

***THE DRUGS RULES, 1945¹**

[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 III-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

wholly or in respect of any of the drugs to which it relates ^J[or direct the licensee to stop manufacture, sale or distribution of the said drugs and ²[thereupon order the destruction of drugs and] the stocks thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.]

⁴[(3) A licensee whose licence has been suspended or cancelled by the Central Licence Approving Authority or licensing authority under sub-rule (1) or sub-rule (2), as the case may be, may within ninety days of the receipt of a copy of the order by him prefer an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government may after giving the licensee an opportunity of being heard, confirm, reverse or modify such order.]

⁵[PART VIIA
⁶[MANUFACTURE FOR SALE OR FOR DISTRIBUTION]
OF HOMOEOPATHIC MEDICINES]

85A. Manufacture on more than one set of premises.—If Homoeopathic medicines are manufactured in 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.

85B. Application for licence to manufacture Homoeopathic medicines.—

(1) Application for grant or renewal of ¹²⁵[licences to manufacture for sale or for distribution] of Homoeopathic medicines shall be made to the licensing authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the licensing authority) and shall be made in Form 24C.

⁷[(2) The application in Form 24C shall be accompanied—

(a) by a fee of ¹²⁵[rupees two hundred] for the manufacture of Homoeopathic mother tinctures and potentised preparations and an inspection fee of ¹²⁵[rupees one hundred] for the first inspection or ¹²⁵[rupees fifty] in case of inspection for renewal of licence;

(b) by a fee of ¹²⁵[rupees two hundred] for the manufacture of Homoeopathic potentised preparations only, and an inspection fee of ¹²⁵[rupees one hundred] for the first inspection and ¹²⁵[rupees fifty] in case of inspection for renewal of licence;

(c) by a fee of ¹²⁵[rupees two hundred] for the manufacture of potentised preparations from back potencies by pharmacies which are already licensed to sell Homoeopathic medicines by retail and an inspection fee of ¹²⁶[rupees one hundred] for the first inspection or ¹²⁵[rupees fifty] in case of inspection for renewal of licence.

(3) If a person applied for renewal of a licence after its expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be—

(a) ¹²⁶[rupees two hundred] plus an additional fee at the rate of ¹²⁶[rupees one hundred] per month or part thereof and an inspection fee of ¹²⁶[rupees fifty] for the manufacture of Homoeopathic mother tinctures and potentised preparations;

²[(b) ¹²⁷[rupees two hundred] plus an additional fee at the rate of ³[rupees one hundred] per month or part thereof and an inspection fee of ⁴[rupees fifty] for the manufacture of Homoeopathic potentised preparations only;]

(c) ³[rupees two hundred] plus an additional fee at the rate of ³[rupees one hundred] per month or part thereof and an inspection fee of ¹²⁶[rupees fifty] for the manufacture of potentised preparations from back potencies by pharmacies who are already licensed to sell Homoeopathic medicines by retail.]

(4) A fee of ¹²⁶[rupees fifty] shall be paid for a duplicate copy of the licence for the manufacture of Homoeopathic mother tincture and potentised preparations issued under sub-rule (1) if the original is defaced, damaged or lost; while the fee to be paid for such a duplicate copy of the licence for the manufacture of Homoeopathic potentised preparations only shall be ¹²⁶[rupees fifty].

⁴[(5) Applications by licensee to manufacture additional items of Homoeopathic medicines shall be made to the licensing authority and such

applications shall be accompanied by a fee of ³[rupees fifty] for each additional item.]

85C. Application to manufacture 'New Homoeopathic medicines'.—
Subject to the other provisions of these Rules,—

(1) No 'New Homoeopathic medicine' shall be manufactured unless it is previously approved by the licensing authority mentioned in Rule 21;

(2) the manufacture of 'New Homoeopathic medicine', when applying to the licensing authority mentioned in sub-rule (1) shall produce such documents and other evidence as may be required by the licensing authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it;

(3) while applying for a licence to manufacture a 'New Homoeopathic medicine' an applicant shall produce alongwith his application evidence that the 'New Homoeopathic medicine' for the manufacture of which application is made has already been approved.

Explanation.—The term 'New Homoeopathic medicine' in this rule shall have the same meaning as in rule 30AA.

¹[85D. Form of licence to manufacture Homoeopathic medicines.—
Licence for manufacturer of Homoeopathic medicines is a license to manufacture potentised preparations from back potencies by Pharmacies who are already licensed to sell Homoeopathic medicines by retail shall be granted in Form 25C.]

85E. Conditions for the grant or renewal of a licence in Form 25C.—
Before a licence in Form 25C is granted or renewed the following conditions shall be complied with by the applicant:—

(1) The manufacture of Homoeopathic medicines shall be conducted under the direction and supervision of competent technical staff consisting at least of one person who is a whole time employee ²[and who is—

(a) a graduate in Science with Chemistry as one of the subjects with three years' experience in manufacture of Homoeopathic medicines; or

(b) a graduate in Pharmacy with 18 months of experience in the manufacture of Homoeopathic medicines; or

(c) holds qualification as defined under sub-clause (g) of clause (1) of section 2 of the Homoeopathy Central Council Act, 1973 (59 of 1973) with 18 months of experience in the manufacture of Homoeopathic medicines:

Provided that the persons who are already in employment with five years' experience in the manufacture of Homoeopathic medicines and whose name was accordingly entered in any licence granted in Form 25C for manufacture of different classes of Homoeopathic medicines included in them shall be deemed to be qualified for the purpose of this rule.]

³[(2) The factory premises shall comply with the requirements and conditions specified in Schedule MI:

Provided that where the licensing authority considers it necessary or expedient so to do, it may be having regard to the nature and extent of manufacturing operations, relax or suitably alter the said requirements or conditions in any particular case for reasons to be recorded in writing.]

¹[(2A) Certificate of Good Manufacturing Practice.- The certificate of Good Manufacturing Practice to manufacturers, who comply with the requirements of Good Manufacturing Practices of Homoeopathy drugs, as specified in Schedule M-I, shall be issued up to the date of validity of licence]

(3) The applicant for manufacture of Homoeopathic mother tinctures shall either (i) provide and maintain adequate staff, premises and laboratory equipment for identifying the raw materials and for testing the mother tinctures wherever possible, or (ii) make arrangements with some institution approved by the licensing authority ¹²⁸[under Part XV (A) of these rules] for some tests, wherever possible, to be regularly carried out on his behalf by that institution.

(4) The premises where Homoeopathic medicines are manufactured shall be distinct and separate from the premises used for residential purposes.

(5) Homoeopathic medicines shall not be manufactured simultaneously with drugs pertaining to other systems of medicine.

(6) The applicant shall make arrangements for proper storage of Homoeopathic medicines manufactured by him:

³[Provided that in case potentised preparations are made in a Pharmacy holding licence in Form 20C, the conditions (2) and (3) shall not apply. The licensee shall ensure to the satisfaction of the licensing authority that the products manufactured by it, conform to the claims made on the label.]

⁴**[85EA. Inspection before grant or renewal of licence.]**—Before a licence under this Part is granted or renewed in Form 25C or Form 26C, the licensing authority shall cause the establishment, in which the manufacture is proposed, to be conducted or being conducted, to be inspected by one or more Inspectors appointed under the Act. The inspector or Inspectors shall examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed alongwith the means to be employed or being employed for standardising and testing the substances to be manufactured and inquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the requirements of plant and equipment as laid down in Schedule M I read with the requirements of maintenance of records as laid down in Schedule U.]

⁴**[85EB. Report by Inspector.]**—The Inspector of Inspectors shall forward a detailed descriptive report giving his or their findings on each aspect of inspection alongwith his or their recommendations after completion of his or their inspection to the licensing authority.]

⁴**[85EC. Grant or refusal of licence.]**—(1) If the licensing authority after such further enquiry, if any, as he may consider necessary is satisfied that the requirements of the rules under the Act have been complied with and that conditions of the licence and the rules under the Act shall be observed, he shall grant or renew a licence in Form 25C or Form 26C.

(2) If the licensing 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 a licence can be granted or renewed and shall supply the applicant with a copy of inspection report.]

¹**[85ED. Further application after rejection.**—If within a period of six months from the rejection of an application for a licence, the applicant informs the licensing authority that the conditions laid down have been fulfilled and deposits an inspection fee of ¹²⁹[rupees two hundred], the licensing authority may, if after causing further inspection to be made, he is satisfied that the conditions for the grant of licence have been complied with, issue a licence in Form 25C or Form 26C.]

¹**[85EE. Appeal to the State Government.**—Any person who is aggrieved by the order passed by the Licensing Authority refusing to grant or renew a licence under this Part may within ninety days from the date of receipt of such order, appeal to the State Government and the State Government, may, after such enquiry into the matter as is considered necessary and after giving the said person an opportunity for representing the case pass such order as it thinks fit.]

85F. Duration of licence.—An original licence or a renewed licence unless it is sooner suspended or cancelled shall be ²[valid for a period of five years on and from the date on which], it is granted or renewed;

³[Provided that if the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if application for its renewal is not made within six months of its expiry.]

85G. Certificate of renewal.—The certificate of renewal of a licence in Form 25C shall be issued in Form 26C.

85H. Conditions of licence.—A licence in Form 25C shall be subject to the conditions stated therein and to the following further conditions, namely:—

- (a) the licensee shall provide and maintain staff and premises as specified in rule 85E;

(b) the licensee shall allow an ¹³⁰[Inspector appointed under the Act] to enter, with or without prior notice, any premises where the manufacture of a Homoeopathic medicine in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured Homoeopathic medicines;

(c) the licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the rules made thereunder have been observed;

¹[(d) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and defects notice;]

(e) the licensee shall comply with the following conditions in respect of mother tinctures manufactured by him:—

(i) the crude drug used in the manufacture of the mother tincture shall be identified and records of such identification shall be kept ²[for a period of five years];

(ii) the total solids in the mother tincture shall be determined and records of such tests shall be kept ²[for a period of five years];

(iii) the alcohol content in the mother tincture shall be determined and records of the same shall be maintained ²[for a period of five years];

(iv) the containers of mother tinctures shall preferably be of glass and shall be clean and free from any sort of impurities of adhering matter. The glass shall be neutral as far as possible;

(v) in the process of manufacture of mother tinctures hygienic conditions shall be scrupulously observed by the licensee. Storage and handling conditions shall also be properly observed by the licensee according to Homoeopathic principles;

³[(ea) no colour shall be added to any Homoeopathic medicines:

Provided that caramel may be added to combinations of Homoeopathic preparations with syrup base;]

(f) records shall be maintained of Homoeopathic medicines containing alcohol and the quantities sold together with names and addresses of parties to whom sold. ¹[Such records shall be maintained for a period of five years.]

⁴**[85HH. Additional information to be furnished by an applicant for licence or a licensee to the licensing authority.]**—The applicant for the grant of licence or any other person granted a licence under this Part shall, on demand, furnish to the licensing authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation in rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence as the case may be.]

85-I. Cancellation and suspension of licences.—(1) The licensing authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.

¹[(2) A licensee whose licence has been suspended or cancelled may, within three months of the date of the order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.]]

PART VIII

MANUFACTURE FOR EXAMINATION, TEST OR ANALYSIS

86. Conditions relating to manufacture for examination, test or analysis.—The provisions of section 18 of the Act shall not apply to the manufacture of any drug in small quantities for the purpose of examination, test or analysis if the conditions prescribed in this Part are fulfilled.

87. Labelling.—Any drug manufactured for the purpose of examination, test or analysis shall be kept in containers bearing labels, indicating the purpose for which it has been manufactured.

88. Labelling of drugs supplied to other persons.—If any drug manufactured for the purpose of examination, test or analysis is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the substance if known, or if not known a reference which will enable the substance to be identified and the purpose for which it has been manufactured.

89. Licence.—If the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a licence in Form 25 or Form 28 in respect of such drugs he shall, before commencing such manufacture, obtain a licence in Form 29:

²[Provided that in the case of a drug the composition of which is such that the drug is not generally recognised among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use, no licence in Form 29 shall be granted unless the applicant produces a certificate from the licensing authority mentioned in rule 21, to the effect that there would be no objection to such licence being granted.]

90. Form of application.—¹³¹[(1)] An application for a licence in Form 29 shall be made to the licensing authority appointed by the State Government for the purposes of this Part (hereafter in this Part referred to as the licensing authority) in Form 30 and shall be made by or countersigned by the head of the institution in which, or a director of the firm or company by which, the substance will be manufactured.

⁴[(2) Every application in ¹³²[Form 30] shall be accompanied by ¹³³[a fee of rupees two hundred and fifty].]

⁷[(3) The license in Form 29 may be granted by the licensing authority within a period of seven working days from the date of receipt of the application duly completed in Form 30, and in case where no communication is received by the applicant from licensing authority within the said period of seven days, the licensing authority shall be deemed to have granted the license.]

91. Duration of licence.—A licence in Form 29 shall, unless sooner cancelled, be in force for a period of ¹³⁴[three years from the date of issue], and may thereafter be renewed for periods of one year at a time.

92. Conditions of Licence.—A licence in Form 29 shall be subject to the following conditions:—

- (a) the licensee shall use the drugs manufactured under the licence exclusively for purpose of examination, test or analysis, and shall carry on the manufacture and examination, test or analysis at the place specified in the licence;
- (b) the licensee shall allow any ¹[Inspector appointed under the Act] to enter, with or without notice, the premises where the drugs are manufactured and to satisfy himself that only examination, test or analysis work is being conducted;
- (c) the licensee shall keep a record of the quantity of drugs manufactured for examination, test or analysis and of any person or persons to whom the drugs have been supplied;
- (d) the licensee shall comply with such further requirements, if any, applicable to the holders of licences in Form 29 as may be specified in any Rules subsequently made under the Act and of which the licensing authority has given him not less than one month's notice.
- (e) the licensee shall maintain an Inspection Book to enable an Inspector to record his impressions and defects noticed.

93. Cancellation of licences.—(1) The licensing authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part, either wholly or in respect of some of the substances to which it relates, if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provision of the Act or rules thereunder.

²[(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within three months of the date of the order.]

PART IX
LABELLING AND PACKING OF DRUGS OTHER THAN
HOMOEOPATHIC MEDICINES

94. Exemption of certain drugs from certain provisions of this Part.—

(1) Labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the country to which the drug is to be exported but the following particulars shall appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed—

- (a) name of the drug;
- (b) the name, address of the manufacturer and the number of the licence under which the drug has been manufactured;
- (c) batch or lot number;
- (d) date of expiry, if any:

³[Provided that where a drug, not classified under Schedule F, Schedule F(l) and Schedule X, ⁴[or blood products defined under rule 122 EA] is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the licensing authority mentioned in rule 21.]

³[Provided further that where a drug classified as Narcotic Drug or Psychotropic Substance is to be exported under a code number, the same may be permitted by the said Licensing Authority on the following conditions, namely:—

- (i) each consignment of export shall be accompanied with requisite import licence from the importing country;
- (ii) the applicant shall obtain a no objection certificate from the Drugs Controller, India for manufacture of such formulations to be exported with code number against each export order alongwith certificate from the regulatory authority of the importing country controlling Narcotics drugs