

## Drugs & Cosmetics Rules, 1945

### Conditions of Licence for Allopathic Loan Licence Manufacturing

#### 74-B. Conditions of license in Form 25-A.-

- (1). The license in Form 25-A shall be deemed to be cancelled or suspended, if the license owned by the licensee in Form 25 whose manufacturing facilities have been availed of by the licensee is cancelled or suspended as the case may be, under these rules.
- (2). 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.
- (3). The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product 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 manufacture. 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 these rules have been observed.
- (4). The licensee shall either-
  - (i). Provide and maintain to the satisfaction of the licensing authority adequate staff and adequate laboratory facilities for carrying out tests of strength, quality and purity of the substances manufactured by him; or
  - (ii). 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.]
- (5). 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 samples shall be maintained for a period of three years from the date of manufacture.
- (6). The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

## Drugs & Cosmetics Rules, 1945

### Conditions of Licence for Allopathic Drug Manufacturing

**74. Conditions of licence in [Form 25 and Form 25-F].-** A licence in [Form 25 and Form 25-F] shall be subject to the conditions stated therein and to the following further conditions, namely-

- (a) the licensee shall provide and maintain staff, premise and the equipment as specified in Rule 71;
- (b) 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;
- (c) the licensee shall either in his own laboratory or in any other laboratory approved by the licensing authority [under Part XV(A) of these Rules] test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product 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 5 years from the date of manufacture;
- (d) (d) the licensee shall keep records of the details of manufacture as per particulars given in Schedule U of each batch of the drugs manufactured by him and such records shall be retained for a period of five years;
- (e) the licensee shall allow an [Inspector authorised by the Act] to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture and the means employed in standardizing and testing the drugs;
- (f) the licensee shall allow an [Inspector authorised by the Act] to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs and shall supply to such Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the rules thereunder have been observed;
- (g) the licensee shall, from time to time, report to the licensing authority any changes in the expert staff responsible for the manufacture or testing of the drugs and any material alterations in the premises or plant used for the purpose which have been made since the date of the last inspection made on behalf of the licensing authority;
- (h) the licensee shall, on request, furnish to the licensing authority, the controlling authority or to such authorities as the licensing authority or the controlling authority may direct, from every batch or batches of drugs as the licensing authority or the controlling authority may from time to time specify, a sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish full protocols of tests which have been applied;

- (i) if the licensing authority [or the controlling authority] so directs and if requested by the licensee who had also furnished *prim a facie* reasons for such directions, the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under clause (h) until a certificate authorising the sale of batch has been issued to him by or on behalf of the licensing authority [or the controlling authority];
- (j) the licensee shall on being informed by the licensing authority [or the controlling authority] that any part of any batch of the drug has been found by the licensing authority [or the controlling authority] not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch;
- (k) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed;
- (l) 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 samples shall be maintained for a period of three years from the date of manufacture;
- (m) the licensee, who has been granted a license in Form 25-F, shall-
  - (i). forward to the licensing authority of the concerned States of manufacture and supply of the drug a statement of the sales effected to the manufacturers, wholesalers, retailers, hospitals, dispensaries and nursing homes and Registered Medical Practitioners every three months;
  - (ii). maintain accounts of all transactions giving details as indicated below in a register bound and serially page numbered and such records shall be retained for a period of five years or one year after the expiry of potency, whichever is later:-

A. Accounts of the drugs specified in Schedule X used for the manufacture:-

1. Date of issue.
2. Name of the drug.
3. Opening balance of stock on the production day.
4. Quantity received, if any, and source from where received.
5. Quantity used in manufacture.
6. Balance quantity on hand at the end of the production day.
7. Signature of the person in charge.

B. Accounts of production:-

1. Date of manufacture.
2. Name of the drug.
3. Batch Number.
4. Quantity of raw material used in manufacture.
5. Anticipated yield.
6. Actual yield.
7. Wastage.
8. Quantity of the manufactured goods transferred.

C. Accounts of the manufactured drugs:-

1. Date of manufacture.
2. Name of the drug.
3. Batch Number.
4. Opening Balance.
5. Quantity manufactured.
6. Quantity sold.
7. Name of the purchaser and his address.
8. Balance quantity at the end of the day.
9. Signature of the person in charge.

- (n) The licensee shall store drugs specified in Schedule X in bulk form and when any of such drug is required for manufacture in a place other than its place of storage it shall be kept in a separate place under the direct custody of a responsible person.
- (o) The licensee shall comply with the requirements of 'Good Manufacturing Practices' as laid down in Schedule M.

**78. Conditions of licence.-** A licence in Form 28, Form 28-B or Form 28-D shall be subject to the special conditions, if any, set out in Schedule F or Schedule F(1), as the case may be, which relate to substance in respect of which the licence is granted and to the following general conditions:

- (a)
- (i) The licensee shall provide and maintain an adequate staff and adequate premises and plant for the proper manufacture and storage of the substances in respect of which the licence is issued.
  - (ii) Without prejudice to the generality of the foregoing requirements, every holder of a licence who for any purpose engaged in the culture or manipulation of pathogenic spore-bearing micro-organisms shall provide to the satisfaction of the Licensing Authority separate laboratories and utensils and apparatus required for the culture or manipulation of such micro-organisms, the laboratories, utensils and apparatus so provided not being used for the manufacture of any other substance.
- (b) The licensee shall provide and maintain staff, premises and equipment as specified in Rule 76.
- (c)

- (i) The licensee shall maintain records of manufacture as per particulars given in Schedule U.
- (ii). The licensee shall either in his own laboratory or in any laboratory approved by the Licensing Authority under Part XV(A) to these Rules test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product 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 in the case of a substance for such date, and in the case of other substances for a period of five 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 is carried on and to inspect the premises, and in the case of substances specified in Schedule C and C(1), to inspect the plant and the process of manufacture and the means employed for standardizing and testing the substance.
- (e) 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 each Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.
- (f) The licensee shall from time to time report to the Licensing Authority any changes in the expert staff responsible for the manufacture or testing of the substances and any material alterations in the premises or plant used for that purpose which have been made since the date of the last inspection made on behalf of the Licensing Authority before the issue of the licence.
- (g) The licensee shall on request furnish to the Licensing Authority, controlling authority or to such authorities as the Licensing Authority or the controlling authority may direct, from every batch of drugs as the Licensing Authority or the controlling authority may from time to time specify, a 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 tests which have been applied.
- (h) If the Licensing Authority or the controlling authority so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is, or protocols are furnished under the last preceding subparagraph until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the Licensing Authority or the controlling authority.
- (i) The licensee shall on being informed by the Licensing Authority or the controlling authority that any part of any batch of the substance has been found by the Licensing Authority or the controlling authority not to conform with the standards of strength, quality or purity specified in

these Rules and on being directed so to do, withdraw the remainder of the case be practicable recall all issues already made from that batch.

- (j) 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.
- (k) 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.
- (l) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and defects noticed.
- (m) 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 samples shall be maintained for a period of three years from the date of manufacture.
- (n) The licensee, who has been granted a license in Form 28-B shall-
  - (i) Forward to the Licensing Authority of the concerned State of manufacture and supply of drug a statement of the sales effected to the manufacturers, wholesalers, retailers, hospitals, dispensaries, Nursing Homes and Registered Medical Practitioners every three months.
  - (ii) Maintain accounts of all transactions giving details as indicated below in a register bound and serially page numbered, and such records shall be retained for a period of five years or one year after the date of expiry of potency, whichever is later.
    - A. Accounts of the drugs specified in Schedule X used for the manufacture:-
      1. Date of issue.
      2. Name of the drug.
      3. Opening balance of stock on the production day.
      4. Quantity received, if any, and source from where received.
      5. Quantity used in manufacture.
      6. Balance quantity on hand at the end of the production day.
      7. Signature of the person in charge.
    - B. Accounts of Production:-
      1. Date of manufacture.
      2. Name of the drug.
      3. Batch Number.
      4. Quantity of raw material used in manufacture.
      5. Anticipated yield.
      6. Actual yield.

7. Wastage.
  8. Quantity of the manufactured goods transferred to stock.
- C. Accounts of manufactured drugs:-
1. Date of manufacture.
  2. Name of the drug.
  3. Batch Number.
  4. Opening Balance.
  5. Quantity manufactured.
  6. Quantity sold.
  7. Name of the purchaser and his address.
  8. Balance quantity at the end of the day.
- (o) The licensee shall store drugs specified in Schedule X in bulk form and when any such drug is required for manufacture it shall be kept in a separate place under direct custody of a responsible person.
- (p) The licensee shall comply with the requirements of 'Good Manufacturing Practices' as laid down in Schedule M.

**78-A. Conditions of licence in Form 28-A.**

- (1). The licence in Form 28-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 28 whose manufacturing facilities have availed of by the licensee is cancelled or suspended, as the case may be, under these rules.
- (2). 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, those would come into force four months after publication in the official Gazette.
- (3). The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in the Schedule U. Records or registers shall be retained, in the case of a substance for which a potency date is fixed, for a period of two years from the expiry of such date and in the case of other substances, for a period of five years from the date of manufacture. 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 these rules have been observed.
- (4). The licensee shall either (1) provide and maintain to the satisfaction of the Licensing Authority adequate Laboratory facilities for carrying out tests of the Strength, quality and purity of the substances manufactured by him, or (2) make arrangements with some institution approved by the Licensing Authority for such tests to be regularly carried out on the behalf by the institution.
- (5). The licensee shall furnish to the Licensing Authority, if required to do so, data on the stability of drugs which are likely to deteriorate for fixing the date

of expiry which would be printed on the labels of such drugs on the basis of the data so furnished.

- (6). The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is atleast 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 labels, the reference samples shall be maintained for a period of three months beyond the dated of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.
- (7). The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.