GOVERNMENT OF INDIA

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

THE DRUGS AND COSMETICS ACT AND RULES

THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

(As amended up to the 31st December, 2016)

and

THE DRUGS AND COSMETICS RULES, 1945

(As amended up to the 31st December, 2016)

74A. *Conditions for licence in Form 25B.*– A licence in Form 25B 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 at least 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 [3][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;

[2][(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 any [4][Inspector appointed under the Act] to enter with or without notice, any premises where the packing of drugs in respect of which the licence is issued is carried on, to inspect the premises and to take samples of repacked drugs;

[2][(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;]

1. Ins. by G.S.R. 735 (E), dt. 24-6-1988.
2. Subs. by Notfn. No. F.1-20/64-D, dt. 26-10-1968.
3. Ins. by G.S.R. 1172 (E), dt. 23-8-1977.
4. Subs. by G.S.R. 444 (E), dt. 31-3-1973.

[1][(g) the licensee shall maintain an Inspection Book, in Form 35, to enable an Inspector to record his impressions and the defects noticed;]

[2][(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 sample 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.

[4][(i) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.]

[3][**74B**.*Conditions of licence in Form 25A*. —(*1*) The licence in Form 25A shall be deemed to be cancelled or suspended, if the licence 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.

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1. Ins. by Notfn. No. 1-14/68-D, dt. 26-10-1968.
2. Ins. by G.S.R. 444 (E) dt. 31-3-1973 .
3. Subs. by Notfn. No. F. 1-14/68-D, dt. the 26-10-1968.
4. Ins. by G.S.R. 289 (E) dt. 15-4-2015.

(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 test of the strength, quality and purity of the substances manufactured by him, or

(ii) make arrangements with some institution approved by the Licensing Authority [7][under Part XV (A) of these rules] for such tests to be regularly carried out on his behalf by the institution.

[1][(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.]

[2][(6) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.]

[8][(7) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.]

[3][**75**. *Form of application for licence to manufacture for sale or distribution of drugs specified in Schedules C and C(1) and X* [4][*excluding those specified in Part XB and Schedule X*].-(1) Applications for the grant or renewal of licence to manufacture for sale or distribution of drugs specified in Schedules C and C(1) [4][excluding those specified in Part X-B and Schedule X], shall be made to the Licensing Authority in Form 27 and [5][shall be made up to ten items for each category of drugs [6][referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics] and shall be accompanied by a licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred for every inspection or for the purpose of renewal of licences:]

Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry, the fee payable for renewal of the licence shall be [5][a licence fee of rupees six thousand plus an additional fee of rupees one thousand per month or a part thereof in addition to an inspection fee of rupees one thousand and five hundred.]

(2) Application for grant or renewal of licence to manufacture for sale or distribution of drugs specified in Schedules C, C(1) and X shall be made to the licensing authority in Form 27-B, and [5][shall be made up to ten items for each category of drugs [6][referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics] and shall be accompanied by a licence fee of rupees six thousand and an inspection fee of rupees one thousand five hundred for every inspection or for the purpose of renewal of licences]:

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1. Ins. by G.S.R.. No. 444, dt. 28-4-1973.
2. Ins. by G.S.R. 331 (E), dt. 8-5-1984.
3. Subs. by G.S.R. 462 (E), dt. 22-6-1982.
4. Subs. by G.S.R. 28(E), dt. 22-1-1993.
5. Subs. by G.S.R. 601(E), dt. 24-8-2001.
6. Subs. by G.S.R. 640(E), dt. 29-6-2016.
7. Subs. by G.S.R. 1172(E), dt. 23-8-1977.
8. Ins. by G.S.R. 289(E), dt. 15-4-2015.