FORM 25 - D
(See Rule 154)

LICENCE TO MANUFACTURE FOR SALE OF AYURVEDA / SIDDHA / UNANI DRUGS

No. of Licence:

(1) _____
is/are here by licenced to manufacture the following Ayurvedic/Siddha/Unani Drugs on the premises situated at

_____

under the direciton and supervision of the following technical Staff :

(a) Technical Staff (Names) :

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

(2) The Licence shall be inforce from _____to _____

(3) The Licence is subject to the conditions stated below and to such other conditions as may be specified in the rules of the time being inforce under the Drugs and Cosmetics Act,1940.

Date of Issue :

Signature :

DESIGNATION :

CONDITIONS OF LICENCE

1. The licence and any certificate of renewal of force shall be kept on the approved promises and shall be produced at the request of a Inspector, appointed under the Drugs and Cosmotics Act, 1940.

2. Any change in the Technical Staff named in the licence shall be reported forthwith to the Licensing Authority.

3. This Licence shall be deemed to extend to such additional items as the Licence may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

4. The Licence shall inform the Licensing Authority in writing 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 take 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. Licence for preparing Eye drops in Ayurvedic, Siddha and Unani Systems should fulfill the conditions laid in schedule F.F.

6. The Licence shall test each batch of the final product containing alcohol for the tests prescribed for each preparation and shall maintain records showing the particulars in respect of such tests, the records shall be maintained for a period of three years from the date manufacture.

7. The records shall be maintained of Ayurvedic medicines containing alcohol mentioning the quantities sold, batch number, names and addresses of parties to whom sold.

8. The licence shall maintain reference samples of each batch of drugs manufactured by him at least for two years.

9. The licence shall keep records of the details of each batch of drugs manufactured by him and raw materials used therein as per particulars schedule II(I) and such records shall be retained for a period of 3 years.

10. The licence shall allow an inspector appointed under the act to enter with or without prior notice, any premises where manufacture of drugs, in respect of which licence is issued is carried on to inspect the premises and to take samples of the raw materials as well as the finished products and the manufactured products under a receipt and to inspect the records maintained under these rules.

11. The licence shall make arrangement for proper storage of drugs manufactured by him.

12. The licence shall maintain an Inspection Book in Form 35 to enable an inspector to record his impressions and the defects noticed.

13. The licencing authority shall obtain the opinion of the technical experts appointed under the rule 154-A regarding the suitability of the drug manufactured by the licence or the applicant in case of any doubts. The opinion shall be the final if it is not disapproved by the applicant or the licence with in 28days of the renewed of the opinion.