

FORM 25-C
(See rule 85D)

LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF HOMOEOPATHIC
MEDICINES

No. of Licence and date of issue.....

1. is / are hereby licenced to manufacture the following Homoeopathic medicines on the premises situated at under the direction and supervision of the following competent technical staff: —

Name of Homoeopathic preparations.

(Each item to be separately specified)

2. Competent Technical staff (Names).

3. The licence shall be in force from

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

Conditions of Licence

1. Any change in the Technical staff named in the licence shall be forthwith reported to the Licensing Authority.
2. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.
3. 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.
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 five years or as needed as per risk based approach.
5. The licence is issued only after fulfillment of the requirements of Good Manufacturing Practices (GMP) of Homoeopathic medicines as laid down in Schedule M-I of the Drugs Rules, 1945.