

FORM 37
(See rule 150-C)

**Approval for carrying out tests on drugs and raw materials used in the manufacture
on behalf of licensees for manufacture for sale of drugs.**

Number of approval and date of issue: **MH/104247 Dt. 24.11.2021**

- (1) Approval is hereby granted to to **M/s. BOMBAY TEST HOUSE PRIVATE LIMITED** for carrying out tests for Identity, purity, quality and strength on the following categories of drugs and the raw materials used in the Manufacture thereof on the premises situated **Unit No: 1 – 2nd, 3rd & 4th Floor, Banking Complex – II, Plot No: 9 & 10, Sector – 19A. Near APMC Market – 2, Vashi, Navi Mumbai 400703.**

Categories of drugs :

- (a) Drugs other than those specified in Schedules C and C (1) and also excluding Homoeopathic Drugs:-**

1. Crude vegetable drugs.
2. Mechanical contraceptives.
3. Surgical dressings.
4. Drugs requiring the use of ultra violet / Infra Red. or Chromatography.
5. Disinfectants.
6. Other drugs.

- (b) Drugs specified in Schedules C and C (1):—**

1. Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages and similar Immunological Products.
2. Antibiotics.
3. Vitamins
4. Parenteral preparations.
5. Sterilized surgical ligature / suture.
6. Drugs requiring microbiological tests.
8. Drugs requiring the use of Ultraviolet/ Infra Red/ Spectrophotomete or Chromatography.
9. Other drugs.

- (c) Ayurvedic**



(2) Names of approved (Competent technical staff) employed for testing and the person-in-charge of testing.

Staff Name	Section	Designation	Qualification
Prakash M.Deshpande	Chem & Instrumentation	Tech.Advisor (Chem & Inst)	PHD
Sudhir G.Pawar	Chem & Instrumentation	HOD – Chem & Instrumentation	MPH
Amit S.Gaikwad	Microbiology	HOD - Microbiology	MSC

(3) The approval shall be in force from 24.11.2021 to 23.11.2026

(4)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 : 24.11.2021



(N.P. Supe)

Licensing Authority

Food and Drugs Administration
KONKAN Division, Maharashtra State

Conditions of Approval

1. This approval and any certificate of renewal in Form 38 shall be kept in the approved premises and shall be produced at the request of the Inspectors 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 cosmetics it should apply to the approving authority for necessary endorsement as provided in Rule 150-B. This approval will be deemed to extend to the item 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 mean time, a fresh approval has been taken from the approving authority in the name of the Institution with the changed constitution.