or distribute] by retail on the premises situated at /[4][* * *] ……the following rugs being drugs specified in [5][Schedule C (1)] 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.

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[1] Ins. by G.O.I. Notification No. F. 1-63/61-D dtd 17.7.1963.
[2] Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982
[3] Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.
[4]Omitted by G.O.I. Notification No. GSR 231(E) dt 4.6.1996

[5] Subs. by G.O.I. Notification No. GSR 487(E) dt 2.7.1984.

2. The licence will be in force from……..to……..
3. Particulars of [1][Schedule C (1)] drugs to be sold…….

4. [* * * Omitted as per G.O.I. Notification No. GSR 504(E) dt 18.7.2002.]

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 public or shall be kept on the process of the vendor who shall produce it on demand by an Inspector or an officer authorised by the State Government in this behalf.

2. [* * * Omitted as per G.O.I. Notification No. GSR 17(E) dt 7.1.1986.]

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.

FORM 21-B

[See Rule 61 (2)]

[2]*[Licence to sell, stock or exhibitor offer for sale or distribute] by wholesale drugs specified in Schedules C and C (1)* [3] *[excluding those specified in Schedule X].*

1…….is hereby licensed to sell, stock or exhibit for sale or distribute by wholesale on the premises situated at……..the following categories of drugs specified in Schedule C and C (1) [3][excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

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[1]Subs. by G.O.I. Notification No. GSR 487(E) dt 2.7.1984.
[2]Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.
[3]Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982

Categories of drugs

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

[1][2-A. The sale shall be made under the person 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.
2. [* * * Deleted by G.O.I. Notification No. GSR 17(E) dt 7.1.1986.]
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 Schedule 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.

[3]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
[4](c) a manufacturer of hydrogenated vegetable oils, beverages, confectionary and other

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[1]Ins. by G.O.I. Notification No.GSR 681(E) dt 6.6.1988.
[2]Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982
[3]Added under G.O.I. Notification No. F. 1-63/61-D, dtd 17.7.1963.

[4]Added under G.O.I. Notification No. F. 1-113/69-D, dtd 23.12.1969.

non-medicinal products, where such drugs are required for processing these products.

5. The licence 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.

FORM 21-BB
[See Rule 62-D]

Licence to sell by wholesale or to distribute drugs specified in Schedule C and Schedules 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 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 Schedule 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

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

(c) a manufacture of hydrogenated vegetable oils, beverages, confectionary and other non-medical products, where such drugs are required fo r processing their products.

5. The licenses 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, afresh 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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FORM 21 - C

[See Rule 63-A]

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

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

2. Categories or particulars of drugs…….

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

Date……. *Licensing Authority*

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[1]Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.
[2]Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982

FORM 21-CC
[See Rule 63-B]

Certificate of renewal of [1][*licence to sell, to 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 having registration No. _____ assigned under the Motor Vehicle Act, 1939 has been renewed for a period from _____ to _____

2. Categories of the drugs:
_____ _____

Date _____ Licensing Authority
_____

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 Schedules C and C (1).*

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 Schedules C and C (1) 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] Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985

FORM 24-A
[See Rule 69-A]

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

1. I / We*……off ……..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 specifies in Schedule C and C (1) 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 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 expert staff, equipment and premises for manufacture of each item required by me / us and that they will ana lyze every batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separatly in this behalf.
(c) Specimens of labels, cartoons 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.
f.Enter here the name of the applicant form 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.O.I. Notification No. GSR 788(E) dt 10.10.1985

FORM 24-B

[See Rule 69]

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) [1][*excluding those specified in Schedule X*]

1. I / 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 forty has been credited to Government under the head of account……..

Date…….. *Signature of applicant*……

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

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[1]FORM 24-C

[See Rule 85-B]

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 20-C*

[3][1. I / We …….. of …….. holder of licence no……in Form 20-C hereby apply for the grant / renewal of licence to manufacture the under mentioned 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.

---

[1]Amended by G.O.I. Notification No. F. 1-598-D, dtd 19.11.1969

[2]Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985

[3]Subs. by G.O.I. Notification No. GSR 13(E) dt 7.1.1983.

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]FORM 24-D

[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, qualification 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.

---

[2]FORM 24-E

[See Rule 154-A]

Application for grant or renewal of a loan licence to manufacture or 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 ***……..

---

[1]Ins. by G.O.I. Notification No.1-23/67-D dt 2.2.1970.
[2] Added by G.O.I. Notification No.GSR 376 (E) dtd 20.7.1978.

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 manufacture 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 separatly in this behalf.

c) Specimen 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…….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][FORM 24-F

[*See* Rule 69]

Application for 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.

---

[1] Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982
[2]Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.

2. Name 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 ……..]

FORM -25
[See Rule 70]

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

Number of Licence and date of issue……

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

a) [2][competent technical staff]
b) Names of Drug (each item to be separately specified)……

2. The licence authorizes 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……

---

[1] Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985
[2] Subs. by G.O.I. Notification No. GSR 5(E) dt 6.1.1997.

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 & Cosmetics Act, 1940.

Date…… *Signature*……

Designation…….
[1][*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 form with the changed constitution.

FORM 25-A
[See Rule 70-A]
Loan [2][*licence to manufacture for sale or for distribution of*] *drugs other than those specified in Schedules C and C (1)*

1. Number of licence and date of issue……

[1] Subs. by G.O.I. Notification No. GSR 923(E) dt 14.12.1992.

[2] Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985

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

a) [1][competent technical staff]
b) Name of drugs……

3. The licence authorizes 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 & 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.

3. If the licensee wants to undertake during the currency of the licence the manufacture for 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 form with the changed constitution.

---

[1] Subs. by G.O.I. Notification No. GSR 923(E) dt 14.12.1992.

[1]FORM 25-B
[See Rule 70]

Licence to repack for sale or distribution of drugs be ing 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 authorizes 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.

---

[1] Added under G.O.I.Notification No. F. 1-22/59-D, dtd 9-4-1960.
[2] Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982

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 proceeded 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 form with the changed constitution.

---

[1]FORM 25-C

[See Rule 85-D]

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

Number of Licence and date of issue…….

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

Name 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…….

---

[1] Added under G.O.I. Notification No. F.1-36/64-D, dated 18th August 1964.

[2] Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985

[3] Subs. by G.O.I. Notification No. GSR 13(E) dt 7.1.1983.

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.

[1]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 form with the changed constitution.

———————

[2]FORM 25-D
[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 (Name)
b) Names of drugs (each item to be separatly specified).

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

[1] Added by G.O.I. Notification No.S.O. 903 dtd 28-2-1976.
[2] Added under G.O.I. Notification No. 1-23/67-D, dtd 2-2-1970

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.

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 form with the changed constitution.

———————

[1]FORM 25-E
[See Rule 154-A]

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.

———————————————————————————————

[1] Added by G.O.I. Notification No. GSR 376 (E), dtd 20.7.1978

a) Technical staff
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 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. 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 form with the changed constitution.

---

[1][FORM 25-F

[*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.

---

[1]Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982

[2]Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.

2. Name of drugs.

3. Names of approved [1][competent technical staff]

4. The licence authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the onditions 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 …….
Licence No. ……

Signature ……..
Designation……..

[2][*Licensing Authority
*Central Licence Approving Authority.

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 [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 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 form 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'.]

---

[1]Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996.

[2]Subs. by G.O.I. Notification No. GSR 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 and C (1) and X
*drugs covered 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 rene wed from……to ……

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

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

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

**Delete* whatever portion is not required.

---

[1]FORM 26-A
[See Rules 73-A and 83-A]

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

1. Certified that loan licence No……..granted on the……..to……...for the manufacture of the under mentioned drugs being
*drugs other than those than drugs in Schedule C, C (1) and X
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).

---

[1] Subs.by G.O.I. Notification No. GSR 462(E) dt 22.6.1982.
[2] Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996
[3] Ins. by G.O.I. Notification No. GSR 370(E) dt 7.4.1994.

3. Name of the [1][competent technical staff]

Signature…….
Designation……..

Date…….

* Delete whichever is no t applicable.

---

[2]FORM 26-B
[See Rule 73-B]

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) [3][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 ……
[4][*Licensing Authority.
* Central Licence Approving Authority.

* Delete whichever is not applicable.

FORM 26-C
[See Rule 85-G]
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…….

---

[1]Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996
[2]Added under G.O.I. Notification No. F.1-22/59-D, dtd 9.4.1964
[3]Subs.by G.O.I. Notification No. GSR 462(E) dt 22.6.1982.

[4]Subs. by G.O.I. Notification No. GSR 923(E) dt 14.2.1992.

2. Name of the technical staff……..

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

Signature……..
Designation……...

Date…….

---

[2]FORM 26-D
[*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. Name of technical staff…….

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

Signature…….
Designation…….

Date……

---

[3]FORM 26-E
[See Rule 155-A]

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 of Ayurvedic / Siddha or Unani drugs at the premises situated at…….C/o……..has been renewed from…….to…….

---

[1] Ins. by G.O.I. Notification No. GSR 370(E) dt 7.4.1994.
[2]Ins. by G.O.I. Notification No. 1-23/67-D, dtd 2-2-1970.
[3]Ins. by G.O.I. Notification No. GSR 376 (E), dtd 20.7.1978

2. Name of technical staff…….

Date…….

Signature……..
Designation……..

———————

[1][FORM 26-E-1

(*See* Rule 157 155-B)

(*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 Cosmetic Rules, 1945.

This certificate is valid for a period of three years.

Dated :…..
Place : ….

Signature…..…..
Designation…..……..
Licensing Authority for Ayurveda/ Siddha/ Unani Drugs.]

———————

[2][FORM 26-F

[*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).

---

[1]Ins. by G.O.I. Notification No.GSR561(E) dt 23.6.2000 and subs. By G.O.I.Notification No.G.S.R.198(E) dt.07.03.2003.
[2] Ins. by G.O.I. Notification No. GSR 462(E) dt 22.6.1982.

3. Names of the [1][competent technical sta ff].

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

* Delete whichever is not applicable.

Date of issue ……..……..

---

[3][FORM 26-G

[*See* Rule 122-F]

Certificate of renewal of licence to operate f 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…….. 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.
   4.
   5.

Date ……..

Signature ……..
Name and Designation ……
Licensing Authority.
Central Licence Approving Authority.

* Delete whichever is not applicable.]

---

[1]Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996.
[2]Subs. by G.O.I. Notification No. GSR 923(E) dt 14.12.1992.

[3]Subs. by G.O.I. Notification No. GSR 244(E) dt 5.4.1999.

[1][FORM 26-H

[*See* Rules 68-A, 76, 78]

Certificate of renewal of licence to manufacture for sale of Large Volume Parenterals/Sera and Vaccines 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 Large Volume Parenterals/Sera and Vaccines 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

a) 1.
b) 2.
c) 3.
d) 4.

Signature ……
Designation …….
Licensing Authority
Central Licence Approving Authority

Date……..]

---

[2][FORM 26-I
[*See* Rules 122-I]

Certificate of renewal of licence for manufacture of blood products.

1. Certified that Licence No. ……. granted on the …… to…… for the manufacture of blood products at the premises situated at …….has been renewed from …… to …….

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

---

[1]Ins. by G.O.I. Notification No. GSR 119(E) dt 11.3.1996.

[2]Ins. by G.O.I. Notification No. GSR 245(E) dt 5.4.1999.

3.Name(s) of competent technical staff:

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

Signature ……
Designation …….
Licensing Authority
Central Licence Approving Authority

Date ……..]

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 Schedule X]*

1. I / We ……hereby apply for the grant / renewal of a licence to manufacture on the premises situated at……..the under mentioned drugs, being drugs specified in Schedule C and C (1) [2][excluding those specified in 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

---

[1]Ins. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.
[2]Subs. by G.O.I. Notification No. GSR 462(E) dt 22.6.1982.

has been credited to Government under the head of account.

Date……. *Signature*……
Designation……

FORM 27-A
[See Rule 75-A]
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)

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) 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 the manufacture 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.

* 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] Ins. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.

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

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

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[1][FORM 27-B

Application for grant or renewal of a [2][licence to manufacture for sale or for distribution of] drugs specified in Schedule 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 under-mentioned drugs, specified in Schedule C, C(I) and X to the Drugs and Cosmetics Rules, 1945.

2. Name of drugs.

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

e) Name(s) of staff responsible for test
f) 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 ……..

The application shall be accompanied by a plan of the premises.]
* *Delete whichever is not applicable.*

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[3][FORM 27-C
[*See* Rule 122-F]

Application for grant/renewal of licence for the operation of a Blood Bank for processing of while 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

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[1]Ins. by G.O.I. Notification No. GSR 462(E) dt 22.6.1982.
[2] Ins. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.

[3] Subs. by G.O.I. Notification No.GSR 245(E) dt 5.4.1999.

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.*

Note :

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].

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[1][FORM 27-D
[*See* Rule 75]

Application for grant or renewal of a licence to manufacture for sale or for distribution of Large Volume Parenterals/Sera and Vaccines excluding those specified in Schedule X.

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[1] Ins. by G.O.I. Notification No. GSR119(E) dt 11.3.1996.

1. I/We……of……..hereby apply for grant/renewal of a licence to manufacture for sale or distribution on the premises situated at…….the under-mentioned Large Volume Parenteral/Sera and Vaccines, 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), qualification and experience of the competent technical staff responsible for the manufacture of the above mentioned drugs.

(a) Name(s) of staff responsible for testing……
(c) 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……

** Delete whichever is not applicable.*

Note :

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 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 each to the Central Licence Approving Authority and concerned Zonal/Sub-Zonal Officers of the Central Drugs Standard Control Organization].

———

[1][FORM 27-E
[*See* Rule 122-F]

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 ……

[1]Ins. by G.O.I. Notification No. GSR 245(E) dt 5.4.1994.

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) 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.*

***Note* :**

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].

FORM 28

[*See* Rule 76]

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

Number of Licence and date of issue…….

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

---

[1]Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985

Names of drugs……

2. Names of approved [1][competent technical staff]…….

3. The licence authorizes 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 of Issue…….

Signature……..
Designation ……
[2][*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 for any drug specified in Schedules C and C (1) not included above, he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in Rule 75 (3). This licence will be deemed to extend to the items so endorsed.

3. Any change in the expert staff named in the licence 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 form with the changed constitution.

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[1]Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996.
[2]Subs. by G.O.I. Notification No. GSR 923(E) dt 14.12.1992.

FORM 28-A
[*See* Rule 76-A]

Loan[1]*[Licence to manufacture for sale or for distribution of] drugs specified in Schedules C and C (1)*

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) to the Drugs and Cosmetics Rules, 1945.

Names of Drugs……

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

[3]3-A The licence shall be in force from……to……

4. The licence authorizes 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 wants to undertake during the currency of the licence the manufacture for any drug specified in Schedules C and C (1) not included above, he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in Rule 75 (3). This licence will be deemed to extend to the items so endorsed.

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

---

[1] Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985
[2] Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996.
[3] Ins. by G.O.I. Notification No. F.1-10/62-D, dtd 11.4.1964

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 form with the changed constitution.

---

[1][FORM 28-B
[*See* Rule 76]

[2][Licence to manufacture for sale or for distribution of] drugs specified in Schedules C, CI and X.

No. of Licence……

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

Name of drugs.

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

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

4. The licence shall 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 of issue …….
Licence No. ……

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

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.

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[1]Subs. by G.O.I. Notification No.GSR 462(E) dt 22.6.1982
[2]Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.
[3]Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996.
[4]Subs. by G.O.I. Notification No. GSR 923(E) dt 14.2.1992.

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 provide 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 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 form 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'.]

---

[2][FORM 28-C
[*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 while blood and/or its components.

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

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

---

[1] Subs. by G.O.I. Notification No. GSR 923(E)dt 14.12.1992
[2] Ins. by G.O.I. Notification GSR 245(E) dt 5.4.1999.

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 be prepare blood components from the blood collected from such 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 cnange 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 been 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][FORM 28-D
[*See* Rules 76]

Licence to manufacture for sale of Large Volume Parenterals/Sera and Vaccines specified in Schedules C and C(I) excluding those specified in Schedule X.

Number of licence……and date of issue……

---

[1] Ins. by G.O.I. Notification No. GSR 119(E) dt 11.3.1996.

1. ……is hereby licensed to manufacture at the premises situated at……..the following Large Volume Parenterals/Sera and Vaccines 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
3	3

4. The license authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject o 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.

Signature ……
Designation …….
Licensing Authority
Central Licence Approving Authority

Date ….……..]

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 competent technical staff shall be forthwith reported to the Licensing 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 for 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][FORM 28-E
[*See* Rule 122-G]

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

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, sore, sell or distribute the blood products, subject to conditions applicable to this licence.

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

7. The licence shall be subject to the conditions stated belo w 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.

---

[1]Ins. by G.O.I. Notification GSR 245(E) dt 5.4.1999.

Conditions of Licence

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 the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
3. Any cnange 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 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 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 and/or Central Licence approving Authority in the name of the firm with the changed constitution.]

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 VII of the Drugs and Cosmetics Rules, 1945.

3. This licence shall be in force from 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

I……of…….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*…….

FORM 31
[See Rule 139]

Application for grant or renewal of a[1] *[licence to manufacture cosmetics for sale for distribution.]*

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

2. Name 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 head of account……

Date…….. *Signature*…….

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

[2][FORM 31-A
[See Rule 138-A]
Application for grant or renewal of loan[1] *[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.

---

[1] Subs. by G.O.I. Notification No. GSR 788(E) dt 10.10.1985.
[2] Ins. by G.O.I. Notification No. GSR 444 dtd 28-4-1973.

4. I /We enclose

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

b) A true copy of a letter from the [2] 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……..

Date…… *Signature*……

FORM 32
[See Rule 140]

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

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 Drugs and Cosmetics Rules, 1945.

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

---

[1]Ins. by G.O.I. Notification No. GSR 788 (E) 10.10.1985.

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

[1]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 form with the changed constitution.

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[2]FORM 32-A

[See Rule 139-B]

Loan [3]*[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……..

1.

[1]Ins.by G.O.I. Notification No. S.O. 903 dtd 28-2-1976.
[2]Ins. by G.O.I. Notification No.GSR 444 dtd 28-4-1973.
[3]Ins. by G.O.I. Notification No. GSR 788 (E) 10.10.1985.

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 138-A (5). This licence shall be deemed to extend to the cosmetics so endorsed.

FORM 33
[See Rule 141]
Certificate of renewal of loan 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……..

1. Names of cosmetics
2. Names of technical staff

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

---

[1]FORM 33-A
[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…….

1. Names of cosmetics.
2. Names of technical staff.

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

---

[1]Ins. by G.O.I. Notification No.GSR 444 dtd 28-4-1973.

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 [1][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 to claims made on the label as to the nature and quality of the cosmetic
does not conform to claims made on the label as to the nature nature and quality of the cosmetic

[2][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 Laboratory / Government Analyst

_____

[1]Subs. by G.O.I. Notification No. GSR 59(E) dt 7.2.1995.
[2]Subs. by G.O.I. Notification No. GSR 510(E) dt 26.7.1982.

[1]FORM 35

[2][See Rule 65, 67-G, 74, 74A, 74B, 78A, 85H, 142 and 142-A, 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 license number…….
In Form…….under the Drugs and Cosmetics Rules.

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 Licence. The duplicate copy shall be sent to the Licensing Authority. The triplicate copy shall be taken as record by the Inspector.

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[1]Ins. by G.O.I. Notification No.F.1-14/68-D, dtd 26.10.1968.

[2] Subs. by G.O.I. Notification No. GSR 331(E) dt 8.5.1984.

[1]FORM 36
[See Rule 150-B]

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 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 Schedule 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 Spectrophotometer or Chromatography.
5. Disinfecta nts
6. Other drugs

(b) Drugs specified in Schedule 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 the use of Ultravoilet/ Infra Red/ Spectrophotometer or Chromatography.
8. 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.

* *Delete whichever is not applicable*

[1] Ins.by G.O.I. Notification No.X. 11014/7/76-D&MS, dtd 23-8-1977.

.

(4) List of testing equipments provid ed.

(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 Head of Account……

Date…….. *Signature*……

FORM 37
[See Rule 150-C]

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 [1][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…….

---

[1]Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996.

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 meant 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 to the approving authority.

[1][(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.]

FORM 38

[*See* Rule 150-J]

Certificate of renewal of approval for carrying out tests on drugs / cosmetics and raw materials used un 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.

…….

…….

---

[1] Ins. by G.O.I. Notification No. GSR 681(E) dt 5.12.1980.

[2] Subs. by G.O.I. Notification No. GSR 231(E) dt 4.6.1996

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

FORM 39

[See Rule 150-E (f)]

Report of test or analysis by approved institution

(1) Name of the 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 / 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.
[1][(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] Subs. by G.O.I. Notification No.GSR 681(E) dt 6.6.1988.

*Form 40

[*See* rule 24-A]

Application for issue of Registration Certification 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.

(1)

(2)

(3)

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 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 original).

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

---

* Ins. by G.O.I. Notification G.S.R. No.604(E) dt. 24-8-2001 w.e.f. 1-1-2003.

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 authorized 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).

*Form No. 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 many be imported under this Registration Certificate:
(1)
(2)
(3)

_____

***** Ins. by G.O.I. Notification G.S.R. No.604(E) dt. 24-8-2001 w.e.f. 1-1-2003

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 authorized 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 authorized 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 authorized 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 or origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed.

The despatch 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 authorized agent in India shall inform the licensing authority within 30 days in writing in the vent of any change in manufacturing process, or in packaging, or in labeling or in testing, or in documentation of any of the drug 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 authorized 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 authorized agent in India shall inform the licensing authority immediately in writing in the event or 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.

(Forms 40 to 43 pertaining to Ayurveda, Siddha and Unani drugs replaced by Forms Nos.47 to 50.)

**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 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 / date is given below :

**Forms 44 to 46 A inserted as per G.O.I. Notification No.G.S.R.900 (E) dt. 12.12.2001.

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 license

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 pre-reviewed journals/text books)
(2) Data on pharmacokinetics / pharmacodynamics combination.
y 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 …….

FORM 45
[*See* rules 122 A, 122 D and 122 DA]
Permission to import Finished Formulation of the 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 is 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."**

(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.

FORM 45 A

[*See* rules 122 A and 122 DA]

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.

(2) 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."

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 122 B / 122 D / 122 DA of the Drugs and Cosmetics Rules, 1945, namely :-

(1) Name of the formulation:
(2) Dosage form:
(3) Composition:
(3) Indications:

Signature ……
Date : …….. 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 he innermost container of the drug or every other covering in which the container is packed.

(3) The label of the innermost co ntainer 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 is prescription drug.

(4) The label on the immediate container of the drug as well s 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"
(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.

FORM 46 A
[See rules 122 B and 122 DA)

Name of the permission / approval and date of issue ……

Permission / Approval for manufacture of raw material (new bulk drug substance) M/s. ……of……..(address) is hereby granted Permission / Approval to manufacture the following raw material (new bulk drug substance) under rule 122 B / 122 DA 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 122-B shall be obtained from the Licensing Authority.

[**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, Halwa
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.	Varti	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

**Ins. by G.O.I. Notification G.S.R. No.701(E) dt. 27-9-2001 and subs.by G.O.I. Notification No.G.S.R.73(E) dt31.01.2003.

23.	Rasayoga-Centuram	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: (a) Plant based (b) Mineral based (c) Metal based (d) Animal based (e) Synthetic (f) Any other Ayurvedic, Siddha, Unani formulation	34.	Ghaza, Utban, Sabagh
35.	Pushp (Phool)	35.	Capsule
36.	Nasya	36.	Huqna
37.	Swarasa (Fresh juice)	37.	Naurah

38.	Karna Bindu (Ear drops)	38.	Latook
39.	Any other dosage of patent and Proprietary and Ayurvedic, Siddha, Unani Drug	39.	Vajoor (Throat paint)
		40.	Mazmazah (Mouth washer)

(3) Names, qualifications 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 whichever is not applicable.

[**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) The approval and any certificate of renewal in Form 42 shall be displayed in the approved premises and shall be produced in 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.

** Ins. by G.O.I. Notification G.S.R. No.702(E) dt. 27-9-2001 and subs.by G.O.I. Notification No.G.S.R.73(E) dt31.01.2003.

(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.]

[**Form 49

(*See* rule 160 I)

Certified of renewal for carrying out tests of analysis on Ayurvedic Siddha or Unani drugs of 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……..2001 for carrying out tests of identity, purity, quality and strength on the

following categories of Ayurvedic, Siddha or Unani, dugs 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) Names of experts and the person-in-charge of testing ……(experts) and …….. (person-in-charge).

Date: ……..
Place : ……

Signature ……..
Designation ……
Seal of State Licensing Authority]

[**FORM 50
(*See* Rule 160 D(f))

Report of test analysis by approved Laboratory

** Ins. by G.O.I. Notification G.S.R. No.701(E) dt. 27-9-2001 and subs.by G.O.I. Notification No.G.S.R.73(E) dt31.01.2003.

.

(1) Name of manufacturer from which sample received together with his manufacturing license 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 packed …….

(b) Batch number …….

(c) Batch size as represented by sample…….
(d) Date of manufacture, if any …….

(6) Results of test or analysis with protocols of test or analysis applied or as per Ayurvedic, Siddha or Unani Pharmacopocial 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 standards quality as defined in the Act or the rules made thereunder for the reasons given below
……
……

Date :

(F.No. ……)

Place :

Name & Designation & Seal ……
Name & Address of the Laboratory ……..
Licence No. ……..

Note : Final product includes repacked material.

* Delete whichever is not applicable.]