

**Directorate of Health Services**  
**Andaman & Nicobar Administration**

**Procedure for applying of manufacturing drug license in offline mode**

- At present in offline mode, the applicant has to apply in the prescribed Form-24 for seeking manufacturing drug license addressed to the Licensing Authority/ DHS along with the relevant documents and payment of Rs. 7500.00 towards the inspection fees in the form of Demand Draft from any nationalized bank.
- The duly filled Form-24 along with the required document of the applicant shall be forwarded to Central Drugs Standard control organization Kolkata for inspection of the premises.
- The official of CDSCO will inspect the premises on receipt of the application and submit the compliance report to the Licensing Authority/ DHS.
- On the basis of the report received from, the Deputy Drugs control General India, CDSCO, Kolkata, the license in Form-25 shall be issued by Licensing Authority/ DHS.
- As such, you are hereby requested to provide the procedure for applying of manufacturing drug license as mentioned above in the existing module. Matter may be treated on top priority.

***Note: At present, the manufacturing drug license is issued only by offline mode.***

## FORM 24

[See Rule 69]

**Application for the grant of or renewal of a license to manufacture for sale [or for distribution of] drugs other than those specified in [Schedules C, C(I) and X]**

1. I/We .....of  
.....hereby apply for the grant/renewal of a license  
to manufacture on the premises situated at .....  
the following drugs being drugs other than those specified in [Schedules C, C(I) and X]  
to the Drugs and Cosmetics Rules, 1945.
2. 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 25**

(See Rule 70)

**License of manufacture for sale (or for distribution) of drugs other than those specified in schedule C, C(1) and X)**

Number of license and date of issue    **Lic No.** ..... **dated** .....

1. M/s ..... is hereby licensed to manufacture the following categories of drugs other than those specified in schedules C, C(1), and X to the Drugs and Cosmetics Rules, 1945, on the premises situated at ..... Under the direction and supervision of the following competent technical staff:
  - a) Expert Staff Name:
  - b) Names of Drugs (each item to be separately specified)
2. The license authorised the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the license, subject to the conditions applicable to license for sale.
3. The license shall be in force from ..... to .....
4. The license is subject to the conditions stated below and to such either conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Dated: .....

**State Drug Controller /  
Director of Health Services**

**CONDITIONS OF LICENSE**

1. This license 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 (Competent technical Staff) named in the license 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 license 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 license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for maximum periods of three months from the date on which the change take place unless, in the meantime, a fresh license has been taken form the Licensing Authority in the name of the firm with the changes constitution.