



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)

obtaining, if necessary, the report of the Director of the Central Drugs Laboratory shall pass orders thereon which shall be final.

(4) If the Drugs Controller or any other officer empowered by him in this behalf with the approval of Central Government reports to the Collector of Customs after the inspection of the sample of cosmetic and if necessary, after obtaining a test report thereon that the sample of the said cosmetic contravenes in any respect the provisions of Chapter III of the Act or the Rules made thereunder but that the contravention is such that it can be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer and permit him to import the cosmetic on his giving an undertaking in writing not to dispose of the cosmetic without the permission of the officer authorised in this behalf by the Central Government.

132. Exemption of cosmetics—Cosmetics as may be specified in Schedule D shall be exempted from the provisions of Chapter III of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule.

133. Import through points of entry—No cosmetic shall be imported into India except through the points of entry specified in rule 43A.

¹**134. Cosmetic to contain Dyes, Colours and Pigments.**— No Cosmetic shall contain Dyes, Colours and Pigments other than those specified by the Bureau of Indian Standards (IS:4707 Part 1 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.]

²**134-A Prohibition of import of cosmetic containing Hexachlorophene.**— No cosmetic containing hexachlorophene shall be imported.

135. Import of cosmetic containing Lead or Arsenic compound prohibited.—No cosmetic shall be imported in which a Lead or Arsenic compound has been used for purposes of colouring.

³**135-A. Import of cosmetics containing mercury compounds prohibited.**—No cosmetic shall be imported which contains mercury compounds.]

⁵**135-B. 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.]

136. Import of cosmetic 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 intended for, the *bona fide* use of the passenger; and
- (ii) The cosmetics shall be declared to the Customs authorities, if they so direct.

⁴**[PART XIV
MANUFACTURE OF COSMETIC 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 obtained for each such premises.

1. Subs. by G.S.R. 811 (E), dt. 14-11-1994.

2. Added by G.S.R. 116, dt. 25-1-1975.

3. Ins. by X.11013/76-D & MS, dt. 19-8-1978.

4. Subs. by G.S.R. 788 (E), dt. 10-10-1985.

5. Ins. by G.S.R. 718 (E), dt. 13-10-2014.

138. Application for ⁵ [licence to manufacture cosmetics for sale and distribution]—

³[(1) Application for grant or renewal of ⁵ [licence to manufacture any cosmetic for sale or for distribution] ¹ [shall be made up to ten items of each category of cosmetics categorized in Schedule MII 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) 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 or for the purpose of renewal of licence].

²[* * * * *]

³[(2) If a person applies for the renewal of licence after expiry but within six months of such expiry, the fee payable for the renewal of such licence shall be ¹ [rupees two thousand five hundred plus an additional fee at the rate of rupees four hundred per month or part thereof in addition to an inspection fee of rupees one thousand.]

²[* * * * *]

(3) Application by a licensee to manufacture additional items of cosmetics shall be accompanied by a fee of ¹ [rupees one hundred for each item subject to a maximum of rupees three thousand for each application.]

²[* * * * *]

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

⁴ [**138A. Application for loan licence to manufacture cosmetics.**—(1) Application for grant or renewal of a loan licence for the manufacture for sale of cosmetics ¹ [shall be made up to ten items of each category of cosmetics categorized in Schedule M-II in Form 31-A 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 to manufacture but who intends to avail himself of the manufacturing facilities owned by a licensee in Form 32.

(2) If a person applies for the renewal of a loan licence after the expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be

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

2. Omitted by G.S.R. 331(E), dt. 8.5.1984.

3. Amended by G.S.R. 245, dt. 21.2.1976.

4. Ins. by G.S.R. 444, dt. 28-4-1973.

5. Subs. by G.S.R. 788 (E), dt. 10-10-1985.

6. Subs. by G.S.R. 331(E), dt. 8.5.1984.

¹[rupees two thousand and five hundred plus an additional fee at the rate of rupees four hundred for each month or part thereof.]

(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 cosmetic involves any special process of manufacture or use of equipment 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 ¹[rupees one hundred for each item subject to a maximum of rupees three thousand per application.]

(6) A fee of ¹[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. Conditions for the grant or renewal of a licence in Form 32—Before a licence in Form 32 is granted or renewed, the following conditions shall be complied with by 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 recognized by the Licensing Authority as equivalent to it.

²[* * * * *]

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

2. Omitted by. G.S.R. 331(E), dt. 8.5.1984

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

²[* * * * *]

(5) The applicant shall either--

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

(ii) make arrangements with some institution approved by the Licensing Authority ³[under Part XV (A) of these rules] for such tests to be regularly carried out in this behalf by the institution.

⁴[**139A. Form of ⁵[licence to manufacture cosmetics for sale or for distribution].**—A ⁵[licence to manufacture cosmetics for sale or for distribution] against application in Form 31, shall be granted in Form 32.]

⁶[**139AA. Inspection before grant or renewal of licence.**— Before a licence under this Part is granted or renewed in Form 32, Form 32A 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 along with the means to be employed or being employed for standardizing and testing the substances to be manufactured and enquire 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 plant, testing equipments and the requirements of plant and equipments as laid down in Schedule M-II read with requirements of maintenance of records as laid down in Schedule U-1.]

⁶[**139AB. Report by Inspector.**— The Inspector or Inspectors shall forward a detailed descriptive report giving his or their findings on each aspect of inspection along with his or their recommendations after completion of his or their inspection to the Licensing Authority.]

⁶[**139AC. 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 the conditions of the licence and the rules under the Act shall be observed, he shall grant or renew a licence in form 32, Form 32-A or Form 33.]

1. Subs. by G.S.R. 723 (E), dt. 11-8-1992.
2. Omitted condition (3) and (4) by G.S.R. 723 (E), dt. 11-8-1992.
3. Ins. by G.S.R. 1172 (E), dt. 23-8-1977.
4. Ins. by G.S.R. 444, dt. 28-4-1973.
5. Subs. by G.S.R. 788 (E), dt. 10-10-1985.
6. Ins. by G.S.R. 493 (E), dt. 9-6-1995.

(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[**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 ²[fee of rupees two hundred and fifty], 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 32, Form 32-A or Form 33.]

¹[**139AE. 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.]

³[**139B. Form of loan ⁴licence to manufacture cosmetics for sale or for distribution.**—A loan ⁴[licence to manufacture cosmetics for sale or for distribution] against application in Form 31-A shall be granted in Form 32-A.

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

⁵[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.]

141. Certificate of renewal.—The certificate of renewal of a licence in Form 32 shall be issued in Form 33.

1. Ins. by G.S.R. 493 (E), dt. 9-6-1995.
2. Subs. by G.S.R. 601 (E), dt. 24-8-2001.
3. Ins. by G.S.R. 444, dt. 28-4-1973.
4. Subs. by G.S.R. 493 (E), dt. 9-6-1995.
5. Amended by S.O. 2139, dt. 12.8.1972.

¹[**141A. Certificate of renewal of a loan licence**—The certificate of renewal of a licence in Form 32-A shall be issued in Form 33-A.]

¹[**141AA. Duration of a loan licence.**—An original loan licence in Form 32A or a renewed loan licence in Form 33-A, unless 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:

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

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 licensee 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;

³ [(b1) 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 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 ¹ [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;

1. Ins. by G.S.R. 444, dt. 28-4-1973.

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

3. Ins. by G.S.R. 1594, dt. 28-10-1976.

(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;

¹[(f) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and the defects noticed:

²[Provided that clauses (b-1) 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 the manufacturer of soap shall be such as are approved by the Licensing Authority.]

⁴[**142A. 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.]

¹[**142B. Conditions of licence in Form 32-A.**—

(a) A licence in Form 32-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee, in Form 32, whose manufacturing facilities are 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 each 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.

³[(b1) 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 of registration 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.

1. Ins. by G.S.R. 444, dt. 28-4-1973.

2. Ins. by G.S.R. 681 (E), dt. 6-6-1988.

3. Ins. by G.S.R. 1594, dt. 28-10-1976.

4. Ins. by S.O.2139, dt. 12-8-1972.

(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 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 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 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 the rules made thereunder.

(2) A licensee whose license 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.

¹[**144. Prohibition of manufacture of cosmetics containing colours other than those prescribed.**— No Cosmetic shall be manufactured which contains 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.]

²[**144A. Prohibition of manufacture of cosmetics containing Hexachlorophene.**—No cosmetic containing Hexachlorophene shall be manufactured:]

1. Subs. by G.S.R. 811(E), dt. 14-11-1994.

2. Ins. by G.S.R. 116, dt. 15.1.1975.

¹[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.

²[**145A. Form of intimation for purpose 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.]

³[**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.]

²[**145B. Form of receipt for seized cosmetics.**—A receipt by an Inspector for the stock of any cosmetic seized under clause (c) of sub-section (1) of section 22 of the Act shall be in Form 15.]

⁴[**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 Drugs Inspector concerned and the person from whom they were seized, or, as the case may be, who produced such records.]

⁵[**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.]

⁶[**145D. Prohibition of manufacture of cosmetics containing mercury compounds.**—No cosmetics containing mercury compounds shall be manufactured.]

1. Ins. by G.S.R. 1049 (E), dt. 29-8-1986.

2. Ins. by S.O. 2139, dt. 5.6.1972.

3. Ins. by G.S.R. 292 (E), dt. 29-5-1997.

4. Ins. by G.S.R. 89(E), dt. 16-2-1985.

5. Ins. by G.S.R. 1594, dt. 28-10-1976.

6. Ins. by G.S.R. 1074, dt. 19.8.1978 (w.e.f. 2.9.1978).