

Drugs & Cosmetics Rules, 1945

Conditions of Licence for Repacking of Drugs

74-A. Conditions for license in Form 25-B.- A license in form 25-B shall be subject to the conditions stated therein and to the following conditions-

- (a) the repacking of drugs shall at all times be conducted under the personal supervision of atleast one person who is approved as a competent person by the licensing authority;
- (b) the licensee shall either provide and maintain adequate arrangements in his own premises for carrying out tests of the strength, quality and purity of the drugs repacked or 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 on his behalf by the institution;
- (c) the licensee shall make adequate arrangements for the storage of drugs;
- (d) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under 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;

- (e) the licensee shall allow an [Inspector appointed under the Act] to enter with or without notice, any premises where the repacking of drugs in respect of which the license is issued is carried on, to inspect the premises and to take samples of repacked drugs;
- (f) the licensee shall, either in his own laboratory or, in any other laboratory approved by the Licensing Authority, test each batch or lot of raw material used by him for repacking and also each batch of the product thus repacked and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of five years from the date of repacking. The licensee shall allow the 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 these rules have been observed;
- (g) the licensee shall maintain an Inspection Book, in Form 35, to enable an Inspector to record his impressions and the defects noticed;
- (h) the licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference sample shall be maintained for a period of three years from the date of manufacture.