

991| FORM 36

(See rule 150 B)

APPLICATION FOR GRANT ⁹⁹²[*] OF APPROVAL FOR CARRYING OUT TESTS ON DRUGS/⁹⁹³[***] OR RAW MATERIALS USED IN THE MANUFACTURE THEREOF ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS/⁹⁹³[***] ⁹⁹⁴[OR FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY]**

(1) I/We,, of..... hereby apply for the grant ⁹⁹⁵[***] of approval for carrying out tests of identity, purity, quality and strength on the following categories of drugs/⁹⁹⁶[***] or raw materials used in the manufacture thereof on behalf of licensees from manufacture for sale of drugs/⁹⁹³[***]⁹⁹⁴[or for an individual or organisation or procurement agency].

(2) *Categories of drugs, ⁹⁹⁶[***].—

(a) Drugs other than those specified in Schedules C and C(I) and also excluding Homoeopathic Drugs:—

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

6. Other drugs.

(b) Drugs specified in Schedules C and C(I):

1. Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages and similar Immunological Products.

2. Antibiotics.

3. Vitamins.

4. Parenteral preparations.

5. Sterilised surgical ligature/suture.

6. Drugs requiring the use of animals for their test.

7. Drugs requiring microbiological tests.

8. Drugs requiring the use of Ultraviolet/Infra Red Spectrophotometer or Chromatography.

9. Homoeopathic drugs.

(c) Homoeopathic drugs. सत्यमेव जयते

(d) 997[***]

(3) Names, qualifications and experience of expert staff employed for testing and the person-in-charge of testing.

(4) List of testing equipment provided.

(5) I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.

(6) An inspection fee of rupees.....has been credited to Government under the head of account.....

Dated.....Signature.....]