License for Retail / Wholesale & Manufacturing of Drugs

Stage at which service applicable (pre-establishment or pre-operation)	pre-establishment or pre-operation
Eligibility – please list down who all can apply for service (property/ business/ industry etc.)	All citizen of India.
Inspection Required Is inspection required in the process?	Yes. By the concerned Drugs Inspector.
Validity : The validity period (if any) of the service/ certificate/ license is required to be stated.	To pay retention fee every 5 years.
Processing Time / Timeline The overall time required within which the service will be provided by the Department / Agency.	45 days

Step by step process:

Instruction: Kindly illustrate the detailed step wise procedure for obtaining the service. The details of levels that the application passes through also needs to be mentioned; such as Scrutinizing, Verification & Approval. For every step, the involved authority should be mentioned. You may also illustrate the process through a flow chart >

Enclosed : ANNEXURE-I

Acts / Rules / Notification / Government Orders:

Instruction: Please list down and share the copies of the relevant applicable Acts / Rules / Notification / Government Orders with respect to providing the service.

Name of Document	Description	**Type:** Acts / Rules / Notification / GO
Drugs & Cosmetics Act,1940		Act
Drugs & Cosmetics Rules,1945		Rules
Medical Devices Rules, 2017		Rules

Forms:

Please provide the scanned copy of the form (s) so applicable for applying for the service.

Sl.No.	Name of Form	Description
1	**Form 19 (See Rule 59 (2)**	Application Form for Retail Drug Licence, Wholesale Licence, Restricted Drug Licence, , Veterinary Drug Licence.
2	**Form 24**	Application for grant / renewal of Manufacture Licence.
3	**Form 19 C (See Rule 59 (2)**	Renewal of Schedule X Drug Licence
4	**Form 3F [See Rule 52-0 (1)]**	Application Form for Essential Narcotic Drugs (END)
5	**Form 27 C [See Rule 122F]**	Application Form for Blood Bank.
6	**Form 31**	Application for Cosmetic manufacturing licence.

Fees Structure:

The detailed fees which the applicant is required to pay for availing the service is required to be stated.

Sl.No	Licence	Amount	Remarks
1	Retail Drug Licence / Retention	3000 / 3000	Payment through T.Challan to Account No. **Med-0210.**
2	Wholesale Drug Licence / Retention	3000 / 3000	Payment through T.Challan to Account No. **Med-0210.**
3	Restricted Drug Licence / Retention	1500 / 1500	Payment through T.Challan to Account No. **Med-0210.**
4	Schedule X Drug Licence / Retention	500 / 500	Payment through T.Challan to Account No. **Med-0210.**
5	Blood Bank Licence / Renewal	7500 / 7500	Payment through T.Challan to Account No. **Med-0210.**
6	Manufacturer Licence / Renewal	7500 / 7500	Payment through T.Challan to Account No. **Med-0210.**

Final Certificate:

Please share the scanned copy of the sample of certificate/ license / approval so provided to the applicant, with respect to this service.

Sl.No	Certificate/ License	Form No.
1	Retail Drug Licence, Veterinary Drug Licence.	Form 20 & 21
2	Wholesale Drug Licence	Form 20B & 21B
3	Restricted Drug Licence	Form 20A & 21A
4	Renewal of Schedule X Drug Licence	Form 19 C (See Rule 59 (2)
5	Schedule X Drug Licence	Form 20F [See Rule 61 (3)]
6	Certificate of Recognition for Essential Narcotic Drugs (END)	Form 3G [See Rule 52-0 (2)]
7	Licence of Blood Bank.	Form 28 C (See Rule 122G)
8	Blood Bank.	Form 26G (See Rule 122-F)
9	Approval of Blood Storage Centres.	5B of Schedule K of Drugs & Cosmetics Rules
10	Manufacturer Licence.	Form 25 [See Rule 70]
11	Renewal of Manufacturer Licence.	Form 26 [See Rule 73 and 83]
12	Cosmetic Manufacturing Licence	Form 32
13	Certificate of renewal for Cosmetic manufacturing licence	Form 33

Annexure-I

Category	*Step 1*	*Step 2*	*Step 3*	*Step 4*	*Step 5*	*Step 6*	*Step 7*	*Step8*	*Step 9*	*Step 10*	*Step 11*	*Step 12*
Sale License	Download application form	Uploading of Application with documents	Verification Of documents	Inspection	Upload Inspection Report	Verification / Processing	Payment of License Fee	Approval/ Rejection	Uploading of License			
Authority	**Drugs Controller**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Licensing Authority**	**Licensing Authority**	**Licensing Authority**	**Licensing Authority**			
Blood Storage Centre	Download application form	Uploading of Application with documents	Verification Of documents	Inspection	Upload Inspection Report	Verification / Processing	Payment of Inspection Fee	Approval/ Rejection	Uploading of Certificate of Approval			
Authority	**Drugs Controller**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Licensing Authority**	**Licensing Authority**	**Licensing Authority**	**Licensing Authority**			
Essential Narcotic Drugs (END) License	Download application form	Uploading of Application with documents	Verification Of documents	Inspection	Upload Inspection Report	Verification / Processing	Payment of Inspection Fee	Approval/ Rejection	Uploading of Certificate of Recognition			
Authority	**Drugs Controller**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Licensing Authority**	**Licensing Authority**	**Licensing Authority**	**Licensing Authority**			
Blood Centre License	Download application form	Uploading of Application with documents	Verification Of documents	Inspection	Upload Inspection Report	Verification / Processing	Forward to CLAA	Scrutiny	Joint Inspection	Report submission	Approval	Issue License
Authority	**Drugs Controller**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Licensing Authority**	**Licensing Authority**	**CLAA**	**CDSCO & SDCO**	**SCLA**	**CLAA**	**SCLA**
Manufacturer License. Drugs / Cosmetics	Download application form	Uploading of Application with documents	Verification Of documents	Inspection	Upload Inspection Report	Verification / Processing	Payment of License Fee	Approval / Rejection	Uploading of License			
Authority	**Drugs Controller**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Drugs Inspector**	**Licensing Authority**	**Licensing Authority**	**SCLA**	**SCLA**			

NOTE : **SCLA – State Controlling & Licensing Authority.** **CLAA – Central License Approving Authority.**

CDSCO – Central Drugs Standard Control Organization. **SDCO – State Drugs Control Organization.**

[FORM 27C

(*See* rule 122-F)

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

1.I/We,.....

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

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

1.

2.

3.

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

(a) Name(s) of Medical Officer :

(b) Name(s) of Technical Supervisor :

(c) Name(s) of Registered Nurse :

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

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

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

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

* *Delete whichever is not applicable.*

Notes:

1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for collection, processing, storage and testing of whole blood and its components, memorandum of association/constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the premises.

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

1[**FORM 28C**

(*See* rule 122-G)

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

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

.....

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

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

2.

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: .....

Licensing Authority

Central Licence Approving Authority

* *Delete whichever is not applicable*

Conditions of Licence

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

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

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

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

FORM 26-G

Rule 122F.

CERTIFICATE OF RENEWAL OF LICENCE TO OPERATE A BLOOD BANK FOR PROCISSING OF WHOLE HUMAN BLOOD AND/OR FOR PREPARATION FOR SALE OR DISTRIBUTION OF ITS COMPONENTS.

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

2. Name(s) of items: i).
   ii)

3. Name(s) of Competent Technical Staff :
   i)
   ii)
   iii)
   iv)
   v)
   vi)

Date.....

Signature.....

Name and Designation.....

Licensing Authority

Central Licence Approving Authority

CERTIFICATE OF APPROVAL OF BLOOD STORAGE CENTRE
FOR STORAGE OF WHOLE HUMAN BLOOD AND* / OR ITS COMPONENTS
[See (5B) of Schedule K of the Drugs and Cosmetics Rules]

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 staff : -

1. Name of the approved medical officer :
2. Name of the items :
3. Name of the qualified Blood Bank Technician :
4. Name & address of the licensed Blood Bank from whom the blood units would be procured :
6. The approval shall be inforce : from ..... to .....

Dated: .....

Licensing Authority

CONDITIONS

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 :-

1. The captive consumption of Whole Human Blood or its components in the above said centre shall not be more than 2000 units annually.
2. In the event of any change in the technical staff shall be forthwith reported to the licensing authority.
3. 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 centre shall apply for renewal of the approval to the licensing authority three months prior to the date of expiry of the approval.
5. The centre shall maintain records and registers including the details of procurement of blood* /its components.
6. The centre shall store samples of donors' blood as well as patients' sera for a period of 7 days after transfusion.