

FORM 25

(See rule 70)

**⁸⁷⁷LICENCE TO MANUFACTURE FOR SALE OR FOR
DISTRIBUTION OF] DRUGS OTHER THAN THOSE SPECIFIED IN
⁸⁷⁹[SCHEDULES C, C(1) AND X]**

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

I.....is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in ⁸⁷⁹[Schedules C, C(1) and X] to the Drugs Rules, 1945, on the premises situated at.....under the direction and supervision of the following ⁸⁸⁰[Competent Technical Staff]:—

(a) ⁸⁸⁰[Competent Technical Staff] (Names).....

(b) Names of Drugs (each item to be separately specified).....

2. 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.

⁸⁸¹3. 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 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.....

⁸⁸²[*Licencing Authority/ "Central Licence Approving.]

* Delete whichever is not applicable.

Conditions of Licence

1. This licence ⁸⁸³[***] 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 ⁸⁸⁴[Competent Technical Staff] named in the licence shall be forthwith reported to the licensing authority.

3. If the licensee wants to manufacture for sale additional items of drugs not included above, he should apply to the licensing authority for the necessary endorsement as provided in rule 69(5). This licence will be deemed to extend to the categories so endorsed.

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.

STANDARD CONTROL