

Drugs & Cosmetics Rules, 1945

Conditions of Licence for Cosmetic Manufacturing (Including loan Licence)

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, premise and equipment specified in Rules 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-1) 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(I) and such records shall be retained fro 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.
- (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 compiled.
- (f) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and the defects noticed:

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 a manufacturer of soap shall be such as are approved by the "Licensing Authority".

142-B. 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, 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-1) 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.
- (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.