

# The Health Master

## **Procedure for obtaining Drug Manufacturing License (Fresh)**

### **Stage1**

The Applicant has to apply online to the State Drugs Controller –cum- Licensing Authority of the State and submit hard copy. The following documents have to be uploaded and copies to be handed over to Inspecting Officer during the inspection:-

The applicant has to make application in the requisite Forms. The details of Forms and necessary requisite fees are given below:-

Application form on Form 24 for Non-biological drugs manufacturing License with a fee of Rs. 7500/- for ten items per category and Rs. 300/- per item for more than 10 products per category

Application on Form 27 for manufacturing of Biological drugs with a fee of Rs. 7500/- for ten items per category and Rs. 300/- per item for items more than 10 items per category.

Application form on Form 24A for loan drugs manufacturing License for Non-biological drugs and application for loan License of bio-logical drugs is to be submitted on Form 27A.

Applicant can pay fee online through Net Banking / Debit Card / Credit Card.

The fee can also be paid through challan at Government Treasury, under Head of Account- 0210 - Medical and Public Health. 04 - Public Health. 104 - Fees and Fines, etc.

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## **Stage 2**

The applicant shall submit complete application through online mode to the State Drugs Controller – cum- licensing authority along with all relevant documents. Application is scrutinized and forwarded to the Inspecting Officer of the area for inspection of the premises of the firm. After inspection, the Inspecting Officer shall send the inspection report along with his recommendation to State Drugs Controller / Licensing Authority of the State.

## **Stage 3**

### **Grant of License**

If all conditions are full filled Drug manufacturing licenses shall be granted by the State Drugs Controller / Licensing Authority of the State.

**Note:** Requirements of some of documents and procedure for submission of application may vary from State to State