*THE DRUGS RULES, 1945[1]

[21st December, 1945]

In exercise of the powers conferred by [1][sections 6(2), 12, 33 and 33(N)] of the Drugs [2][and Cosmetics] Act, 1940 (23 of 1940), the Central Government is pleased to make the following Rules:—

PART I
PRELIMINARY

1. **Short title, extent and commencement.**—(1) These Rules may be called the Drugs [3][***] Rules, 1945.

(2) They extend to the whole of India [3][***].

2. Definitions.—In these Rules, unless there is anything repugnant in the subject or context—

(a) "the Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940), as amended from time to time;

[6][(aa) "biopharmaceutical classification system" means a system used to classify drugs on the basis of solubility and permeability, classified as category I-high solubility and high permeability, category II-low solubility and high permeability, category Ill-high solubility and low permeability, and category IV-low solubility and low permeability;] [7][(b) "Central Licence Approving Authority" means the Drugs Controller, India, or the Joint Drugs Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government;]

(c) "Director" means the Director of the Central Drugs Laboratory;

(d) "Form" means a Form set forth in Schedule A;

[8][(dd) "Homoeopathic medicines" include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such

Andhra Pradesh Drugs Rules, 1945.
Assam Drugs Rules, 1945.
Bihar Drugs Rules, 1945.
Bombay Drugs Rules, 1946.
East Punjab Drugs Rules, 1945.
C.P. & Berar Drugs Rules, 1945.
Madras Drugs Rules, 1945.
Orissa Drugs Rules, 1945.
Rajasthan Drugs Rules, 1953.
Saurashtra Drugs Rules, 1953.
Travancore-Cochin Drugs Rules, 1953.
United Provinces Drugs Rules, 1945.
West Bengal Drugs Rules, 1946.
[1][Mysore Drugs Rules, 1954.]

PART XIII

[2][***]

PART XV(A)

APPROVAL OF INSTITUTIONS FOR CARRYING OUT TESTS ON DRUGS, [2][***] AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS [6][***] [3][OR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY]

150B. Application for grant of approval for testing drugs/[4][***].—(1) Application for grant [5][***] of approval for carrying out tests for identity, purity, quality and strength of drags [6][***] or the raw materials used in the manufacture thereof on behalf of licensees for manufacture [7][for sale of drugs [8][***] or an individual or organisation or procurement agency 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 [10][rupees six thousand] in the case of testing of drugs specified in Schedules C and C (1) and [10][rupees one thousand and five hundred] in the case of testing of drugs other than those specified in Schedules C and C (1), homoeopathic drugs [8][***]:

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:

[9][***]:

[1] [(2) A separate application shall be made for grant of approval for carrying out tests on additional categories of drugs or items of [178][***] and shall be accompanied by an inspection fee of rupees one thousand and five hundred in the case of drugs specified in Schedule C and Schedule C(l) and rupees one thousand each in case of drugs other than those specified in Schedule C and Schedule C(l). Homoeopathic medicines [179][***].

Explanation.—For the purpose of this Part, the words 'drugs' [3][***] shall also mean and include raw materials used in the manufacture of drugs including homoeopathic drugs [180][***], as the case may be.]

150C. Form in which approval to be granted for carrying out tests on drugs/[2][***] on behalf of licensees for manufacture of drugs/[2][***][181][or for an individual or organisation or procurement agency] and conditions for grant [6][***]of such approval.—(1) Approval for carrying out such tests of identity,, purity, quality and strength of drugs [182][***] required under the provisions of these rules, on behalf of licensee for manufacture of drugs [4][***] [5][or an individual or organisation or procurement agency] shall be granted in Form 37.

(2) Before approval in Form 37 is granted [183][***], the following conditions shall be complied with by the applicant:—

(1) The premises where the tests are being carried on shall be well lighted and properly ventilated except where the nature of tests of any drug [4][***] warrants otherwise. Whenever 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 [4][***] 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 test 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 provision 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 ofthe Prevention of Cruelty to Animals Act, 1960 (59 of 1960).

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

(4) The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of drugs [1][***] intended to be tested which shall be adequate in the opinion of the approving authority.

(5) The testing of drugs [184][***], 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 identity, purity, quality and strengthshall 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 standard recognised 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.

[3]**[150D. Duration of approval.**—(1) A licence issued under Form 37 shall remain valid if the licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date ofits issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence.

(3) If the licence holder fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent, of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.]

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 150C [185][and Schedule L-l].

(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, [186][***] 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 [2][***] or in the expert staff responsible for testing as the case may be and any material alterations 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 [187][***] of approval.

[4][(f) The approved institution shall furnish reports of the results of test or analysis on the samples received from manufacturer in Form 39 and from an individual or organisation or procurement agency in Form 39A.]

(g) In case any sample of a drug [188][***] is found on test to be not of standard quality, the approved institution shall furnish the approving authority [6][and the licensing authority of the State where the manufacturer and/or sender of the drug [2][***] is located] with a 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 such further requirements, if any, as 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 Inspector to record his impressions 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 [1][***] is proposed to be earned 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 [189][***] and inquire into the professional qualifications of the expert staff to be employed.

150G. Report of Inspection.—The Drugs Inspector mentioned in rule 150F shall forward to the approving authority a detailed report of the results 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.

150-1. 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 [190][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.

150-J. [191][***]

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 therefore, 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 [192][***] to which it relates, if in his opinion the approved institution had failed to comply with any of the conditions of the approval or with any provision 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.]

[6][PART XVI

MANUFACTURE FOR SALE OF AYURVEDIC [7][SIDDHA] OR UNANI DRUGS

151. Manufacture on more than one set of premises.—If Ayurvedic [193][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.

[1]**[153. Application for licence to manufacture Ayurvedic, Siddha or Unani drugs.—(**1) An application for the grant of licence to manufacture for sale of Ayurvedic, Siddha or Unani drug, shall be made—

(a) as defined under clause (a) of section 3 of the Act, in Form 24D to the licensing authority alongwith a fee of rupees two thousand; and

(b) as defined in sub-clause (i) of clause (h) of section 3 of the Act, in Form 24D to the licensing authority alongwith a fee of mpees three thousand for the first ten products and after the said ten products, an additional fee of rupees two thousand per product, through the portal e-AUSHADHI (www.e-aushadhi. gov.in) as per the format provided in