

**972** | **FORM 28D**

(See rule 76)

**LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION  
OF <sup>973</sup>[LARGE VOLUME PARENTERALS/SERA AND  
VACCINE/RECOMBINANT DNA (R-DNA) DERIVED DRUGS]  
SPECIFIED IN SCHEDULE C AND C(I) EXCLUDING THOSE  
SPECIFIED IN SCHEDULE X**

Number of licence.....and Date of issue.....

1.....is hereby licensed to manufacture at the premises situated at..... the following <sup>973</sup>[Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs] specified in Schedule C and C(I) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

2. Name(s) of drug(s) (each item to be separately specified).....

3. Name(s) of competent technical staff.....

(a) responsible for manufacturing      (b) responsible for testing

1.

1.

2.

2.

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

<sup>974</sup>[5. 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

Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

6. The licence shall be subject to the conditions stated below and to such other conditions as shall be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Signature.....

Designation.....

Licensing Authority/Central Licence Approving Authority

Date.....

*Conditions of Licence*

1. The licence <sup>978</sup>[\*\*\*] 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. If the licensee wishes to undertake during the currency of the licence to manufacture any drug specified in Schedule C and/or C(I) excluding those specified in Schedule X 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 shall be deemed to extend to the items so endorsed.

3. Any change in the competent technical staff named in the licence shall be forthwith reported to the licensing authority and/or Central Licence Approving Authority.

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 applied for alongwith prescribed fee and necessary documents to the licensing authority and/or

Central Licence Approving Authority in the name of the firm with the changed constitution.]