

**FORM 28B**

[See rule 76]

**LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS SPECIFIED IN SCHEDULES C, C(I) AND X**

No. of licence.....

1.....is hereby licensed to manufacture at the premises situated at.....the following drugs specified in Schedules C, C(I) and X to the Drugs Rules, 1945.

Name of drugs.....

2. Names of approved expert staff.

3. 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.

4. 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.]

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

Date.....

Signature.....

Designation.....

[\*Licensing Authority/\*Central Licence Approving Authority]

\* Delete whichever is not applicable.

*Conditions of Licence*

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

2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule X not included above, he should apply to the licensing authority for the necessary endorsement as provided in rule 75(4). This licence will be deemed to be applicable to the items so endorsed.

3. Any change in the expert staff shall be forthwith reported to the licensing authority.

4. The licensee shall inform the licensing 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 in the name of the firm with the changed constitution.

5. The licensee shall furnish to the licensing authority copies of invoices of sales made to dealers.

6. The licensee shall ~~not~~ manufacture drugs specified in Schedule X covered by this licence for use as "Physician's Samples".

