

*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

- (a) in cosmetics intended for use only in the area of eye, the level of mercury not exceeding seventy parts per million (0.007 per cent.) of mercury, calculated as the metal, as a preservative;
- (b) in other finished cosmetic products, unintentional mercury shall not exceed one part per million (1 ppm).

135B. Prohibition of import of cosmetics tested on animals.—No cosmetic that has been tested on animals after the commencement of the Drugs and Cosmetics (Fifth Amendment) Rules, 2014 shall be imported into the country.

236. Import of cosmetics for personal use.—Small quantities of cosmetics the import of which is otherwise prohibited under section 10 of the Act, may be imported for personal use subject to the following conditions—

- (i) the cosmetics shall form part of a passenger's baggage and shall be the property of, and be intended for, the bona fide use of the passenger; and
- (ii) the cosmetics shall be declared to the Customs authorities if they so direct."

PART XIV

1. Part XTV (containing rules 137, 138, 138A, 139, 139A, 139AA, 139AB, 139AC, 139AD, 139AE, 139B, 140, 141, 141 A, 141AA, 142, 142A, 142B, 143, 143A, 144, 144A, 145, 145A, 145AA, 145B, 145BA, 145C, 145D) omitted by G.S.R. 763(E), dated 15th December, 2020 (w.e.f. 15-12-2020). Part XIV before omission, stood as under:

"PART XTV MANUFACTURE OF COSMETICS FOR SALE OR FOR DISTRIBUTION

137. Manufacture on more than one set of premises.—If cosmetics are manufactured on more than one premises, a separate application for each such premises shall be made and a separate licence obtaining for each such premises.

138. Application for licence to manufacture cosmetics for sale or for distribution.—(1) Application for grant of licence to manufacture cosmetics for sale or for distribution shall be made upto ten items for each category of cosmetics categorised in Schedule Mil to the Licensing Authority appointed by the State Government for the purpose of this part (hereinafter in this Part referred to as Licensing Authority) in Form 31 and shall be accompanied by a licence fee of rupees two thousand and five hundred and an inspection fee of rupees one thousand for every inspection thereof [***].

(3) Application by a licensee to manufacture additional items of cosmetics shall be accompanied by a fee of 4[rupees one hundred for each item subject to a maximum of rupees three thousand for each application]:

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(4) A fee of rupees two hundred and fifty shall be paid for duplicate copy of a licence issued under sub-rule (1), if the original is defaced, damaged or lost.

138A. Application for loan licence to manufacture cosmetics.—(1) Application for grant [***] of a loan licence for the manufacture for sale of cosmetics shall be made up to ten items of each category' of cosmetics categorised in Schedule Mil in Form 31A to the Licensing Authority and shall be accompanied by a licence fee of rupees two thousand and five hundred and an inspection fee of rupees one thousand for every inspection thereof.

Explanation.—For the purpose of this rule a 'loan licence' means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by a licensee in Form 32.

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(3) The licensing authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities to undertake the manufacture on behalf of the applicant for a loan licence.

(4) The loan licence shall be granted by the licensing authority to only such applicants who propose to avail of the facilities of manufacture of cosmetics in the premises of a manufacturer located in the same State where the applicant is located. In case the manufacture of cosmetics involves any special process of manufacture or use of equipments which are not available in the State where the applicant is located, the licensing authority, after consulting the licensing authority where the manufacturing unit is located, may grant the loan licence.

(5) Subject to the provisions of sub-rule (2), application for manufacture of additional items on a loan licence shall be accompanied by a fee of rupees one hundred for each item subject to a maximum of rupees three thousand per application.

(6) A fee of rupees two hundred and fifty shall be paid for a duplicate copy of a licence issued under sub-rule (1) if the original is defaced, damaged or lost.

139. *Condition for the grant I***] of a licence in Form 32.*—Before a licence in Form 32 is granted [***], the following conditions shall be complied with by the applicant:—

(1) The manufacture shall be conducted under the direction and personal supervision of a competent technical staff consisting of at least one person who is a whole time employee and who possesses any one of the following qualifications:

(a) holds a Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 (8 of 1948), or

(b) is registered under the Pharmacy Act, 1948 (8 of 1948), or

(c) has passed the Intermediate Examination with Chemistry as one of the subjects or an examination recognised by the licensing authority as equivalent to it.

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(2) The factory premises shall comply with the requirements and conditions specified in Schedule M II.

(5) The applicant shall either—

(i) provide and maintain adequate staff, premises and laboratory equipment for testing the cosmetic manufacture, and the raw materials used in the manufacture, or ^

(ii) make arrangements with some institution approved by the licensing authority under Part XV(A) of these rules for such tests to be regularly carried out in this behalf by the institution.

139A. Form of licence to manufacture cosmetics for sale or for distribution.—A licence to manufacture cosmetics for sale or for distribution against application in Form 31, shall be granted in Form 32.

*139AA. Inspection before grant [***] of licence.*—Before a licence under this Part is granted [***] in Form 32, Form 3.2A or Form 33, 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. It 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-II read with the requirements of maintenance of records as laid down in Schedule U-I.

139AB. 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.

3 39AC. Grant or refusal of licence.—(1) If the Licencing 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 the conditions of the licence and the rules under the Act shall be observed, he shall grant [***] a licence in Form 32, Form 32A or Form 33.

(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 [***] and shall supply the applicant with a copy of inspection report.

139AD. 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 rupees two hundred and fifty, the Licencing 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 32, Form 32A or Form 33.

139AE. Appeal to the State Government.—Any person who is aggrieved by the order passed by the licensing authority refusing to grant [***] 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.

139B. Form of loan licence to manufacture cosmetics for sale or for distribution.—A loan licence to manufacture cosmetics for sale or for distribution against application in form 31A shall be granted in Form 30A.

140. Duration of licence.—(1) A licence issued under Form 32 and Form 32A shall remain valid if the licensee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its 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 excluding inspection fee paid for grant of 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

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six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.

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142. *Conditions of licence.*—A licence in Form 32 shall be subject to the conditions stated therein and to the following other conditions, namely:—

- (a) The license shall provide and maintain staff, premises and equipment as specified in rule 139,
- (b) The licensee shall comply with the provisions of the Act and the rules made thereunder and with such further requirements, if any, as may be specified in any rules to be made hereafter under Chapter IV of the Act.
- (b) The licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in Schedule U(1) and such records shall be retained for a period of three years.
- (c) The licensee shall test each batch or lot of the raw materials used by him for the manufacture of the cosmetics and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests. The records or registers shall be retained for a period of three years from the date of manufacture.
- (d) The licensee shall allow any Inspector appointed under the Act to enter with or without prior notice any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured products under a receipt.
- (e) The licensee shall allow an Inspector to inspect all register 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 complied.
- (f) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and the defect noticed:

Provided that clauses (b) and (c) shall not apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the "licensing authority".

742A. *Additional information to be furnished by an applicant for licence or a licensee to the licensing authority.*—The applicant for the grant of a licence or any 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 on 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.

142B. Conditions of licence in Form 32A.—(a) A licence in Form 32A shall be deemed to be cancelled or suspended, if the licence owned by the licensee, in Form 32, whose manufacturing facilities, is cancelled or suspended, as the case may be, under these rules.

(b) The licensee shall comply with the provisions of the Act and these rules and with such further requirements, if any, as may be specified from time to time in Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

(b) The licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in Schedule U(1) and such records shall be retained for a period of three years.

(c) The licensee shall test each batch or lot of the raw materials used by him for the manufacture of the cosmetics and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests. The records or registers shall be retained for a period of three years from the date of manufacture.

(d) The licensee shall allow an Inspector appointed under the Act to enter with or without prior notice any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured products under a receipt.

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(e) 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 complied.

(f) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

143. Cancellation and suspension of licence.—(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 therefore, 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 the rules made thereunder.

(2) A licensee whose licence has been suspended or cancelled may appeal within a period of three months from the date of the order to the State Government which shall after considering the appeal, pass orders, and such orders shall be final.

243A. Inspection for grant of licence and verification of compliance.—(1) Before a licence in Form 32 or Form 32A [***] is granted, the licensing authority shall cause the establishment in which the manufacture of cosmetics is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act, who shall examine the establishment intended to be used or being used for the manufacture of cosmetics.

(2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector appointed by the Central Government and the State Government to verify the compliance, with the conditions of licence and the provisions of the Act and these rules, not less than once in three years or as needed as per risk based approach.

244. *Prohibition of manufacture of cosmetics containing colours other than those prescribed.*—(1) No cosmetics shall be manufactured which contain dyes, colours and pigments other than the one specified by the Bureau of Indian Standards (IS : 4707 Part I as amended) and Schedule Q.

The permitted synthetic organic colours and natural organic colours used in the Cosmetic shall not contain more than—

- (i) 2 parts per million of Arsenic calculated as Arsenic Trioxide.
- (ii) 20 parts per million of Lead calculated as Lead.
- (iii) 100 parts per million of Heavy Metals other than lead calculated as the total of the respective metals.

144A. *Prohibition of manufacture of cosmetic containing Hexachlorophene.*—No cosmetic containing Hexachlorophene shall be manufactured:

Provided that in the case of soaps Hexachlorophene may be used in concentrations not exceeding one per cent weight by weight:

Provided further that the following cautionary note shall be printed and shall appear in a conspicuous manner on the wrapper of package of each soap, namely:—

"Contains Hexachlorophene—not to be used on babies".

145. *Use of Lead and Arsenic compounds for the purpose of colouring cosmetics prohibited.*—The use of Lead and Arsenic compounds for the purpose of colouring cosmetics is prohibited.

145A. *Form of intimation for purposes of taking samples of cosmetics.*— Where an Inspector takes a sample of a cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.

145AA. *Form of receipt of samples of cosmetics where fair price tendered is refused.*—Where the fair price, for the samples of cosmetics taken for the purpose of test or analysis, tendered under sub-section (1) of section 23 has been refused, the Inspector shall tender a receipt therefor to the person from whom the said samples have been taken as specified in Form 17A.

145B. *Form of receipt for seized cosmetics.*—A receipt by an Inspector for the stock of any cosmetics seized under clause (c) of sub-section (1) of section 22 of the Act, shall be in Form 16.

145BA. *Manner of certifying copies of seized documents.*—The Drugs Inspector shall return the documents, seized by him under clause (cc), or produced before him under clause (cca), of sub-section (1) of section 22 of the Act, within a period of twenty days of the date of such seizure or production, to the person from whom they were seized or, as the case may be, the person who produced them, after copies thereof or extracts therefrom have been signed by the concerned Drugs Inspector and the person from whom they were seized, or, as the case may be, who produced such records.

PART XV

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145C. Form of order not to dispose of stocks of cosmetics.—An order in writing by an Inspector under clause (c) of sub-section (1) of section 22 of the Act requiring a person not to dispose of any stock of cosmetics in his possession shall be in Form 15.

145D. Regulation of use of mercury compounds in cosmetics.—Cosmetics manufactured in the country shall contain mercury in the following proportions, namely,—

- (a) in cosmetics intended for use only in the area of eye, the level of mercury not exceeding seventy parts per million (0.007 per cent.) of mercury, calculated as the metal, as a preservative;
- (b) in other finished cosmetic products, unintentional mercury shall not exceed one part (per million (1 ppm).

1. Part XV (containing rules 146, 147, 148, 148A, 148B, 148C, 149, 149A, 150, 150A) omitted by G.S.R. 763(E), dated 15th December, 2020 (w.e.f. 15-12-2020). Part XV before omission, stood as under:

"PART XV

LABELLING, PACKING AND STANDARDS OF COSMETICS

146. Prohibition of sale or distribution.—Subject to the other provisions of these rules, no person shall sell or distribute any cosmetic unless the cosmetic, if of Indian origin, is manufactured by a licensed manufacturer and labelled and packed in accordance with these rules.

147. Exemption of Cosmetics not manufactured for consumption or sale in India from the provisions of this Part.—Labels on packages or containers of cosmetics not manufactured for consumption or sale in India shall be adapted to meet the specific requirements, if any, of the consignee:

Provided that where a cosmetic 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.

148. Manner of labelling.—Subject to other provisions of the rules, a cosmetic shall carry—

- (1) On both the inner and outer labels:
 - (a) the name of the cosmetics,
 - (b) the name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured:

Provided that if the cosmetic is contained in a very small size container where the address of the manufacturer cannot be given, the name of the manufacturer and his principal place of manufacture shall be along with pin code.

- (c) Use before..... (month and year).

(2) On the outer label:

A declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, weight for semi-solids, combined with numerical count if the content is sub-divided:

Provided that this statement need not appear in case of a package of perfume, toilet water or the like, the net content of which does not exceed 60 ml or any package of solid or semi-solid cosmetic the net content of which does not exceed 30 grams.

(3) On the inner label; where a hazard exists:

- (a) adequate direction for sale use,
- (b) any warning, caution or special direction required to be observed by the consumer,
- (c) a statement of the names and quantities of the ingredients that are hazardous or poisonous.

(4) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the letter B:

Provided that this clause shall not apply to any cosmetic containing 10 grams or less if the cosmetic is in solid or semi-solid state, and 25 millilitres or less if the cosmetic is in a liquid state:

Provided further that in the case of soaps, instead of the batch number, the month and year of manufacture of soap shall be given on the label.

(5) Manufacturing licence number, the number being preceded by the letter M.

(6) Where a package of cosmetic has only one label such label shall contain all the information required to be shown on both the inner and the outer labels, inder these rules.

(7) The list of ingredients, present in concentration of more than one per cent shall be listed in the descending order of weight or volume at the time they are added, followed by those in concentration of less than or equal to one per cent, in any order, and preceded by the word "INGREDIENTS":

Provided that this statement need not appear for packs of less than 60 ml of liquids and 30 gm of solid and semi solids.

(8) Labeling requirements, if any, specified in the relevant Indian Standards laid down by the Bureau of Indian Standards for the cosmetics covered under Schedule "S".

148A. Prohibition against altering inscriptions on containers, labels or wrappers of cosmetic.— No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufactuier on the container, label or wrapper of anv cosmetic:

Provided that nothing in tiis rule shall apply to any alteration, inscription to mark made on the container, label or wrapper of any cosmetic at the instance or direction or with the permission of the licensing authority. , ,