

Drugs & Cosmetics Rules, 1945

Conditions of Licence for Ayurvedic Drug Manufacturing (Including Loan Licence)

158. Conditions of licence.- A licence in Form 25-D shall be subject to the conditions stated therein and to the following further conditions, namely:-

- (a) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw materials and finished products.
- (b) The licensee shall allow an Inspector appointed under the Act to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises, to take samples of the raw materials as well as the finished products, and to inspect the records maintained under these rules.
- (c) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

158-A. Conditions of loan licence.- A licence in Form 25-E shall be subject to the conditions stated therein and to the following further conditions, namely:

- (a) The licence in Form 25-E shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25-D whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.
- (b) The licensee shall comply with the provisions of the Act and of the rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV-A 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.
- (c) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or any other person on his behalf, of the raw materials and finished products.
- (d) The licensee shall allow an Inspector appointed under the Act 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 have been observed.
- (e) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.