

[Guidance to applicants for the grant or renewal of license to manufacture](#)

[Large Volume Parenterals](#)

General

Large Volume Parenterals (LVP) are single dose injections for administration through the intravenous route. These products should be in volumes of 100 ml or above. Products like Dextrose injection I.P., Sodium Chloride injection I.P., Ciprofloxacin injection etc. are some LVPs. Any injection having volume less than 100 ml and for multi dose administration falls under the category of Small Volume Parenterals (SVP).

Licensing

The procedure of licensing of LVPs has been modified in the Drugs & Cosmetic Rules by GSR No. GSR923 (E) dated 14/12/1992, whereby it falls under the category of drugs that are to be approved by the Central Licensing Approving Authority (CLAA) which is the CDSCO. Licenses issued by the State Licensing authority have to be approved by the CLAA before they are issued to the applicants.

Procedure

Application for the Grant or renewal of license for the manufacture of LVPs is to be submitted on form [27D](#) along with the required information to the [State Licensing authority](#) and a copy to the respective [Zonal office](#) of the CDSCO and CDSCO, [HQ](#), New Delhi.. The data submitted should be printed/typed on A4 paper with arial font. All photocopies should be legible and authenticated.

The Licensing authority of the State in co-ordination with the CDSCO Zonal Office will carry out a joint inspection of the applicant's premises to examine in detail the capacity of the applicant to manufacture and test the products it intends to manufacture. A copy of the report will be handed to the applicant.

If the report is satisfactory further action will be taken by the licensing authority for sending the same to the CLAA for approval. If the report indicates that there are deficiencies, the applicants premises may be re-inspected jointly or independently, depending on the criticality of the deficiency, after the removal of the same.

Requirements

The manufacturing premises have to be as per the requirements of Schedule M, Good Manufacturing Practices. The applicant should have documentation in place as per the requirements of [Schedule M](#) and [Schedule U](#). It is recommended that the applicant does not apply for license until the premise is ready with respect to most of the requirements, as unfinished premise inspection can not be a final inspection and there may be delay in re-inspection.

Documents to be submitted

The following documents are to be submitted at the time of submitting the application. The documents may also be submitted as soft copies in floppies or CDs for easy storage:

1. [Site Master File](#)
2. Plan of the premises, blue print along with details of the areas of each section
3. Name, address, qualification and experience of the technical staff responsible for manufacture and testing. The qualification and experience should be backed up with attested proof.
4. Name and address of the Directors, Partners or Proprietor

5. Proof of Payment of fee (Challan)
6. Ownership, rent or lease details of the premises*
7. List of drugs intended to be manufactured. This should include formula, pack size and details of primary packing material (glass or plastic), Literature and insert/insert (if any), draft level of product intended to manufacturer)
8. Stability Studies data of the applicants products¹
9. List of machinery installed
10. List of laboratory equipments
11. Validation and calibration of essential and critical equipment and instruments
12. Validation of HVAC system
13. Copies of procurement documents of machinery and equipments (bills etc)*
14. Description of the manufacturing process*
15. Any other document requested by the inspecting authorities

1 Stability Studies for *all* products is to be submitted in case of renewal of license.

In case of grant of license only established pharmacopoeial products will be allowed. However real time/accelerated stability studies has to be commenced immediately after the products are manufactured.

* These may not be submitted during renewal of license.

Any further clarifications can be obtained from the respective Zonal Offices of CDSCO, the State Licensing authority or by email ddci@nb.nic.in .