Grant of Drug and Manufacturing License in Loan Premises.

Food and Drug Administration, Puducherry Grants Manufacturing Licences for Drugs (Allopathy, Ayurvedic, Siddha, Unani) and Cosmetics to be carried out in Loan premises in Forms 25A, 28A, 25E and 32A.

Procedure to obtain Drug Manufacturing licence (Fresh) in Loan Premises

Stage 1

Application for grant of Loan Manufacturing Licence

The applicant has to make application in the requisite application form in Form 24A, 27A, 24E respectively and pay Necessary fees as given in fee chart.

“0210 - A MEDICAL AND PUBLIC HEALTH 04-PUBLIC HEALTH (104) FEES & FINES LICENSE FEES UNDER PREVENTION OF FOOD ADULTERATION ACT 1954, DRUGS AND COSMETICS ACT 1940 FRESH/RENEWAL FOR THE YEAR”

Documents to be attached along with the application form:

- Receipt of payment of Fees.
- Documents such as partnership-deed, Memorandum and Articles of Association.
- List of Drugs/Cosmetics to be manufactured in duplicate.
- Copy of the letter written to the manufacturer whose premises, machinery equipments are to be taken on loan.
- Copy of consent letter of the manufacturer who gives his premises, Machinery and equipments on loan. Labels and cartons of the Drugs to be manufactured.
- In case, the application is for the products covered under C and C (1) category, then the details of stability data are required.
- If the products are covered under ‘Patent and Proprietary’ definition, then the two Copies of methods of Analysis of the products be supplied.

Stage 2

Inspection

The application is scrutinized and premises inspected.

Stage 3

Grant of Licence

If all conditions as prescribed by the act are complied license is granted.
Procedure to Renew Drug Manufacturing licence in loan premises
Licenses in Forms 25A, 28A, 25E can be renewed.

Stage 1

Application for renewal of Loan Manufacturing Licence
The applicant has to make application in the requisite form(24A,27A,24E) and pay Necessary fees as given in fee chart.
The mode of payment of fees is same as fresh licence.

Documents to be enclosed along with application of renewal of licence :-

- Copy of cash receipt or challan for payment of fees
- Xerox copy of Licence /Previous renewal certificate.
- Xerox copy of the list of Drugs previously approved.
- List of Drugs along with names of proprietary medicines and dates of its approval (two copies).
- Full particulars of the competent technical staff appointed for manufacturing and testing along with their educational qualification and experience certificates
- Copy of the letter written to the own licence whose manufacturing capacity is decided to be utilised on loan.
- Copy of the consent letter of the own licencee who has agreed to give his manufacturing capacity to be utilised on loan.
- Label, cartons of all the drugs to be manufactured.

Stage 2

Inspection
The application is scrutinized and premises inspected.

Stage 3

Grant of Licence
If all conditions as prescribed by the act are complied license is granted