Procedure for granting of Drug Manufacturing License

Procedure to be followed by the applicant and step by step movement of the application within the Department along with timelines for completion of each step is same irrespective of risk category (Low, Medium, High), size of firm (Micro, Small, Medium & Large), Investor type (Foreign, Domestic), Business location (Rural, Urban).

Procedure to be followed by applicant:

1. The applicant shall register through E Vesoj (Drug License) tab of the official website of the Department of Health & Family Welfare https://www.wbhealth.gov.in/ or through this link https://evesoj.wbhealth.gov.in/WBDL/
2. On registration, applicant will be given a user ID and Password for future reference.
3. There are two steps associated with this process, **i. Site Suitability & Lay out Approval, ii. Apply for Drug Manufacturing license.**
4. Applicant needs to click on Manufacturing License Section.
5. Then to click on site Registration.
6. Enter the details for site registration.
7. Applicant will pay for the registration charges through payment portal.
8. After payment is done, the application is sent to admin for approval. After approval, the applicant can download the approval letter for site registration.
9. Then Click on Apply for Manufacturing License
10. Enter the mandatory details.
11. Enter the Product name and composition which will be manufactured in the factory.
12. Pay for the license charges through payment portal.
13. Wait for the approval.
14. After approval manufacturing License will be generated and applicant can download the signed license from portal.

Note - The applicant can track his application through the online system. At each stage of the process of application, system generated email / SMS alert will be sent to the applicant, as and when application status is changed.

Step by step movement of application for Site Suitability & Lay out Approval & issue of Drug Manufacturing license within department along with timeline

Step No	Procedure	Official involved	Timeline
1	Receiving of application online for **Site Suitability & Lay out Approval**	Sr. Inspector / Inspector of Drugs	1 day
2	Verification of Documents online for Site Suitability Approval	Sr. Inspector / Inspector of Drugs	2 days
3	Site Inspection & online Report submission for Site Suitability Approval	Sr. Inspector / Inspector of Drugs	7 days
4	2nd level verification of documents online for Issuance of Site Suitability Approval.	ADDC (Mfg.)	2 days
5	Issuance of **Site Suitability Approval online.**	Dy DDC & LA & CA	2 days
6	Joint approval of Lay out as submitted online by CDSCO & SLA	Sr. Inspector / Inspector of Drugs & CDSCO Drug Inspector	15 days
7	Verification of Documents for Issuance of Layout Approval	ADDC (Mfg.)	2 days
8	Issuance of **Layout Approval Letter** online.	Dy DDC & LA & CA	2 days
9	Receiving of Formal Application for **Drug Manufacturing license** online in Statutory Forms	Sr. Inspector / Inspector of Drugs	1 day
10	Verification of documents online	Sr. Inspector / Inspector of Drugs	2 days
11	Joint Inspection conducted by the Officers of SLA & CDSCO and submission of Joint Inspection Report	Sr. Inspector / Inspector of Drugs & CDSCO Drug Inspector	30 days
12	Online processing for Issuance of Licenses along with Product List	Sr. Inspector / Inspector of Drugs	15 days
13	2nd level verification of documents for Issuance of License along with Product List	ADDC (Mfg.)	3 days
14	Online issue of **Drug Manufacturing License & Product List**	Dy DDC & LA & CA	6 days
	Total timeline in WBRTPS Act		**90 days**

Comprehensive list of documents for granting of Drug Manufacturing License

Comprehensive list of documents required for application are same irrespective of risk category (Low, Medium, High), size of firm (Micro, Small, Medium & Large), Investor type (Foreign, Domestic), Business location (Rural, Urban).

There are two steps associated with this process**, i. Site Suitability & Lay out Approval, ii. Apply for Drug Manufacturing license.**

Required Documents for Site Suitability & Lay out Approval

1. Power of Attorney (if any) of applicant in Non-Judicial Stamp Paper as per Proforma

2. Trade License/ Trade Enlistment Certificate, mentioning nature of trade

3. Possession Document of the Premises: Current House Tax receipt/Consolidated Rate bill/ Registered Deed of Conveyance/Consent Letter from the Owner/ N.O.C in the form of affidavit before 1st Class Judicial Magistrate, rent bill signed by owner or authorized signatory/as the case relate to Parcha/ Khajna, Dakhila from B.L & L.R.O

4. In case of Partnership Firms, Registered Partnership Deed along with firm registration receipt. In case of Limited or Pvt. Ltd. Company - copy of Memorandum and Article of Association. In case of LLP (Limited Liability/ Partnership Firm) Copy of Memorandum and Articles of Association

5. Copy of resolution of the Board meeting along with list of Present Board of Directors with respect to Limited or Pvt Ltd companies

6. Sketch map of proposed Land / premises with location and surrounding (CAD Mode)

Required Documents for Apply for Drug Manufacturing license

1. Power of attorney (if any) in non-judicial stamp paper as per proforma

Fees required for granting of Drug Manufacturing License

Fees required is same irrespective of risk category (Low, Medium, High), size of firm (Micro, Small, Medium & Large), Investor type (Foreign, Domestic), Business location (Rural, Urban).

Information of fees required for obtaining Drug Manufacturing License is available at "**Payment Structure"** tab under https://evesoj.wbhealth.gov.in/WBDL/welcome.jsp