

Drugs & Cosmetics Rules, 1945

Conditions of Licence for Blood Banks

122-P. Conditions of licence

[A licence in Form 28-C, Form 28-E, Form 26-G or Form 26-I shall be subject to the special conditions, set out in Schedule F, Part XIIB and Part XIIC, as the case may be, which relate to the substance in respect of which the licence is granted or renewed and to the following general conditions, namely---]

- (i)
 - (a) The licensee shall provide and maintain adequate staff, plant and premises for the proper operation of a Blood Bank of processing whole human blood, its components and/or manufacture of blood products.
 - (b) The licensee shall maintain staff, premises and equipment as specified in Rule 122-G. The licensee shall maintain necessary records and registers as specified in Schedule F, Parts XII-B and XII-C.
 - (c) The licensee shall test in his own laboratory whole human blood, its components and blood products and [maintain records and] registers in respect of such tests as specified in Schedule F, Parts XII-B and XII-C. The records and registers shall be maintained for a period of five years from the date of manufacture.
 - (d) The licensee shall maintain/ preserve reference [sample and] supply to the Inspector the reference sample of the whole human blood collected by him in an adequate quantity to conduct all the prescribed tests. The licensee shall supply to the Inspector the reference sample for the purpose of testing.
- (ii) The licensee shall allow an Inspector appointed under the Act to enter, with or [without] prior notice, any premises where the activities of the Blood Bank are being carried out, for the processing of Whole Human Blood and/ or Blood Products, to inspect the premises and plant and the process of manufacture and the means employed for standardizing and testing the substance.
- (iii) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.
- (iv) The licensee shall from time to time report the Licensing Authority and changes in the expert staff responsible for the operation of a Blood Bank/ processing of whole human blood for components and/ or manufacture of blood products and any material alterations in the premises or plant used for that purpose which have been made since the date of last inspection made on behalf of the Licensing Authority before the grant of the licence.
- (v) The licensee shall on request furnish to the Licensing Authority, or Central Licence Approving Authority or to such Authority as the Licensing Authority or the Central Licence Approving Authority may direct, from any batch unit of drugs as the Licensing Authority or Central Licence Approving Authority may from time to time specify, sample of such quantity as may be considered adequate by such Authority for any

examination and, if so required, also furnish full protocols of the test which have been applied.

- (vi) If the Licensing Authority or the Central Licence Approving Authority so directs, the licensee shall not sell or offer for sale any batch/unit in respect of which a sample is, or protocols are furnished under the last preceding sub-paragraph until a certificate authorizing the sales of batch/unit has been issued to him by or on behalf of the Licensing Authority or the Central Licence Approving Authority.
- (vii) The licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch/unit of the substance has been found by the Licensing Authority or the Central Licence Approving Authority not to conform with the standards of strength, quality or purity specified in these Rules and on being directed so to do, withdraw, from sales and so far as may be in particular circumstances of the case be practicable recall all issues already made from that batch/unit.
- (viii) No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture. Further no batch/unit manufactured under this licence shall be supplied/ distributed to any person without prescription of Registered Medical Practitioner.
- (ix) 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 Gazette¹
- (x) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and defects noticed.
- (xi) The licensee shall destroy the stock of batch/unit, which does not comply with standards tests in such a way that it would not spread any disease/infection by way of proper disinfections method.]
- (xii) All bio-medical waste shall be treated, disposed off or destroyed as per the provisions of The Bio-Medical Wastes (Management and Handling) Rules, 1996.
- (xiii) The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components and/or manufacture blood products from the blood drawn from such a donor.