



**DRUGS CONTROL DEPARTMENT**

**KERALA STATE**

**CITIZEN'S CHARTER 2009**

SERVICES OFFERED FOR THE PUBLIC

**VISION:**

**HEALTH FOR ALL WITH MINIMAL USE OF DRUGS**

**Mission:** ensure the quality of drugs and cosmetics and make them available to the public at controlled prices by regulating and controlling the manufacture and sale.

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## I.

### **INTRODUCTION**

This charter is made based on the directions under Government Order (MS) 30/99 P & ARD dated 22.11.99, with the guidance of Smt. Anishya Jayadev, IMG. Thiruvananthapuram and opinion of the public.

The validity of this citizen charter is one year and shall be updated in compliance with the directions from the Government and in tune with the trends in the field of services. The opinion of public is always welcomed which, we believe, will contribute to update this charter every year.

This charter is available in each office of the department and in the enquiry counter of the office of the Drugs Controller for verification and examination for the public.

## II. **PLEDGE**

We, the Drugs Control Department of Kerala State here by ensure that we are committed to provide transparent and timely service to all the beneficiaries of this Department on a most friendly atmosphere.

Thiruvananthapuram

M P. George

Drugs Controller

### **III. MAIN FUNCTIONS**

The main functions of the department are the following.

1. To regulate the manufacture, distribution and sale of drugs including homoeopathic drugs & cosmetics.
  - To ensure availability of all essential drugs.
  - To detect spurious, adulterated and Sub-Standard drugs and Cosmetics and to prevent its sale.
  - To detect and prohibit manufacture & sale of banned drugs.
2. To prevent sales of drugs at more price than marked on the label.
3. To detect and prohibit false and misleading advertisements of drugs for certain diseases and disorders.
4. To check the pilferage of drugs from Government hospitals & stores.
5. To control the sale and possession of certain poisons.
6. To regulate the manufacture of Ayurvedic drugs.
7. To recognize Pain & Palliative Care Centre and to ensure the availability of narcotic drugs therein.
8. To allot narcotic drugs to manufacturers,dealers and hospitals

### **IV. LAWS ENFORCED BY THE DEPARTMENT**

We implement the following legislations-

1. Drugs & Cosmetics Act 1940 & Drugs & Cosmetic Rules 1945.
2. The Drugs Price Control Order 1995 under the Essential Commodities Act.
3. Drugs & Magic Remedies (Objectionable Advertisement) Act 1954 & Rules 1955
4. The Kerala Drugs & Other Stores (Unlawful possession Act 1971)
5. Kerala Poison Rules 1996

### **VII. WINGS OF THE DEPARTMENT**

The department has 2 wings

1. **The Enforcement Wing**

**The enforcement wing for modern drugs:**

- (i) Regulating the manufacture, distribution and sale of drugs, cosmetics & Homoeopathic drugs.
- (ii) Detecting spurious, adulterated misbranded and substandard drugs & cosmetics and preventing its distribution.
- (iii) Detecting & prohibiting manufacturing and sale of banned drugs.
- (iv) Preventing sale of drugs at excess price
- (v) Detecting & Prohibiting false and misleading advertisement of drugs.
- (vi) Checking the pilferage of drugs from Government Hospitals and Other Stores.
- (vii) Controlling the sale and possession of certain poisons
- (viii) Suspending/Cancelling the licences issued to manufacturing/ sale premises violating the provisions of Drugs & Cosmetics Act 1940 & Rules made there under.
- (ix) Prosecuting the persons/firms/companies for breaching the provisions of –
  - (a) Drugs & Cosmetics Act 1940 & Rules 1945
  - (b) The Drugs Price Control Order 1996
  - (c) Drugs & Magic Remedies (Objectionable Advertisement) Act 1954 & Rules 1955
  - (d) The Kerala Drugs & Other Stores Act 1971
  - (e) The Kerala Poison Rules 1996
- (x) Controlling the use of narcotic drugs in institutions like hospitals by issuing the essentiality certificate for such institutions for procurement of such drugs.
- (xi) Drawing sample of drugs, cosmetics and homoeopathic medicines for test/analysis and action including the prosecution against the offenders.
- (xii) Regulating the blood bank by way of licensing, inspection & sampling to ensure safe blood transfusion, approving the blood storage centers for the storage of blood.
- (xiii) Preventing the misuse of habit forming drugs by surprise inspections and verification of records and taking action against the offenders.
- (xiv) Prosecuting quacks under the provisions of Drugs & Cosmetics Act and Rules there under.
- (xv) Conducting enquiries against the complaints from public and taking action against the offenders.
- (xvi) Preventing the misuse of certain poisons like methyl alcohol.
- (xvii) Preventing the distribution of banned drugs and irrational combinations of drugs.
- (xviii) Preventing the distribution of drugs with same /similar brand names.
  
- (xix) Ensuring the proper storage of drugs like insulin, vaccines, etc to ensure potency.
- (xx) Taking steps in cases of reported adverse reactions after administering drugs.
- (xxi) Preventing the illicit traffic of drugs.
- (xxii) Preventing the sale of bulk drugs and formulations exceeding the ceiling price fixed by National Pharmaceutical Pricing Authority.
- (xxiii) Ensuring the availability of drugs in the management of Pain & Palliative Cares.
- (xxiv) Approval of Laboratories for testing of drugs.

**B. The enforcement wing for Ayurvedic drugs is regulating the manufacture of Ayurvedic drugs**

## **2. The Testing Wing –**

The testing wing is functioning at the Drugs Testing Laboratory, Thiruvananthapuram. The testing wing is responsible for testing/analysis of modern drugs, cosmetics, homeopathic drugs and ayurvedic drugs.

This is done by.

- (i) Testing and Reporting the results of tests and analysis in the prescribed form and forwarding it to the concerned drugs inspectors without delay.
- (ii) Testing the samples produced by the public on payment of fees and giving the results.

- The analytical report of allopathic drugs are sent to the Drugs Inspector in Form 13 of Drugs & Cosmetics Rules 1945.

## **VIII. LICENSING**

Enforcement of the provisions of the Acts and Rules is achieved through a system of Licensing and periodical inspections.

- Licences are issued for  
The manufacture for sale of drugs & cosmetics, ayurvedic drugs, homoeopathic drugs  
Operation of blood bank and processing of components of blood  
and for sale of drugs including homoeopathic medicines.
- Giving approval for the blood storage centers in Government hospitals

### **LICENSING AUTHORITY**

1. The Drugs Controller is the authority to grant manufacturing licences for:

Drugs, Cosmetics and Homoeopathic drugs

For approval of Drugs Testing Laboratories.

To grant licences to operate blood banks, to manufacture for sale vaccines, sera and I V fluids are granted jointly by the State Drugs Controller and the Drugs Controller (General) of India.

2. The ASU Drugs Controller (Ayurveda) is the licensing authority for the manufacture of Ayurvedic drugs.

3. The Assistant Drugs Controllers at the Zonal Offices are the licensing authorities for  
 Grant of sales licences of drugs  
 Grant of sales licences of homoeopathic drugs  
 Grant of poison licences and permits.

**IX. LICENCE FEES AS PER STATUTE (validity for 5 years)**

With Chelan receipts and relevant documents are to be submitted to the licensing authorities concerned.

**Details of fees for obtaining different licences under the Drugs and Cosmetic Act**

Sl. No.	Applicati on Form No.	Licence	Licence Fee/Ren ewal Fee	Inspection Fee/Renew al Inspection Fee	Reinspecti on Fee	Late Fee* (Per month)	Duplicate Licence Fee	Additi onal Item
1	24	Mfg Lic for other than C & C1 and X(25)	6000	1500	-	1000	1000	300
2	24F	Mfg licence for sch X(25F)	6000	1500	-	1000	1000	
3	24A	Loan licence for other than C & C1 and X(25A)	6000	1500	-	1000	1000	300
4	27	Mfg lic: for C & C1(28)	6000	1500	-	1000	1000	300

	27A	Loan Lic: for C&C1(28A)	6000	1500	-	1000	1000	
5	24C	Mfg of homoeo Drugs(25C)	200	100/50	-	100	50	50
6	27C	Blood Bank Licences(28C)	6000	1500	500	1000	1000	300
7	27D	Mfg lic: for LVP/Vaccines/Sera(28D)	6000	1500	-	1000	1000	300
8	31	Mfg Lic: for Cosmetics(32)	2500	1000	1000	400	250	100

9	31A	Loan Lic: for Cosmetics (32A)	2500	1000	1000	400	250	100
10	36	Lic: for testing Labs(37).	-	1)6000(C&C1) 2)1500(other than C&C1, Homoeo and Cosmetics)	-	1000	-	1)1500 for addl category of C &C1 2) 1000 for others
11	19/19C	Retail and wholesale licences for Allopathic/Sch X Drugs.	1500 each For licences in form 20,21,20B, 21B, 20Fand 20G	-	-	500 for each licence	150 per licence	-



12	19A/19A A/19B	Lic: for House hold remedies(20A,21A) /Van Sales(20BB,21BB)/ Hom med(20C,20D)	500 each for licences in form 20A , 21A,20B B, 21BB,20 C and 20D	-	-	250 for each licence	50 for 20C and 20D and150 for all others.	-
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\* Renewal is for a maximum of 6 months from the expiry of licence

## **X. FEEES FOR NON- STATUTORY SERVICES**

Sl No	Certificates	fees	Fee for addl/duplicate
1	Validity of drugs Licences(Modern drug manufacturing)	110	55
2	Validity of drugs Licences (Homoeo Drug Manufacturing, Cosmetics)	55	55
3	Validity of drugs Licences(Sales Premises)	55	55
4	Non conviction(Modern drug manufacturing)	110	55
5	Non conviction(Homoeo drug manufacturing)	55	55
6	Non conviction(Sales Premises)	55	55
7	Performance(Modern drug manufacturing)	110	55
8	Performance(Homoeo drug manufacturing)	55	55
9	Capacity of Manufacturing(Modern drug manufacturing)	110	55
10	Capacity of Manufacturing(Homoeo drug manufacturing)	55	55
11	Market Stranding(Modern drug manufacturing)	110	55
12	Market Stranding(Homoeo drug manufacturing)	55	55
13	WHO GMP	1100	550
14	GMP(Modern drug manufacturing)	550	275

15	Free Sale Certificate	110	-
16	CoPP	1100	550
17	Approval of Technical Staf	Nil	-
18	Approval of project	550	275
19	Approval of plan	110	55

***Remittance shall be made by Chelan under the head of account –  
0210-04-104-99***

## **xi. LICENCES FOR SALES OF DRUGS**

**A. Statutory forms of Licences under the Drugs and cosmetics Rules for sales of different types are as follows:**

- (i) Form 20 – Licence to sell, stock or exhibit or offer for sale or distribute drugs by retail other than those specified in Schedule C, C1 and X
- (ii) Form 21 - Licence to sell, stock or exhibit or offer for sale or distribute drugs by retail drugs specified in Schedule C and C, (excluding those specified in Schedule X)
- (iii) Form 20B - Licence to sell, stock or exhibit or offer for sale or distribute drugs by wholesale drugs other than those specified in Schedule C, C1 and X.
- (iv) Form 21B - Licence to sell, stock or exhibit or offer for sale or distribute drugs by wholesale drugs specified in Schedule C and C1 (excluding those specified in Schedule X).
- (v) Form 20A – Restricted licence to sell, stock or exhibit (or offer) for sale or distribute drugs by retail other than those specified in Schedule C, C1 and X for dealers who do not engage services of qualified person.  
**Form 19A** is prescribed for the fresh/renewal application of the above licence form 20A.
- (vi) Form 20BB – Licence to sell, stock or exhibit or offer for sale by whole sale or distribute drugs other than those specified in Schedule C, Schedule C1 to Drugs & Cosmetic Rules 1945 from a motor vehicle.
- (vii) Form 21BB – Licence to sell by wholesale or to distribute drugs specified in Schedule C & C1 to the Drugs & Cosmetic Rules, 1945 from a motor vehicle.  
For the fresh/renewal application of the above licences form 19 AA is prescribed.
- (viii) Form 20 C – Licence to sell, stock or exhibit or offer for sale or distribute Homeopathic Medicines by retail.
- (ix) Form 20D – Licence to sell, stock exhibit (or offer) for sale or distribute Homoeopathic medicines by wholesale.  
For fresh/renewal application of the above licence form 19B is provided.
- (x) Form 20F – Licence to sell, stock or exhibit (or offer) for sale, distribute by whole sale drugs specified in Schedule X.

(xi) Form 20 G – Licence to sell, stock or exhibit (or offer) for sale or distribute by whole sale drugs specified in Schedule X.

For the fresh or renewal application of the above licence in form 19 C is prescribed.

Certificate of renewal of licence to sell, stock or exhibit or offer for sale or distribute drugs in the case of all the above licences except form 20BB and form 21BB are issued in form 21C and that of 20BB and 21BB are issued in form 21 CC.

## **B. Basic Requirements for grant of sale licence**

### **1. AREA**

1. Retail (in form 20,21&20F) / wholesale licences (in form 20B,form 21B): minimum of 10 square metres

2. both retail & wholesale drugs licences : minimum of 15 square meters

### **2. Technical staff:**

For a medical store (retail sale) : Registered Pharmacist.

For wholesale drug licences: the competent person

Registered Pharmacist or has passed the matriculation examination or its equivalent examination from a recognized Board with 4 years experience in dealing with sale of drugs or holds a degree of a recognized University with 1 year experience in dealing with drugs.

For granting homoeopathic drug licences in form 20C or 20 D the competent person should have passed SSLC with adequate experience in dealing homoeopathic medicines.

### **3. Storage facilities**

Adequate Storage facilities should be provided for stocking drugs for maintaining their potency.

#### **Retail (Allopathy)**

A minimum of 50 Cubic Feet Wooden Cupboard with shutters and 50 cubic feet Cupboard with glass shutters and Refrigerator (Minimum 165 liters capacity)

#### **Wholesale (Allopathy)**

Racks, Cupboards, Refrigerator, Generator/UPS (if there is cold storage drugs).

#### **Retail and Wholesale (Homoeopathy)**

Adequate storage facilities like racks and/or cupboard

## **C. Documents to be submitted along with the application for grant of sales licences**

### **General Directions:**

All application shall be submitted with Chelan receipt- see Fee particulars

**Form 19** is prescribed for the fresh/renewal applications of the above licences in Form 20, 21, 20B and

Affidavits are TO BE PREPARED IN STAMP PAPER WORTH RS 50/ AND ATTESTED BY NOTARY PUBLIC HAVING JURISDICTION OVER THE CONCERNED AREA

21B . Copies of certificates should be attested by a Gazetted Officer

- The documents are to be submitted in duplicate, if application is submitted in the office of the Drugs Inspector.
- In case of renewal application, all above documents except items listed in 9 to 12. In addition to the above documents, the previous renewal certificates in original/copy of Drugs License are also to be attached.
- In case of application made in form 19AA the attested copy of RC book of the vehicle is to be provided along with application.
- In case of application in form 19A the questionnaire, Chalan receipt , affidavit and attested copies of documents of constitution of the proposed firm , proof of identity etc are to be provided.
- In case of limited companies/Trust/Society etc., applicant shall be one of the Directors/Trustee/Secretary or president as authorized by the Board.

### 1. Retail sale licences

1. Request letter specifying the list of documents submitted, affixed with court fee stamp worth Rs.5/-
2. Copy of identity card with photo to prove the identity of the applicant (Voter Id/Passport/Driving Licence/ IT PAN Card/ration Card)
3. Form 19/19B/19C
4. Questionnaire.
5. Original Chelan receipt for required amount of fees.
6. Copy of pharmacy registration certificate/ Educational and experience certificate
7. Declaration in own handwriting of the pharmacist/competent person
8. Self addressed envelope with postal stamp worth Rs 27/-
9. Copies of the documents of constitution of the proposed firm
10. Copy of ownership certificate/Tax receipt of the proposed building
11. Request for option in prescribed form.
12. Affidavit of the applicant/applicants in prescribed form.

Note:



### 4. QUESTIONNAIRE

(To be attached with Form 19/19C for Fresh/Renewal of Retail/Wholesale/ Retail& Wholesale)  
Sole Proprietor /Partnership Firm /Company /Govt./Co-op Society /Others

1. Name of the applicant in block letters : \_\_\_\_\_
2. Age : \_\_\_\_\_ years Sex : M/F
3. Educational qualification : \_\_\_\_\_
4. Permanent Address (Res.) : \_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_Pin\_\_\_\_\_

Phone No. \_\_\_\_\_ Email \_\_\_\_\_

5. Name and address of the shop/Firm :  
 .....  
 .....  
 .....  
 .....Pin.....

Phone no. \_\_\_\_\_

6. Whether Owned or Rented building :

6 (i) If rented, a) Name& Address of the owner :  
 b) date of occupancy :

10. Dimensions in meter

Room 1	: L	..	: B	..	: H	..
Room 2	: L	..	: B	..	: H	..
Room 3	: L	..	: B	..	: H	..

Total Area of the shop :.....m<sup>2</sup>

12. Storage Facilities

a)Cold Storage

:Refrigerator : Make.....: Capacity.....Litres

Walk in cooler : Make.....: Capacity.....Litres

b)Cool & Dry places :

i)cup board with wooden shutters : ..... m<sup>3</sup>

ii)cup board with glass shutters : ..... m<sup>3</sup>

13. Flooring :

14. Ceiling :

15. Electricity Consumer No :

16. Name of Registered Pharmacist/Competent Person :

Qualification :

Experience in No. of years :

17. If Pharmacy provided ,specify area :

18. Business hours of the shop and holiday :

19. If Convicted under any law, give details :

20. Details of godown :

21. Details of other DL if any :

### Declaration

I,.....name and address.....hereby declare that the statement made above are true and correct. I also declare that I shall follow the provisions of the Drugs and Cosmetics Act 1940 and Rules 1954 framed there under

Place: Signature.....  
Name :  
date : Designation :

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**OPTION FORM**

I, (*name and address*)..... Prop/Mg Partner of..... (*name and address of the firm*)..... hereby Opt to maintain carbon copies of the cash/credit memo in lieu of the registers to be maintained vide Rule 65(3) (1) & 65(4) (1) of the Drugs and Cosmetic Rules 1945. I shall maintain the carbon copies neatly and legibly showing all the particulars.

Place: Signature.....  
Name :  
date : Designation :

**AFFIDAVIT FOR SOLE PROPRIETARY CONCERN**

I , ... (*name*).... aged ... S/O ... residing at .. (*address*) .. hereby declare that I am the sole proprietor of M/s ..... (*name and full address of the proposed shop with details such as building number, ward number, Post office and Postal Index Number..*) .

**INCLUDE DETAILS OF PURCHASE/ SHIFTING/CHANGE IN COSTITUTION / PREVIOUS LICENCE/ ETC.**

I further declare that I am the occupant of the said premises in my capacity as its lawful owner/ legal tenant as per rent agreement dated..... The said premise is owned by (name and address)

These declarations are made for the grant of Drugs Licences under the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder.

DEPONENT

**AFFIDAVIT FOR PARTNERSHIP FIRM/COMPANY**

(TO BE PREPARED IN STAMP PAPER WORTH RS 50/ AND ATTESTED BY NOTARY PUBLIC HAVING JURISDICTION OVER THE CONCERNED AREA)

1) I, (name)... aged ... S/O .. residing at .. (address)..... solemnly declare that I am the Managing Partner/Managing Director of M/s (name and full address of the proposed shop with details such as building number, ward number, Post office and Postal Index Number).

**INCLUDE DETAILS OF PURCHASE/ SHIFTING/CHANGE IN COSTITUTION / PREVIOUS LICENCE/ ETC.**

2). The following are the partners/ directors of M/s....., as per partnership deed/memorandum and articles of association dated .....registered at.....as per registration no..... dated.....

1. ....name and address.....
2. ....name and address.....
3. ....name and address.....
4. ....name and address.....

3) I further declare that the following person/persons shall be responsible for the conduct of the business under Section 34 of the Drugs and Cosmetics Act, 1940, unless and until notified otherwise.

1. ....name and address.....
2. ....name and address.....

4) I, also declare that we are the occupant of the building (building no & address) in our capacity as its lawful owners /legal tenants by virtue of the consent given by its owner, as per rent agreement dated.....

5) The premises is owned by ..... (Name & address).....

These declarations are made for the grant of Drugs Licences under the Drugs and Cosmetics Act, 1940 and Rules made there under.

DEPONENT

### **AFFIDAVIT FOR OWNERSHIP CHANGE**

I .....aged.....son/daughter of ..... residing at ..... here by declare and affirm solemnly as follows.

I was carrying on business/dealings in drugs under the name and style M/s.....vide licence bearing nos..... & renewed up to.....

I hereby solemnly declare that I have transferred the ownership of the above said premises along with stock of medicines available/furniture/refrigerator etc to .....with effect from.....

I hereby also assign the assets and liabilities of the said premises to..... I have no objection in granting fresh licences to .....at the premises (address with building no).....under the name& style .....

The above statements are true and correct to the best of my knowledge.

sd/-

DEPONENT

(TO BE PREPARED IN STAMP PAPER WORTH RS 50/ AND ATTESTED BY NOTARY PUBLIC HAVING JURISDICTION OVER THE CONCERNED AREA)



### **Declaration of Pharmacist**

(Hand written declaration to be signed before an officer not below the rank of Drugs Inspector)

I ...name .....aged.....son/daughter of .....residing at ..... holder of Degree/, Diploma in Pharmacy having Pharmacy Registration Certificate No. .... renewed for life hereby declare that I shall work full time as Registered Pharmacist / competent person to supervise the sale of drugs for the purpose of rules 64 and 65 under the Drugs And Cosmetics Rules, 1945 at ..... with effect from ..... during the full working hours.

I was employed at M/s.....and left the services on ..... /This is my first employment.

I am not engaged in service anywhere else.

Place

Signature

Date

Name

### **Declaration of Competent Person**

(Hand written declaration to be signed before an officer not below the rank of Drugs Inspector. 3 copies of declarations with photograph are to be submitted)

I, ..... aged ..... years S/o, D/o, W/o ..... residing at ..... (full address) having educational qualification of ..... and .... years of experience at M/s ..... here by declare that I shall work full time as competent person at M/s ..... (Name & Address of the shop) with effect from ..... for the purpose of Rules 64 & 65 of the Drugs & Cosmetics Rules 1945 with effect from.

I was employed at M/s.....and left the service on .....

I am not engaged in service anywhere else.

Place

Signature

Date

Name

## **(b) Manufacturing Licences**

- **Form 25** – Licence of manufacture for sale or for distribution of drugs other than those specified in Schedules C, C1 and X.

Application for grant of form 25 licence is made in form 24

- **Form 25A** – Loan licence to manufacture for sale (or for distribution of) drugs other than those specified in Schedules C, C1 and X.

- **Form 25B** – Licence to report for sale or distribution of drugs being drugs other than those specified in Schedule C and C1 (excluding those specified in Schedule X).

- **Form 25C** – Licence to manufacture (or for distribution) Homeopathic medicines.

For the fresh or renewal application of the above licence form 24 C is prescribed.

- **Form 25D** – Licence to manufacture for sale of Ayurvedic (including Siddha) or Unani Drugs.

For the fresh or renewal application of the above licence form 24 D is prescribed.

- **Form 25E** – Loan licence to manufacture for sale Ayurvedic (Including Siddha) or Unani Drugs.

For the fresh or renewal application of the above licence form 24E is prescribed.

- **Form 25F** – Licence to manufacture for sale (or distribution) of drugs specified in Schedule X and not specified in Schedules C and C1.

For the fresh or renewal application of the above licence form 24 prescribed.

- Certificate of renewal of licence to manufacture for sale of drugs other than those specified in Schedule X is issued in form 26 and that of loan licence is form 26A.
- Certificate of renewal of licence to manufacture for sale of homeopathic medicines is issued in form 26C and that of ayurvedic drugs are issued in form 26D.
- Certificate of renewal of licence to manufacture for sale of drugs specified in Schedule X is issued in form 26F

- **Form 28** – Licence to manufacture for sale (or for distribution of) drugs specified in Schedules C and C1 (excluding those specified in Schedule X)

Fresh/renewal application of the above licence form 27 is prescribed.

- **Form 28A** – Loan licence to manufacture for sale (or for distribution of) drugs specified in Schedule C and C1 (excluding those specified in Schedule X).

For fresh/renewal application of the above licence form 27A is prescribed.

- **Form 28B** – Licence to manufacture for sale (or for distribution of) drugs specified in Schedules C, C1 & X

For fresh/renewal application of the above licence form 27B is prescribed.

- **Form 28C** – Licence to operate a Blood bank, processing whole human blood for components and/or manufacture of blood products.

For fresh/renewal application of the above licence form 27C is prescribed.

- **Form 28D** – Licence to manufacture for sale for distribution of Large Volume Parenterals /sera and vaccines specified on Schedules C and C1 excluding those specified in Schedule X

For fresh/renewal application of the above licence form 27D is prescribed.

Certificate of renewal of licence for the operation of blood bank and/or processing of whole human blood for component and/or manufacture of blood products is issued in form 26 D and that of Large Volume Parenterals/Sera and vaccines specified in Schedules C and C1 excluding those specified in Schedule X is issued in form 26 H

- **Form 29** – Licence to manufacture drugs for purpose of examination, test or analysis.

For fresh/renewal application of the above licence form 30 is prescribed.

- **Form 32** – Licence to manufacture cosmetics for sale or for distribution.

For fresh/renewal application of the above licence form 31 is prescribed

- **Form 32A** – Loan Licence to manufacture cosmetics for sale (or for distribution)

For fresh/renewal application of the above licence form 31 A is prescribed.

Certificate of renewal of licence to manufacture cosmetics for sale is issued in form 33 and that of loan licence is issued in form 33 A.

The approval for carrying out tests on drugs, cosmetics and raw materials is issued in form 37 and application for this purpose is made in form 36.

Certificate of renewal of form 37 approval is issued in form 38.

The Report of test or analysis by the approved institution is issued in form 39.

### **Documents required for grant/renewal of manufacturing licences.**

1. Concerned Form(Refer statutory forms)
2. Original chalan receipt required amount of fees.

3. Plan of the premises
4. Notarized affidavit in the prescribed form
5. Declaration of technical staffs on manufacturing and testing.
6. Documents to prove their qualification and experience
7. Details of products applied with their master formula records & SOPs (In the case of renewal details of products approved is also to be submitted)
8. Details of similar products in the market.
  - In the case of renewal of licences the previous renewal certificate in original & copy of original Drugs Licences are to be attached.
  - By remitting Rs. 7500/- as the licence fee along with application of allopathic drugs (form 25,27) a maximum of approval of 10 products could be obtained. For products beyond 10 numbers additional fee of Rs. 300/- is to be remitted.

**The manufacture shall be conducted under the active direction and supervision of qualified person who is a whole-time employee and is-**

a) A graduate in Pharmacy or Pharmaceutical Chemistry of a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose) and has had at least (eighteen months' practical experience) after the graduation in the manufacture of drugs . This period of experience may, however, be reduced by six months if the person has undergone training in manufacture of drugs for a period of six months during his University course; or

b) A graduate in Science or a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose) who for the purpose of his degree has studied Chemistry as a principal subject and has had at least three years practical experience in the manufacture of drugs after his graduation; or

c) A graduate in Chemical Engineering or Chemical Technology or Medicine of ( a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose) with general training and practical experience, extending over a period of not less than three years in the manufacture of drugs, after his graduation; or

d) Holding any foreign qualification the quality and content of training of which are comparable with those prescribed in clause (a), clause (b) or clause (c) and is permitted to work as competent technical staff under this rule by the Central Government:]

Provided that any person who was immediately before the 29<sup>th</sup> June, 1957, actively directing and personally supervising the manufacture of drugs and whose name was accordingly entered in any licence granted in Form 25 (or Form 26-F) as it existed before that date shall be deemed to be qualified for the purpose of this rule:

For drugs other than those specified in Schedules C, C(1) and X and meant for veterinary use, the whole time employee under whose supervision the manufacture is conducted shall be a graduate in Veterinary

Science or Pharmacy or General Science or Medicine of a University recognized by the Central Government and who has had at least three years' practical experience in the manufacture of drugs.

In the matter of manufacture of disinfectant fluids, insecticides, liquid paraffin, medicinal gases, non chemical contraceptives , plaster of Paris and surgical dressings the licencing authority may permit a competent technical staff who although not having any of the qualification mentioned above.

**Before a repacking licence in Form 25-B is granted or renewed the following condition shall be complied with by the applicant-**

The operation should be carried out under the direct supervision of a competent person.

A person who satisfies the following minimum qualifications shall be deemed to be a "competent person"

A person who holds the Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 (VIII of 1948) or a person who is registered under the said Act, or

a. A person who has passed the Intermediate examination with Chemistry as one of the principal subjects or an examination equivalent to it or an examination recognized by the licensing authority as equivalent to it, or

b. A person who has passed the Matriculation examination or an examination recognized by the licensing authority as equivalent to it and has had not less than four years practical experience in the manufacture, dispensing or repacking of drugs)

**Before a licence in Form 25-C is granted or renewed the following conditions shall be complied with by the applicant-**

(1) The manufacture of Homoeopathic medicines shall be conducted under the direction and supervision of competent technical staff consisting at least of one person who is a whole time employee (and who is-

(a) A graduate in Science with Chemistry as one of the Subjects with three years experience in manufacture of Homoeopathic Medicines; or

(b) A graduate in Pharmacy with 18 months of experience in the manufacture of Homoeopathic medicines; or

(c) Holds qualification as defined under sub-clause (g) of clause (1) of Section 2 of Homoeopathy Central Council Act, 1973 (59 of 1973) with 18 months of experience in the manufacture of Homoeopathic medicines:

Provided that the persons who are already in employment with five years experience in the manufacture of Homoeopathic medicines and whose name was accordingly entered in any licence granted in Form 25-C for manufacture of different classes of Homoeopathic medicines included in them shall be deemed to be qualified for the purpose of this rule.)

### **Declaration of technical staff**

I.....aged.....S/o/D/o/W/o.....(address) holder of  
.....(qualification) having .....yrs/months experience in .....here by  
declare that I am working as .....at.....(name an address of the  
unit) under the Drugs and Cosmetics Rules 1945.

I am not engaged in any other services.

Place

Sd/-

Date

Name

### **Approval of recognised laboratories**

Documents to be submitted to the licencing authority for obtaining approval are

- Covering letter with 5 rupees court fee stamp affixed
- Form 36(Refer Statutory forms)
- Chalan of Rs.7500
- List of equipments
- Standard Operating Procedures
- Certificate proving qualification & experience certificate of technical staff
- Declaration of technical staff

- Plan of the building

The validity of approval is for 5 years from the date of grant of approval.

### **(c) Blood Bank Licences**

- The licence for operating a blood bank shall be issued in form 28 C.
- A blood bank shall have an area of 100 square metres for its operations and an additional area of 50 square metres for preparation of blood components.

### **Documents required for grant/renewal of blood bank licences**

1. Covering letter with court fee stamp with 5 rupees affixed.
2. Form 27.C( Refer Statutory forms)
3. Questionnaire.
4. Chalan for Rs. 7500/- remitted under the head of account 0210-04-104-99.
5. Plan of the building.
6. Declaration of the medical officers, technicians and technical supervisor (blood component units) and registered nurses.
7. Attested copies of qualification of the medical officers, technicians and technical supervisors
8. Experience certificates of medical officers, technicians and technical supervisors
9. List of equipments provided.
10. List of blood products required.
11. Details of labels.
12. Standard operating procedures.

The validity of Drug Licence is 5 years from the date of grant of drug licence.

**The operation of Blood bank and/or processing of whole human blood for components shall be conducted under the active direction and personal supervision of whole-time competent technical staff consisting of :**

**(i) Medical Officer, possessing-**

- a. Postgraduate degree in Medicine-M.D. (Pathology/Transfusion Medicines) or
- b. Degree in Medicine (M.B.B.S.) with Diploma in Pathology or Transfusion Medicines having adequate knowledge in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components; or

- c. Degree in Medicine (M.B.B.S.) having experience in Blood Bank for one year during regular service and also have adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components.

The degree or diploma being from a University recognized by the Central Government.

(ii) **Blood Bank Technician (s)**, possessing-

- a. Degree in Medical Laboratory Technology (M. L. T) with six months experience in the testing of blood and/or its components; or
- b. Diploma in Medical Laboratory Technology (M. L. T) with one year experience in the testing of blood and/or its components,

The degree or diploma being from a University /Institution recognized by the Central Government or State Government.

(iii) **Registered Nurse(s)**

(iv) **Technical Supervisor** (where blood components are manufactured), possessing –

- a. Degree in Medical Laboratory Technology (M. L. T) with six month`s experience in the preparation of blood components ; or
- b. Diploma in Medical Laboratory Technology (M. L. T) with one year experience in the preparation of blood components,

The degree or diploma being from a University /Institution recognized by the Central Government or State Government.

### **Permit for Blood Storage Centres**

The validity of permit is 2 years from the date of grant of permit

### **Documents required for the approval of blood storage centres**

1. Covering letter with court fee stamp with Rs. 5 affixed.
2. Prescribed application form (see below)
3. List of equipments provided.
4. Declaration of the medical officer and laboratory technician.



5. Attested copy of qualification and experience certificate of medical officer and technician.
6. Consent of the mother blood bank supplying the blood units.
7. Plan of the proposed building.

**APPLICATION FOR STARTING STORAGE CENTRE OF WHOLE  
HUMAN BLOOD I. P/ OR ITS COMPONENTS**

1. Name and postal Address of the institution :
  
1. Status : FRU/PHC/CHC/HOSPITAL
  
2. Name, Designation and Qualification of  
Medical Officer in charge of Blood Storage Centre:
  
3. Name and Qualification of the Blood Bank :  
  
Technician
  
5. Source of Procurement of Blood Units :
  
4. Requirement of Whole Human Blood/ and  
or its components for one year :
  
5. Area of the premises proposed for the  
Blood Storage Centre :

**DECLARATION**

I .....here by declare that  
the particulars furnished above are true and correct to the best of my knowledge.

Place:

Signature

Date

Name & designation with official seal

## QUESTIONNAIRE

(To be accompanied with the application for Blood Storage Centre)

1. NAME OF APPLICANT :  
2. AGE :  
3. RESIDENTIAL ADDRESS ;  
(Permanent & Present)  
4. NAME AND ADDRESS OF THE BLOOD BANK  
(With Pincode & Phone No. :  
5. BLOOD BANK LICENCE NO ;  
6. VALID UP TO :  
7. DETAILS OF THE TECHNICAL STAFF WORKING IN THE BLOOD BANK.

SL. NO:	NAME OF THE STAFF	EDUCATION QUALIFICATION	EXPERIENCE	DATE OF JOINING
---------	-------------------	-------------------------	------------	-----------------

8. Total No. of Units of Blood Collected during years :  
9. Total Floor Area of the Blood Bank :  
10. Details of alterations/modifications to the structure made after Licencing :

I hereby agree to abide the provisions of the Drugs Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. I hereby declare that our Blood Bank shall not collect blood from professional

Date:

Applicant

**CERTIFICATE OF APPROVAL TO BLOOD STORAGE CENTRE FOR STORAGE OF WHOLE HUMAN BLOOD AND\*/OR ITS COMPONENTS**

No.

Date of Issue:

M/s.....  
.....is hereby approved to store the following items on the premises situated at.....  
.....under the supervision of the following Technical Staffs.

- 1. Name(s) of the approved Medical Officer :
- 2. Name(s) of the items :
  
- 3. Name of the Qualified Blood Bank Technician :
- 4. Name and address of the licensed blood bank from whom the blood units would be procured :
- 5. The approval shall be in force from :

Signature

Designation  
Licensing Authority

Dated:

\*Delete whichever is not applicable

**CONDITIONS**

- 1. The blood storage centre shall comply with the conditions as stipulated under item 5B of Schedule K of the Drugs and Cosmetics Rules which also includes as under.
- 2. The captive consumption of Whole Human Blood or its components in the above said centre shall not be more than 2000units per annum.
- 3. In the event of any change in the Technical Staff shall be forthwith reported to the Licensing Authority. In the event of any change in the name of the licensed blood bank from whom the blood units are procured, the same shall be intimated to the licensing authority for approval.
- 4. The center shall apply for renewal of the approval to the licensing authority 3 months prior to the date of expiry of the approval.

5. The center shall maintain records and registers including the details of procurement of blood /its components.
6. The center shall store samples of donors blood as well as patients sera for a period of 7 days after transfusion.

## **XII. Certificates**

The following certificates are issued from this office

**(1) Good Manufacturing Practices Certificate (GMP)** Application for GMP Certificate shall be made with a chalan receipt for Rs.550/- (for Modern Drugs ) GMP Certificate.

Chalan receipt for Rs. 1100/-is required for WHO GMP Certificate

There is no fee for Ayurvedic GMP Certificate.

The GMP certificates will be issued within one month.

**(2) Non Conviction Certificate**

Application for Non-Conviction Certificate shall be made along with chalan receipt for fees remitted as follows –

Modern Drugs - Rs.110/-

Ayurveda/Homoeopathic Drugs – Rs.55/-

Sales Premises – Rs. 55/-

**(3) Market Standing Certificate**

Application for Market Standing Certificate shall be made on plain paper with chalan receipt for fees remitted as follows: –

Modern drugs - Rs. 110/-

Ayurveda /Homoeopathic Drugs - Rs.55/-

**(4) Validity Certificate**

Application for certificate of validity of licences shall be made on plain paper with chalan receipt for fees remitted as follows:-

Modern drugs manufacturing unit - Rs. 110/-

Ayurveda /Homoeopathic manufacturing units – Rs. 55/-

Sales premises – Rs.55

**(5) Certificate of Performance**

Application for certificate of performance shall be made on plain paper with chalan receipt for fees remitted as follows:-

Modern Drugs Manufacturing Units Rs. 110/-

Ayurveda / Homoeo Manufacturing Units Rs. 55/-

**(6) Certificate of Capacity**

Application for certificates of capacity shall be made on plain paper with chalan receipt for fee remitted as follows:-

Modern Drugs Manufacturing Units Rs. 110/-

Ayurveda Homoeopathic Manufacturing Units Rs. 55/-

### **(7) Approval of Plan**

Application for approval of plans shall be made on Plain paper with detailed plan and chalan receipt for fee remitted as follows:-

Approval of Plan of Manufacturing Units Rs.110/-

## **XIII. PERMIT**

The following permit is issued by the department

Permits for possession and use of the for the poison Methyl Alcohol

Applications for poisons permit shall be made in prescribed form with chalan receipt for fee of Rs. 250/-.

The permit will be issued within 10 days. In the case of Wholesale or retail licences if the documents and conditions are satisfactory, it will be issued within 30 days.

### **Poison permit**

The Licensing authority may issue permits to enable professionals and educational and scientific establishment to obtain poisons from wholesale dealers for their own bonafide professional use or for use or in the institution or other establishment.

### **Documents required for poison permit**

1. Covering letter with court fee stamp worth Rs. 5/- affixed.
2. Form 1
3. Affidavit regarding the constitutions of the firm/company/proprietorship concerned.
4. Questionnaire.
5. Chalan for Rs. 250/- remitted in the head of account 0210-04-104-99.
6. Attested copy of partnership/memorandum & articles of association if the concern is a partnership firm/company respectively.
7. Copy of identity proof of the applicant.
8. Declaration of person in-charge of stocking and usage of poisons.

### **Documents required for poison licences**

1. Covering letter with court fee stamp worth Rs. 5/- affixed.

2. Form 2/3 for retail/wholesale.
3. Affidavit regarding the constitution of the firm/company/proprietorship concerned.
4. Questionnaire.
5. Chalan for Rs. 1000/500 in the case of retail/whole sale licences remitted in the head of account 0210-04-104-99.
6. Attested copy of partnership/memorandum & articles of association if the concern is a partnership firm/company respectively.
7. Copy of the identity proof for the applicant.
8. Declaration of the person in-charge of the stocking and usage of poison.
9. The validity of poison permit/poison licence is one year from the date of issue of licence.

**FORM No. I**

**Application for Licence/Renewal of Licence for possession and sale by Wholesale of poisons included in Schedule I**

1. I/We .....of  
 .....aged.....hereby apply for a licence/renewal of the  
 licence to possess and sell by wholesale poisons included in Schedule I to the Kerala Poison Rules,1996  
 On the premises situated  
 at.....  
 .....

2. Name of Poisons.....

3. Name of person(s) to be appointed for storage and sale and their qualifications.

(1)

(2)

4. A fee of Rs.....has been credited to Government under the Head of  
 Account.....

Signature

Name

Date

Designation

**FORM No. 2**

**Application for Licence/Renewal of Licence for possession and sale by Wholesale of poisons included in Schedule II**

1. I/We.....Of  
 .....aged.....hereby apply for a licence/renewal of the

licence to possess and sell by wholesale poisons included in Schedule II to the Kerala Poison Rules,1996  
on the premises situated  
at.....  
.....

1. Name of Poisons.....
2. Name of person(s) to be appointed for storage and sale and their qualifications.  
(1)  
(2)

3. A fee of Rs.....has been credited to Government under the Head of  
Account.....

Signature

Name

Date

Designation

**FORM No. 3**

**Application for inclusion of additional items in a licence**

- 1) I/We , holder of licence.....(ere enter details of the licence) hereby  
apply for inclusion of additional items of poisons included in Schedule I or Schedule II of  
the Kerala Poison Rules,1996 in the licence.
- 2) Licence No. Date of Issue and Validity:
- 3) Additional Items of poisons : (Please state the name and number of the items. Attach  
separate list if required)
- 4) A fee of Rs.....has been remitted to Government under the head of  
Account.....

Date :

Signature

Name and Address of the licensee

**FORM No. 4**

**Application for Licence/Renewal of Licence for possession and sale by retail of poisons included in  
Schedule I**

1.I/We .....of  
.....aged.....hereby apply for a licence/renewal of the  
licence to possess and sell by retail poisons included in Schedule I to the Kerala Poison Rules,1996 On the  
premises situated  
at.....  
.....

2.Name of Poisons.....

3.Name of persons to be appointed for storage and sale and their qualifications.

(1)

(2)

4.A fee of Rs.....has been credited to Government under the Head of Account.....

Signature

Name

Date

Designation

**FORM No. 5**

**Application for Licence/Renewal of Licence for possession and sale by retail of poisons included in Schedule II**

1.I/We .....of

.....aged.....hereby apply for a licence/renewal of the licence to possess and sell by retail poisons included in Schedule II to the Kerala Poison Rules,1996 on the premises situated

at.....  
.....

2.Name of Poisons.....

3.Name of persons to be appointed for storage and sale and their qualifications.

(1)

(2)

4.A fee of Rs.....has been credited to Government under the Head of Account.....

Signature

Name

Date

Designation

**FORM No. 6**

**Application for permit to purchase and possess poisons specified in Schedule I and II**



1 . I /We .....of  
.....aged.....hereby apply for a permit to possess  
poisons specified in Schedule I and II to the Kerala Poison Rules,1996 on the premises situated  
at.....  
.....

2 . Name of Poisons.....

3 . Name of person in- charge of poisons and his qualification.

(1)

(2)

4 . A fee of Rs.....has been credited to Government under the Head of  
Account.....

Signature

Name

Date

Designation

**FORM NO. 7**

Licence of possession and sale by wholesale of poisons included in Schedule I

1.Sri/Smt/M/s.....  
is hereby licensed to stock, possess or exhibit for sale or sell by wholesale at.....  
..... poisons  
specified in Schedule I to the Kerala Poisons Rules, 1996, subject to the condition specified below and in  
accordance with the provisions of the Poisons Act, 1919 and the Rule there under.

2. Licence will be in force from.....to.....

3. Name of Poisons:

4. Name of person in-charge of storage and sale:

Qualifications:

1. Licence No.....

Date:

Licensing Authority.

**Conditions of Licence**

This licence shall be displayed in a conspicuous place in the premises, open to the public and shall be produce on demand by an Inspector or an Officer authorized by the Government in this behalf.

**Renewal Particulars**

Licence renewed upto:

File No.....Date of application.....

Fee remitted.....

Signature of Licensing Authority

**FORM NO. 8**

Licence for possession and sale by retail of poisons included in Schedule II

1. Sri/Smt./M/s.....is hereby licensed to stock, possess or exhibit for sale or sell by wholesale at..... Poisons specified in Schedule II to the Kerala Poisons Rules, 1996, subject to the conditions specified below and in accordance with the provisions of the Poisons Act, 1919 and the Rule there under.

- 2. Licence will be in force from.....
- 3. Name of Poisons to be sold:
- 4. Name of person in –charge of Poisons  
Qualifications:
- 5. Licence No.

Date:

Licensing Authority

**Conditions of Licence**

This licence shall be displayed in a conspicuous place in the premises, open to the public and shall be produce on demand by an Inspector or an Officer authorized by the Government in this behalf.

**Renewal Particulars**

Licence renewed upto:

File No.....Date of application.....  
Fee remitted.....

Signature of Licensing Authority

**FORM No. 9**

Licence for possession and sale by retail of poisons included in Schedule I

1. Sri/Smt./M/s..... is hereby licensed to stock, possess or exhibit for sale or sell by retail at.....Poisons specified in Schedule I to the Kerala Poisons Rules, 1996, subject to the conditions specified below and in accordance with the provisions of the Poisons Act. 1919 and the Rule there under.

3. Licence will be in force from..... to .....

4. Name of Poisons to be sold:

5. Name of person in-charge of Poisons:

Qualifications:

6. Licence No.....

Date:

Licensing Authority

### Conditions of Licence

This licence shall be displayed in a conspicuous place in the premises, open to the public and shall be produce on demand by an Inspector or an Officer authorized by the Government in this behalf.

### Renewal Particulars

Licence renewed upto:

File No.....Date of application.....

Fee remitted.....

Signature of Licensing Authority

### FORM No. 10

Licence for possession and sale by retail of poisons included in Schedule I

1. Sri/Smt./M/s..... is hereby licensed to stock, possess or exhibit for sale or sell by retail at.....Poisons specified in Schedule I to the Kerala Poisons Rules, 1996, subject to the conditions specified below and in accordance with the provisions of the Poisons Act. 1919 and the Rule there under.

7. Licence will be in force from..... to .....

8. Name of Poisons to be sold:

9. Name of person in-charge of Poisons:

Qualifications:

10. Licence No.....

Date:

Licensing Authority

**Conditions of Licence**

This licence shall be displayed in a conspicuous place in the premises, open to the public and shall be produce on demand by an Inspector or an Officer authorized by the Government in this behalf.

**Renewal Particulars**

Licence renewed upto:

File No.....Date of application.....

Fee remitted.....

Signature of Licensing Authority

**FORM No. 11**

Permit to purchase/possess poisons for professional use Shri/Smt./Madam/M/s.....

.....

..... is

permitted to purchase/possess the following poison.

Name of poisons

Quantity permitted to be purchased/possessed at the time

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

Name of person in-charge of stock of poisons.

Permit No

Date:

### **Conditions**

1. The poison shall be purchased from licensed dealers as per the Rules.
2. The poison shall be stored under proper storage condition as prescribed in the Rules.
3. Records of nature of disposal of the poison and stock registers shall be maintained.
4. An Inspector appointed under these Rules shall be permitted to inspect premises and the Records as and when required.

The undersigned certified that notices have been promulgated or observed on the persons interested and that evidence for such promulgation or service forms part to the records.

Licensing Authority.

## **XIV. Matters related to ND3 permit**

The Drugs Control Department issues allotment order for procuring Narcotic drugs like Pethidine and morphine injections, fentanyl citrate and Sufentanyl Citrate injections for institutions and practitioners whose names have entered in the register under NDPS Rules.

Procedure for issuing essentiality certificate for the purpose of grant of ND3 permit by the Excise Department for te multispeciality hospitals

For issuing the permit the essentiality certificate from this department is essential.

Documents required

- Request with court fee stamp worth Rs 5 affixed to the Drugs Controller.
- Details of total bed strength ,total number of operations, details of specialities, details of drug licence and quantity of narcotic drugs required.

Documents required for issuing allotment order for procuring narcotic drugs (Pethidine Hydrochloride injection,Morphine sulphate injection,fentanyl Citrate injection and Sufentanyl citrate injectection)

- Request with court fee stamp worth Rs 5 affixed to the concerned Assistant Drugs Controller.
- Copy of ND3 permit duly renewed.

- Statement of consumption of Narcotic drugs for the period after procuring the last consignment duly signed by the authorized medical officer.

#### Approval of Recognized Medical Institutions(RMIs)

This approval is necessary for procurement of morphine solutions and tablets in the palliative care institutions. This is done primarily by using the machinery of the Drugs Controller. But the advisory panel of palliative care physicians will assist this process.

#### Minimum requirements

- There should be one doctor with a minimum of 10 days of 'hands on' training in pain relief and use of morphine from an approved centre.
- There should be one nurse or pharmacist or nursing auxiliary with a minimum of 10 days 'hands on' training in pain relief and use of morphine from an approved centre.
- There should be adequate space for caring for patients.
- There should be adequate provision for safe storage of morphine and for adequate documentation of receipts and disposal.

Based on the recommendation of the advisory panel of palliative care physicians approval as RMI is issued by the Drugs Controller.

There is no objection to RMIs holding injection morphine provided they possess necessary permit from the Excise Department.

There is no objection to buy Sustained Release Morphine (other formulations of morphine that are not manufactured in Kerala) from other States.

### **XV. Information available from the Department**

- a. List of banned drugs.
- b. List of Not of Standard Quality drugs.
- c. List of spurious drugs and adulterated drugs.
- d. Condition for safe blood donation and blood storage.
- e. Information regarding Good Manufacturing Practice.
- f. Information regarding Good Laboratory Practices.
- g. Information regarding new drugs.
- h. Information regarding safe usage of drugs.

- i. List of medical shops in Kerala.
- j. List of manufacturing firms (including allopathic, ayurvedic & homoeopathic units).
- k. List of blood banks and blood storage centres.
- l. List of Recognized Medical Institutions.
- m. List of drugs exceeding the ceiling price fixed by National Pharmaceutical Authority.
- n. List of irrational combination
- o. List of firms against which legal action is initiated by the department.
- p. List of firms against which departmental action has been .

## **XVI. Solutions to Public Problems**

This department is taking appropriate actions for offenders who has-

- 1. Sold the date expired drugs.
- 2. Sold the banned/Not of Standard/Adulterated drugs.
- 3. Stocked/sold drugs not stored in accordance with the labelled requirements.
- 4. Sold the drugs on excess price.
- 5. Sold/stocked government drugs or other stores.
- 6. Stocked/sold/manufactured drugs without drug licence on complaints

Actions against publishing false and misleading advertisement of drugs, diseases and disorders listed below are also taken by this department.

### **Schedule. J**

**Diseases and ailments (by whatever name described) which a drug may not purport to prevent or cure or make claims to prevent or cure.**

- 1. AIDS
- 2. Angina Pectoris
- 3. Appendicitis
- 4. Arteriosclerosis
- 5. Baldness
- 6. Blindness
- 7. Bronchial Asthma
- 8. Cancer and Benign tumour
- 9. Cataract
- 10. Change in colour of the hair and growth of new hair.
- 11. Change of foetal sex by drugs.
- 12. Congenital malformations
- 13. Deafness
- 14. Diabetes
- 15. Diseases and disorders of uterus.
- 16. Epilepticfits and psychiatric disorders



17. Encephalitis
18. Fairness of the skin
19. Form, structure of breast
20. Gangrene
21. Genetic disorders
22. Glaucoma
23. Goitre
24. Hernia
25. High/low Blood Pressure
26. Hydrocele
27. Insanity
28. Increase in brain capacity and improvement of memory.
29. Improvement in height of children/adults.
30. Improvement in size and shape of the sexual organ and in duration of sexual performance
31. Improvement in the strength of the natural teeth.
32. Improvement in vision
33. Jaundice/Hepatitis/Liver disorders
34. Leukaemia
35. Leucoderma
36. Maintenance or improvement of the capacity of the human being for sexual pleasure.
37. Mental retardation, subnormalities and growth
38. Myocardial infarction
39. Obesity
40. Paralysis
41. Parkinsonism
42. Piles and Fistulae
43. Power to rejuvenate
44. Premature ageing
45. Premature greying of hair
46. Rheumatic Heart Diseases
47. Sexual Impotence, Premature ejaculation and spermatorrhoea
48. Spondylitis
49. Stammering
50. Stones in gall-bladder, kidney, bladder
51. Varicose Vein.

The actions from the department include –

1. Suspension of licences.
2. Cancellation of licences.
3. Warning to the licences.
4. Prosecution action.

## **(2) The Testing Wing –**

The testing wing is functioning at the Drugs Testing Laboratory, Thiruvananthapuram. The testing wing is responsible for testing/analysis of allopathic drugs, cosmetics, homeopathic drugs and ayurvedic drugs.

This is done by

- (iii) Allocating the samples received in the concerned section depending on the tests to be performed.
- (iv) Reporting the tests and results, in the prescribed form and forwarding it to the concerned drugs inspection without delay.
- (v) Testing the samples produced by the public.

- The analytical report of allopathic drugs are sent to the drugs inspector in form 13 of Drugs & Cosmetic Rules 1945

### FORM 13

(See rule 46)

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

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

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

Date.....

*Government Analyst.*

---

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

The analytical report ayurvedic drugs are issued in form 13 A of Drugs and Cosmetic Rules 1945.

<sup>1</sup>[FORM 13A

[See rule 163 (5)]

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

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

*Date.....*

*Government Analyst..*

---

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

Unless the sample has already been tested or analysed in the Central Drugs Laboratory, the analytical report of the Drugs Testing Laboratory is treated as conclusion. In other cases the analytical report of the Director, Central Drugs Laboratory is issued in the form 2 of Drugs and Cosmetics Rules 1945.

**FORM 2**

(See rule 6)

*Certificate of test or analysis by the Central Drugs Laboratory*

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

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

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

Date.....

*Director*

*Central Drugs Laboratory or other authorised officer*

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

Date.....

*Director*

*Central Drugs Laboratory or other authorised officer*

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

**The documents required for applying for approval of institutions for carrying out tests on drugs, cosmetics and raw materials used in their manufacture on behalf of licences for manufacture for sale of drugs.**

1. Covering letter with court fee stamp with Rs. 5/- affixed.
2. Form 36 (Refer Statutory forms)).
3. Chalan of Rs. 7500/- remitted under the Head of Account 2210-04-104-99.
4. Details of constitution of the firm/company.
5. Affidavit for proving occupancy and constitution of the firm/company/proprietor ship.
6. List of equipments provided.
7. Attested copy of qualification certification, experience certificate etc. Of the technical staff.
8. Plan of the building above testing has been

The duration of the licence will be 5 years from the state of grant of licence.

The approved institutions shall furnish the reports of the result of test/analysis in form 39 (Refer Statutory forms) of the Drugs & Cosmetic Rules 1945.

**SCHEDULE B**

*Fees for test or analysis by the Central Drugs Laboratories or State Drugs Laboratories for various categories of drugs*

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

Rupees

Adrenocorticotrophic hormone assay	1000
Gonadotrophic hormone for LH activity	1000
FSH Activity	1000
Posterior pituitary extract or its synthetic substitute for oxytocin activity	400
Vasopressor activity	400

Insulin and insulin in combination for hypoglycaemic activity	2000
Hyaluronidase	500
Glucagon	2000
Heparin for anticoagulant activity	600
Protamine sulphate	300
Depressor or Histamine like substance	300
Pyrogen test	500
Antigenicity or foreign protein test	300
Abnormal or undue toxicity or safety test	200
Determination of Lethal doses, LD <sub>10</sub> or LD <sub>50</sub> in mice	800
Skin sensitivity/eye irrigation	250
Implantation test	2000
<b>2. Microbiological tests and assays -</b>	
Bioassay of Antibiotic	400
Microbiological assay of vitamins	300
Phenol coefficient	300
Preservatives – Microbial challenge test	2000
Sterility test – Parenteral preparations	100
Surgical dressings	200
Syringes and needles	300
Transfusion and infusion sets or assemblies	
Other sterile devices	400

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### **3. Identification tests -**

(a) Chemical Methods	50
(b) Microscopical	50
(c) IR Spectroscopy	150
(d) UV Spectroscopy	100
(e) Chromotography	
(i) Paper	100
(ii) Thin layer	150
(iii) Column	100
(iv) GLC	250
(v) HPLC	500
(vi) Gel Filtration	300
(f) Electrophoresis	
(i) Paper and Cellulose acetate	200
(ii) Polyacrylamide Gel, starch gel, agar gel	300 each

### **4. Physical tests –**

(a) Optical rotation, specific gravity, refractive index, weight per ml, fluorescence.	75 each
(b) Viscosity	100
(c) pH, Solubility, loss on drying, net content, ash, sulphated ash etc.	20 each
(d) Absorbancy, wt/unit area (surgical), foreign matter, extractive value, thread count etc.	30 each
(e) Uniformity of weight	
(i) Tablets	15
(i) Capsules	20
(f) Acid value, iodine value, peroxide value, Saponification value, acetyl value.	100 each

(g) Disintegration tests –	
(i) Ordinary tablets	20
(ii) Capsule	30
(iii) Sugar Coated tablets	50
(iv) Enteric coated tablets	100
(h) Dissolution test	250
(i) Uniformity of content.	500
(j) Wt. per unit area (powder), particle size, count, methoxy value.	200 each
(k) Limit test for impurities	100 each
(l) Related substances	
(i) T LC method	
(A) Without reference standard	150
(B) With reference standard	250
(ii) Gas Liquid Chromatography	
(A) Without reference standard	250
(B) With reference standard	350
(iii) High pressure Liquid Chromatography	100
(A) Without reference standards	500
(B) With reference standards	500
(m) Water (Karl Fisher)	200
<b>(5) Assays -</b>	
(a) General chemical methods	100 for each ingredient
(b) Non-aqueous/instrumental	200 for each ingredient
(c) Chromatography	
(i) TLC	250



(ii) Column	200
(iii) GLC	350
(iv) HPLC	500
(v) Gel filtration	400
(d) Nitrogen determination	200
(e) Medicinal gases	400
<b>(6) Polymorph test –</b>	
(Content of polymorph A in chloramphenicol palmitate)	300
Surgical sutures (Depending on number of tests to be carried)	200-500
Other miscellaneous tests	100-500
<i>II Fees for Sera and Vaccine –</i>	
Sterility test	100
Abnormal toxicity test	400
Specific toxicity test	800
Inactivation test (Rabies)	200
Potency testing of rabies vaccine	2025
Potency testing of pertussis fraction of DPT vaccine	2025
Potency testing of tetanus fraction of DPT/DT/TT vaccine	2500
Potency testing of diphtheria Fraction of DPT/DTE vaccine.	2700
Testing of antisera for the specific titre	1000
Potency testing measles/Mumps/Rubella vaccine	760 each
Testing of Oral Polio Vaccine (OPV) –	
Potency	4550
Identity	1000
Stability	800
Potency testing of Japanese Encephalitis Vaccine	3900
Potency testing of Snake Venom serum	400 for each venom

Identity testing for vaccines/sera	
Cell culture (Other than OPV)	400
Other than cell culture	100
Estimation of volume/pH/total solids/No. of organisms/Physical checking.	50 each
Estimation of total proteins/aluminium content/phenol/formaldehyde/thiomersal/moisture	200 each
Pyrogen testing	500
Stability test for vaccines other than Oral Polio Vaccine	4550
<b>III</b>	
<i>Cosmetics</i>	400 – 1500
(The exact amount of the fee shall be determined by the Director of Laboratory or the Government Analyst, as the case may be).	
<i>IV Rubber Condoms</i>	1000
<i>IV Homoeopathic medicines:</i>	
1. Identification test for raw material of botanical origin (other than assay of constituents).	125
2. Identification test for raw material of chemical origin (other than assay)	100
3. Limit test for drugs of chemical origin	150
4. Assay of total alkaloids or of drugs of chemical origin	100
5. Identification test for drugs of animal origins or microbiological.	100
6. Fees for testing of Mother tincture, lower potencies upto 3x or equivalent.	100
7. U.V. or I.R. or H.P.C.L. defect determination	75
Determination of Biochemic drug through atomic absorbance spectrophotometer.	75

**Note :-**

1. For tests not listed in the Schedule, charges will be determined by the Director or

the Government Analyst of the laboratory / institute as the case may be.

2. For the tests relating to Ayurvedic, Unani and Siddha medicines, charges will be determined by the Adviser (Indigenous System of Medicine), Director or Government Analyst of the Laboratory / Institute, as the case may be.]

## **Analysis**

In order to improve the quality of analysis a central expert committee conducts regular inspections. The DTAB monitors the functions of the department.

## **Dos and Don'ts for Dealers and Public**

### Dealers

	Dos	Don'ts
1	Check the validity of your drugs Licences.	Do not sell/distribute drugs if your drugs licence is not valid.
2	Any change of constitution of the firm necessitates taking a fresh Drugs Licence within 3 months of the change.	Do not procure drugs from unknown sources.
3	Always procure drugs against a cash /credit memo.	Do not sell / distribute drugs without cash/credit memos.
4	Ensure that supplier possesses valid Drug licences.	Do not stock drugs in any place which is not licenced.
5	You are required by law to know the identity of the supplier.	Do not switch off your refrigerator at nights.
6	Ensure cold chain for drugs requiring cold storage.	Do not expose drugs to moisture, light and heat.
7	Ensure proper storage of drugs in your sales premises.	Do not purchase, stock or sell a drug which does not have a proper label.
8	Ensure uninterrupted power supply to your cold storage system. Constant thawing and cooling damages the drug faster.	Do not sell any drug at a price exceeding the notified/printed/labeled price which ever is less plus tax.
9	Try to know the details of banned drugs/drugs declared as not of standard quality. Try to know the notified prices of drugs. Watch for public notices in these matters.	Do not substitute prescribed drugs. Do not use the licenced premises for keeping poisons, observation materials, meat, manures, vegetables etc.
10	Ensure validity of full time Competent person/Pharmacist.	Do not dispense such human drugs without prescription.
11	Maintain proper records for all your transactions. Maintain hard copies duly authenticated for records.	Do not purchase drugs if the label is tampered.

Public

	Dos	Don'ts
1	Always insist on a cash/credit memo for all purchases.	Do not purchase a drug with out a label or a tampered label or labels with 1. Stickers pasted 2. Tone prints 3. Erased
2	Purchase medicines from known medical shops as far as possible.	Do not purchase Schedule X and H drug with out a prescription. It is dangerous to resort self medication.
3	Check the labels of the drug.	Do not enter in to quarrels with doctors. Bring to the notice of the Dept., any suspected irregularity.
4	Always produce the original prescription of the doctor.	Do not purchase medicines on the basis of advertisements.
5	Check the market price of the drug and the amount charged.	
6	Note whether dispensing is done under the supervision of a Registered Pharmacist	
7	Always purchase whole strips and sealed bottles.	

**XVII. Where to apply for licences**

Sl no	District	Address	Phone No	Details of licences
1	office of the Drugs Controller , Red Cross Road, 95035Thiruvananthapuram		0471-2471896	Manufacturing licences of and various certificates pertaining to manufacturing of Drugs in the State
1	Thiruvananthapuram	office of the Assistant Drugs Controller, Jyotsna, Athani Junction, Vanchiyoor, Trivandrum-695035	0471-2470507	sales licences
2	kollam	Office of the Assistant	0474-	Sales licences of

		drugs controller/ Drugs Inspector, Mananiya Shopping complex, 2 <sup>nd</sup> Floor, Andamukkom , Chinnakada, Kollam-691001	2741856	Kollam Dist, and Manufacturing Licences of Kollam, Kottayam, and Pathanamthitta
<u>3</u>	<u>Pathanamthitta</u>	Office of the Drugs Inspector, Akkarakunath u Building, Near KSRTC Bus Stand, Pathanamthitta-689645	0468-2270236	Sales licences
<u>4</u>	<u>Kottayam</u>	Office of the Drugs Inspector, Mini Civil Station, Thirunakkara, Kottayam.-686001	0481-2303380	Sales licences
<u>5</u>	<u>Ernakulam</u>	Office of the Assistant drugs controller/ Drugs Inspector, Civil station, Kakkanadu, Kochi.-682030	0484-2422819	Sales licences of Ernakulam Dist, and Manufacturing Licences of Ernakulam Alappuzha and Idukki
<u>6</u>	<u>Idukki</u>	Office of the Drugs Inspector Kattapana, Idukki-685508	04868-224562	Sales licences
<u>7</u>	<u>Alappuzha</u>	Office of the Drugs Inspector, Our Building Zilla Court Road, Thathampally Post Alappuzha-688013	0477-2230649	Sales licences
<u>8</u>	<u>Thrissur</u>	Office of the Assistant drugs Controller, Cheroor Ramanilayam Junction shopping Complex, 2 <sup>nd</sup> floor, Near Jawahar Balabhavan, Chempookkavu, Thrissur-680020	0487-2320591	Sales licences of Thrissur Dist, and Manufacturing Licences of Thrissur and Palakkad
<u>9</u>	<u>Palakkad</u>	Office of the Drugs Inspector, Municipal	0491-2503643	Sales licences

		Building, Opposite Dist Hospital, Court road, Palakkad-678001		
<u>10</u>	<u>Kozhikode</u>	Office of the Assistant drugs controller/ Drugs Inspector, Civil Station , Kozhikode-673020	0495-2371184	Sales licences of Kozhikode Dist, and Manufacturing Licences of Kozhikode, Malapuram and Wayanad.
<u>11</u>	<u>Malappuram</u>	Office of the Drugs Inspector, Civil Station, Malappuram-676505	0483-2735287	Sales licences
<u>12</u>	<u>Wayanad</u>	Office of the Drugs Inspector Pallithazham Road, Kalpetta, Wayanad-673121	04936-202790	Sales licences
<u>13</u>	<u>Kannur</u>	Office of the Assistant drugs Controller/ Drugs Inspector, Kakkad Road, Kannur.-670002	0497-2707499	Sales licences of Kannur Dist, and Manufacturing Licences of Kannur, and Kasargode.
<u>14</u>	<u>Kasargode</u>	Office of the Drugs Inspector, Avikkara, Kanhangad, Kasargode.-671315	0467-2286260	Sales licences

# STATUTORY FORMS

**FORM 19AA**

(See rule 62C)

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

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

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

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

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

Date \_\_\_\_\_

Signature \_\_\_\_\_

\*Delete if not required.

1. Ins. by. Notfn.No.X.11013/7/76-DandMS, dt. 25.1.1979.

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

**FORM 19B**

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

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

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

Name .....

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

Date.....

. Signature .....

\*Delete whichever is not required.

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



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

1. I/We\* ..... of.....hereby apply for a licence to sell by \*wholesale/\*retail drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945. We operate a pharmacy on the premises, situated at .....
  2. \*\* The sale and dispensing of drugs will be made under the personal supervision of the registered pharmacists mentioned below:-  
(Name) ..... (Qualification)  
(Name) .....(Qualification)
  3. Name of drugs to be sold.
  4. \*\*\* Particulars of storage accommodation.
  5. A fee of rupees .....has been credited to Government account under the head of account.....  
Date..... . Signature .....
- \* Delete whichever is not applicable.*  
*\*\* To be deleted if drugs will be sold only by wholesale.*  
*\*\*\*Required only if products requiring special storage are to be sold.]*
- 

**FORM 20**

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

1. .... is hereby 1[licensed to sell, stock or exhibit or offer for sale, or distribute] by retail drugs other than those specified in 2[Schedules C, C (1) and X] of the Drugs and Cosmetics Rules 1945, \*and to operate a pharmacy on the premises situated at..... subject to the conditions specified below and to provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.
- 2 The licence shall be in force from.....to .....
3. Name (s) of registered pharmacist(s) in charge .....
4. Categories of drugs.....  
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 of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.
3. The licensee shall report to the Licensing Authority any change in the qualified staff in charge within one month of such change.  
*Drugs and Cosmetics Rules, 1945 191*
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.

---

**FORM 20A**

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

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

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

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

<sup>4</sup>\* \* \* \* \*

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

Date.....

Licensing Authority

*Conditions of Licence*

1. This licence shall be displayed in a prominent place in a part of the premises open to the public. <sup>3</sup>\* \* \*.

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

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

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

---

**FORM 20B**

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

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

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

<sup>3</sup>[3. The sale shall be made under the personal supervision of a competent person

(Name of the competent person.)]  
Date..... Licence No.....

Licensing Authority.

*Conditions of Licence*

1. This licence shall be displayed in a prominent place in part of the premises open to the public.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.
- 4[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 <sup>1</sup>[licence to sell, stock or exhibit for sale, or distribute] the drug. Provided that this condition shall not apply to the sale of any drug to—  
(a) an officer or authority purchasing on behalf of Government, or  
(b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or  
<sup>5</sup>[(c) a manufacturer of beverages, confectionery 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.

**<sup>1</sup>[FORM 20BB**

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

1 . ..... i s h e r e b y <sup>2</sup>[l i c e n s e d to sell, stock or exhibit or offer for sale by wholesale, or distribute] drugs other than those specified in Schedule C and Schedule C(1) from the vehicle bearing registration no. \_\_\_\_\_ assigned under under Motor Vehicles Act, 1939, subject to the conditions specified below and to the *Drugs and Cosmetics Rules, 1945* 193

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

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

3. Categories of drugs.....

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

Licensing Authority.

*Conditions of Licence*

1. This licence shall be displayed in a prominent place on the vehicle.
  2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.
  - 3 (i) No drugs shall be sold by wholesale or distributed unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.  
(ii) No sale by wholesale or distribution of any drug shall be made to a person not holding the requisite <sup>2</sup>[l i c e n s e d to sell, stock or exhibit or offer for sale by wholesale, or distribute] the drug:  
Provided that this condition shall not apply to the sale of any drug to—  
( a) an officer or authority purchasing on behalf of the Government, or  
( b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or  
(c) a manufacturer of beverages, confectionery, biscuits and other non-medical products, where such drugs are required for processing these products.
  4. The licensee shall inform the Licensing Authority in writing in the event of change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.
  5. The licensee shall inform the Licensing Authority in writing in the event of any change in ownership of the vehicle specified in this licence within seven days of such change.
- 

<sup>1</sup>[FORM 20-C

<sup>2</sup>[Licence to sell, stock or exhibit or offer for sale, or distribute] Homoeopathic medicines by retail

1. ....is hereby <sup>2</sup>[l i c e n s e d to sell, stock or exhibit or offer for sale by wholesale, or distribute]by retail Homoeopathic medicines on the premises situated at.....subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

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

3. Name of the competent person in-charge.

Date.....

*Licensing Authority*

*Conditions of Licence*

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

2. The licensee shall comply with the provisions applicable to homoeopathic *Drugs and Cosmetics Rules, 1945* 194 medicines under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.

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

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

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

---

**1[FORM 20D**

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

1. .... is hereby 3[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale Homoeopathic medicines on the premises situated at.....subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

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

*Licensing Authority.*

*Conditions of Licence*

1. This licence shall be displayed in a prominent place on the premises.
  2. The licensee shall comply with the provisions as applicable to Homoeopathic medicines under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.
  3. No sale of any drug shall be made to a person not holding the requisite 2[l i c e n s e d to sell, stock or exhibit or offer for sale, or distribute] the drug. Provided that this conditions shall not apply to the sale of any drug to (a) an authority purchasing on behalf of Government, or (b) a hospital, medical, educational or research institute or a Homoeopathic medical practitioner for the purpose of supply to his patients.
- 3[4 The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence and the current licence shall be valid only for a period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.]
- 

**1[FORM 20E**

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

1. Number of licence and date of issue .....  
*Drugs and Cosmetics Rules, 1945 195*

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

2. Name of competent persons in-charge.

Date..... *Licensing Authority.*

---

**1[FORM 20F**

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

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

2. Names of drugs.

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

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

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

*Date:*.....

*Licence No.*.....

Licensing Authority.

*Conditions of the licence.*

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

2. The licensee shall 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**

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

1. ....is hereby 2[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale drugs specified in Schedule X to the Drugs and Cosmetics Rules, *Drugs and Cosmetics Rules, 1945* 196

1945 on the premises situated at.....

2. Names of drugs.....

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

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

*Date:*.....

*Licence No.*.....

*Licensing Authority.*

*Conditions of the licence.*

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the rules made there under.
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 <sup>2</sup> [licence to sell, stock or exhibit or offer for sale, or distribute] drugs specified in Schedule X :

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

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

<sup>3</sup> [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

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

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

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

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

*Drugs and Cosmetics Rules, 1945* 197

<sup>3</sup>[4. Categories of drugs .....]

Date.....

*Licensing Authority*

*Licence No* .....

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

2[excluding those specified in Schedule X] but not included in this licence, he should apply to the Licensing Authority for the necessary permission. This licence will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the licence by the Licensing Authority.

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.

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**FORM 21A**

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

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

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

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

Name of dealer(s)..... Licence No.....

Date.....

*Licensing Authority*

*Conditions of Licence.*

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

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

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

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

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**FORM 21B**

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

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

*Categories of drugs*

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

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

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

*Licence No .....*

*Date.....*

*Licensing Authority.*

*Conditions of Licence*

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

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

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

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

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

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

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

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

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

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

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

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

3. Categories of drugs .....

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

*Licensing Authority.....*

*Conditions of licence*

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

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

3. If the licensee wants to sell by wholesale or distribute during the currency of the licence, additional categories of drugs listed in Schedules C and C (1) not included *Drugs and Cosmetics Rules, 1945* 200

in this licence, he shall apply to the Licensing Authority for necessary permission.

This licence shall be deemed to extend to the categories of drugs in respect of which such permission is given. This shall be endorsed on the licence by the Licensing Authority.

4. (i) No drugs shall be sold by wholesale or distributed unless such drug is purchased under a cash or credit memo from a duly licensed manufacturer.

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

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

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

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

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

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

6. The licensee shall inform the Licensing Authority in writing in the event of any change in the ownership of the vehicle specified in this licence within seven days of such change.

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

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

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

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

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

Date..... *Licensing Authority.*

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**FORM 21CC**

*Certificate of renewal of <sup>1</sup>[licence to sell, stock or exhibit or offer for sale by wholesale, or distribute] drugs from a motor vehicle*

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

1. Certified that licence no.....in Form 20-BB or Form 21-BB granted on the .....to.....for sale by wholesale or *Drugs and Cosmetics Rules, 1945* 201

distribution of the following drugs from the vehicle bearing registration

No..... assigned under the Motor Vehicles Act, 1939 has been renewed for a period from.....to .....

2. Categories of the drugs:

.....

.....

Date.....

*Licensing Authority.*

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**FORM 24**

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

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

2. Names of drugs categorized according to Schedule M.

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

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

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

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

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**FORM 24A**

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

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

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

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

3. I/We enclose—

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

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

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

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

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

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

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

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

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**FORM 24B**

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

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

2. Names of the drugs to be repacked.....

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

4. A fee of rupees ..... 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.

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**<sup>1</sup>[FORM 24C**

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

3[1. I / We\* ..... of ..... holder of licence  
no ..... in Form 20-C hereby apply for the grant/renewal of  
licence to manufacture the undermentioned Homoeopathic mother tinctures/potentised  
preparations on the premises situated at.....  
Name of the Homoeopathic preparations .....  
(Each item to be separately specified)].  
2. Names, qualifications and experience of technical staff employed for manufacture and  
testing of Homoeopathic medicines.  
3. A fee of rupees ..... has been credited to Government under head  
of account .....  
Date.....  
Signature.....

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

**1[FORM 24D**

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

1. I/We .....of.....hereby apply for the  
grant / renewal of a licence to manufacture Ayurvedic (including Siddha) or Unani drugs on  
the premises situated at.....  
2. Names of drugs to be manufactured (with details)  
3. Names, qualifications and experience of technical staff employed for manufacture and  
testing of Ayurvedic (including Siddha) or Unani drugs .....  
4. A fee of rupees ..... has been credited to the Government under the head  
of account ..... and the relevant Treasury Challan is enclosed herewith.  
Date..... Signature.....  
(applicant)

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

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**1[FORM 24E**

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

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

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

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

4. I / We\* enclose,

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

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

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

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

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

*(applicant)*

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

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

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

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**FORM 24F**

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

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

2. Names of drugs.

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

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

*Signature .....*

*Date:..... Designation .....* ]

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**FORM 25**

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

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

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

(a) <sup>2</sup>[Competent technical staff].(Names).....

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

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

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

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

<sup>4</sup>[Date].....

Signature .....

Designation .....

Licensing Authority\_\_\_\_\_

\*Central Licence Approving Authority.]

*Conditions of Licence*

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

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

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

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

*Loan* <sup>1</sup>[*licence to manufacture for sale or for distribution of*] *drugs other than those specified*  
*In* <sup>2</sup>[*Schedules C and C (1) and X*]

1. Number of licence and date of issue .....
- 2..... of ..... is hereby granted a loan licence to manufacture the following drugs other than those specified in <sup>2</sup>[Schedules C and C(1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated at C/o under the direction and supervision of the following <sup>2</sup>[competent technical staff]:
  - (a) <sup>2</sup>[competent technical staff]. (Names):.....
  - (c) Names of drugs .....
3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.
4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.  
*Date*..... *Signature*... ..  
*Designation*.. ..

*Conditions of Licence*

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the <sup>3</sup>[competent technical staff] named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to undertake during the currency of the licence the manufacture for of sale additional drugs he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in Rule 69-A. This licence will be deemed to extend to the drugs so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

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**FORM 25B**

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

Number of licence and date of issue.

1. .... of ..... is hereby granted a licence to repack the following drugs for sale or distribution on the premises situated at..... under the supervision of the following competent staff.  
*Drugs and Cosmetics Rules, 1945 207*
  - (a) Names of drugs to be repacked.
  - (b) Names of competent staff.



2. The licence shall be in force from..... to.....
3. The licence authorises the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs repacked under the licence subject to conditions applicable to licences for sale.
4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date.....

Signature.....

*Conditions of Licence*

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

**FORM 25C**

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

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

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

Names of the Homoeopathic preparations.

*(Each item to be separately specified).*

Names of the Technical Staff..... ]

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

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

Designation....

*Conditions of Licence*

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
  2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.
  3. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.]
- \*Delete the words “who holds a licence in Form 20C” in case this is not applicable.*

**1[FORM 25D**

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

No. of Licence.....

1. .... is / are hereby licensed to manufacture the following Ayurvedic (including Siddha) or Unani drugs on the premises situated at..... under the direction and supervision of the following technical staff: —
    - (a) Technical staff (Names)
    - (b) Names of drugs (each item to be separately specified).
  2. The licence shall be in force from.....to .....
  3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.
- Date: ..... Signature.....*  
*Designation .....*

*Conditions of Licence*

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

**1[FORM 25E**

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

1. Number of Licence.....
  - 2 .....of. ....is hereby granted a loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani drugs, on the premises situated at .....C/o.....under the direction and supervision of the following expert technical staff:
    - (a) Technical staff (Names).....
    - (b) Names of drugs (each item to be separately specified)
  3. The licence shall be in force from.....to.....
  4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.
- Date of Issue*.....  
*Signature* .....  
*Designation*.....

*Conditions of Licence*

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

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**1[FORM 25F**

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

1. ....of.....is hereby licensed to manufacture at the premises situated at .....the following drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945.  
*Drugs and Cosmetics Rules, 1945* 210
2. Names of drugs.
3. Names of approved 3[competent technical staff]
4. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale.
5. The licence shall be in force ..... to.....
6. The licence is subject to conditions stated below and to other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act,

1940.

<sup>4</sup>[Date ..... Signature .....

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

\_\_\_\_\_ \*Licensing Authority

Central Licence Approving Authority.]

\*Delete whichever portion is not required.

*Conditions of Licence*

1. The licence and any certificate of renewal in force shall be kept on the licensed premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule X not included above, he should apply to the Licensing Authority for the necessary endorsement of this licence. This licence shall be deemed to extend to only those items so endorsed.
3. Any change in the <sup>3</sup>[competent technical staff] shall be forthwith reported to the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.
5. The licensee shall furnish to the Licensing Authority copies of the invoices of sales made to dealers.
6. The licensee shall not manufacture drugs covered by this licence for use as 'Physician's Samples'.]

**<sup>1</sup>[FORM 26**

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

1. Certified that licence No ..... granted on the.....to ..... for the manufacture of the following categories of drugs being

\*drugs other than those specified in Schedules C, C (1) and X\_\_\_\_\_

\*drugs specified by Schedules C and C (1) excluding those specified in Schedule X

to the Drugs and Cosmetics Rules, 1945, at the premises situated at .....

..... has been renewed from..... to.....

2. Name(s) of approved <sup>2</sup>[competent technical staff] .....

*Drugs and Cosmetics Rules, 1945 211*

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

Signature .....

<sup>4</sup>[Date.....

Designation.....

\_\_\_\_\_ \*Licensing Authority

\*Central Licence Approving Authority.]

\*Delete whichever portion is not required.

**FORM 26A**

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

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

at.....C/o .....has been renewed from ..... to.....

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

3. Names of the approved <sup>1</sup>[competent technical staff]

Signature.....

Designation.....

<sup>2</sup>[Date .....

.....\*Licensing Authority

\*Central Licence Approving Authority.]

\* Delete whichever is not applicable.

**<sup>1</sup>[FORM 26B**

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

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

to .....

Names of drugs to be repacked.....

2. Names of competent staff. ....

<sup>3</sup>[Date : ..... Signature.....

Designation.....

Drugs and Cosmetics Rules, 1945 212

\*Licensing Authority.

\*Central licence Approving Authority.]

\* Delete whichever is not applicable.]

**FORM 26C**

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

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

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

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

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

Designation.....

---

**1[FORM 26D**

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

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

2. Names of technical staff .....

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

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

---

**FORM 26E**

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

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

*Drugs and Cosmetics Rules, 1945 213*

2 Names of technical staff.

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

**1[FORM 26E1**

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

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

This certificate is valid for a period of three years.

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

Place : . . . . Designation.....

Licensing Authority for Ayurveda/ Siddha/ Unani Drugs.]

---

**1[FORM 26F**

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

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

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

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

3[Date: .....

Signature.....

Designation.....

\_\_\_\_\_ \*Licensing Authority

\*Central Licence Approving Authority.]

\* Delete whichever is not applicable.

---

**1[FORM 26G**

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

1. Certified that Licence No..... granted on ..... to  
Drugs and Cosmetics Rules, 1945 214

M/s..... for the operation of a Blood Bank for  
processing of whole human blood and\*/or for preparation of its components at the  
premises situated..... is hereby renewed with effect  
from..... to .....

2. Name(s) of items :

1.

2.

3.

3. Name(s) of competent Technical Staff:

1.

2.

3.

4.

5.

6.

Dated.....

Signature .....

Name and Designation.....

\_\_\_\_\_ Licensing Authority.

Central Licence Approving Authority.]

---

**1[FORM 26H**

*Certificate of renewal of licence to manufacture for sale of Large Volume Parenterals/Sera and Vaccines specified in Schedules C and C(I) excluding those specified in Schedule X*

1. Certified that licence No..... granted on the ..... to ..... for the manufacture of following Large Volume Parenterals/Sera and Vaccines at the premises situated at..... has been renewed from.....to.....

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

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

1. 1.
2. 2.
3. 3.
4. 4.

*Drugs and Cosmetics Rules, 1945 215*

*Signature: .....*

*Designation: .....*

\_\_\_\_\_Licensing Authority

Central Licence Approving Authority

*Date: .....*]

---

**1[FORM 26-I**

*Certificate of renewal of licence for manufacture of blood product.*

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

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

- 1.
- 2.
- 3.

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

1. 1.
2. 2.
3. 3.
4. 4.

*Signature .....*

*Designation.....*

\_\_\_\_\_Licensing Authority

Central Licence Approving Authority

*Date .....*



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

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

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

*Drugs and Cosmetics Rules, 1945 216*

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

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

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

3. The premises and plan are ready for inspection\_\_\_\_\_ will be ready for inspection on

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

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

*Designation*.....

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

---

**FORM 27A**

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

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

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

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

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

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

3. I /We enclose:

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

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

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

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

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

*Designation*.....

*Drugs and Cosmetics Rules, 1945 217*

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

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

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

---

**1[FORM 27B**

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

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

2. Names of drugs.

3. The names, qualifications and experience of the expert staff responsible for the manufacture and testing of the 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 of rupees ..... and an inspection fee of rupees .....has been credited to the Government under the head of account .....

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

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

\* Delete whichever is not applicable.

---

**1[FORM 27C**

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

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

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

1.

2.

3.

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

(a) Name(s) of Medical Officer.

*Drugs and Cosmetics Rules, 1945 218*

(b) Name(s) of Technical Supervisor

(c) Name(s) of Registered Nurse.

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

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

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

..... (receipt enclosed)

*Signature .....*

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

\* Delete whichever is not applicable.

**Notes:**

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

**1[FORM 27D**

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

1. I/We ..... of .....hereby apply for grant/renewal of a licence to manufacture for sale or distribution on the premises situated at.....the under-mentioned Large Volume Parenterals/Sera and Vaccines, specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945.
2. Name(s) of drug(s) .....  
(each item to be separately specified).
3. The name(s), qualifications and experience of the competent technical staff responsible for the manufacture of the above mentioned drugs.  
(a) Name(s) of staff responsible for testing .....  
(b) Name(s) of staff responsible for manufacturing .....
4. The premises and plant are ready for inspection/will be ready for inspection on.....
5. A fee of rupees ..... and an inspection fee of rupees .....has been credited to the Government under the Head of Account.....

*Date: .....*

*Signature .....*

*Designation.....*

*\*Delete whichever is not applicable.*

**Notes:**

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

**1[FORM 27E**

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

1. I/We ..... of M/s ..... hereby apply for the grant of licence/renewal of licence number ..... dated..... to manufacture Blood products on the premises situated at .....
2. Name(s) of the item(s)
  - 1.
  - 2.
  - 3.
  - 4.
3. The name(s), qualification and experience of competent Technical Staff are as under:
  - (a) responsible for manufacturing (b) responsible for testing
    1. 1.
    2. 2.
    3. 3.
4. The premises and plant are ready for inspection/will be ready for inspection on.....
5. A licence fee of rupees .....and an inspection fee of rupees ..... has been credited to the Government under the Head of Account..... (receipt enclosed)

*Signature .....*

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

*\* Delete whichever is not applicable.*

**Notes:**

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

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**FORM 28**

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

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

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

Names of drugs .....

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

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

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

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

<sup>4</sup>[Date : .....

Signature.....

Designation.....

\_\_\_\_\_ \*Licensing Authority.

\* Central Licence Approving Authority.]

\*Delete whichever is not applicable.

*Conditions of Licence*

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

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

3 Any change in the 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.

---

**FORM 28A**

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

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

2. .... of.....is

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

Names of Drugs .....

3. Names of <sup>3</sup>[competent technical staff] .....

<sup>4</sup>[3A. The licence shall be in force from ..... to.....

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

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

*Date of issue:* .....

*Signature*.....

*Designation* .....

*Conditions of Licence*

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

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

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

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.

---

**<sup>1</sup>[FORM 28B**

*<sup>2</sup>[Licence to manufacture for sale or for distribution of] drugs specified in Schedules C, CI and X*

No of Licence.....

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

Name of drugs.....

2. Names of <sup>3</sup>[competent technical staff]

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

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

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

<sup>4</sup>[Date .....

Signature .....

Designation.....

.....\*Licensing Authority

\*Central Licence Approving Authority.

\*Delete whichever is not applicable.

*Conditions of Licence*

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

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

be deemed to be applicable to the items so endorsed.

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

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

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

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

---

**[FORM 28C**

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

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

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

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

- 1.
- 2.
- 3.
- 4.

Name(s) of the Competent Technical Staff:

- 1.
- 2.
- 3.
- 4
- 5
- 6

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

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

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

*Dated: .....*

*. Signature.....*

*Name and Designation.....*

Licensing Authority

Central Licence Approving Authority

*Conditions of Licence*

1. The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components from the blood collected from such a donor.
2. The licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
3. Any change in the technical staff shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.
4. The licensee shall inform the Licensing Authority and/or Central Licence approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes places, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

**1[FORM 28D**

*Licence to manufacture for sale or for distribution of Large Volume Parenterals/Sera and Vaccines specified in Schedules C and C(1) 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 Vaccines specified in Schedules C and C(1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

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

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

1. 1.
2. 2.
3. 3.

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

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

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

Date: .....

*Signature.....*

*Designation.....*

Licensing Authority

Central Licence Approving Authority

*Conditions of Licence*

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



2. If the licensee wishes to undertake during the currency of the licence to manufacture of any drug specified in Schedule C and/or C(I) excluding those specified in Schedule X not included above, he should apply to the Licensing Authority and or Central Licence Approving Authority for the necessary endorsement as provided in the rules. This licence shall be deemed to extend to the items so endorsed.
3. Any change in the competent technical staff named in the licence shall be forthwith reported to the Licensing Authority.
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 along with prescribed fee and necessary documents to the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

**[FORM 28E**

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

1. Number of licence ..... date of issue .....at the premises situated at.....
2. M/s.....is hereby licensed to manufacture, store, sell or distribute the following blood products:-
3. Name(s) of the item(s) :
  - 1.
  - 2.
  - 3.
4. Name(s) of the competent technical staff:
  - (a) responsible for manufacturing (b) responsible for testing
  1. 1.
  2. 2.
  3. 3.
5. The licence authorises licensee to manufacture, store, sell or distribute the blood products, subject to the conditions applicable to this licence.
6. The licence shall be in force from..... to.....
7. The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time to time in the rules made under Drugs and Cosmetics Act, 1940.

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

*Name and Designation*.....

\_\_\_\_\_Licensing Authority  
 \_\_\_\_\_Central Licence Approving Authority

*Conditions of Licence*

1. The licensee shall not manufacture blood products from the blood drawn from any professional donor or paid donor.
2. The licence and any certificate of renewal in force shall be displayed on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

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

**FORM 29**

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

1. ....of.....  
is hereby licensed to manufacture the drugs specified below for purposes of examination, test or analysis at .....
2. This licence is subject to the conditions prescribed in Part VIII of the Drugs and Cosmetics Rules, 1945.
3. This licence shall be in force for one year from date specified below.

*Names of drugs*

*Date : .....*

*Licensing Authority.....*

**FORM 30**

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

s

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

*Names of Drugs*

*Date.....*

*. Signature.....*

**FORM 31**

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

- 1.1/ We.....of..... hereby apply for grant /renewal of a licence to manufacture on the premises situated at..... the following cosmetics :-
2. Names of Cosmetics .....
3. Names, qualifications and experience of technical staff employed for manufacture and testing.....
4. A fee of rupees .....has been credited to Government under the head of account.....

*Date.....*

*Signature.....*

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

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**1[FORM 31A**

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

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

2. Names of Cosmetics.....

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

4. I /We enclose-

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

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

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

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

*Date.....*

*. Signature.....*

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

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**FORM 32**

*1[Licence to manufacture cosmetics for sale or for distribution]*

Number of Licence and date of issue

1 .....is hereby licensed to manufacture on the premises situated at  
..... the following cosmetics under the supervision of the following  
technical staff:-

(a) Names of cosmetics.

(b) Names of technical staff

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

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

*Date.....*

*. Signature .....*

*Designation .....*

*Conditions of Licence*

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

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

the Licensing Authority.

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

2[4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.]

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**[FORM 32A**

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

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

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

(a) Names of technical staff.

(b) Names of cosmetics.

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

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

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

*Designation.....*

*Conditions of Licence*

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

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

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

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**FORM 33**

*Certificate of renewal of licence to manufacture cosmetics for sale*

1. Certified that licence No.....granted on the.....  
*Drugs and Cosmetics Rules, 1945 229*  
to.....for the manufacture for sale of the following cosmetics at the  
premises situated at.....has been renewed from.....and shall expire  
on.....

2. Names of cosmetics.

3. Names of technical staff

*Date*.....

*Signature*.....

*Designation*.....

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**FORM 33A**

*Certificate of renewal of loan licence to manufacture cosmetic for sale*

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

2. Names of cosmetics.

3. Names of technical staff.

*Date*.....

*Signature*.....

*Designation*.....

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**FORM 34**

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

1. Name of the officer or Inspector from whom received .....

2. Serial number and date of the Officer's / Inspector's  
memorandum.....

3. Number of sample .....

4. Date of receipt.....

5. Name of the Cosmetic purporting to be contained in the  
sample

6. Condition of seals on the 1[packet or on portion of sample or container]

7. *Results of test or analysis* :—

The sample of cosmetics—

(a) contains a prescribed colour only \_\_\_\_\_  
does not contain a prescribed colour.

(b) does not contain harmful ingredients \_\_\_\_\_  
contains harmful ingredients

(c) conforms to claims made on the label as to the nature and quality of the cosmetic. \_  
does not conform to claims made on the label as to the nature and quality of the cosmetic

2[d] contains not more than .....parts per  
million of Lead and..... parts per

million Arsenic.....  
contains more than.....parts per  
million of Lead and.....parts per  
million of Arsenic.]

Date: .....

Director,  
Central Drugs Laboratory / Government Analyst.

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**1[FORM 35**

*Form in which the Inspection Book shall be maintained*

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

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

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

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

Date of Inspection.....

Observations of the Inspector .....

*Signature of the Inspector*

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

Inspection Book maintained by M/s.....

situated at.....for licence number.....

in Form.....under the Drugs and Cosmetics Rules, 1945.

*Seal and Signature of the Licensing Authority.*

**Notes:**

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

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

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

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**FORM 36**

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

(1) \*I/We.....of.....hereby apply for  
the grant or renewal of approval for carrying out tests of identity, purity, quality and  
strength on the following categories of drugs / items of cosmetics or raw materials used in  
the manufacture thereof on behalf of licensees for manufacture for sale of drugs / cosmetics.

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

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

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

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

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

(c) Homoeopathic drugs.

(d) Cosmetics.

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

(4) List of testing equipments provided.

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

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

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

\* Delete whichever is not applicable

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### FORM 37

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

Number of approval and date of issue:

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

Categories of drugs / items of cosmetics

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

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

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

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

*Conditions of Approval*

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

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

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

2[(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**

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

(1) Certified that approval number ..... granted on the  
*Drugs and Cosmetics Rules, 1945 233*

.....for carrying out tests of identity, purity, quality and strength on the following categories of drugs/ items of cosmetics and the raw materials used in the manufacture thereof at the premises situated at.....has been renewed from.....to.....

Categories of drugs/items of cosmetics

\_\_\_\_\_  
\_\_\_\_\_

(2) Names of 1[competent technical staff] and person-in-charge of testing.

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

\_\_\_\_\_

**FORM 39**



*Report of test or analysis by approved institution*

- (1) Name of manufacturer from whom sample received together with his manufacturing licence number under the Act and under the rules made thereunder.
- (2) Reference number and date of the letter from the manufacturer under which the sample was forwarded.
- (3) Date of receipt of the sample.
- (4) Name of drug / cosmetics / raw material purporting to be contained in the sample.
- (5) Details of raw material/final product in bulk/final product (in finished pack)\* as obtained from the manufacturer:
  - (a) Original manufacturer's name in the case of raw materials and drugs repacked.
  - (b) Batch number.
  - [(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.