the State Government shall provide information of the advertisements to the Central Government on quarterly basis and also as and when sought by the Central Government.

(15) The State Licensing Authority may suspend or cancel the license of the manufacturer of the Ayurvedic, Siddha or Unani drug as per the provisions of Rule 159, in case the directions given by the said authority is not complied.

(16) The Central Government shall, in the public interest, prohibit any advertisement of the Ayurvedic, Siddha or Unani drugs, by notification in the Official Gazette.]

SCHEDULE A
FORM 1
(See rule 4)
MEMORANDUM TO THE CENTRAL DRUGS LABORATORY

Serial Number..........................

To the Director,

Central Drugs Laboratory..............................................................

From..........................................................

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

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

3. Particulars of offence alleged..................................................................

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

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

Date....................... Magistrate.................................
[Form 1A
(See rule 163C)

[Pharmacopoeia Commission for Indian Medicine and Homoeopathy, Ghaziabad (Uttar Pradesh)]

From..........................................................

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

Serial No..........................................................

To the Director,

Pharmacopoeial Laboratory for Indian Medicine,

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

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

3. Particulars of offence alleged..........................................................

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

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

Date..........................................................

Magistrate/Authorized Signatory.]
FORM 2
(See rule 6)
CERTIFICATE OF TEST OR ANALYSIS BY THE CENTRAL DRUGS LABORATORY

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

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

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

Director
Date.......................... Central Drugs Laboratory or other Authorised Officer

Details of results of test or analysis with protocols of test applied

Director
Date..........................Central Drugs Laboratory or other Authorised Officer

* If opinion is required on any other matter, the paragraph should be suitably amended.
FORM 2A
(See rule 163E)

CERTIFICATE OF TEST OR ANALYSIS FROM THE
PHARMACOPOEIA COMMISSION FOR INDIAN MEDICINE AND
HOMOEOPATHY] OR GOVERNMENT ANALYST

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

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

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

Or

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

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

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

Date.............................................

Place............................................. Name & Designation & Seal.............................................

Name & Address of the Laboratory.............................................

1[***]
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 number, fax, and e-mail no.)

2. Names of the drugs to be imported:
   (1)
   (2)
   (3)

3. I/we*, ............................................., enclose herewith an undertaking in Form 9 dated..................................signed by the manufacturer as required by rule 24 of the Drugs 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 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 Rules, 1945—Central vide Challan No....................... dated...................... (attached in original)

   Signature............................................
   Name.............................................
   Designation....................................
   Seal/Stamp of Manufacturer's agent in India

Place: ...........................
Date: ..........................

* Delete whichever is not applicable]
[FORM 8A
(See rule 24)
APPLICATION FOR LICENCE TO IMPORT DRUGS SPECIFIED IN SCHEDULE X TO THE DRUGS AND COSMETICS RULES, 1945

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

2. Names of the drugs to be imported
   (1)
   (2)
   (3)

3. I/we*, ........................................, enclose herewith an undertaking in Form 9 dated ......................signed by the manufacturer as required by rule 24 of Drugs and 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 Rules, 1945—Central vide Challan No................. dated ......................... (attached in original).

   Signatures...........................................
   Name..............................................
   Designation......................................

   Seal/Stamp of Manufacturer's agent in India

Place.........................
Date.........................

* Delete whichever is not applicable.]
FORM 9
(See rule 24)
FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION
FOR AN IMPORT LICENCE

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

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

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

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

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

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

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

 Names of drugs and classes of drugs

Particulars of premises where manufacture is carried on.

Dated…………………………….               213[Signature……………………………
                                                  Name……………………………]
Designation..................................
Seal/Stamp of manufacturer or on behalf of the manufacturer]

3[FORM 10
(See rules 23 and 27)
LICENCE TO IMPORT DRUGS (EXCLUDING THOSE SPECIFIED IN SCHEDULE X) TO THE DRUGS AND COSMETICS RULES, 1945

Licence Number..................................................            Date..........................

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

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

3. Names of drugs to be imported:

Place................................
Date..................................

LICENSING AUTHORITY
Seal /Stamp

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.

2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing date of release and 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 authorised agent.

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

1[FORM 10A
(See rules 23 and 27)
LICENCE TO IMPORT DRUGS SPECIFIED IN SCHEDULE X TO THE DRUGS AND COSMETICS RULES, 1945

Licence Number................................ Date ................................
................................................................ (Name and full address of the importer) is hereby licensed to import into India during the period for which this 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. Name of drugs to be imported.

Place.....................................
Date............................................... LICENSING AUTHORITY

Seal/Stamp

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence 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 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 alongwith the registration holder and his authorised 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 II**
(See rule 33)

**LICENSE TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST OR ANALYSIS**

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

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

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

<table>
<thead>
<tr>
<th>Names of drugs</th>
<th>Quantity which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India  Page 214 of 874
Date........................................................           LICENSING AUTHORITY

Seal/Stamp

<table>
<thead>
<tr>
<th>Names of drugs</th>
<th>Quantity which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Place........................................

Date........................................................           LICENSING AUTHORITY

Seal/Stamp

**Conditions of Licence**

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

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

3. The drugs 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 of Head of the Autonomous Medical Institution which shall be produced, on demand by an Inspector appointed under the Act.]

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**FORM 12**

*(See rule 34)*
APPLICATION FOR LICENCE TO IMPORT DRUGS FOR PURPOSE OF EXAMINATION, TEST OR ANALYSIS

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

1[214[ 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).]]

<table>
<thead>
<tr>
<th>Names of drugs</th>
<th>Quantity which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Place..................................
Date.................................................. LICENSING AUTHORITY

1FORM 12A
(See rule 36, second proviso)

APPLICATION FOR THE ISSUE OF A PERMIT TO IMPORT SMALL QUANTITIES OF DRUGS FOR PERSONAL USE

1........................................居民 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.

<table>
<thead>
<tr>
<th>Names of drugs</th>
<th>Quantity which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date.................................................. Signature.........................]
APPLICATION FOR LICENCE TO IMPORT SMALL QUANTITIES OF NEW DRUGS BY A GOVERNMENT HOSPITAL OR AUTONOMOUS MEDICAL INSTITUTION FOR THE TREATMENT OF PATIENTS

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

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

2. Name of new drug to be imported

<table>
<thead>
<tr>
<th>Names of drugs</th>
<th>Quantity which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

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.........................
1. FORM 12B

(See rule 36, second proviso)

PERMIT FOR THE IMPORT OF SMALL QUANTITIES OF DRUGS
FOR PERSONAL USE

...............................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
[till such time as the patient requires the drug as per the prescription of a
registered medical practitioner and the permit holder shall submit details of
drugs imported and utilised to the licensing authority on yearly basis] from the
date specified below.

<table>
<thead>
<tr>
<th>Names of drugs</th>
<th>Quantity which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

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 ................................
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Name of Inspector from whom received .................................................................</td>
</tr>
<tr>
<td>2.</td>
<td>Serial No. and date of Inspector's memorandum.......................................................</td>
</tr>
<tr>
<td>3.</td>
<td>Number of sample.......................................................................................................</td>
</tr>
<tr>
<td>4.</td>
<td>Date of receipt ..........................................................................................................</td>
</tr>
<tr>
<td>5.</td>
<td>Names of ingredients purporting to have been used in the preparation of the sample......</td>
</tr>
<tr>
<td>6.</td>
<td>Condition of seal on the package...............................................................................</td>
</tr>
<tr>
<td>7.</td>
<td>Results of test or analysis.........................................................................................</td>
</tr>
</tbody>
</table>

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

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

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

FORM 14A
(See rule 47)
APPLICATION FROM A PURCHASER FOR TEST OR ANALYSIS OF A DRUG UNDER SECTION 26 OF THE DRUGS AND COSMETICS ACT, 1940

1. Full name and address of the applicant.................................................................

2. Occupation..............................................................................................................

3. Name of drug purporting to be contained in the sample.........................................

4. Name and full address of the pharmacy or concern where the drug was purchased...........................................................................................................

5. Date on which purchased........................................................................................

6. Reasons why the drug is being submitted for test or analysis...............................

7. A fee of rupees......................................................... vide Schedule B to the Drugs 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 14B  228, 238, 239

(See rule 47)
CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT
ANALYST UNDER SECTION 26 OF THE DRUGS AND COSMETICS
ACT, 1940

1. Name of person from whom sample received..............................................

2. Date of receipt..............................................................

3. Name of drug purporting to be contained in the sample...............................

4. Opinion of the Government Analyst—The sample referred to above is/is
   not of standard quality as defined in the Drugs and Cosmetics Act, 1940, and
   rules thereunder.

   Date.............................................................Government Analyst...............[FORM 15

ORDER UNDER SECTION 22(1) (C) OF THE DRUGS AND
COSMETICS ACT, 1940 REQUIRING A PERSON NOT TO DISPOSE
OF STOCK IN HIS POSSESSION

Whereas, I have reason to believe that the stocks of drugs/217[***] 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/2[***].

    Date................................. Inspector]
[FORM 16
(See rules 55 and 145B)
RECEIPT FOR STOCK OF DRUGS \[^{18}\]** FOR RECORD, REGISTER DOCUMENT OR MATERIAL OBJECT SEIZED UNDER SECTION 22(1)(C) OR (CC) OF THE DRUGS AND COSMETICS ACT, 1940

The stock of drugs or \[^{2}\]** 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 \[^{2}\]** Act, 1940 (23 of 1940), from the premises of ........................................ situated at...........................

Date........................................................................................................Inspector........................

Details of drugs, \[^{2}\]** records, registers, documents or material objects seized.

Date........................................................................................................Inspector........................

[FORM 17
(See rules 56 and 145A)
INTIMATION TO PERSON FROM WHOM SAMPLE IS TAKEN

To

..........................

I have this day taken from the premises of ........................................ situated at............samples of the drugs \[^{19}\]** specified below for the purpose of test or analysis.

Date.............. ........................................................................Inspector................

Details of sample taken

Date.............. ........................................................................Inspector................
3[FORM 17A
(See rules 56A and 145AA)

RECEIPT FOR SAMPLES OF DRUGS 220[***] TAKEN WHERE FAIR PRICE TENDERED THEREOF UNDER SUB-SECTION (1) OF SECTION 23 OF THE DRUGS AND COSMETICS ACT, 1940 IS REFUSED

To

.................................

Whereas I, this..................day of........221[20]........., have taken from the premises of situated at.................... samples of drugs/cosmetics as specified below:—

Details of samples

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

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

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

Date..................................................[Inspector....................]

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 2[***] 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 [drug][***] which it purports to contain—

Date....................................................Inspector.............................

[FORM 18A
[See rule 163(1)]
MEMORANDUM TO GOVERNMENT ANALYST

Serial No......................

From

To

The Government Analyst

The portion of sample/container described below is sent herewith for test or analysis under the provision 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.............................

[FORM 19
[See rule 59(2)]

APPLICATION FOR GRANT [*][***] OF A [LICENCE TO SELL, STOCK, 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 wholesale/retail drugs specified in Schedules C and C(l) excluding those specified in Schedule X* and/or drugs other than those specified in Schedules C, C(l) 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 person supervision of the qualified persons namely:—

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

3. Categories of drugs to be sold.

4. # Particulars for special storage accommodation.

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

Date........................................Signature...............................

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

FORM 19A

[See rule 59(2)]

APPLICATION FOR THE GRANT [*] OF A RESTRICTED [***] LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] DRUGS BY RETAIL BY [*] DEALERS WHO DO NOT ENGAGE THE SERVICE OF QUALIFIED PERSON

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

or (ii) Drugs specified in [*][Schedule C(I)] on the premises situated at................./ Drugs specified in [*][Schedule C(I)] as vendor in the 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 Schedule C(l) drugs on the premises referred to above.

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

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

6. A fee of rupees 3[***]/#twenty has been credited to Government under the head of account..............................

Date.......................................................... Signature..............................

* Delete if not required.

! Applies only to an itinerant vendor.

# Rupees five for itinerant vendors and applicants from a village or town having a population of 5,000 or less, and rupees twenty for other restricted licence.

6[FORM 19AA
(See rule 62C)
APPLICATION FOR GRANT *[***] OF A *[***] LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE BY WHOLESALE, OR DISTRIBUTE* DRUGS FROM A MOTOR VEHICLE

1. I/We........................................, of........................................hereby apply for 3[licence to sell, stock or exhibit or offer for sale by wholesale, or distribute] drugs specified in Schedules C and C(l) and/or drugs other than those specified in Schedule C and Schedule C(l) from the vehicle bearing registration No........................................... assigned under the Motor Vehicles Act, 1939.

2. Categories of drugs to be sold/distributed.................................

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

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

Date........................................ Signature............... ]
* Delete if not required.

**FORM 19B**
*(See rule 67A)*

**APPLICATION FOR **

3[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] HOMOEOPATHIC MEDICINES

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

*2. The sale and dispensing of Homoeopathic medicines shall be made under the person 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...................................

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

* Delete whichever is not applicable.

**FORM 19C**
*(See rule 59(2))*

**APPLICATION FOR GRANT 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.....................

!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. Name of drugs to be sold.

4. **Particulars of storage accommodation.**

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

    Date............................................. Signature  .........................

* Delete whichever is not applicable.

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

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

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**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 SCHEDULES C, C(l) AND X**

1. .......................................................... is hereby [licensed to sell, stock or exhibit or offer for sale or distribute] by retail drugs other than those specified in [Schedules C, C(l) 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 the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder.

2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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

4. Categories of drugs..............................

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

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

   Licensing Authority.........................

* Delete if not applicable.
Conditions of Licence

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

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

3. The licensee shall report to the licensing authority any change in the qualified staff incharge within one month or such change.

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

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

RESTRICTED ^LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] DRUGS BY RETAIL OTHER THAN THOSE SPECIFIED IN 229[SCHEDULE C, C(I) AND X] FOR 230[***] DEALERS WHO DO NOT ENGAGE THE SERVICES OF A QUALIFIED PERSON

1.......................................................... is hereby 1[licensed to sell, stock or exhibit or offer for sale, or distribute] on the premises situated at 3[***] ...........................................the following drugs being drugs other than those specified in 2[Schedules C, C(I) 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.

4[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the
provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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

5 [***]

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 3[***]

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

3. No drugs shall be sold unless such drug is purchased under a case or credit memo from 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 20B

[See rule 61(1)]

HLICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY WHOLESALE, DRUGS OTHER THAN THOSE SPECIFIED IN 2[SCHEDULES C, C(1) AND X]

1,................................................ is hereby 1[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale drugs other than those specified in 2[Schedules C, C(1) and X] on the premises situated at........................subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940, and the rules thereunder.
4[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

Conditions of Licence

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

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

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 the 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]

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

3[* * *]

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 20BB
(See rule 62D)

[FORM 20BB
(See rule 62D)

5. 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(I) TO DRUGS AND COSMETICS RULES, 1945, FROM A MOTOR VEHICLE

1. .................................................. is hereby 5[licensed to sell, stock or exhibit or offer for sale by wholesale, or distribute] drugs other than those specified in Schedule C and Schedule C(I) 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 unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

3. Categories of drugs ................................
Date.............................................Licence No.............................................
Licensing Authority.................................

Conditions of Licence

1. This licence shall be displayed in a prominent place on the vehicle.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder for the time being in force.
3. (i) No drug 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 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 the 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, confectionary 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 takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

5. The licensee shall inform the licensing authority in writing in the event of any change in ownership of the vehicle specified in this licence within seven days of such change.]

FORM 20C
(See rule 67C)

[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] HOMOEOPATHIC MEDICINES BY RETAIL

1., ......................................................, is hereby 231 licensed to sell medicines by retail, stock or exhibit or offer 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. 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 applicable to Homoeopathic medicine under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.

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

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

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, 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 20D**

(See rule 67C)

"[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] HOMOEOPATHIC MEDICINES BY WHOLESALE"

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

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

Date.................................

Licensing Authority.........................

*Conditions of Licence*

1. This licence shall be displayed in a prominent place on the premises."
2. The licensee shall comply with the provisions as applicable to Homoeopathic medicines under the Drugs and Cosmetics Act, 1940 and the rules made thereunder for the time being in force.

3. No sale of any drug shall be made to a person not holding the requisite 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 institution or a Homoeopathic medical practitioner for the purpose of supply to his patients.]

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.]

1 [FORM 20E
(See rule 67EE)
CERTIFICATE OF RENEWAL OF LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] HOMOEOPATHIC MEDICINES

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

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


Date................................................... Licensing Authority..............]
FORM 20F

[See rule 61(3)]

LICENCE TO SELL, STOCK OR EXHIBIT FOR SALE OR DISTRIBUTE BY RETAIL DRUGS SPECIFIED IN SCHEDULE X

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

2. Names of drugs.

3. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

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 authority.........................

Conditions of Licence

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

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

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

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

1[FORM 20G
[See rule 61(3)]

2[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY WHOLESALE DRUGS SPECIFIED IN SCHEDULE X

1........................................................................, is hereby 233[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945, on the premises situated at....................

2. Names of drugs ...........................................

3[3. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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

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

Licensing Authority.........................

Conditions of Licence

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

2. The licensee shall 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 the drugs specified in Schedule X:

Provided that the 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 25E or 28B to manufacture the drugs containing drugs included in Schedule X.

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**

[See rule 61(2)]

^LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY RETAIL DRUGS SPECIFIED IN SCHEDULES C AND C(I) 234[EXCLUDING THOSE SPECIFIED IN SCHEDULE X]

3[1..................................is hereby 2[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(I) 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.]

4[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach."

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

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

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

Licensing Authority..........................

* Delete if not applicable

Conditions of Licence

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

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

4. If the licensee wants to sell, stock or exhibit or offer for sale, or distribute during the currency of the licence, additional categories of drugs listed in Schedules C and C(l) [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.

6[5. No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.]

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

FORM 21A

[See rule 61(2)]

RESTRICTED 'LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY RETAIL DRUGS SPECIFIED IN
2 [SCHEDULE C(l)] 235 [EXCLUDING THOSE SPECIFIED IN SCHEDULE X] FOR 236 [***] DEALERS WHO DO NOT ENGAGE THE SERVICES OF A QUALIFIED PERSON

1..........................................................is hereby 1 [licensed to sell, stock or exhibit or offer for sale, or distribute] by retail on the premises situated at 4 [***]........................................ the following drugs being drugs specified in 237 [Schedule C(l)] 3 [excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945 subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder.

5 [2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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

Date...........................................                Licensing Authority ...............  

Conditions of Licence

1. This licence shall be displayed in a prominent and conspicuous place in a part of the premises open to the public 238 [***].
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 a duly licensed dealer or a duly licensed manufacturer.

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

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**FORM 21B**

[See rule 61(2)]

2.LICENSE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY WHOLESALE DRUGS SPECIFIED IN SCHEDULES C AND C(I) [EXCLUDING THOSE SPECIFIED IN SCHEDULE X]

1,..............................................................., is hereby 2[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale on the premises situated at.................................the following categories of drugs specified in Schedules C and C(I) 3[excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

**Categories of drugs**

4[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

5[2A. The sale shall be made under the personal supervision of a competent person. (Name of the competent persons.))
3. This licence is subject to the conditions stated below and to the provisions of Drugs and Cosmetics Act, 1940, and the Rules thereunder.

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

Licensing Authority..................................

Conditions of Licence

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

3. If the licensee wants to sell, stock and exhibit for sale or distribute during the currency of the licence additional categories of drugs listed in Schedule C(l) [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[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,

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

2[(c) a manufacturer of hydrogenated vegetable oils, beverages, confectionery and other non-medicinal products, where such drugs are required for processing these products.]
3[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.]

4[FORM 21BB

(See rule 62D)

LICENCE TO SELL BY WHOLESALE OR TO DISTRIBUTE DRUGS SPECIFIED IN SCHEDULE C AND SCHEDULE C(I) 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(I) from the vehicle bearing registration No. .................. assigned under Motor Vehicles Act, 1939 subject to the conditions specified below to the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder.

5[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

3. Categories of drugs .........................

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

Licensing Authority......................

Conditions of Licence

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

2. No drugs to which this licence applies shall be sold by wholesale or distributed unless the precautions as are published by the licensing authority
from time to time in the Official Gazette have been observed throughout the period during which it has been in the possession of the licensee.

3. If the licensee wants to sell by wholesale or distribute during the currency of the licence additional categories of drugs listed in Schedule C and Schedule C(I) 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 drug 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 by 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 drugs.

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 hydrogenated vegetable oils, beverages, confectionery and other non-medicinal products, where such drugs are required for processing their products.

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

FORM 21C

FORM 21CC

FORM 22 M

FORM 23

(See rule 69)

APPLICATION FOR THE GRANT OF A LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C, C(I) AND X

1. I/We,..........................................., of..........................................hereby apply for the grant of a licence to manufacture on the premises situated at ...........................................the following drugs being drugs other than those specified in Schedules C, C(I) and X to the Drugs and Cosmetics Rules, 1945.
2. Name 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 plant of the premises.
FORM 24A

(See rule 69A)

APPLICATION FOR GRANT \[2^{nd}**\] OF A LOAN \[3^{rd}**\] LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF [DRUGS OTHER THAN THOSE SPECIFIED IN “[SCHEDULES C, C(l) AND X]"

1. I/We*, ........................................... of ! ....................................... hereby apply for the \[5^{th}**\] [grant] of a licence to manufacture on the premises situated at ....................... C/o # ................... the undermentioned drugs, other than those specified in “[Schedules C, C(x) and X]” to the Drugs and Cosmetics Rules, 1945.

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

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

3. I/We enclose

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilised by me/us.
(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me/us and that they will analyse every batch of finished product and maintain the register of raw materials, finished products and reports of analysis separately in this behalf.
(c) Specimens of labels, cartons of the products proposed to be manufactured.

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

Date.........................................Signature....................

* Enter here the name of the proprietor, partners or Managing Director as the case may be.
! Enter here the name of the applicant firm and the address or 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[FORM 24B
(See rule 69)
APPLICATION FOR GRANT \[246[***] OF A LICENCE TO REPACK FOR SALE OR DISTRIBUTION OF DRUGS, BEING DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C AND C(l) \[247[EXCLUDING THOSE SPECIFIED IN SCHEDULE X]

1. I/We, ............................., of......................hereby apply for 247[grant] 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 application shall be accompanied by a plan of the premises.

5[FORM 24C
(See rule 85B)
APPLICATION FOR GRANT \[248[OR RENEWAL] OF A \[249[LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] HOMOEOPATHIC MEDICINES OR A LICENCE TO MANUFACTURE POTENTISED PREPARATIONS FROM BACK POTENCIES BY LICENSEEES HOLDING LICENCE IN FORM 20C

8[1. I/We, ............................., of......................holder of licence No............in Form 20C hereby apply for 250[grant or renewal] of licence to manufacture the undermentioned Homoeopathic Mother Tincture/Potentised and other preparations on the premises situated at..............................
Names of the Homoeopathic preparations..........................

(Each item to be separately specified).

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

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

Date................................................ Signature..................

Note.—(1) Delete whichever portion is not applicable.

(2) The application should be accompanied by a plan of the premises.

FORM 24D
(See rule 153)

APPLICATION FOR THE GRANT OF A LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA OR UNANI DRUGS

1. I/W e ........................................... of ........................................ hereby apply for the grant of a licence to manufacture Ayurvedic, Siddha or Unani drugs on the premises situated at.................................................................

2. Names of drugs categorized according to Schedule T to be manufactured (with details)

3. Names, qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic, 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/online transaction slip is enclosed herewith.

Date................................................ Signature......................................

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

2[FORM 24E
(See rule 153A)
APPLICATION FOR THE GRANT OF A LOAN LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA OR UNANI DRUGS

1. I/We* .............................., of ............................. hereby apply for the grant of a loan licence to manufacture Ayurvedic, Siddha or Unani drugs on the premises situated at..........................C/o # ..........................

2. Names of drugs categorized according to Schedule T to be manufactured (with details).

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

4. I/We* enclose.

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

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

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

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

Date...............................    Signature..............................
APPLICATION FOR THE CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA OR UNANI DRUGS MANUFACTURING UNITS

1. I/We……………………………………….of……………………………………………………herewith apply for the grant of a Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing on the premises situated at………………………………………………

2. A fee of rupees …………………………. has been credited to the Government under the head of account …………………………… and the relevant Treasury Challan/online transaction slip is enclosed herewith.

Date……………………………………………. Signature……………………………………

(Applicant)

Note.—The application should be accompanied by a Plan of the premises.]
...the undermentioned drugs, specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

2. Names of drugs.

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

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

Date........................................   Signature........................................

Designation...................................

FORM 25
(See rule 70)

4 LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS OTHER THAN THOSE SPECIFIED IN §[SCHEDULES C, C(l) AND X]

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

1..........................is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in §[Schedules C, C(l) and X] to the Drugs Rules, 1945, on the premises situated at...........................under the direction and supervision of the following [Competent Technical Staff]:—

(a) 1[Competent Technical Staff] (Names)............................................................

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

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

3. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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

Date................................   Signature..................................

Designation................................

3[*Licencing Authority/ "Central Licence Approving.]

* Delete whichever is not applicable.

**Conditions of Licence**

1. This licence 4[***] 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 5[Competent Technical Staff] named in the licence shall be forthwith reported to the licensing authority.

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

4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.
FORM 25A
(See rule 70A)

LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C, C(I) AND X

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

2.........................of.............................................is hereby granted a loan licence to manufacture the following drugs being drugs other than those specified in Schedules C, C(I) and X to the Drugs and Cosmetics Rules, 1945, on the premises situated at .......................C/o .....................under the direction and supervision of the following Competent Technical Staff:—

(a) 3[Competent Technical Staff] (Names)............................................

(b) Names of drugs .................................................................

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

4[4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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 Drugs and Cosmetics Act, 1940.

Date...................................................   Signature..........................

Designation..............................

Conditions of Licence
1. This licence and **[***]** shall be kept on the approved premises and shall be produced on the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the **[Competent Technical Staff]** named in the licence shall be forthwith reported to the licensing authority.

3. If the licensee wants to undertake during the currency of the licence to manufacture for sale additional drugs he should apply to the licensing authority for the necessary endorsement to the licence as provided in Rule 69A. 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 changes 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 25B**

See rule 70

**LICENCE TO REPACK FOR SALE OR DISTRIBUTION OF DRUGS BEING DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C AND C(I) [EXCLUDING THOSE SPECIFIED IN SCHEDULE X]**

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

1...........................................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) Name of drugs to be repacked.

(b) Names of competent staff.

3[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
3. The licence authorises the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs repacked under the licence subject to conditions applicable to licence 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 [*] 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. Any change in the competent 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. The licence shall be deemed to extend to only those items so endorsed.

4. The drugs repacked under this licence shall bear on their label, apart from other particulars required by these Rules, the name and address of the licensee and the number of the licence under which the drug is repacked preceded by the words 'Rpg. Lic. No. '

5. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]
[FORM 25C
(See rule 85D)

[ LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] HOMOEOPATHIC MEDICINES

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

1. I, ............... of ................. *who holds a licence in Form 20C is hereby licensed to manufacture the under mentioned Homoeopathic Mother Tincture/potentised and other preparations on the premises situated at................. under the direction and supervision of following technical staff:—

Names of the Homoeopathic preparations.

(Each item to be separately specified)

Names of the Technical Staff.................................................................

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

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

Date................................................ Signature....................................

Designation........................................

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

Conditions of Licence

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

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

1[FORM 25D
(See rule 154)

LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC,
SIDDHA OR UNANI DRUGS

No. of Licence and date of issue.................................................................................................

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

(a) Competent Technical staff (Names).

(b) Names of drugs categorized as per Schedule T (each item to be separately specified) with specific Product Code/QR Code for each approved drug.

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

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. Any change in the Technical staff named in the licence shall be forthwith reported to the Licensing Authority.
2. This licence shall be deemed to extend to such additional items as the licencsee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

3. The licencsee 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.

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.

5. The licence is issued only after fulfillment of the requirements of Good Manufacturing Practices (GMP) of Ayurveda, Siddha or Unani drugs as laid down in Schedule T of the Drugs Rules, 1945.
3. The licence shall be in force from.................................

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………………… Designation………………
Signature ……………

Conditions of Licence

1. Any change in the technical staff named in the licence shall be forthwith reported to the Licensing Authority.

2. 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.

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

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.]
[FORM 25F
(See rule 70)
[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 Rules, 1945.

2. Name of drugs.

3. Names of approved [255] [Competent Technical Staff].

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

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

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

Date of issue……………………………………Signature………………

Licence No…………………Designation………………

1 [Licensing Authority………………]

*Central Licence Approving Authority]

* Delete whichever is not applicable.

Conditions of Licence

1. This licence [256][***] 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 to this licence. This licence shall be deemed to extend to only those 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 in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

5. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

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

FORM 26

FORM 26A

FORM 26B

FORM 26C

(See rule 85G)

CERTIFICATE OF RENEWAL OF LICENCE TO MANUFACTURE FOR SALE OF HOMOEOPATHIC MEDICINES

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

2. Names of technical staff...........................................................................................................

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

Date............................................................Signature ....................................

Designation...............................................

2[FORM 26D
(See rule 155)
CERTIFICATE OF RENEWAL OF LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC/SIDDHA OR UNANI DRUGS

1. Certified that Licence No....................................granted on the........................................ to Shri/Messrs ........................................ for the manufacture of Ayurvedic/Siddha or Unani Drugs at the premises situated at ........................................ has been renewed from ............to..............

2. Names of technical staff............................................................

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

Date................................................................Signature..................................

Designation...............................................

3[FORM 26E
(See rule 155A)
CERTIFICATE OF RENEWAL OF LOAN LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC/SIDDHA OR UNANI DRUGS

1. Certified that loan licence No..............................granted on the ........................................to ...............for the manufacture of Ayurvedic/Siddha/Unani drugs at the premises situated at...............C/o .........................has been renewed from...............to..............
2. Names of technical staff.................................................................................................

Date........................................................................................................Signature ..........

Designation........................................]

1[FORM 26E-I

(See rule 157B)

CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP)
TO MANUFACTURER OF AYURVEDA, SIDDHA OR UNANI DRUGS

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

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

Dated........................................Signature.....................

Place..................................................Designation...........

Licensing Authority for Ayurveda/ Siddha/Unani Drugs.]

3[FORM 26E2-I

(See rule 158C)

State Drug Controller or Licensing Authority for Ayurveda, Siddha and
Unani Medicines Name of the State or Union territory........
Free Sale Certificate

It is certified that M/s........(Name of the company)........situated
at..........(Address) .............is holding valid Ayurvedic/Siddha/Unani Drug
Manufacturing Licence Number............and certificate of Good Manufacturing
Practices for the State or Union territory of ......
It is also certified that the manufacturing plant situated at...........(Address)........ in which the Ayurvedic or Unani or Siddha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.

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

(i) ...............  
(ii) ...............  
(iii) ...............  

Date .............  
(Seal of issuing Officer) .............  
(Signature and Name)  
State Drug Controller/Licensing Authority  
Address............................................  
Name of State or Union territory.............

1[FORM 26E2-II  
(See rule 158C)  
State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines Name of the State or Union territory........  
Free Sale Certificate  

It is certified that M/s...........(Name of the company)........situated at.........(Address) ....................... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing Loan Licence Number .................. and the valid certificate of Good Manufacturing Practices for the State or Union territory of......

It is also certified that the manufacturing plant situated at...........(Address)........ in which the Ayurvedic or Unani or Siddha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.
The firm has been permitted under Loan Licence Number........to manufacture and market the following products (attach list of products, if multiple) freely for sale in India under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder.

(i) ......................

(ii) ......................

(iii) ......................

Date:.......................        (Seal of issuing Officer):.......................  
(Signature and Name)  
State Drug Controller/Licensing Authority  
Address...................................................  
Name of State or Union territory.............]

2 [FORM 26 E3  
(See rule 158C)  
State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines Name of the State or Union territory........  
Non-Conviction Certificate  

It is certified that M/s.............. (Name of the company)........situated at ........ (Registered Address) ................. is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing Licence Number...........in Form 25D/25E and valid certificate of Good Manufacturing Practices/valid Good Manufacturing Practices certificate of principal or original manufacturer for the State or Union territory of...........

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

This certificate shall be valid only for one year from the date of issue.

Date :.........................        (Seal of issuing Officer) .......................
(Signature and Name)
State Drug Controller/Licensing Authority for Ayurveda, Siddha and Unani Medicines.
Address ........................................................
Name of State or Union territory.........................

ANNEXURE-1
(Proforma of Affidavit to be executed on appropriate non-judicial stamp paper of minimum value and attested by Notary Public)

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

1. That I, in the capacity of Authorized Signatory of ............ (name and address of the company) ............ am duly competent to depose and verify the present affidavit.

2. That I apply for Non-conviction Certificate on behalf of M/s ........................

3. That I declare that I am aware of the details of my organization and day to day activities from .............to ............

4. That I hereby undertake that the Non-Conviction Certificate, if issued, will be utilized for the bona fide purpose only.

5. I declare that the aforesaid firm is not convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the last three years.

6. That it is my true statement.

Signature of Deponent

Verification

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

Signature of Deponent

Witness with Address

1....................................

2....................................

1[FORM 26 E4
(See rule 170)

APPLICATION FORM FOR ADVERTISEMENT OF AYURVEDIC, SIDDHA AND UNANI DRUGS

(Note: Application may be made only for one advertisement)

1.1............................(name of the applicant with designation) am the authorised signatory of.......................................(name and full address of the manufacturing company) License number .................... valid up-to ............... hereby apply for consideration of following contents of the intended advertisement:

<table>
<thead>
<tr>
<th>Name of the Ayurvedic/ Siddha/ Unani drug</th>
<th>Contents of the advertisement including picture/audio/video (s) (Enclose copy)</th>
<th>Reference of indication(s)</th>
<th>Language of advertisement</th>
<th>Medium of advertisement (print/electronic/internet' audio-visual)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. The prescribed fee of rupees one thousand has been deposited to the Government under the head of account..........................and the relevant Treasury Challan is enclosed herewith.

3. Copies of the following documents are attached—

i) Valid license
ii) References of indications/claims

iii) Proof of safety

iv) Proof of efficacy

v) Quality standards

vi) Any other (please specify)

   a.

   b.

   c.

Date....................................     Signature

(Applicant)

Address and contact details

1[FORM 26 E5

[See rule 170]

STATE LICENSING AUTHORITY FOR AYURVEDIC, SIDDHA OR UNANI DRUGS

Name of the State or Union territory ........................

[Note: Out of (a), (b) and (c) paras, only one shall be ticked and filled]

It is recorded that M/s.................... (Name of the manufacturer / company) situated at .......................... (Address), is holding Ayurvedic / Siddha / Unani drug manufacturing License Number......................valid upto...................and it is conveyed that—

(a) Following contents of the intended advertisement for the.......... (name of the drug) are noted in the register vide Unique Identification Number ........................................... (Name of the State/ number/ year):—

The advertisement contents as above are valid till the validity of the current license. Invalid advertisement or any distortion in the contents of advertisement shall be liable for legal action as per rules.

(b) Following clarification with relevant supporting information is needed within thirty days of issue of this communication, failing which application shall be declined and application fee forfeited.—

(c) Application dated .......is hereby declined due to following reason(s)—
**Note:** The permission shall not be reflected or shown in the advertisement in any form.

Date............ Seal of issuing Officer (Signature and Name)  
State Licensing Authority/Drug Controller  
Name of State or Union territory.................

**FORM 26F 262[***]**

1. [FORM 26G]  
*(See rule 122F)*  
**CERTIFICATE OF RENEWAL OF LICENCE TO OPERATE A**  
2. [BLOOD CENTRE] 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 3. [Blood Centre] for processing of whole human blood and/or for preparation of its components at the premises situated at ..................is hereby renewed with effect from...........to ..............

2. Name(s) of items:

1. ...........................................
2. ...........................................

3. Name(s) of Competent Technical staff...........................................

1. ...........................................
2. ...........................................

Date............................... Signature ........................................

Name and Designation.................  
Licensing Authority/  
Central Licence Approving Authority.................]

* Delete, whichever is not applicable

**FORM 26H 4[***]**
CERTIFICATE OF RENEWAL OF LICENCE FOR MANUFACTURE OF BLOOD PRODUCTS

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

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

1....................
2....................

3. Name(s) of Competent Technical staff...............................

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

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

Date.............................        Signature..........................................

Name and Designation............... Licensing Authority/
 Central Licence Approving Authority

CERTIFICATE OF RENEWAL OF LICENCE FOR COLLECTION, PROCESSING, TESTING, STORAGE, BANKING AND RELEASE OF UMBILICAL CORD BLOOD STEM CELLS

Certified that licence number..............granted on..............to M/s........................for collection, processing, testing, storage, banking and release of umbilical cord blood stem cells at the premises situated at..............is hereby renewed with effect from ................. to ............

1. Name(s) of competent Technical Staff:
FORM 26J

APPLICATION FOR GRANT OF A LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS SPECIFIED IN SCHEDULES C AND C(I) EXCLUDING THOSE SPECIFIED IN PART XB AND SCHEDULE X

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

Name of drugs.....................................(each item to be separately specified).

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

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

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

3. The premises and plan are ready for inspection/will be ready for inspection on.........................
4. A fee of rupees ..................................and an inspection fee of rupees .......................has been credited to Government under the head of account..........................

Date..........................................................Signature..........................

Designation..........................

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

FORM 27A
(See rule 75 A)
APPLICATION FOR GRANT [***] OF A LOAN [2][LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS SPECIFIED IN SCHEDULES C AND C(l) [3][EXCLUDING THOSE SPECIFIED IN 266 [PART XB AND] SCHEDULE X]

1. I/We*, ........................................, of ........................................ hereby apply for the [grant] of loan licence to manufacture on the premises situated at ........................................ C/o# ........................................ the undermentioned drugs, being drugs specified in Schedules C and C(l) [excluding those specified in 266] [Part XB and] Schedule X] to the Drugs Rules, 1945.

Name 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 the specified products in the manufacturing premises.

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

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

3. I/We enclose

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

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

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

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

Date.................................................................Signature.................................

* Enter here 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 letter operates.

1 FORM 27B

APPLICATION FOR GRANT OF A LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS SPECIFIED IN SCHEDULES C, C(I) AND X

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

2. Names of drugs.

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

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

(b) Name(s) of staff responsible for manufacture.
4. The premises and plant* are ready for inspection/will be ready for inspection
on.......................... 

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

Date..............................................................Signature.................................

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

* Delete whichever is not applicable.

[FORM 27C

(See rule 122F)

APPLICATION FOR GRANT/RENEWAL* OF LICENCE FOR THE OPERATION OF A [BLOOD CENTRE] FOR PROCESSING OF WHOLE BLOOD AND/OR* PREPARATION OF BLOOD COMPONENTS

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

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

   1.

   2.

3. 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 Centre] 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.

Note 2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the concerned Zonal/ Sub-Zonal Officers of the Central Drugs Standard Control Organisation.

[FORM 27D
(See rule 75)
APPLICATION FOR GRANT 3[***] OF A LICENCE TO
MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF “[LARGE VOLUME PARENTERALS/ SERA AND VACCINE/RECOMBINANT DNA (R-DNA) DERIVED DRUGS] EXCLUDING THOSE SPECIFIED IN SCHEDULE X

1. I/We,.......................... of..............................hereby apply for the 5[grant] of a licence to manufacture for sale or distribution on the premises situated at .....

2. Name(s) of drug(s)....................(each item to be separately specified).
3. The name(s), qualifications and experience of the competent technical staff responsible for the manufacture of the above mentioned drugs.
   (a) Name(s) of staff responsible for testing..............................
   (b) Name(s) of staff responsible for manufacture............................

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

5. A fee or rupees......................................and an inspection fee of rupees.............. has been credited to the Government under the Head of Account..............

   Signature......................
   Date...............................................................Designation......................

Notes 1. The application is to be accompanied by a plan of the premises; list of equipments and machinery to be employed for manufacture and testing; memorandum of association/constitution of the firm; copies of qualification and experience of competent technical staff and documents relating to ownership or tenancy of the premises.

Notes 2. A copy of the application together with relevant enclosure shall also be sent each to Central Licence Approving Authority and concerned Zonal/Sub-Zonal Officers of Central Drugs Standard Control Organisation.]

--- FORM 27DA (See rule 75A) ---

APPLICATION FOR GRANT OF A LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF LARGE VOLUME PARENTERALS/SERA AND VACCINE/RECOMBINANT DNA (R-DNA) DERIVED DRUGS EXCLUDING THOSE SPECIFIED UNDER SCHEDULE X

1. I/We*,........................................of #.................................................hereby apply for the [grant] of a loan licence to manufacture on the premises situated at c/o @......................... the under-mentioned drugs being Large Volume Parenterals/Sera and Vaccine/ Recombinant DNA (r-DNA) derived drugs specified in Schedules C, C(l), excluding those specified in Schedule X to the Drugs Rules, 1945.
2. Name(s) of drugs........................................................... (each item to be separately specified).

3. The name(s), qualifications and experience of the competent technical staff responsible for the manufacture of the above-mentioned drugs.

   (a) Name(s) of competent technical staff responsible for testing..............................

   (b) Name(s) of competent technical staff responsible for manufacture.........................

4. I/we enclose:

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

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

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

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

Date.................................................. Signature........................................

Designation.................................

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

# Enter here name of the applicant firm and the address of the principal place of business.
1. I/We, ............ of M/s. ................. hereby apply for the grant of licence/renewal of licence number ................. dated ....................... to manufacture blood products on the premises situated at .............

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

1. 

2. 

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

   (a) responsible for manufacturing   (b) responsible for testing

   1. 

   2. 

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).

Dated .................................................................................................................. Signature .................................................

Name and Designation ......................

* Delete whichever is not applicable.
Note 1. The application shall be accompanied by a plant 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.

Note 2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the concerned Zonal/ Sub-Zonal Officers of the Central Drugs Standard Control Organisation.

[FORM 27F
(See rule 122F)
APPLICATION FOR GRANT/RENEWAL* OF LICENCE FOR COLLECTION, PROCESSING, TESTING, STORAGE, BANKING AND RELEASE OF UMBILICAL CORD BLOOD STEM CELLS

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

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

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

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

Signature…………………………
Dated..........................................................Name & 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, testing, storage, banking and release of umbilical cord blood stem cells, memorandum of association/constitution of the Firm, copies of certificate relating to educational qualification 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 enclosure 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)

**LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF** DRUGS SPECIFIED IN SCHEDULES C AND C(I) **EXCLUDING THOSE SPECIFIED IN SCHEDULE X**

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

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

Names of drugs...........................................................

2. Names of approved “[Competent Technical Staff]”

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

1[4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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 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 Schedules C and C(l) “[excluding those specified in Schedule X] not included above, he should apply to the licensing authority for the necessary endorsement as provided in rule 753. This licence will be deemed to extend 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 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 28A
(See rule 76A)

LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS SPECIFIED IN SCHEDULE C AND C(l) EXCLUDING THOSE SPECIFIED IN SCHEDULE X

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

2. 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(l) [excluding those specified in Schedule X] to the Drugs Rules, 1945.

Names of drugs ...........................................................

3. Names of approved Competent Technical Staff] ...........................................

3A. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

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

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

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

Designation..........................
Conditions of Licence

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

2. If the licensee wishes to undertake during the currency of the licence to manufacture any drug specified in Schedules C and/or C (1) [excluding those specified in Schedule X] not included above, he should apply to the licensing authority for the necessary endorsement as provided in rule 75A. This licence will be deemed to extend 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 in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

1 [FORM 28B]

See rule 76)

2 [LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS SPECIFIED IN SCHEDULES C, C(I) AND X

No. of licence.............................................

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

Name of drugs...............................  

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

4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

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

Date......................................................  Signature...........................
Designation..........................

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

* Delete whichever is not applicable.

Conditions of Licence

1. The licence shall be kept at the approved premises and shall be produced at the request of the 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 expert staff shall be forthwith reported to the licensing authority.

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

5. The licensee shall furnish to the licensing authority copies of invoices of sales made to dealers.

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

1[FORM 28C
(See rule 122G)

LICENCE TO OPERATE A 280[BLOOD CENTRE] FOR COLLECTION, STORAGE AND PROCESSING OF WHOLE HUMAN BLOOD AND/OR* ITS COMPONENTS FOR SALE OR DISTRIBUTION

1. Number of Licence.............date of issue...............at the premises situated at............

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

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

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

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 the Drugs and Cosmetics Act, 1940.

Dated................................................Signature..................................................

Name and Designation......................
*Licensing Authority/
*Central Licence Approving Authority

* Delete, whichever is not applicable.

**Conditions of Licence**

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

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

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

4. The licensee shall inform the licensing authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the licensing authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]
FORM 28D
(See rule 76)

LCENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF LARGE VOLUME PARENTERALS/SERA AND VACCINE/RECOMBINANT DNA (R-DNA) DERIVED DRUGS SPECIFIED IN SCHEDULE C AND C(I) EXCLUDING THOSE SPECIFIED IN SCHEDULE X

Number of licence..........................and Date of issue..............................

1..........................is hereby licensed to manufacture at the premises situated at................. the following [Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs] specified in Schedule C and C(I) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

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

3. Name(s) of competent technical staff..............................
   (a) responsible for manufacturing (b) responsible for testing
   1. 1.
   2. 2.

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

5. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

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.
Conditions of Licence

1. The licence shall be kept on the approved premises and shall be produced at the request of an inspector appointed under the Drugs and Cosmetics Act, 1940.

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

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

4. The Licensee shall inform the licensing authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current 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 applied for alongwith 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.]
**[FORM 28DA]**

*(See rules 76A, 78A, 83AA)*

**LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF LARGE VOLUME PARENTERALS/SERA AND VACCINE/RECOMBINANT DNA (R-DNA) DERIVED DRUGS EXCLUDING THOSE SPECIFIED UNDER SCHEDULE X**

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

1. ........................................ of ........................................... is hereby granted a loan licence to

manufacture on the premises situated at ....................... c/o ......................... the following

drugs being Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs specified in Schedules C, C(I), excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

1. Names of drugs.................................................................

2. Name (s) of competent technical staff.............................

3. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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 time being in force under the Drugs and Cosmetics Act, 1940.

Date.................................

Signature.................................................................

Designation.................................................................

Licensing/ Authority.................................................................
Central Licence Approving Authority

Conditions of licence

1. This licence [***] 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 competent technical staff shall be forthwith reported to the Licensing Authority and Central Licence Approving authority.

3. If the licensee wants, during the currency of the licence, to manufacture for sale additional items of drugs not included above, he should apply to the Licensing Authority and/or Central Licence Approving Authority for the necessary endorsement as provided in the rules. This licence will be deemed to extend to the items so endorsed.

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 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 and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

[FORM 28E
(See rule 122G)

LICENCE TO MANUFACTURE AND STORE BLOOD PRODUCTS FOR SALE OR DISTRIBUTION

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

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

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

1.
2.  
3.  
4.  
5.  

4. Name(s) of Competent Technical Staff:  

(a) responsible for manufacturing  (b) responsible for testing  

1.  
2.  
3.  

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

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

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

Signature ....................................................  
Name and Designation..........................  
Date.........................

*Licensing Authority/©Central Licence Approving Authority  

Conditions of Licence  

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

2. This licence and any certificate of renewal in force shall be displayed on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
3. Any change in the technical staff shall be forthwith reported to the licensing authority and/or Central Licence Approving Authority.

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

1[FORM 28F
(See rules 122F to 122-1, 122.K, 122P)

LICENCE TO COLLECT, PROCESS, TEST, STORE, BANKING AND RELEASE OF UMBILICAL CORD BLOOD STEM CELLS

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

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

3. Name(s) of competent Technical Staff:
   1. 
   2. 
   3. 
   4. 
   5.

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

5. The licence shall be in force from.....................to.................................
6. The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time-to-time in the Rules made tinder the Drugs and Cosmetics Act, 1940.

Signature............................................
Name & Designation......................
Licensing Authority.......................  
Central Licence Approving Authority

Dated......................

Conditions of Licence

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

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

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

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

5. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing 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 maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]
FORM 29
(See rule 89)

LICENCE TO MANUFACTURE DRUGS FOR PURPOSES OF EXAMINATION, TEST OR ANALYSIS

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

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

3.  This licence shall be in force for 'three years' from the date specified below.

   Name 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 .................... by occupation ................... hereby apply for a 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

1 [***]

FORM 31A

2 [***]
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 up to which the licence is valid ....................

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

Name and designation of the Inspector who inspects the premises of the licensee........................

Date of Inspection...........................
Observations of the Inspector

Signature of the Inspector

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

'Inspection Book maintained by M/s....................situated at..............for licence number .................in Form................under Drugs Rules, 1945.

Seal and Signature of the Licensing Authority

Notes.—(i) Printed copy of the inspection Book may be obtained by the licensee from the licensing authority on payment.

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

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

[FORM 36

(See rule 150 B)

APPLICATION FOR GRANT OF APPROVAL FOR CARRYING OUT TESTS ON DRUGS/ [***] OR RAW MATERIALS USED IN THE MANUFACTURE THEREOF ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS/ [***] [OR FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY]

(1) I/We, ......................................................., of................................ hereby apply for the grant of approval for carrying out tests of identity, purity, quality and strength on the following categories of drugs/ or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs/ [***] [OR FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY].

(2) *Categories of drugs, [***]:—
(a) Drugs other than those specified in Schedules C and C(l) and also excluding Homoeopathic Drugs:—

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

(b) Drugs specified in Schedules C and C(l):

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

(c) Homoeopathic drugs.

(d) ¹ [***]
(3) Names, qualifications and experience of expert staff 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..........................

* Delete whichever is not applicable.

FORM 37
(See rule 150C)

APPROVAL FOR CARRYING OUT TESTS ON DRUGS/ AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS/ [OR FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY]

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/ and the raw materials used in the manufacture thereof on the premises situated at.............................. Categories of drugs/.

(2) Names of approved Competent Technical Staff] employed for testing and person-in-charge of testing.

(3) The approval, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of approval and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and [Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]
4. The approval is subject to the conditions stated below and such other conditions as may be specified in the Rules for the time being in force under the Act.

Date......................................   Signature...................................

Designation....................................

Conditions of Approval

(1) This approval shall be kept in the approved premises and shall be produced at the request of the Inspector 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 it should apply to the approving authority for necessary endorsement as provided in Rule 150B. This approval will be deemed to extend to the items so endorsed.

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

[(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 150E(f)]

REPORT OF TEST OR ANALYSIS BY APPROVED INSTITUTION

(1) Name of manufacture 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/ raw material purporting to be contained in the sample.

(5) Details of raw material/ final product (in bulk)/ final product (in finished pack)* as obtained from the manufacturer:
   (a) Original manufacturer's name in the case of raw materials and drugs repacked.
   (b) Batch number.
   (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 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.
[FORM 39A
[See sub-rule (f) of rule 150E]
REPORT OF TEST OR ANALYSIS BY APPROVED INSTITUTION
FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT
AGENCY

(1) Name of individual or organisation or procurement agency from whom sample is received..........................

(2) Serial number and date of sender's memorandum..........................

(3) Number of samples..........................................................................

(4) Date of receipt of the sample..........................................................

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

(6) Details of raw material or final product in bulk or final product in finished pack298, as obtained by sender:

(a) Name and address of the Manufacturer and Licence number mentioned on the label.................................

(b) Name of original Manufacturer in the case of raw materials and re-packed drugs ..........................................................

(c) Batch number.................................................................

(d) Date of manufacture, if any..................................................

(e) Date of expiry, if any..........................................................

(7) 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.]

2[FORM 40
(See rule 24A)
APPLICATION FOR ISSUE OF REGISTRATION CERTIFICATE FOR IMPORT OF DRUGS INTO INDIA UNDER THE DRUGS AND COSMETICS RULES, 1945

I/We*,............................................................................................(name and full address) hereby apply for the grant of Registration Certificate to 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. Name of Drugs for registration.

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

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

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

Address(es)........................................................................................................

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

Place....................

Date............................... Name.................................

Signature..............................

Designation...........................

Seal/Stamp of manufacturer or his authorised agent in India.

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

*Delete whichever is not applicable.*

1. [FORM 41]

REGISTRATION CERTIFICATE REGISTRATION CERTIFICATE TO BE ISSUED FOR IMPORT OF DRUGS INTO INDIA UNDER THE DRUGS 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 27A as a manufacturer and is hereby issued this Registration Certificate.

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

3. This Registration Certificate shall be in force from......................to...................... unless it is sooner suspended or cancelled under the rules.
4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/s (name and full address)…………………………………………………who will be responsible for the business activities of the manufacturer, in India in all respects.

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

Place…………………………………….. Licensing Authority

Date……………………………………….. Seal/Stamp

**Conditions of the Registration Certificate**

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

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

3. The manufacturer or his authorised agent in India shall comply with the conditions of the import licence issued under the Drugs 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 authorisation, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed. The 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 authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the 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 authorised agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub-rule (3) of rule 24A.

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

FORM 42

FORM 43
APPLICATION FOR GRANT OF PERMISSION TO IMPORT OR MANUFACTURE A NEW DRUG OR TO UNDERTAKE CLINICAL TRIAL

I/we...........................................of M/s................................................. (address) hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information/data is given below:

1. Particulars of new drug:
   (1) Name of the drug:
   (2) dosage form:
   (3) Composition of the formulation:
   (4) Test specification:
      (i) active ingredients:
      (ii) inactive ingredients
   (5) Pharmacological classification of the drug:
   (6) Indication for which proposed to be used:
   (7) Manufacture of the raw material (bulk drug substances):

2. Data submitted along with the application (as per Schedule Y with indexing and page nos.)

   A. Permission to market a new drug:
      (1) Chemical and Pharmaceutical information
      (2) Animal pharmacology
      (3) Animal Toxicology
(4) Human/Clinical Pharmacology (Phase 1)

(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 label and cartoons

(10) Application for test license

(11) New Chemical Entity and Global Clinical Trial—
   (a) Assessment of risk versus benefit to the patients
   (b) Innovation vis-à-vis existing therapeutic option
   (c) Unmet medical need in the country

B. Subsequent approval/permission for manufacture of already approved new drug:—

(a) Formulation:
   (1) Bio-availability/bio-equivalence protocol
   (2) Name of the investigator/centre
   (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 peer-reviewed journals/text books)

(2) Data on pharmacokinetics/pharmacodynamics combination.

(3) Any other data generated by the application 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 or quality parameters.

A total fee of rupees............. (in words) ..................................................... has been credited to the government under the head of account.......................................... . (Photocopy of receipt is enclosed).

Dated................................................             Signature................................

Designation........................................

Note.—Delete, whichever is not applicable.
[FORM 45
(See rule 122A, 122D, 122DA)
PERMISSION TO IMPORT FINISHED FORMULATION OF A NEW
DRUG

Number of the permission and date of issue..............................................

M/s..........................................................of ................................ (address) is hereby permitted to import the following new drug formulation under rule 122A/122D/ 122DA of the Drugs Rules, 1945.

(1) Name of the New drug:

(2) Dosage from:

(3) Composition:

(4) Indication

Dated................................   Signature.......................................

Name and Designation of Licensing Authority.........................

Condition for grant of approval/permission

(1) The formulation shall confirm to the specification approved by the Licensing Authority.

(2) The proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written below or after 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 [caution or warning, as applicable, depending on whether the drug is covered under Schedule G or Schedule H or Schedule HI or Schedule X, as specified in rule 97, in legible
(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 the retail on the prescription of a........................only."

(5) As Post Marketing Surveillance, the applicant shall submit Periodic Safety Update Reports every six months for the first two years. For subsequent two years, the Periodic Safety Update Reports shall be submitted annually.

(6) All reported adverse reaction 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 cartoon, 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.

(9) Each consignment of imported drug shall be accompanied by a test/analyse report.

[FORM 45A
(See rules 122A and 122DA)
PERMISSION TO IMPORT RAW MATERIAL (NEW BULK DRUG SUBSTANCE)]

Number of the permission and date of issue............................

M/s...................................................of ..........................................(address) hereby permitted to import the following raw material (new bulk drug substances) under ride 122A/122DA of the Drugs 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 122B shall be obtained from the Licensing Authority.

(3) The permission to import shall not be used to convey or imply that the raw material (new bulk drug) is categorized as "life saving or essential drug".

FORM 46
(See rule 122B, 122D, 122DA)

PERMISSION/APPROVAL FOR MANUFACTURE OF A NEW DRUG FORMULATION

Number of the permission and date of issue.................................
M/s........................................ of .......................................................... (address) is hereby granted Permission/Approval to manufacture following new drug formulation under rule 122B/122D/122DA of the Drugs and Cosmetics Rules, 1945, namely:—

(1) Name of the formulation:

(2) Dosage form:

(3) Composition:

(4) Indications:
Name and Designation of Licensing Authority.

Conditions for grant of approval/permission

(1) The formulation shall confirm to the specification approved by the Licensing Authority.

(2) The proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written below or after 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 caution or warning, as applicable, depending on whether the drug is covered under Schedule G or Schedule H or Schedule HI or Schedule X, as specified in rule 97, in legible black coloured font size in a completely red rectangular box without disturbing the other condition 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 the retail on the prescription of a..................only."

(5) As Post Marketing Surveillance, the applicant shall submit Periodic Safety Update Reports every six months for the first two years. For subsequent two years, the Periodic Safety Update Reports shall be submitted annually.

(6) All reported adverse reaction 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 cartoon, labels, package insert that will be adopted for marketing the drug in the country, shall be get approved from the Licensing Authority before the drug is marketed.

FORM 46A

(See rules 122B and 122DA)

PERMISSION/APPROVAL FOR MANUFACTURE OF RAW MATERIAL (NEW BULK DRUG SUBSTANCE)

Number of the permission and date of issue

M/s………………………….of…………………….(address) is hereby granted Permission/Approval to manufacture the following raw material (new bulk drug substances) under rule 122B/122DA of the Drugs Rules, 1945:

Name of the raw material (new bulk drug substance):

(1) ...................................................

(2) ...................................................

(3) ...................................................

Dated..........................................  Signature..................................................

Name and Designation of the Licensing Authority..............

Conditions for Grant of Permission/Approval

(1) The raw material (new bulk drug substance) shall confirm to the specifications approved by the Licensing Authority.

(2) The raw material (new bulk drug substance) can be sold to only those manufacturers who have permission, in writing, from Licensing Authority, either to use the drug for development purpose/clinical trial/bio-equivalence study or to manufacture the formulation.
(3) For manufacture of the formulation in the country, separate approval under rule 122B shall be obtained from the Licensing Authority.

**[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:

<table>
<thead>
<tr>
<th>AYURVEDA AND SIDDHA</th>
<th>UNANI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Asava and Arista</td>
<td>1. Nabeez, Khal (Sirka)</td>
</tr>
<tr>
<td>5. Guggulu</td>
<td>5. Raughan</td>
</tr>
<tr>
<td>8. Taila-Tailam</td>
<td>8. Shiyaaf</td>
</tr>
<tr>
<td>10. Lavana-Uppu</td>
<td>10. Kohal (Surma), Kajal</td>
</tr>
<tr>
<td>11. Kshara-Saram</td>
<td>11. Satt, Usara</td>
</tr>
<tr>
<td>12. Lepa-Pacai</td>
<td>12. Kushta</td>
</tr>
</tbody>
</table>
15. Netrabindu (Aschyotan)  15. Sayyal, Arq (Distillates)
16. Anjana-Kanmai  16. Qurs (Tablet)
17. Sattva-Sattu  17. Marham, Qairooti
20. Pishiti  20. Nabati Advia
22. Mandura-Atai Kutinir  22. Ajsad Advia
23. Rasayoga-Centuram  23. Haiwani Advia
27. Panak (Syrup)-Manappaku  27. Shamoom
29. Capsule  29. Mazoogh 30 Tila
30. Ointment-Kalimapu  30. Lashooq
31. Phalavarti  32. Gulqand
32. Dhoomravarti/Doopan  33. Fateela
33. Kshar Sutra/Kshar Varti  34. Ghaza, Ubtan, Sabhgh
34. Single drugs:
(a) Plant based
(b) Mineral based
(c) Metal based
(d) Animal based
(e) Synthetic
(f) Any other Ayurvedic, Siddha, Unani formulation.

35. Pushp (Phool)  35. Capsule
36. Nasya  36. Huqna
37. Swarasa (Fresh juice)  37. Naurah
38. Kama Bindu (Ear drops)  38. Latookh
39. Vajoor (Throat pain)
40. Mazmazah (Mouth washer)
(3) Names, qualifications and experience of experts employed for testing and the person-in-charge of testing.

(4) List of testing equipment provided.

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

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

Dated ...................................

Signature ...................................

Full address of the Applicant

* Delete whichever is not applicable

FORM 48
(See rule 160B)

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 for identity, purity, quality and strength on the following categories of Ayurvedic, Siddha or Unani drugs and the raw materials used in the manufacture thereof on the premises situated at ..................................................

Categories of Ayurvedic, Siddha and Unani drugs.

(2) Name of experts employed for testing and the person-in-charge of testing

.............. (experts) and ................. (person-in-charge)

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

Date..................................................................................Signature.................................

Place..............................................................................Designation..............................

Seal of State Licensing Authority

Conditions of Approval

(1) This approval and any certificate of renewal in Form 42 shall be displayed in the approved premises and shall be produced at the request of theInspectors appointed under the Act.

(2) If the applicant wishes to undertake during the currency of the approval the testing of any other category of Ayurvedic, Siddha or Unani drugs it should apply to the approving authority for necessary endorsement as provided in rule 160A. This approval will be deemed to extend to the items so endorsed.

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

(4) The applicant shall inform the approving authority in writing in the event of any change of the constitution of the laboratory operating under this Form. Where any change in the constitution of the laboratory takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh approval has been taken from the approving authority in the name of the laboratory with the changed constitution.]
[FORM 49]
(See rule 160-1)
CERTIFICATE OF RENEWAL FOR CARRYING OUT TESTS OR ANALYSIS ON AYURVEDIC, SIDDHA OR UNANI DRUGS OR RAW MATERIALS USED IN THE MANUFACTURE THEREOF ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA OR UNANI DRUGS

(1) Certified that approval number .................................................. granted on the .................. day of......................... 2001 for carrying out tests of identity, purity, quality and strength on the following categories of Ayurvedic, Siddha or Unani drugs and the raw materials used in the manufacture thereof at the premises situated at..............................has been renewed from................to...................... (Date).

Categories of Ayurvedic, Siddha or Unani drugs.

...........................................................................................................

...........................................................................................................

(2) Names of experts and the person-in-charge of testing.................. (experts) and ................................(person-in-charge).

Date.......................................................... Signature..................................

Place.......................................................... Designation..............................

[Seal of State Licensing Authority]

[FORM 50]
[See rule 160 D(f)]
REPORT OF TEST OR ANALYSIS BY APPROVED LABORATORY

(1) Name of manufacturer from whom sample received together with his manufacturing 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 or raw material purporting to be contained in the sample

(5) Details of raw material of final product (in bulk finished pack)* as obtained from the manufacturer:
   
   (a) Original manufacturer's name in the case of raw materials and drugs repacked
   
   (b) Batch number

   (c) Batch size as represented by sample

   (d) Date of manufacture, if any

   (e) Date of expiry, if any

(6) Results of test or analysis with protocols of test or analysis applied or as per Ayurvedic, Siddha or Unani Pharmacopoeial standards.

(7) Other specific tests for identity, purity, quality and strength of Patent and Proprietary drugs.

In the opinion of the undersigned, the sample referred to above is of standard Equality/is not of standards quality as defined in the Act or the rules made thereunder for the reasons given below:

(Signature of the person-in-charge of testing)

Date ............................................ (F.No................................................)

Place ............................................. Name and Designation and Seal

Name and Address of the Laboratory .............................................

Licence No.............................................

Note.—Final product includes repacked material.
"Delete whichever is not applicable.]

**FORM 51**  
*[See rules 71(9), 71A(5), 71B(v), 76(11) and 76A(v)]*

**FORM OF UNDERTAKING TO THE LICENSING AUTHORITY FOR MARKETING A DRUG UNDER A BRAND NAME OR TRADE NAME**

(1) I .................................. of................................... intend to market the drug specified below under a brand name or trade name—

(............................................................)

(i)  Name of the drug:

(ii)  Dosage form:

(iii)  Composition:

(2)  I hereby give this undertaking that to the best of my knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

Place.........................................   .................................................

Date................................................................[Signature, Name, Designation

Seal/Stamp of manufacturer or on behalf of the manufacturer]]

**[SCHEDULE B**

*(See rules 7 and 48)*

**FEES FOR TEST OR ANALYSIS BY THE CENTRAL DRUGS LABORATORIES OR STATE DRUGS LABORATORIES**

1.  Fees for test and assay of Drugs requiring use of animals—

   **Rupees**

   Adrenocorticotrophic hormone assay 1000
APPENDIX

FORM COS- 1

[See rule 12(2), and 12(7)]

Application for issue of registration certificate for import of cosmetics into India

I/We* ___(Name and full address) hereby apply for the grant of registration certificate to the manufacturer, M/s ____ (full address with telephone number, fax and e-mail address of the foreign manufacturer) for his manufactured cosmetics meant for import into India.

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

<table>
<thead>
<tr>
<th>Serial number</th>
<th>Product or brand of cosmetic</th>
<th>Brand name</th>
<th>Variant name</th>
<th>Pack sizes</th>
<th>Actual manufacturer and its premises</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. I/We* enclose herewith the information and undertaking specified in Part-I of Second Schedule duly signed by the manufacturer for grant of registration certificate for the premises stated below:—

3. A fee of.................... for registration of cosmetics for import as specified at serial number 2 above has been credited to the Central Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Cosmetics Rules, 2020 - Central vide Challan No.............., dated............... , (attached in original).

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

Address(s) :_

Telephone :_______

Fax:__
E-mail: __

I/we undertake to comply with all the terms and conditions required to obtain registration certificate and to keep it valid during its validity period.

Place: ...................

Date: ...................

Signature__

Name__

Designation ___________

Seal/Stamp of manufacturer or his Authorised agent in India.

(Note: In case the applicant is an Authorised agent of the manufacturer in India, an undertaking for the purpose of registration is to be enclosed as per Part-I of Second Schedule)

**FORM COS- 2**

[See rule 13(1) and 13(4)]

**Import registration certificate to be issued for import of cosmetics into India**

Registration Certificate No.____ Date___M/s_(Name and full address of registered office) having factory premises at_(full address) has been registered under rule 13 as a manufacturer and is hereby issued this Registration Certificate.

2. Name (s) of cosmetics, along with their brand names and pack size(s) and variants which may be imported under this registration certificate.

<table>
<thead>
<tr>
<th>Serial number</th>
<th>Product or brand of cosmetic</th>
<th>Brand name</th>
<th>Variant name</th>
<th>Pack sizes</th>
<th>Actual manufacturer and its premises</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 manufacturer or his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer, namely M/s..............................(name and full address)..........................who shall be responsible for the business activities of the manufacturer, in India in all respects.

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

Place: ....................

Date: .......................
taken with reference to the concerned cosmetic in the country of origin or in the
country of marketing shall be followed in India also, in consultation with the
Licensing Authority. The Licensing Authority may, however, direct any further
modification to this course of action, including the withdrawal of the cosmetic
from Indian market within 48 hours time period.

3. The manufacturer or his authorised agent or importer or distributor or
subsidary in India shall inform the Licensing Authority within thirty days, in
writing, in the event of change in labelling or composition or testing, or
specification or in documentation of any of the cosmetic pertaining to this
Registration Certificate along with an undertaking that the products comply
with standards laid down by the Bureau of Indian Standards as referred in the
Ninth Schedule.

4. The manufacturer or his authorised agent in India shall inform the
Licensing Authority immediately in writing, in the event, of any change in the
constitution of the firm operating under this registration certificate. Where any
such change in the constitution of the firm takes place, the current Registration
Certificate shall be deemed to be valid for a maximum period of one hundred
and eighty days 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.

5. In case of change in name or address of a registration holder or overseas
manufacturer, operating under this registration certificate, an application for
amendment shall be made in online portal of Central Government for prior
approval from the Central Licensing Authority for the said changes in
registration certificate within a period of sixty days from the date of such
change.

6. The importer shall notify to the Licensing Authority immediately in
writing, on the class of the cosmetic product which present a risk to the human
health and the corrective measure taken.
FORM COS- 3

[See rule 13(3), 23(3), 32(2) and 32(3)]

Permission to import or manufacture new cosmetics in India

Number of the permission and date of issue..........................M/s........................................

having address...........................is hereby permitted to import or manufacture the following new cosmetic under rule 32 of the Cosmetics Rules, 2020.

1. Name of the cosmetic
2. Category or intended use
3. Composition of the product
4. Any special instruction

Dated: .....................

Signature:

Name and Designation of Central Licensing Authority:

Conditions for the grant of permission to import or manufacture new cosmetic

1. The cosmetic product shall conform to the specifications as permitted by the Central Licensing Authority

2. Name of the cosmetic shall be printed or written in indelible ink and shall appear in a conspicuous manner.

3. Any special instructions as permitted shall be printed on the label.

4. No claims other than those permitted shall be made on the label without the prior approval of the Central Licensing Authority
FORM COS- 4

[See rule 17(11)]

Application for issue of Import Registration Number for Import of already registered cosmetics.

I/We* __ (Name and full address of importer) hereby apply for the grant of registration number for Import of already registered cosmetics, meant for import into India.

1. Detail of cosmetics

<table>
<thead>
<tr>
<th>Serial number</th>
<th>Name of cosmetic</th>
<th>(Name of manufacturer and address)</th>
<th>Pack sizes</th>
<th>Registration Certificate Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. I/We* enclose herewith the information and undertaking specified in Sixth Schedule duly signed.

3. I/we undertake to comply with all the terms and conditions required to obtain registration number and to keep it valid during its validity period.

Address(s) :_
Telephone :_
Fax :_
E-mail :___
Place:___
Date:___

Signature_
Name_
Designation__
FORM COS- 4A
[See rule 17(2)]

Import Registration Number to be issued for import of already registered cosmetics into India

Import Registration No.:______ Date__

1. M/s__(Name and full Address of importer) has been registered under rule 17 as an importer and is hereby issued this Import Registration Number for import of already registered cosmetics into India.

2. Detail of cosmetics

<table>
<thead>
<tr>
<th>Serial number</th>
<th>Name of cosmetic(s)</th>
<th>Pack size(s)</th>
<th>Name and address of manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. This Import Registration Number shall remain valid for three years unless it is sooner suspended or cancelled under the Cosmetics Rules, 2020.

4. This Import Registration Number 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 Cosmetics Rules, 2020.

Place:___

Date:_

Central Licensing Authority

Seal / Stamp

Conditions of the Import Registration Number

1. This Import Registration Number shall be produced by the importer as and when required by the Licensing Authority or regulatory authority.
2. The importer shall inform to the Licensing Authority forthwith in the event of any administrative action taken namely, market withdrawal, deletion of product from the original Registration Certificate holder's or any regulatory restrictions of any cosmetics pertaining to this registration.

3. The importer shall provide the statement of details of cosmetics imported by them annually to the Central Licensing Authority.

FORM COS-5

[See rule 23(2)]

Application for grant of a license to manufacture cosmetics for sale or for distribution

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

2. Details of cosmetic products:

<table>
<thead>
<tr>
<th>Serial Number</th>
<th>Name of cosmetic</th>
<th>Name of ingredients</th>
<th>Specifications or Standards or Grade of ingredients</th>
<th>Percentage of Ingredients</th>
<th>Function of ingredients</th>
</tr>
</thead>
</table>

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.
FORM COS-6
[See rule 23(2)]
Application for grant of a loan license to manufacture cosmetics for sale or for distribution

1. I/We ..................... of.........................hereby apply for grant of a loan license to manufacture cosmetics, for sale, on the Premises situated at ....................C/o.....................the following cosmetics:

2. Details of cosmetic products:

<table>
<thead>
<tr>
<th>Serial Number</th>
<th>Name of cosmetic</th>
<th>Name of ingredients</th>
<th>Specifications or Standards or Grade of ingredients</th>
<th>Percentage of Ingredients</th>
<th>Function of ingredients</th>
</tr>
</thead>
</table>

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

4. I/We enclose

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

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

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

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

Date.........................................
Signature

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

**FORM COS- 7**

[See rule 23(4) and 23(7)]

Self-certificate of compliance of Good Manufacturing Practices (GMP)
for manufacture of cosmetics

(To be given by the applicant along with Form COS- 5 or Form COS- 6 at the time of application for manufacturing licence or loan licence)

1. I/We...............................of..............................hereby applied for the grant of a License

i:o manufacture at premises situated at....................... the following cosmetics.

1.............

2.............

3.............

2.1/We hereby declare that the above premises having facilities of good manufacturing practices, requirements of premises, plants and equipment for manufacture of above cosmetics as per the Seventh Schedule of the Cosmetics Rules, 2020.

3. I/We undertake to provide facility to inspect the above premises as per the Cosmetics Rules, 2020 to the State Licensing Authority or any officer appointed by the authority.

4. I/We undertake that in case State Licensing Authority or any officer appointed by the authority found any deficiency during an inspection the State Licensing Authority have a full right to cancel or give any direction for improvement for Good
Manufacturing Practice in the said premises in respect of the above said cosmetics. Further I will not claim any damages, etc. for any action of the State Licensing Authority in this regard.

Date:

Place:

Name:

Signature:

Designation:

**FORM COS- 8**

[See rule 25, 26(g), 27(1), 28 and 30(1)]

License to manufacture cosmetics for sale or for distribution Number of license 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) Details of cosmetic products:

<table>
<thead>
<tr>
<th>Serial Number</th>
<th>Name of cosmetic</th>
<th>Name of ingredients</th>
<th>Specifications or Standards or Grade of ingredients</th>
<th>Percentage of Ingredients</th>
<th>Function of ingredients</th>
</tr>
</thead>
</table>

(b) Names of the technical staff..............................................................................................

2. The licence unless sooner suspended or cancelled shall continue to remain valid. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act and Rules shall be assessed at least once in a year.

3. The license is subject to the conditions stated below and to such other conditions as may be specified in the Cosmetics Rules, 2020.
Conditions of License

1. This license 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 license as provided in rule 23. This license shall be deemed to extend to the cosmetics 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 license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of six-months from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM COS-9

[See rule 25, 26(g), 27(1), 27(3), 28 and 30(1)]

Loan license to manufacture cosmetics for sale or for distribution

1. Number of license and date of issue..............................

2..........................of.................................... here by granted a loan license 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 the technical staff....................................

b. Details of cosmetic products

<table>
<thead>
<tr>
<th>Serial Number</th>
<th>Name of cosmetic</th>
<th>Name of ingredients</th>
<th>Specifications or Standards or Grade of ingredients</th>
<th>Percentage of Ingredients</th>
<th>Function of ingredients</th>
</tr>
</thead>
</table>

3. The licence unless sooner suspended or cancelled shall continue to remain valid. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act and Rules shall be assessed at least once in a year.

4. The license 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.

State Licensing Authority

Date....................

Signature....................

Designation....................

**Conditions of Licence**

1. The license 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 necessary endorsement to the license as
provided in rule 23. This license shall be deemed to extend to the cosmetics 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 license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of six months from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM COS- 10

[See rule 26(i) and 44(1)]

Intimation to person from whom sample is taken

I have this day taken from the premises of......................situated at......................

......................samples of the cosmetics specified below for the purpose of test or analysis.

Date........... ............................ Inspector............

Details of samples taken

Date....................................... Inspector............

FORM COS- 11

[See rule 26(k) and 62(i)]

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. License number and the date up to which the license 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 word, namely :-

'Inspection Book maintained by M/s. ............................................. situated at.............................................for license number.............................. in Form......................... under the Cosmetics Rules, 2020.  

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 Inspector shall be in triplicate. The original copy shall be retained in the inspection Book to be maintained in the premises of the licensee. The duplicate copy shall be sent to the Licensing Authority. The triplicate copy shall be taken as record by the Inspector.
FORM COS- 12

[See rule 32(1)]

Application for grant of permission for new cosmetics for obtaining import registration certificate or manufacturing license

I/We* (Name and full address) hereby

apply for the grant of permission to import or manufacture a new cosmetics in India. The necessary information or data is given below:—

1. Particulars of new cosmetic:—
   a. Name of the cosmetic
   b. Category of cosmetic/intended use
   c. Composition of the product
   d. Test protocols/specification of the raw materials and finished product

2. Assessment of the safety for human health of the finished product, its ingredients, their chemical structure and level of exposure

3. Existing data on undesirable effects on human health resulting from use of the cosmetic product

4. Supporting data for the claimed benefits of cosmetic products should be made available to justify the nature of its effect

5. Draft of the product label and carton

6. Whether the product is marketed in any other country; list thereto

7. Any other data generated on safety, efficacy and quality parameters

8. A total fees of ........ USD...............(in words)...............has been credited to the Government under the head of account.................(photocopy of receipt is enclosed)
Signature of the Manufacturer/Importer/Authorised agent

Name:

Designation:

Stamp/Seal

Place:

Date: .

**FORM COS- 13**

*[See rule 40]*

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

1. Full name and address of the applicant...................................................
2. Occupation...........................................

3. Name of cosmetic purporting to be contained in the sample......................

4. Name and full address of the concern where the cosmetic was purchased...........

5. Date on which purchased........................................................................

6. Reasons why the cosmetic is being submitted for test or analysis...................

A fee of ..................has been credited to Government under the Head of Account

"02.10- Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the

Drugs and Cosmetic Rules 1945, - Central vide Challan

No..........................dated...............(attached in original)
I hereby declare that the cosmetic being submitted for test was purchased by or for me. I further declare that the sample of the cosmetic being sent for test or analysis is exactly as it was purchased and has not been tampered with in any way.

Date:.......................  Signed:......................

FORM COS-14
[See rule 40]

Report 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 cosmetic purporting to be contained in the sample..............................

4. Opinion of the Government Analyst—The sample referred to above is/is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder.

Date :..........................  Government Analyst.............

FORM COS-15
(See rule 42)

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

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

from the premises of..............................situated at............................................

Date:.........................  Inspector:..................

Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India  Page 103 of 112
Details of cosmetics, records, registers, documents or material objects seized.

Date.......................................                                             Inspector.........

FORM COS- 16
[See rule 44(2)]
Receipt for samples of cosmetics taken where fair price tendered thereof 
under sub - section (1) of section 23 of the Drags and Cosmetics Act, 1940 is refused

To........................................

Whereas I, this.............day of.......20..........., have taken from the premises 
of........... situated at..................................samples of cosmetics as specified below:-

Details of Samples....................................

And whereas I had offered to pay you rupees ..................... as the fair price of 
the samples of 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 cosmetics- taken by me.

Date...........................................                             Inspector.........

FORM COS- 17
[See rule 45(1)]
Memorandum to Government Analyst

Serial No. of Memorandum .................................................................

From:

To

The Government Analyst,
The portion of sample or 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 name of cosmetic which it purports to contain—

Date.......................... Inspector....................

FORM COS-18
(See rule 46)

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

Whereas, I have reasons to believe that the stocks of 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 cosmetics

Date................................. Inspector.
FORM COS- 19
[See rule 48]

Report of tests or analysis of cosmetics by 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 packet or on portion of sample or container...

7. Results of test or analysis:—

The sample of cosmetics—

(a) contain a prescribed colour only or does not contain a prescribed colour.

(b) does not contain harmful ingredients or contains harmful ingredients.

(c) conforms to claims made on the label as to the nature and quality of or does not conform to claims made on the label as to the nature and quality of the cosmetic.

(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.......................... Government Analyst.
FORM COS-20

[See rule 49(1) and 49(3)]

Memorandum to the Director, Central Cosmetic Laboratory

Serial Number...........................................

To the Director, Central Cosmetic Laboratory......................................................

From......................................

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

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

3. Particulars of offence alleged............................................................................

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

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

Date......................

Magistrate
FORM COS- 21
(See rule 51)

Report of test or analysis by the Central cosmetic laboratory

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

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

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

Director,

Date............. Central cosmetic laboratory or other authorized officer

Details of results of test or analysis with protocols of test applied

Director,

Date............. Central cosmetic laboratory or other authorized officer

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

FORM COS- 22
[See rule 55(1)]

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

1. *I/We.................................................................of.................................hereby apply for the
grant of approval for carrying out tests on the following items of cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of cosmetics.

2. Items of cosmetics:

(1) ................................

(2) ................................

(3) ................................

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

4. List of testing equipments provided.

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

6. An application fee of rupees.............................. or an inspection fee (in case of further application after rejection) of rupees ................................. has been credited to Government under the Head of Account......................................................

Date............................................. Signature............

FORM COS- 23
(See rule 56(1), 56(2), 58(1), 59, 60(1) and 62)
Approval for carrying out tests on cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of cosmetics

1. Number of approval and date of issue:.............

2. Approval is hereby granted to......................................................for carrying out tests for identity, purity and quality on the following items of
cosmetics and the raw materials used in the manufacture thereof on the premises situated.................................................................

Items of cosmetics

(1) ................................

(2) ................................

(3) ................................

3. Names of competent technical staff employed for testing and the person-in-charge of testing.

4. The approval shall be in force from.............................to.......................

5. 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

State Licensing Authority

Conditions of Approval

1. This approval 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 items of cosmetics it should apply to the State Licensing Authority for necessary endorsement as provided in rule 56. 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 forth with reported to the State Licensing Authority.

4. The approved institution shall inform the State Licensing 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 State Licensing Authority in the name of the institution with the changed constitution.

**FORM COS- 24**

[See rule 62(f)]

Report of test or analysis by approved institution

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

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

3. Date of receipt of the sample.

4. Name of cosmetic/raw material purporting to be contained in the sample.

5. Details of raw material/final product in bulk/final product (in finished pack) as obtained from the manufacturer:
   (a) Original manufacturer's name in the case of raw materials repacked.
   (b) Batch number.
   (c) Batch size as represented by sample.
   (d) Date of manufacture, if any.
   (e) Date of expiry, if any.

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

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.

REFERENCE

31. Defibrillators (effective from 1, April, 2021)
32. PET Equipment (effective from 1, April, 2021)
33. X-Ray Machine (effective from 1, April, 2021)
34. Dialysis Machine (effective from 1, April, 2021)
35. Bone marrow cell separator (effective from 1, April, 2021)
36. Disinfectants and insecticide specified in Medical Devices Rules, 2017
37. Ultrasound equipment (effective from 1, November, 2020)

APPENDIX
FORM MD-1
[Refer sub-rule (5) of rule 13]
APPLICATION FOR GRANT OF CERTIFICATE OF
REGISTRATION OF A NOTIFIED BODY

1. Name of applicant:
2. Nature and constitution of Body:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. Corporate / registered office address including telephone number, mobile number, fax number and e-mail id:
4. Details of accreditation (self-attested copy of certificate to be attached):
5. Standards (BIS/ISO/Others) for which notified body has been accredited under rule 13:
6. Fee paid on...............Rs...............receipt/challan/transaction id..............
7. Documents enclosed, as specified in the Part I of the Third Schedule of the Medical Devices Rules, 2017, duly signed by me.
8. I undertake to comply with the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017 and other terms and conditions for working as a Notified Body as may be specified from time to time.
FORM MD-2
[Refer sub-rule (6) of rule 13]
CERTIFICATE OF REGISTRATION FOR A NOTIFIED BODY
UNDER THE MEDICAL DEVICES RULES, 2017
Registration No.:..........................

1. M/s...................................................(Name of the firm) situated at.......................... (full address with telephone and e-mail) has been registered as a Notified Body of following Class A [(other than non-sterile and non-measuring)] and/or Class B medical devices.

2. Details of Medical device(s):

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Standards for which it is registered</th>
<th>Class of medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:........................................... Central Licensing Authority
Date:........................................... [To be signed digitally]

FORM MD-3
[Refer sub-rule (2) of rule 20]
APPLICATION FOR GRANT OF LICENCE TO MANUFACTURE FOR SALE AND DISTRIBUTION OF CLASS A [(OTHER THAN NON-STERILE AND NON-MEASURING)] OR CLASS B MEDICAL DEVICE

1. Name of applicant:

2. Nature and constitution of manufacturer:
(i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Corporate /registered office address including telephone number, mobile number, fax number and e-mail id:

(ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:

(iii) Address for correspondence: [corporate/registered office/manufacturing site]

4. Details of medical device(s) to be manufactured [Annexed]:

5. Whether substantial equivalence to a predicate device is claimed: (Yes/No)

6. Fee paid on................Rs................receipt/challan/transaction id......................

7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

8. I hereby state and undertake that:

(i) the manufacturing site is ready for audit or shall be ready for audit on.....................in accordance with the requirements of Medical Devices Rules, 2017.

(ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:...........................................

Signature

Date:..................................  (Name and designation)

[To be signed digitally]

**ANNEXURE**

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-</th>
<th>Brand Name (if registered)</th>
</tr>
</thead>
</table>

**Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India**

Page 208 of 248
FORM MD-4

[Refer sub-rule (2) of rule 20]

APPLICATION FOR GRANT OF LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS A [(OTHER THAN NON-STERILE AND NON-MEASURING)] OR CLASS B MEDICAL DEVICE

1. Name of applicant:

2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Corporate / registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Name and address of manufacturing site including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence: [corporate/registered office/manufacturing site]

4. Details of medical device(s) to be manufactured [Annexed]:

5. Whether substantial equivalence to a predicate device is claimed: (Yes/No)

6. Fee paid on............Rs..............receipt/ challan/ transaction id....................

7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

8. I hereby state and undertake that:
(i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:.............................................  Signature

Date:.............................................  (Name and designation)

[To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Brand Name (if registered under the Trade Marks Act. 1999)</th>
</tr>
</thead>
</table>

[Refer sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

**LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS A [(OTHER THAN NON-Sterile AND NON-MEASURING)] OR CLASS B MEDICAL DEVICE**

Licence Number:......................

1. M/s............................................... (Name and full address of manufacturer with telephone, fax and e-mail) has been licensed to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at.................................................. (address of manufacturing facility where the manufacturing will be carried out).

2. Details of medical device(s) [Annexed],

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.
Place:.................................................. State Licensing Authority

Date:.................................................. [To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Brand Name (if registered under the Trade Marks Act, 1999)</th>
</tr>
</thead>
</table>

FORM MD-6
[Refer sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS A* (OTHER THAN NON-Sterile AND NON-MEASURING) OR CLASS B MEDICAL DEVICE

Loan Licence Number:..........................

1. M/s .......................................................................................................................... (Name and full address of manufacturer with telephone, fax and e-mail) has been licensed to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at .......... ................................................................. (address of manufacturing facility where the manufacturing will be carried out along with the licence number) C/o..................................................(name of manufacturing site licence holder).

2. Details of medical device(s) [Annexed].

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place:.................................................. State Licensing Authority

Date:.................................................. [To be signed digitally]
**ANNEXURE**

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Brand Name (if registered under the Trade Marks Act, 1999)</th>
</tr>
</thead>
</table>

**FORM MD-7**

*Refer sub-rule (1) of rule 21 and sub-rule (2) of rule 21*

**APPLICATION FOR GRANT OF LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D**

1. Name of applicant:

2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
   (i) Corporate/registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence: [corporate/registered office/manufacturing site]

4. Details of medical device(s) to be manufactured [Annexed]:

5. Whether substantial equivalence to a predicate device is claimed: (Yes/No)

6. Fee paid on................Rs..................receipt / challan / transaction id...........................
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

8. I hereby state and undertake that:

(i) the manufacturing site is ready for audit or shall be ready for audit on.........................in accordance with the requirements of Medical Devices Rules, 2017.

(ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:................................................. Signature

Date:................................................. (Name and designation)

[To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Brand Name (if registered under the Trade Marks Act, 1999)</th>
</tr>
</thead>
</table>

FORM MD-8

[Refer sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

APPLICATION FOR GRANT OF LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D

1. Name of applicant:

2. Nature and constitution of manufacturer:
(i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:

(ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:

(iii) Address for correspondence:

[Corporate office/manufacturing site]

4. Details of medical device(s) to be manufactured [Annexed]:

5. Whether substantial equivalence to a predicate device is claimed: (Yes/No)

6. Fee paid on ...................Rs................ receipt/challan/transaction id.............

7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

8. I hereby state and undertake that:

(i) the manufacturing site is ready for audit or shall be ready for audit on.....................in accordance with the requirements of the Medical Devices Rules, 2017.

(ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:................................................ Signature

Date:............................................... (Name and designation)

[To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or</th>
<th>Brand Name (if</th>
</tr>
</thead>
</table>
FORM MD-9

[Refer sub-rule (1) of rule 25]

LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D

Licence Number:.........................

1. M/s .......................................................... (Name and full address of manufacturer with telephone, fax and e-mail) has been licensed to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at ...................................................... (address of manufacturing facility where the manufacturing will be carried out).

2. Details of medical device(s) [Annexed].

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s).

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place:.................................................... Central Licensing Authority
Date:..................................................... [To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Brand Name (if registered under the Trade Marks Act, 1999)</th>
</tr>
</thead>
</table>

Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India
FORM MD-10

[Refer sub-rule (1) of rule 25]

LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D MEDICAL DEVICE

Loan Licence Number:.......................  

1. M/s...........................................(Name and full address of manufacturer with telephone, fax and e-mail) has been licensed to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at.........................................................(address of manufacturing facility where the manufacturing will be carried out along with the licence number) C/o..................................................(name of manufacturing site licence holder).

2. Details of medical device(s) [Annexed].

3. The names, qualifications and experience of competent technical staff responsible for the manufacture and testing of the above mentioned medical device.

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place:.................................................. State Licensing Authority  
Date:.................................................. [To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Brand Name (if registered under the Trade Marks Act, 1999)</th>
</tr>
</thead>
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</tbody>
</table>
FORM MD-11
[Refer clause (vii) of rule 26]
FORM IN WHICH THE AUDIT OR INSPECTION BOOK SHALL BE MAINTAINED

(A) The cover of the audit or inspection book shall contain the following particulars, namely:—

1. The name and address of the licensee....................................................

2. Licence Number.................................................................

(B) (i) The pages of the audit or inspection book shall be serially numbered and duly stamped by the Central Licensing Authority* / State Licensing Authority*. The pages, other than the first and the last pages, shall have the following particulars:—

Name and designation of the auditor or medical device officer who audited or inspected the premises:

Date of audit or inspection:.............................................................

Observations of the auditor or medical device officer:..............................

Signature of the auditor or medical device officer

(ii) The first and last pages of the audit or inspection book shall be endorsed by the Central Licensing Authority* / State Licensing Authority* with the following words, namely:—

Audit or inspection book maintained by M/s ...........................................situated at in Form........................................for licence number under the Medical Devices Rules, 2017.

**"Central Licensing Authority/
*State Licensing Authority
[To be signed digitally]

*Delete whichever is not applicable.

Notes:
(i) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment of fee as may be specified by the concerned Licensing Authority from time to time.

(ii) The audit or inspection book shall be maintained at the premises of the licensee.

(iii) The original copy of observations made by the auditor or medical device officer shall be maintained in the premises of the licensee and duplicate copy shall be sent to the Central Licensing Authority/State Licensing Authority. The triplicate copy shall be taken as record by the auditor or medical device officer.

**FORM MD-12**

*Refer sub-rule (1) of rule 31*

APPLICATION FOR LICENCE TO MANUFACTURE MEDICAL DEVICE FOR PURPOSE OF CLINICAL INVESTIGATIONS, TEST, EVALUATION, EXAMINATION, DEMONSTRATION OR TRAINING

1. Name of applicant:

2. Nature and constitution of manufacturer: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Corporate/registered office address including telephone number, mobile number, fax number and e-mail id:

(ii) Testing or evaluation site address including telephone number, mobile number, fax number and e-mail id:

(iii) Address for correspondence: [corporate office / testing site]

4. Details of medical device(s) to be manufactured [Annexed]:

5. Fee paid on.................Rs.........................receipt/challan/transaction id.

6. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.
ANNEXURE

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Generic name</th>
<th>Class of medical device</th>
<th>Quantity proposed to be manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FORM MD-13

[Refer sub-rule (3) of rule 31]

LICENCE TO MANUFACTURE MEDICAL DEVICES FOR THE PURPOSES OF CLINICAL INVESTIGATIONS OR TEST OR EVALUATION OR DEMONSTRATION OR TRAINING

1. M/s................................. of............................. is hereby licensed to manufacture the medical device(s) specified below for the purposes of clinical investigations or test or evaluation or demonstration or training at.............................. (address of the premise).

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Generic name</th>
<th>Class of medical device</th>
<th>Quantity permitted to be manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

3. This licence shall be in force for a period of three years from the date specified below.

Place:................................................. Central Licensing Authority

Date:................................................. [To be signed digitally]
FORM MD-14
[Refer sub-rule (1) of rule 34]
APPLICATION FOR ISSUE OF IMPORT LICENCE TO IMPORT MEDICAL DEVICE

1. Name of authorised agent:

2. Nature and constitution of authorised agent: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Corporate/registered office address including telephone number, mobile number, fax number and e-mail id:

(ii) Authorised Agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence 61[or registration certificate]:

(iii) Address for correspondence; [corporate / registered office / authorised agent]

4. Particulars of overseas manufacturer, manufacturing site(s):

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name and address of manufacturer</th>
<th>Name and address of manufacturing site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name and address (full address with telephone, fax and e-mail address)</td>
<td>Name and address (full address with telephone, fax and e-mail address)</td>
</tr>
</tbody>
</table>

5. Details of medical device(s) to be imported [Annexed]:

6. Whether substantial equivalence to a predicate device is claimed: (Yes/No)

7. Fee paid on.................................Rs..........................receipt / challan/ transaction id..........................

8. I have enclosed the documents as specified in the Fourth Schedule for grant of licence to import medical device(s).

9. I hereby state and undertake that:
(i) I shall comply with applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:................................................ Signature
Date:................................................ (Name and designation)

[To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Brand Name (if registered under Trade Marks Act, 1999)</th>
</tr>
</thead>
</table>

FORM MD-15
[Refer sub-rule (1) of rule 36]

LICENCE TO IMPORT MEDICAL DEVICE

Licence No.:........................................

1. M/s................................................ (Name, full address, as per wholesale licence/ manufacturing licence or registration certificate), of authorised agent with telephone and e-mail address) is hereby licensed to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name &amp; address of overseas manufacturer (full address with telephone and e-mail address of the manufacturer)</th>
<th>Name &amp; address of overseas manufacturing site (full address with telephone and e-mail address of the manufacturing site)</th>
</tr>
</thead>
</table>
3. Details of medical device(s) [Annexed],

4. The authorised agent M/s.....................................................will be responsible for the business activities of the overseas manufacturer, in India in all respects.

5. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place:.................................................. Central Licensing Authority

Date:.................................................. Seal or Stamp

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Brand Name (if registered under Trade Marks Act, 1999)</th>
</tr>
</thead>
</table>

FORM MD-16
[Refer sub-rule (2) of rule 40]

APPLICATION FOR LICENCE TO IMPORT MEDICAL DEVICES FOR THE PURPOSES OF CLINICAL INVESTIGATIONS OR TEST OR EVALUATION OR DEMONSTRATION OR TRAINING

1. Name of applicant

2. Address of applicant including telephone number, mobile number, fax number and e-mail id

3. Name and Address of device manufacturer

4. Name and Address of site(s) where test or evaluation is proposed to be conducted

5. Details of medical device(s) to be imported [Annexed]
6. Brief description of the medical device

7. Purpose of import

8. Justification for quantity to be imported

9. An undertaking stating that required facilities including equipment, instrument and personnel have been provided to test or evaluate medical device

10. An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified at serial number 7 and shall not be used for commercial purpose

11. Fee paid on ..................... Rs..................... receipt/challan/transaction id..................

12. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: ..........................................
Signature
Date: ............................... (Name and designation)
[To be signed digitally]

---

**ANNEXURE**

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Name of medical device (Generic and brand)</th>
<th>Model No.</th>
<th>Intended Use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
<th>Quantity to be imported</th>
</tr>
</thead>
</table>

**FORM MD-17**

[Refer sub-rule (1) of rule 41]

**LICENCE TO IMPORT MEDICAL DEVICES FOR THE PURPOSES OF CLINICAL INVESTIGATIONS OR TEST OR EVALUATION OR DEMONSTRATION OR TRAINING**
1. M/s.................................................. is hereby licensed to import the medical device specified below from M/s .......................................................... (Name and full address of overseas manufacturer) for the purposes of clinical investigations or test or evaluation or demonstration or training at.......................................................... (Name and address, where clinical investigations or test or evaluation or is to be carried out).

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Class of medical device</th>
<th>Quantity permitted to be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. This licence is subject to conditions prescribed under the Medical Devices Rules, 2017.

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

   Place:................................................ Central Licensing Authority
   Date:................................................ [To be signed digitally]

FORM MD-18
[Refer sub-rule (1) of rule 42]
APPLICATION FOR LICENCE TO IMPORT INVESTIGATIONAL MEDICAL DEVICES FOR THE PURPOSES BY A GOVERNMENT HOSPITAL OR STATUTORY MEDICAL INSTITUTION FOR THE TREATMENT OF PATIENTS

1. I.............................................(Name and designation)................................. of.............................................(Name of the Government Hospital or Statutory Medical Institution) hereby apply for a licence to import small quantities of investigational medical device specified below manufactured by M/s.............................................(Name and full address of overseas manufacturer) for the purpose of treatment of patients for the disease..................................................(Name of the disease)............................... at..................................................(name and address of the hospital).

2. Details of medical device to be imported:
<table>
<thead>
<tr>
<th>Name of the investigational Medical device</th>
<th>Name and address of the manufacturer</th>
<th>Quantities which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

4. A fee of Rs.........................has been credited to the Government under the Head through Challan/receipt No....................dated.................(copy attached).

Place:................................................    Signature........................................

Date:................................................    Name................................................

Seal or Stamp......................................

Certificate

Certified that the investigational medical device specified above for import are urgently required for the treatment of patients suffering from.........................and that the said medical device is not available in India.

Place:................................................    Signature........................................

Date:..................    Medical Superintendent of the Government Hospital

Head of Statutory Medical Institution

Seal or Stamp

FORM MD-19

[Refer sub-rule (2) of rule 42]

LICENCE TO IMPORT INVESTIGATIONAL MEDICAL DEVICE BY A GOVERNMENT HOSPITAL OR STATUTORY MEDICAL INSTITUTION FOR THE TREATMENT OF PATIENTS

Licence No.........................
1. Dr. ........................................ (Name and designation) of .................................. (Name of Hospital or Statutory Medical Institution) hereby grant licence to import from M/s .................................. (Name and full address of manufacturer) the medical devices specified below for the purpose of treatment of patients for the disease .................................................. (name of the disease) at ............................................ (name and address of the hospital).

2. Details of medical device to be imported:

<table>
<thead>
<tr>
<th>Name of medical device</th>
<th>Quantities which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Place: .................................................. Central Licensing Authority

Date: .................................................. Seal or Stamp

FORM MD-20
[Refer sub-rule (2) of rule 43]

APPLICATION FOR PERMISSION TO IMPORT SMALL QUANTITY OF MEDICAL DEVICES FOR PERSONAL USE

To:

The Central Licensing Authority,

Sir/Madam,

1. I........... resident of ........ by occupation........ hereby apply for a permission to import the medical device specified below for personal use manufactured by .................. (Name and full address of manufacturer) for the treatment of .................. (name of the disease)

<table>
<thead>
<tr>
<th>Name of medical device</th>
<th>Quantity which may be imported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. The prescription from a registered medical practitioner prescribing the
need for the said medical device is attached.

3. The particular of the patients is specified below:

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Gender</th>
<th>Complete Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Place:......................

Date:................................................  Signature of applicant

FORM MD-21
[Refer sub-rule (3) of rule 43]

PERMISSION TO IMPORT OF SMALL QUANTITY OF MEDICAL DEVICES FOR PERSONAL USE

Permit No...................................................... Date................................

1. ..................................................................is hereby permitted to import the medical device manufactured by.................................................................(Name and full address of manufacturer) specified below for personal use.

<table>
<thead>
<tr>
<th>Name of the medical device</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. This licence is subject to conditions prescribed in the Medical Devices Rules, 2017.

3. This licence shall, unless previously suspended or revoked, be in force for a period of one hundred and eighty days from the date of issue specified above.

Central Licensing Authority

Seal or Stamp

FORM MD-22
[Refer sub-rule (1) of rule 51]
APPLICATION FOR GRANT OF PERMISSION TO CONDUCT
CLINICAL INVESTIGATION OF AN INVESTIGATIONAL
MEDICAL DEVICE

1. Name of applicant:

2. Nature and constitution of applicant:

(i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Sponsor address including telephone number, mobile number, fax number and e-mail id:

(ii) Clinical investigation site address including telephone number, mobile number, fax number and e-mail id:

(iii) Address for correspondence:

4. Details of investigational medical device(s) and clinical investigation site [Annexed],

5. Clinical investigation plan number with date:

6. Fee paid on.................Rs.....................receipt/challan/transaction id..............

7. I have enclosed the documents as specified in the Seventh Schedule of Medical Devices Rules, 2017.

8. I hereby state and undertake that:

(i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017.

Place:................................................ Signature

Date:................................................ (Name and designation)

[To be signed digitally]

ANNEXURE
Permission No......................

1. M/s.........................................................(Name and full address) is hereby granted permission to conduct clinical investigation for following investigational medical device as per clinical investigation plan........................dated.................... in the below mentioned clinical investigation sites.

2. Details of investigational medical device(s) and clinical investigation site [Annexed].

3. This permission is subject to conditions as prescribed under Medical Devices Rules, 2017.

Place:............................. Central Licensing Authority

Date:............................. [To be signed digitally]

ANNEXURE

Details of investigational medical device(s):

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Intended use</th>
<th>Class of medical device</th>
</tr>
</thead>
</table>

Details of Clinical investigation site:

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Name and address of site(s)</th>
<th>Ethics Committee details</th>
<th>Name of Principal Investigator</th>
</tr>
</thead>
</table>
FORM MD-24
[Refer sub-rule (2) of rule 59]
APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL PERFORMANCE EVALUATION OF NEW IN VITRO DIAGNOSTIC MEDICAL DEVICE

1. Name of applicant:

2. Nature and constitution of applicant:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Sponsor address including telephone number, mobile number, fax number and e-mail id:
   (ii) Laboratory(ies) or institution(s) address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:

4. Details of new in vitro diagnostic medical device and laboratory(ies) or institution(s) [Annexed].

5. Clinical performance evaluation plan number with date:

6. Fee paid on..................Rs..............receipt/challan/transaction id..................

7. I have enclosed the documents as specified in sub-rule (3) of rule 59 of Medical Devices Rules, 2017.

8. I hereby state and undertake that:
   (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017.
ANNEXURE

Details of new \textit{in vitro} diagnostic medical device

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Intended use</th>
<th>Class of medical device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Details of laboratory(ies)/ institution(s) involved

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Name and address of laboratory (ies)</th>
<th>Ethics Committee details</th>
<th>Name of Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

\textbf{FORM MD-25}

[Refer sub-rule (5) of rule 59]

\textbf{PERMISSION TO CONDUCT CLINICAL PERFORMANCE EVALUATION OF NEW \textit{IN VITRO} DIAGNOSTIC MEDICAL DEVICE}

Permission No..................

1. M/s............................................................(Name and full address of manufacturer with telephone and e-mail) is hereby granted permission to conduct clinical performance evaluation of following \textit{in vitro} diagnostic device as per clinical performance evaluation plan........................................dated.......................on the below mentioned laboratory(ies) or institution(s) involved.

2. Details of new \textit{in vitro} diagnostic medical device and laboratory (ies) or institution(s) [Annexed].

3. This permission is subject to conditions as prescribed under Medical Devices Rules, 2017.
ANNEXURE

Details of new *in vitro* diagnostic medical device

<table>
<thead>
<tr>
<th>SL. No.</th>
<th>Generic name</th>
<th>Intended use</th>
<th>Class of medical device</th>
</tr>
</thead>
</table>

Details of laboratory(ies)/institution(s) involved

<table>
<thead>
<tr>
<th>SL. No.</th>
<th>Name and address of laboratory Ethics Committee details</th>
<th>Name of Principal Investigator</th>
</tr>
</thead>
</table>

**FORM MD-26**

[Refer sub-rule (1) of rule 63]

**APPLICATION FOR GRANT OF PERMISSION TO IMPORT /MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF MEDICAL DEVICE WHICH DOES NOT HAVE Predicate MEDICAL DEVICE**

1. Name of applicant:

2. Nature and constitution of applicant:

   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Corporate / registered office address including telephone number, mobile number, fax number and e-mail id:

   (ii) Manufacturing site / Authorised Agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence [or registration certificate]:

   (iii) Address for correspondence:
4. Particulars of Manufacturer, Manufacturing site(s):

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)</th>
<th>Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

5. Details of medical device(s) to be imported or manufactured [Annexed],

6. Fee paid on....................Rs.....................receipt/challan/transaction id....................

7. I have enclosed the documents as specified in the Part IV of the Fourth Schedule to the Medical Devices Rules, 2017.

Place:.............................................. Signature

Date:.............................................. (Name and designation)

[To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

FORM MD-27

[Refer sub-rule (2) of rule 63]

PERMISSION TO IMPORT OR MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF MEDICAL DEVICE WHICH DOES NOT HAVE PREDICATE MEDICAL DEVICE

Permission No....................

1. M/s._________________________________________(Name and full address of manufacturer with telephone, and e-mail) having manufacturing site_________________________________________(address of manufacturing site), is hereby
permitted to import/ manufacture for sale or for distribution of following medical devices.

2. Details of medical device(s) to be imported or manufactured [Annexed].

3. This permission is subject to conditions as specified in the Drugs and Cosmetics Act (23 of 1940) and the Medical Devices Rules, 2017.

Place:........................................ Central Licensing Authority

Date:........................................ [To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Model No.</th>
<th>Dimension</th>
<th>Intended Use</th>
<th>Shelf Life</th>
<th>Sterile/ Non-Sterile</th>
<th>Class of medical device</th>
</tr>
</thead>
</table>

FORM MD-28

[Refer sub-rule (1) of rule 64]

APPLICATION FOR GRANT OF PERMISSION TO IMPORT OR MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF NEW IN VITRO DIAGNOSTIC MEDICAL DEVICE

1. Name of applicant:

2. Nature and constitution of applicant:

(i.e. proprietorship, partnership including Limited Liability Partnership, private/public company, society, trust, other to be specified)

3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:

(ii) Manufacturing site / authorised agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence 64[or registration certificate]:

Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India
(iii) Address for correspondence:

[Corporate / registered office / manufacturing site/ authorised agent]

4. Particulars of Manufacturer, Manufacturing site(s):

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)</th>
<th>Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

5. Details of new *in vitro* diagnostic medical device to be imported or manufactured [Annexed].

6. Fee paid on ...................Rs.....................receipt/challan/ transaction id.................

7. I have enclosed the documents as specified in the Part IV of the Fourth Schedule Medical Devices Rules, 2017.

Place: ................................................ Signature

Date: ................................................ (Name and designation)

[To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Generic name</th>
<th>Model No.</th>
<th>Intended use</th>
<th>Class of medical device</th>
<th>Material of construction</th>
<th>Dimension (if any)</th>
<th>Shelf life</th>
<th>Sterile or Non-sterile</th>
</tr>
</thead>
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</tr>
</tbody>
</table>

**FORM MD-29**

*[Refer sub-rule (2) of rule 64]*

**PERMISSION TO IMPORT OR MANUFACTURE NEW *IN VITRO* DIAGNOSTIC MEDICAL DEVICE**

Permission No......................

1. The new *in vitro* diagnostic medical device(s) specified below manufactured by M/s......................................................... (Name and full address of manufacturer with telephone, and e-mail) having manufacturing site
........................ (address of manufacturing site), is hereby permitted to import or manufacture.

2. Details of new *in vitro* diagnostic medical device to be imported or manufactured [Annexed].

3. This permission is subject to conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: .............................................. Central Licensing Authority

Date: ................................................... [To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>SI. No.</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Model No.</th>
<th>Dimension</th>
<th>Intended Use</th>
<th>Shelf life</th>
<th>Sterile/Noti-Sterile</th>
<th>Class of medical device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

FORM MD-30

[Refer sub-rule (1) of Rule 67]

MEMORANDUM TO THE CENTRAL MEDICAL DEVICE TESTING LABORATORY

Serial Number ........................................
The Director, Central Medical Device Testing Laboratory,

From ....................................................

1. I send herewith, under the provisions of sub-section (4) of section 25 of the Drugs and Cosmetics Act, 1940 (23 of 1940), sample(s) of a medical device purporting to be ........................................ for test or evaluation and request that a report of the result of the test or evaluation may be supplied to this Court.

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

3. Particulars of offence alleged .........................................................
4. Matter on which opinion is required..............................................

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

Date.........................  Magistrate

FORM MD-31
[Refer sub-rule (4) of rule 67]
CERTIFICATE OF TEST OR EVALUATION BY THE CENTRAL MEDICAL DEVICE TESTING LABORATORY

1. Certified that the samples, bearing number..........................purporting to be a sample of..........................received on..........................with memorandum No.................. dated ...................... from ................... has been tested / evaluated and that the result of such test/evaluation is as stated below.

2. The condition of the seals on the packet on receipt was as follow..........................

*3. In the opinion of the undersigned the sample is of standard quality / not of standard quality as defined in the Drugs and Cosmetics Act, 1940 (23 of 1940) and Medical Devices Rules, 2017 for the reasons given below.

Date........................................  Director of Central Medical Device Testing Laboratory/other Authorised Officer

Details of results of testing or evaluation with protocols of test or evaluation applied

Date........................................  Director of Central Medical Device Testing Laboratory / other Authorised Officer

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

FORM MD-32
[Refer sub-rule (2) of rule 68]
REPORT OF TEST OR EVALUATION OF MEDICAL DEVICES BY MEDICAL DEVICE TESTING OFFICER
1. It is certified that the samples having serial number of memorandum or receipt number ............ dated: .................. purporting to be sample of ............received on................. from.........................has been tested or evaluated and the results of tests or evaluation is as stated below.

2. The conditions of seals on the packet or on portion of sample or container were as follows.................

3. Based upon the test or evaluation and in the opinion of undersigned the sample is of standard quality/not of standard quality/adulterated/misbranded/spurious, as defined in the Drugs and Cosmetics Act, 1940 (23 of 1940) for the reasons given below:—

Date......................................

Medical Device Testing Officer

Seal or Stamp

FORM MD-33
[Refer rule 69]

APPLICATION FROM A PURCHASER FOR TEST OR EVALUATION OF A MEDICAL DEVICE UNDER SECTION 26 OF THE DRUGS AND COSMETICS ACT, 1940 (23 OF 1940)

To:

The Central Licensing Authority,

Sir / Madam,

1. Full name and address of the applicant
2. Occupation...........................................................................................................
3. Name of medical device purporting to be contained in the sample..................
4. Name and full address of the pharmacy or concern where the medical device was purchased.
5. Date on which purchased.................................................................(invoice attached)
6. Reasons why the medical device is being submitted for test or evaluation.........
7. A fee of rupees..........................................................as charged by medical
device testing laboratory has been paid under receipt
number..............dated:....................

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

Date:................................. Signature
Seal or Stamp

FORM MD-34
[Refer rule 72]
ORDER UNDER CLAUSE (c) OF SUB-SECTION (1) OF SECTION OF
THE DRUGS AND COSMETICS ACT, 1940 (23 OF 1940),
REQUIRING A PERSON NOT TO DISPOSE OF STOCK IN HIS
POSSESSION

Whereas, I have reason to believe that the stocks of medical devices in
your possession, detailed below contravenes the provisions of Section 18 of
the Drugs and Cosmetics Act, 1940 (23 of 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:................................. Medical Device Officer
Seal or Stamp

Details of stock of medical devices

Date:................................. Medical Device Officer
Seal or Stamp

FORM MD-35
[Refer rule 74]
RECEIPT FOR STOCK OF MEDICAL DEVICES FOR RECORD,
REGISTER, DOCUMENT OR MATERIAL OBJECT SEIZED UNDER
CLAUSE (c) OR CLAUSE (cc) OF SUB-SECTION (1) OF SECTION 22
OF THE DRUGS AND COSMETICS ACT (23 OF 1940)
The stock of medical devices 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:..........................................

Medical Device Officer
Seal or Stamp

Details of stock of medical devices or records, registers, documents or material objects seized

Date:..........................................

Medical Device Officer
Seal or Stamp

FORM MD-36

INTIMATION OF PERSON FROM WHOM SAMPLE IS TAKEN

To:

I have this day taken from the premises of .................... situated at ..................... samples of medical devices specified below for the purpose of test or evaluation.

Date:..........................................

Medical Device Officer
Seal or Stamp

Details of sample of medical devices

Date:..........................................

Medical Device Officer
Seal or Stamp

FORM MD-37

RECEIPT FOR SAMPLE OF MEDICAL DEVICE(S) TAKEN WHERE FAIR PRICE TENDERED THEREOF UNDER SUB-SECTION (1) OF SECTION 23 OF THE DRUGS AND COSMETICS ACT, 1940 IS REFUSED

To:

Whereas I, this..............day of.............., have taken from the premises situated at.......samples of medical devices as specified below:
Details of samples:

And whereas I had offered to you rupees..........as the fair price of the samples of aforesaid medical devices taken;

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

Now, therefore, I give you this receipt as the fair price tendered for the samples of the medical devices taken by me.

Date:........................................... Medical Device Officer

Seal or Stamp

FORM MD-38
[Refer sub-rule (1) of rule 78]
MEMORANDUM TO MEDICAL DEVICE TESTING OFFICER

Serial No. of Memorandum:.............................

From:

To:

The Medical Device Testing Officer

The sample of medical device described below is enclosed for test or evaluation under the provisions of clause (i) of sub-section (4) of section 23 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

The sample of medical device has been marked by me with following mark.

Details of sample of medical device with name of medical device which is purports to contain—

Date:............................................. Medical Device Officer

Seal or Stamp

FORM MD-39
[Refer sub-rule (1) of rule 81]
APPLICATION FOR GRANT OF REGISTRATION TO MEDICAL DEVICE TESTING LABORATORY FOR CARRY OUT TEST OR EVALUATION OF A MEDICAL DEVICE ON BEHALF OF MANUFACTURER
1. Name of applicant:

2. Nature and constitution of applicant:

(i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. (i) Corporate/registered office address including telephone number, mobile number, fax number and e-mail id:

(ii) Testing laboratory address including telephone number, mobile number, fax number and e-mail id:

(iii) Address for correspondence:

[Corporate office / testing laboratory]

4. Details of medical device(s) to be tested or evaluated [Annexed].

5. Fee paid on.....................Rs..................receipt/challan/transaction id..................

6. I have enclosed the documents as specified in the sub-rule (2) of rule 82 of Medical Devices Rules, 2017.

7. I hereby state and undertake that:

(i) the testing laboratory is ready for inspection or shall be ready for inspection on.......................in accordance with the requirements of Medical Devices Rules, 2017.

(ii) I shall comply with the applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940), and the Medical Devices Rules, 2017.

Place:.............................................. Signature
Date:............................................. (Name and designation)
[To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>Sl.No.</th>
<th>Generic name</th>
<th>Class of medical devices</th>
</tr>
</thead>
</table>

Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India
FORM MD-40
[Refer sub-rule (3) of rule 83]
CERTIFICATE OF REGISTRATION TO MEDICAL DEVICE TESTING LABORATORY FOR CARRY OUT TEST OR EVALUATION OF A MEDICAL DEVICE ON BEHALF OF MANUFACTURER

Registration No.:....................

1. M/s................................................(Name of the firm) situated at........................... (full address with telephone and e-mail) has been registered as a Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer under the Medical Devices Rules, 2017.

2. Details of medical device(s) to be tested or evaluated [Annexed].

3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:........................................ Central Licensing Authority

Date:........................................... [To be signed digitally]

ANNEXURE

<table>
<thead>
<tr>
<th>Sl.No.</th>
<th>Generic name</th>
<th>Class of medical devices</th>
</tr>
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Form MD-41
[See sub-rule (2) of rule 87A]
APPLICATION FOR GRANT OF REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR
DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE

1. Name of applicant:

2. Address of the premises to be registered:

3. Contact details of applicant including telephone number, mobile number, fax number and email id:

4. Nature and constitution of applicant: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

5. Name, qualification and experience of competent person appointed:

6. Fee paid on _______________ Rs____________________ receipt/challan/transaction Id___________.

7. I have enclosed the documents as specified in the sub-rule (3) of rule 87A of the Medical Devices Rules, 2017.

Place: __________

Date: __________

Name, designation & signature of Director/Proprietor/Partner

Form MD-42

[See sub-rule(4) of rule 87A and sub-rule (1) of rule 87C]

REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE

Registration No.: ……………

1.M/s,……………………………………………………………………...(Name of the firm) situated at …………………………………………………...(full address with telephone and e-mail) has been registered to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device under the Medical Devices Rules, 2017.
2. Name and qualification of competent person:

3. This registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: __________

Date: __________

State Licensing Authority

Form MD-43
[See sub-rule (8) of rule 87B]

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 registration certificate holder __________

2. Registration certificate number ____________________________

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

Name and designation of the Medical Device Officer who inspected the premises:
Date of inspection ________________________________
Observations of the Medical Device Officer __________________________

Signature of the Medical Device Officer

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

Inspection book maintained by M/s_________________________ situated at ___________________________ for Registration number ___________________________ in Form MD-43 ________________ under the Medical Devices Rules, 2017.