GOVERNMENT OF INDIA

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

THE DRUGS AND COSMETICS ACT AND RULES

THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

(As amended up to the 31st December, 2016)

and

THE DRUGS AND COSMETICS RULES, 1945

(As amended up to the 31st December, 2016)

no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eye-brows or eye-lashes as severe inflammation of the eye or even blindness may result.]

[1][**149A**. **Special provisions relating to toothpaste containing fluoride**.-

(i) Fluoride content in tooth paste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton.

(ii) Date of expiry should be mentioned on tube and carton.]

150. ***Report of result of test or analysis of cosmetics***.—Test reports on samples of cosmetics taken for test or analysis under these rules shall be supplied in Form 34.

[2][**150-A**. ***Standard for cosmetics***.- Subject to the provisions of these rules, the standards for cosmetics shall be such as may be prescribed in Schedule S.]

[3] [PART XV (A)
APPROVAL OF INSTITUTIONS FOR CARRYING OUT TESTS ON DRUGS, COSMETICS AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS / COSMETICS

150-B. ***Application for grant of testing drugs/cosmetics***— (1) Application for grant or renewal of approval for carrying out tests for identity, purity, quality and strength on drugs or cosmetics or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs or cosmetics, shall be made in Form 36 to the Licensing Authority appointed by the State Government for the purposes of Part VII, VII (A) or XIV of these Rules, as the case may be and referred to as the "approving authority" under this Part and shall be accompanied by an inspection fee of [2][rupees six thousand] in the case of testing of drugs specified in Schedules C and C (1) and [2][rupees one thousand five hundred] in the case of testing of drugs other than those specified in Schedules C and C (1), homoeopathic drugs and cosmetics:

Provided that the applicant shall furnish to the approving authority such additional information as may be required by him in connection with the application in Form 36:

[4][Provided further that if the applicant applies for renewal of approval after its expiry but within six months of such expiry, the inspection fee payable shall be rupees six thousand in the case of testing of drugs specified in Schedules C and C (1) and rupees one thousand five hundred in the case of testing of drugs other than those specified in Schedules C and C (1), Homoeopathic medicines and cosmetics plus an additional fee at the rate of rupees one thousand per month.]

[4][(2) A separate application shall be made for grant of approval for carrying out tests on additional categories of drugs or items of cosmetics and shall be accompanied by an inspection fee of rupees one thousand five hundred in the case of drugs specified in Schedule C and Schedule C(1) and rupees one thousand each in case of drugs other than those specified in Schedule C and Schedule C(1), homeopathic medicines and cosmetics.

---

1. Ins. by G.S.R. 223 (E), dt. 19-4-1991.
2. Ins. by G.S.R. 510 (E), dt. 26-7-1982.
3. Ins. rule 150B to 150K by X.1104/7/76-D&M, dt. 23-8-1977.
4. Subs. by G.S.R. 601(E), dt. 24-8-2001.

Explanation—For the purpose of this Part, the words 'drugs' and 'cosmetics' shall also mean and include the raw materials used in the manufacture of drugs including Homoeopathic drugs or cosmetics, as the case may be.]

150-C. ***Form in which approval to be granted for carrying out tests on drugs / cosmetics on behalf of licensees for manufacture of drugs/cosmetics and conditions for grant or renewal of such approval***.– *(1)* Approval for carrying out such tests of identity, purity, quality and strength of drugs or cosmetics as may be required under the provisions of these rules, on behalf of licensee for manufacture of drugs or cosmetics shall be granted in Form 37.

(2) Before approval in Form 37 is granted or renewed, the following conditions shall be complied with by the applicant–

(1) The premises where the tests are being carried out shall be well lighted and properly ventilated except where the nature of tests of any drug or cosmetic warrants otherwise. Wherever necessary, the premises shall be air conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests, microbiological tests, etc.

(2) The applicant shall provide adequate space having regard to the nature and number of samples of drugs or cosmetics proposed to be tested.

Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate.

(3) If it is intended to carry out tests requiring the use of animals, the applicant shall provide for an animal house and comply with the following requirements–

(a) The animal house shall be adequate in area, well lighted and properly ventilated and the animals undergoing tests shall be kept in air conditioned area.

(b) The animals shall be suitably housed in hygienic surroundings and necessary provisions made for removal of excreta and foul smell.

(c) The applicant shall provide for suitable arrangements for preparation of animal feed.

(d) The applicant shall provide for suitable arrangements for quarantining of all animals immediately on their receipt in the institution.

(e) The animals shall be periodically examined for their physical fitness.

(f) The applicant shall provide for isolation of sick animals as well as animals under test.

(g) The applicant shall ensure compliance with the requirements of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960).

(h) The applicant shall make proper arrangements for the disposal of the carcasses of animals in a manner as not to cause hazard to public health.

(4) The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of drugs or cosmetics intended to be tested which shall be adequate in the opinion of the approving authority.

(5) The testing of drugs or cosmetics, as the case may be, shall be under the active direction of a person whose qualifications and experience are considered adequate in the opinion of the approving authority and who shall be held responsible for the reports of test or analysis issued by the applicant.

(6) The testing of drugs or cosmetics, as the case may be, for identity, purity, quality and strength shall be carried out by persons whose qualifications and experience of testing are adequate in the opinion of the approving authority.

(7) The applicant shall provide books of standards recognized under the provisions of the Act and the Rules made thereunder and such books of reference as may be required in connection with the testing or analysis of the products for the testing of which approval is applied for.

150D. ***Duration of approval***. –An approval granted in Form 37 or renewed in Form 38, unless sooner suspended or withdrawn, shall be [1][valid for a period of five years on and from the date on which] it is granted or renewed:

Provided that if an application for the renewal of an approval in Form 37 is made before its expiry or if the application is made within six months of its expiry after the payment of the additional fee, the approval shall continue to be in force until orders are passed on the applications and the approval shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.

150E. ***Conditions of approval*** –An approval in Form 37 shall be subject to the following general conditions: —

(a) The institution granted approval under this Part (hereinafter referred to as the approved institution) shall provide and maintain an adequate staff and adequate premises and equipment as specified in rule 150-C [2][and Schedule L-1].

(b) The approved institution shall provide proper facilities for storage so as to preserve the properties of the samples to be tested by it.

(c) The approved institution shall maintain records of tests for identity, purity, quality and strength carried out on all samples of drugs or cosmetics and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of substances for which an expiry date is assigned for a period of two years from the expiry of such date and in the case of other substances for a period of six years.

(d) The approved institution shall allow the Inspector appointed under this Act to enter with or without prior notice the premises where the testing is carried on and to inspect the premises and the equipment used for test and the testing procedures employed. The institution shall allow the Inspectors to inspect the registers and records maintained under these Rules and shall supply to such Inspectors such information as they may require for the purpose of ascertaining whether the provisions of the Act and Rules made thereunder have been observed.

(e) The approved institution shall from time to time report to the approving authority any changes in the person-in-charge of testing of drugs or cosmetics or in the expert staff responsible for testing as the case may be and any material alteration in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant or renewal of approval.

---

1. Subs. by G.S.R. 601 (E), dt. 24-8-2001.

2. Ins. by G.S.R. 780 (E), dt. 10-11-2008.

(f) The approved institution shall furnish reports of the results of test or analysis in Form 39.

(g) In case any sample of a drug or a cosmetic is found on test to be not of standard quality, the approved institution shall furnish the approving authority [1][and the licensing authority of the State where the manufacturer and/or sender of the drug or cosmetic is located] with copy of the test report on the sample with the protocols of tests applied.

(h) The approved institution shall comply with the provisions of the Act and Rules made thereunder and with each further requirements, if any, may be specified in the rules subsequently made under Chapter IV of the Act of which the approving authority has given the approved institution not less than four months notice.

(i) The approved institution shall maintain an Inspection Book to enable the Inspectors to record his impression or defects noticed.

150F. ***Inspection before grant of approval***.— Before an approval in Form 37 is granted, the approving authority shall cause the institution at which the testing of drugs or cosmetics, as the case may be, is proposed to be carried out to be inspected jointly by the Drugs Inspectors of the Central Drugs Standard Control Organisation and the State Drugs Control Organisation who shall examine the premises and the equipment intended to be used for testing of drugs or cosmetics and inquire into the professional qualifications of the expert staff to be employed.

150G. ***Report of Inspection***.— The Drug Inspector mentioned in rule 150-F shall forward to the approving authority a detailed report of the result of the inspection.

150H. ***Procedure of approving authority***.— (1) If the approving authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules made under the Act have been complied with and that the conditions of the approval and the rules made under the Act will be observed, he shall grant an approval in Form 37.

(2) If the approving authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before an approval could be granted.

150-I. ***Further application after rejection***.— If within a period of six months from the rejection of an application for approval, the applicant informs the approving authority that the conditions laid down have been satisfied and deposits inspection fee of [2][rupees two hundred and fifty], the approving authority may, if, after causing a further inspection to be made, he is satisfied that the conditions for grant of approval have been complied with, grant the approval in Form 37.

---

1. Ins. by G.S.R 93 (E), dt. 24-2-1995.
2. Subs.by G.S.R 601 (E), dt. 24-8-2001.

150J. ***Renewal***. – On an application being made for renewal the approving authority may cause an inspection to be made and if satisfied that the conditions of the approval and the rules made under the Act are and shall continue to be observed shall issue a certificate of renewal in Form 38.

150K. ***Withdrawal and suspension of approvals*** – (1) The approving authority may, after giving the approved institution an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, withdraw an approval granted under this Part or suspend it for such period as he thinks fit either wholly or in respect of some of the categories of drugs or items of cosmetics to which it relates, if in his opinion the approved institution has failed to comply with any of the conditions of the approval or with any provisions of the Act or the Rules made thereunder.

(2) Any approved institution whose approval has been suspended or withdrawn may within three months of the date of the order, appeal to the State Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by it in this behalf and notified in the Official Gazette.]

[1][PART XVI

MANUFACTURE FOR SALE OF AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

151. ***Manufacture on more than one set of premises***.—If Ayurvedic (including Siddha) or Unani drugs are manufactured on more than one set of premises, a separate application shall be made and a separate licence shall be obtained in respect of each such set of premises.

152. *Licensing Authorities*.—For the purpose of this Part the State Government shall appoint such Licensing Authorities and for such areas as may be specified in this behalf by notification in the Official Gazette.

153. ***Application for licence to manufacture Ayurvedic (including Siddha) or Unani drugs*.—** (1) An application for the grant or renewal of a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 24-D to the Licensing Authority along with [2][a fee of rupees one thousand]:

Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry:

Provided further that the applicant may apply for renewal after the expiry of one month but within three months of such expiry in which case the [2][fee payable for renewal of such licence shall be rupees one thousand and two hundred plus an additional fee of rupees six hundred].

(ii) [2][A fee of rupees three hundred] shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.

---

1. Parts XVI, XVII and XVII added by S.O. 642, dt. the 2-2-1970 (w.e.f. 21.2.1970)
2. Subs. by G.S.R 79 (E), dt. 14-2-2005.