FORM 37

(See Rule 150-C)

Approval for carrying out tests on drugs and raw material used in their manufacture on behalf of licensees for manufacture for sale of drugs

Number of approval and Date of issue MH/101513 Dated 23.10.2015

1. Approval is hereby granted to **M/S. Promas Research Laboratories** (101513) for carrying out tests for identity, purity, quality and strength on the following categories of drugs and the raw material used in the manufacturing there of on the premises situated at **2nd Floor, Promas House, Plot No. R- 877, TTC Indl. Area, M.I.D.C., Rabale, Navi Mumbai, Dist. Thane – 400 706, Maharashtra State.**

   Categories of drugs

   a) **Drugs other than those specified in Schedule C and C(1) and also excluding Homoeopathic Drug.**
      1. Drugs requiring the use of ultraviolet/Infra-Red Spectrophotometer or Chromatography.
      2. Other drugs
   b) **Drugs specified in Schedule C and C(1)**
      1. Antibiotics
      2. Vitamins
      3. Drugs requiring the use for Ultraviolet/Infra Red. Spectrophotometer of Chromatography
      4. Other Drugs

8. Name(s) of approved [competent technical staff] employed for testing and person-in-charge of testing. – **As Per List Attached**
9. The approval shall be in force from **23.10.2015** to **22.10.2020**
10. The approval is subject to the conditions stated below and such other conditions as may be specified in the rules for the time being in force under the Act.

Date –23.10.2015

(R. S. Urankar)
Licensing Authority
Food and Drug Administration, M.S., Thane

D/F 0811-23/10153

Conditions of Approval.

1. This approval and any certificate of renewal in Form 38 shall be kept on the approved premises and shall be produced at the request of an inspector appointed under the Act.
2. If the approved institution wishes to undertake during the currency of the approval the testing of any other category of drugs or items of control, should apply to the approving authority for necessary endorsement as provided in Rule 150-B. This approval will be deemed to extend to the items so endorsed.
3. Any change in the analytical staff or in the person-in-charge of the testing shall be forthwith reported to the approving authority.
4. The approved institution shall inform the approving authority in writing in the event of any change of the constitution of the institution operating under this Form. Where any change in the constitution of the institution takes place, the current approval 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 approval has been taken from the approving authority in the name of the institution with the changed constitution.

COMMISSIONER OF FOOD & DRUG ADMINISTRATION ★ THANE ★