

Drugs & Cosmetics Rules, 1945

Conditions of Licence for Homeopathic Medicines Manufacturing

85-H. Conditions of licence.-A licence in Form 25-C 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 85-E;
- (b) the licensee shall allow an Inspector appointed under the Act to enter, with or without prior notice, any premises where the manufacture of a Homeopathic medicine in respect of which licence is issued, is carried on, to inspect the premises and to take samples of the manufactured Homeopathic 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 rules made thereunder have been observed;
- (d) 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 mother tincture shall be identified and records of such identification shall be kept 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 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 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 Homeopathic principles;
- (e) no colour shall be added to any Homeopathic medicines: Provided that caramel may be added to combinations of Homeopathic preparations with syrup base;
- (f) records shall be maintained of Homeopathic medicines containing alcohol and the quantities sold together with names and addresses of parties to whom sold. Such records shall be maintained for a period of five years.