License Procedure

Documents to be Uploaded with the application form for grant of Drug Manufacturing License:-

1. Requisite application form to be filled Online
2. Blue print with site plan of the premises, duly signed by firm's Prop/partner/Director.
3. Rent receipt and lease deed of the premises (original or attested photocopies)
4. Photostat attested copy of partnership deed it is partnership firm. Or Memorandum and Article of Association if it is Limited or Pvt. Ltd. firm duly signed by Directors of the firm.
5. List of present directors of the firm showing their complete name and residential address. See column 15
6. In case of change in Directors (registration, addition, replacement) firm the original, their attested photocopy of Form 32 in respect of such outgoing incoming director.
7. Full particulars of the competent technical staff /registered persons along with copies of their educational qualification, experience and registration certificates.
8. Non-conviction affidavit of approved technical staff as per required which should also finds mention the defaults of his/her academic qualification & approval.
9. Photostat attested copies of academic qualification & approval of technical staff as per conditions lay down in Drugs & Cosmetics Act, 1940 & Rules, 1945.
10. Photostat attested copies of academic qualification & approval of technical staff as per conditions lay down in Drugs & Cosmetics Act, 1940 & Rules, 1945.
11. List of machinery
12. List of lab equipment
13. Purchase bills of machinery and equipments (original or attested photocopies)
14. NOC of fire fighting/NOC of pollution control if applicable (original or attested photocopy)
15. Proof of HSEB load sanction (original or attested photocopy)
16. Attested photocopy of allotment/occupation certificate form HSIDC/HUDA etc. Whichever is applicable.
17. Declaration in this form of affidavit about sleeping/active partner/Director responsible for day to day work and conduct of the company alongwith declaration as to whether such prop/partner/director has been convicted under Drugs & Cosmetics Act, 1940 & Rules, 1945 or not.
18. Resolution of Board of Directors regarding appointment of authorised signatory.
19. Non-conviction affidavit of authorised signatory, if appointed any by the firm.

Food and Drug Administration Haryana Grants Drugs Licenses for Manufacturing of drugs as per the provisions of Drugs Cosmetics Act-1940.

Procedure to obtain Drug Manufacturing License (Fresh)

Stage1

The Applicant has to apply online to the State Drugs Controller –cum- Licensing Authority of the State. The following documents have to be uploaded and to be handed over to Inspecting Officer/Drug Control 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 and 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.Health.

Application form on Form 24A for loan drugs manufacturing license for Non-biological drugs as per conditions

prescribed at Sr. No. 1 above and application for loan license of bio-logical drugs is to be submitted on Form 27A.
Application form on Form 24B for repacking of license with a fee of Rs. 700/- upto 10 items per category and Rs. 100/- per item if the items are more than 10 items.
Application form on Form 24C for Homeopathic manufacturing license with a fee of Rs. 300/- for mother tincture Rs. 300/- for potentised preparations and Rs. 300/- for potentised and Rs. 50/- for additional item if the items are more than 10.
User can pay fee Online through Net Banking/Debit Card/Credit Card and can also download the challan and can pay the fees.
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.
Stage 2
The applicant will submit application through Online mode completed in all respect to the State Drugs Controller – cum- licensing authority alongwith all relevant documents. Application is scrutinized and the application is forwarded to the Senior Drugs Control Officer of the Concerned zone for inspection of the premises of the firm. Premises is inspected by Senior Drugs Control Officer of the Concerned zone and the report is forwarded by Senior Drugs Control Officer along with his recommendation to State Drugs Controller.
Stage 3
Grant of Licence
If all conditions as prescribed by the Act are complied, the licence is granted by State Drugs Controller and applicant gets information through SMS /email.

Procedure for Retention of Drug Manufacturing Licence

1. Govt. of India vide its notification no. GSR-1337 dated 27.10.2017 has omitted the word "Renewal" and instead of renewal procedure of license retention by the licensee, “if the licensee deposits a license retention fee before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the Licensing Authority”.
2. The license retention fee shall be equivalent to the respective fee required for the grant of such license excluding inspection fee paid for grant of license.
3. If the licensee fails to pay license retention fee on or before the due date, he shall be liable to pay license retention fee along with a late fee calculated at the rate of two percent of the license fee for every month or part there of up to six months, and in the event of non-payment of such fee, the license shall be deemed to have been cancelled.
4. Licensee at the time of submission of license retention fee should submit an undertaking that (a) there is no change in constitution (b) there is no change in premises (c) there is no change in approved technical staff (d) list of already approved items and required fee which firm intends to retain.
5. Validity certificate on receipt of license retention fee shall be issued forthwith if full fee in all respect is deposited.