

FORM 37

(See rule 150C)

APPROVAL FOR CARRYING OUT TESTS ON DRUGS/ [*] AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS/ [***] [OR FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY]**

Number of approval and date of issue.....

(1) Approval is hereby granted to.....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 at.....

Categories of drugs/ [***].

(2) Names of approved [Competent Technical Staff] employed for testing and person-in-charge of testing.

(3) The approval, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of approval and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and [***] Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

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.....

Signature.....

Designation.....

Conditions of Approval

(1) This approval ¹⁰⁰³[***] shall be kept in the approved premises and shall be produced at the request of the 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 ¹⁰⁰⁴[***] it should apply to the approving authority for necessary endorsement as provided in Rule 150B. 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.

¹⁰⁰⁵[(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.]]