License for Retail / Wholesale & Manufacturing of Drugs

***Stage at which service applicable* (pre-establishment or pre-operation)**	Pre-establishment
Eligibility *- Please list down who all can apply for service (property/ business/ industry, etc.)*	All Citizen of India
Inspection Required *Is inspection required in this 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 also be mentioned. You may also illustrate the process through a flow chart:

Annexure – I

Procedures & Authority

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.**

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 Act, 1940		Rules
Medical Devices Rules, 2017		Rules

Approving Authority:

Application will be submitted to Scrutiny officer and will be forwarded to Approval Authority for final approval issued.

Name of the Authority	Specific Industrial Area/ State Level	Remarks
State Conrolling and Licencing Authority (SCLA)	Retail/Wholesale/Manufacturer	
Approving Authority: Central Licence Approving Authority (CLAA) – DCG (I) Licencing Authority: State Drugs Licensing Authority (SLA)	Blood Center Licence	

Required Documents

List down the documents that are required to be submitted along with the application in the Online SWS by the applicant as under:

#	Document Name	Description of Document	Mandatory/ Non-Mandatory
1	Retail/Wholesale, Manufacture of Drugs. Medical Devices licence Blood Bank and Blood Storage Centres Essential Narcotic Drugs (END), Cosmetics Manufacture	All documents required to be submitted are enclosed	All are mandatory

For Retail:

GOVERNMENT OF NAGALAND
DIRECTORATE OF HEALTH AND FAMILY WELFARE
DRUGS CONTROL ADMINISTRATION

Check List of documents for application in form 19(Retail)

1. Application Form(Form – 19)
2. Location with approved layout of premises(Min. 10 Sq.m/ 33 Sq. ft)
3. Proof of ownership of the premises/ tenancy agreement with proof of the ownership of the owner of the premises.
4. Proof of availability of cold storage facility.
5. Up to date renewal certificate of Registration of Pharmacist(Under Section 32(2) of Nagaland State Pharmacy Council
6. Consent letter and Appointment letter of Pharmacist
7. Proof of the residential address, Phone number and photo identity of the applicant
8. Xerox copy of Aadhar Card
9. Passport size photograph of the owner.
10. A fee of Rs. 3000 to be deposited under H/A Med-0210 through treasury challan.

(W. H. PATTON)
ADDL. DRUGS CONTROLLER
CONTROLLING AND LICENSING AUTHORITY

For Wholesale:

GOVERNMENT OF NAGALAND
DIRECTORATE OF HEALTH AND FAMILY WELFARE
DRUGS CONTROL ADMINISTRATION

Check List of documents for application in form 19(Wholesale)

1. Application Form(Form – 19)
2. NOC for stockistship from the Manufacturing unit/Company
3. Location with approved layout of premises
4. Proof of ownership of the premises/ tenancy agreement with owner of the premises.
5. Proof of availability of cold storage facility.
6. Experience Certificate of the person Incharge(Min. 4 years)
7. Appointment letter of the person incharge.
8. Proof of the residential address, Phone number and photo identity of the applicant
9. Xerox copy of Aadhar card
10. Passport size photograph of the owner.
11. A fee of Rs. 3000 to be deposited under H/A Med-0210 through treasury challan.

(W. H. PAITON)
ADDL. DRUGS CONTROLLER
CONTROLLING AND LICENSING AUTHORITY

Forms:

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

Name of Form	Description
Form 19 {See Rule 59(2)} *(Enclosed)*	Application Form for Retail Drug Licence, Wholesale Licence, Restricted Drug Licence, Veterinary Drug Licence.
Form 24 *(Enclosed)*	Application for grant/renewal of Manufacture Licence.
Form 19 C {See Rule 59 (2)} *(Enclosed)*	Renewal of Schedule X Drug Licence
Form 3 F {See Rule 52-0(1)} *(Enclosed)*	Application form for essential Narcotic Drugs (END)
Form 27C {See Rule 122 F} *(Enclosed)*	Application Form for Blood Bank
Form 31 *(Enclosed)*	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	Licence	Amount	Remarks
1	Retail Drug Licence/Retention	3000/3000	Payment though Treasury Challan to Account No. **Med-0210**
2	Wholesale Drug Licence/Retention	3000/3000	Payment though Treasury Challan to Account No. **Med-0210**
3	Restricted Drug Licence/Retention	1500/1500	Payment though Treasury Challan to Account No. **Med-0210**
4	Schedule X Drug Licence/Retention	500/500	Payment though Treasury Challan to Account No. **Med-0210**
5	Blood Bank Licence/Renewal	7500/7500	Payment though Treasury Challan to Account No. **Med-0210**
6	Manufacturer Licence/Renewal	7500/7500	Payment though Treasury Challan to Account No. **Med-0210**

Final Certificate:

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

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

FORM 19

(See Rule 59 (2)

Application for grant or renewal of a licence to sell, stock or exhibit for sale or distribution of drugs other than those specified in Schedule X.

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

2. The sale and dispensing of drugs will be made under the personal supervision of a qualified, person, namely :-

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

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

3. Categories of drugs to be sold.

4. Particulars for special storage accommodation.

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

Date.....

Signature.....

changed constitution.

[FORM 24]

Application for the grant of or renewal of a licence to manufacture for Sale [or for distribution of] drugs other than those specified in [Schedules C, C (1) and X]

1. I/ We ..... of ..... hereby apply for the grant/ renewal of a licence tomanufacture on ther premises situated at ..... the following drugs being drugs other than those specified in [Schedules C, C (1) and X] to 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.

FORM 19C

[*See* rule 59(2)]

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

1. I/We*..... of .....

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

.....

2. ** The sale and dispensing of drugs will be made under the personal supervision of the 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

[*See* rule 61(1)]

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

1. ..... is hereby licensed to sell, stock or exhibit or offer for sale, or distribute by retail drugs other than those specified in Schedules C, C (1) 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

Licence No. DL/NL.....

Conditions of Licence

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

FORM 21

[*See* rule 61 (2)]

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

1. ..... is hereby 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) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945 and to operate a pharmacy on the premises situated at .....
subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.

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

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

4. Categories of drugs .....

Date.....

Licence No ..... *Licensing Authority*

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
2. The licensee shall report to the Licensing Authority any change in the qualified staff in charge within one month of such change.
3. 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) 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.
4. 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.
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 20 - B

(See Rule 61 (1))

Licence to sell, stock or exhibit for sale, or distribute by wholesale, drugs other than specified in Schedules C and C (1)

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

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

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

Licencing Authority:

Condition of Licence

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

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

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

4. No sale of any drug shall be made to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug. Provided that this condition shall not apply to the sale of any drug to

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

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

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

4. Where the licence is an agent for distribution of the drugs of a manufacturer, the sale by way of wholesale dealing of such drugs shall be covered by a warranty either in Form 22 or Form 23 to the effect that the drugs sold do not contravence the provisions of section 18 of the Drugs and Cosmetics Act, 1940.

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

FORM 21 B

(See Rule 61 (2)

Licence to sell, stock or exhibit for sale or distribute by wholesale drugs specified in Schedules C and C (1)

1 ..... is hereby licensed to sell, stock or exhibit for sale or distribute by wholesale on the premises situated at ..... the following categories of drugs specified in Schdeules C and C (1) to the Drugs and Cosmetics, Rules 1945.

Categories of drugs

2. This license shall be in force from .....

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

Licence No.....

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

Conditions of Licence.

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

2. No drug to which this licence applies shall besold or stocked and exhibited for sale unless the precautions as are published by the Licensing Authority from time to time in the Gazette have been observed throughout the period during which it has been in the possession of the licence.

3. If the licensee wants to sell, stock and exhibit for sale or distribute during the currency of the liecnce additional categories of drugs listed in Schedules C and C (1) but not included in this licence, he should apply to the 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.

*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 institution or a registered medical practitioner for the purpose of supply to his patients, or

**(c) a manufacturer of hydrogenated vegetable oils, beverages, confectionary and other non medical products, where such drugs are required for processing these products.

5. Wher the licence is an agent for distribution of the drugs of a manufacturer the sale by way of wholesale dealing of such drugs shall be overed by a warrantly either in form 22 or from 23 to the effect that drugs sold do not contravene the provisions of section 18 of the Drugs and Cosmetics Act, 1940

6. The licence shall infrom 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 of 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 20F

[*See* rule 61(3)]

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

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

2. Names of drugs.

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

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

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

Date:.....

Licence No.....

Licensing Authority.

Conditions of 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.