

(See rules 76A, 78A, 83AA)

LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF LARGE VOLUME PARENTERALS/SERA AND VACCINE/RECOMBINANT DNA (r-DNA) DERIVED DRUGS EXCLUDING THOSE SPECIFIED UNDER SCHEDULE X

Number of licence.....and date of issue.....

I..... of..... is hereby granted a loan licence to manufacture on the premises situated at..... c/o..... the following drugs being Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs specified in Schedules C, C(I), excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

1. Names of drugs.....
2. Name (s) of competent technical staff.....

3. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

4. The licence authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale.

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for time being in force under the Drugs and Cosmetics Act, 1940.

Date.....

Signature.....
 Designation.....
 Licensing/ Authority.....
 Central Licence Approving Authority

Conditions of licence

1. This licence ²⁷⁸[***] shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the competent technical staff shall be forthwith reported to the Licensing Authority and Central Licence Approving authority.

3. If the licensee wants, during the currency of the licence, to manufacture for sale additional items of drugs not included above, he should apply to the Licensing Authority and/or Central Licence Approving Authority for the necessary endorsement as provided in the rules. This licence will be deemed to extend to the items so endorsed.

4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]