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)

[1][**74. *Conditions of licence in Form 25.***−A licence in [2][Form 25 and Form 25F] shall be subject to the conditions stated therein and to the following further conditions, namely :

(*a*) the licensee shall provide and maintain staff, premises 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 [4][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*) 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 [3][Inspector appointed under 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 [3][Inspector appointed under 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;

1. Subs. by Notfn. No. F. 1-20/64-D (S.O. 3868), dt. 26-10-1968.
2. Subs. by G.S.R. 462 (E), dt. 22-6-1982.
3. Amended by G.S.R. 444 dt. 28-4-1973.
4. Ins. by G.S.R. 1172 (E), dt. 23-8-1977.

[1][(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 [2][or the Controlling Authority] so directs and if requested by the licensee who had also furnished *prima 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 authorizing the sale of the batch has been issued to him by or on behalf of the Licensing Authority [2][or the Controlling Authority;

(j) the licensee shall on being informed by the Licensing Authority [2][or the Controlling Authority] that any part of any batch of the drug has been found by the Licensing Authority [2][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;

[1][(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 or 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][(m) the licensee, who has been granted a licence in Form 25F, 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 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:-

1. Subs. by G.S.R. No. 444 dt. 31-3-1973.
2. Ins. by G.S.R. No. 444 dt. 31-3-1973.
3. Ins. by G.S.R. 462 (E), dt. 22-6-1982.

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;]

[1][(o) the licensee shall comply with the requirements of [2][Good Laboratory Practices as laid down in Schedule L-I and] 'Good Manufacturing Practices' as laid down in Schedule M.]

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

1. Ins. by G.S.R. 735 (E), dt. 24-6-1988.
2. Ins by G.S.R. 780 (E), dt. 10-11-2008.
3. Ins by G.S.R. 289 (E), dt. 15-04-2015.

[1][**75A**. Loan licences.−(1) Applications for the grant or renewal of loan [2][licences for the manufacture for sale or for distribution] of drugs specified in Schedules C and C(1) [3][excluding those specified in Part X-B and Schedule X] shall be made in Form 27-A to the licensing authority and [4][shall be made upto ten items for each category of drugs [14][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 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:]

[5][Provided that if the applicant applies for the renewal of a licence after its expiry but within six months of such expiry the fee payable for renewal of the licence shall be [4][rupees six thousand and an inspection of fee of rupees one thousand five hundred plus an additional fee at the rate of rupees one thousand] per month or a part thereof.]

[11][*Explanation*. − For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who intends to avail the manufacturing facilities owned by a licensee in Form 28.]

[12][(1A) The application for grant or renewal of loan license to manufacture for sale or distribution of drugs in 'Large Volume Parenterals', 'Sera and Vaccine' and 'Recombinant DNA (r-DNA) derived drugs' shall be made to the licensing authority appointed under this Part, in Form 27DA and be made upto ten items for each category of drugs categorized in Schedule M and accompanied by a license fee of six thousand rupees and an inspection fee of one thousand five hundred rupees for every inspection or for the purpose of renewal of licenses:

Provided that if the application for renewal of a license is made after its expiry but within six months of such expiry, the fee payable for renewal of the license shall be six thousand rupees plus an additional fee of one thousand rupees per month or a part thereof in addition to the inspection fee of one thousand and five hundred rupees;]

(2) The licensing authority, shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities for testing to undertake the manufacture on behalf of the applicant for a loan licence.

[13][***]

[4][(3) Subject to the provisions of sub-rule (2), the application for manufacture of more than ten items of each category of drugs on a loan license, shall be accompanied by an additional fee at the rate of rupees three hundred for each additional item of drugs.

(4) If the licensing authority is satisfied that a loan licence is defaced, damaged or lost, he may, on payment of a fee of rupees one thousand, issue a duplicate copy of loan licence.]

[6][* * * * *]

[7][**76**. [8]*[Forms of licence to manufacture drugs specified in Schedules C and C(1),* [9][*excluding those specified in Part XB and Schedule X*], *or drugs specified in Schedules C, C(1) and X and the conditions for the grant or renewal of such licences*.- [10][A licence to manufacture for sale or for distribution of drugs specified in

1. Ins. by F.1-16/57-D, dt. 15-6-1957.
2. Subs. by G.S.R 788 (E), dt. 10-10-1985.
3. Subs. by G.S.R 28 (E), dt. 22-1-1993.
4. Subs. by G.S.R 601 (E), dt. 24-8-2001.
5. Amended by S.O.2139 dt. 13-8-1972.
6. Rule 75B omitted by G.S.R. 944 (E), dt. 21-9-1988.
7. Amended by F- 1- /57-D, dt. 15-6-1969.
8. Subs. by G.S.R. 462 (E), dt. 22-6-1982.
9. Subs. by G.S.R. 28 (E) , dt. 22.1.1993.
10. Subs. by G.S.R. 119 (E), dt. 11-3-1996.
11. Subs. by G.S.R. 724 (E), dt. 7-11-2013.
12. Ins. by G.S.R. 574 (E) , dt. 17.7.2012.
13. Proviso omitted by G.S.R. 574 (E) , dt. 17.7.2012.
14. Subs. by G.S.R. 640 (E), dt. 29-06-2016.

Schedules C and C(1) other than [4][Large Volume Parenterals, Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs] specified in Part X B and Schedule X shall be issued in Form 28 and a licence to manufacture for sale or distribution of drugs specified under Schedules C and C(1) (other than [4][Large Volume Parenterals, Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs] specified in Part X-B) and Schedule X shall be issued in Form 28B. A licence to manufacture for sale or for distribution of [4][Large Volume Parenterals, Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs] shall be issued in Form 28-D. Before a licence in Form 28 or Form 28B or Form 28D is granted or renewed, the following conditions shall be complied with by the applicant:-

(1) The manufacture will be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person who is a whole time employee and who is—

(a) a graduate in Pharmacy or Pharmaceutical Chemistry of [1][a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] and has had at least eighteen months' practical experience after the graduation in the manufacture of drugs to which this licence applies; this period of experience may however be reduced by six months if the person has undergone training in manufacture of drugs to which the licence applies for a period of six months during his University course; or

(b) a graduate in Science of [1][a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] who for the purpose of his degree has studied Chemistry [3][or Microbiology] as a principal subject and has had at least three years' practical experience in the manufacture of drugs to which this licence applies after his graduation; or

(c) a graduate in Medicine of [1][a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] with at least three years' experience in the manufacture and pharmacological testing of biological products after his graduation; or

[2][(d) a graduate in Chemical Engineering of a University recognised by the Central Government with at least three years' practical experience in the manufacture of drugs to which this licence applies after his graduation; or

(e) holding any foreign qualification the quality and content of training of which are comparable with those prescribed in clause (a), clause (b), clause (c) or clause (d) and is permitted to work as competent technical staff under this Rule by the Central Government.]

1. Subs. by G.S.R. 71(E), dt. 30-1-1987.
2. Ins. by F.1-19/59-D, dt. 13-6-1967.
3. Ins. by G.S.R. 245(E), dt. 3-2-1976.
4. Subs. by G.S.R. 26 (E), dt. 19-1-2006.

Provided that any person who was approved by the licensing authority as an expert responsible for the manufacture of drugs for the purpose of rule 76 read with Rule 78 as these Rules were in force immediately before the 29th June, 1957, shall be deemed to be qualified for the purposes of this rule:

[1][Provided that for the drugs specified in Schedules C and C(1) meant for veterinary use, the whole time employee under whose supervision the manufacture is conducted may be a graduate in Veterinary Science or general science or medicine or pharmacy of a University, recognized by the Central Government and who has had at least three years' experience in the manufacture of biological products:

[5][Provided also that for medical devices, the whole time employee under whose supervision the manufacture or testing is conducted shall be—

(i) a graduate in Pharmacy or Engineering (in appropriate branch) from a University recognised by the Central Government for such purposes and has had at least eighteen months practical experience in the manufacturing or testing of devices to which this licence applies after his graduation; or

(ii) a graduate in science, from a University recognised by the Central Government for such purposes, with Physics or Chemistry or Microbiology as one of the subject and has had at least three years practical experience in the manufacturing or testing of devices to which this licence applies after his graduation; or

(iii) a diploma in Pharmacy or Engineering (in appropriate branch) from a Board or Institute recognised by the Central Government or the State Government, as the case may be, for such purposes and has had at least four years practical experience in the manufacturing or testing of devices to which this licence applies after his diploma; or

(iv) having a foreign qualification, the quality and content of training of which are comparable with those specified in clause (i), clause (ii) and clause (iii) and is permitted to work as competent technical staff under this rule by the Central Government.]

[6][(2) The applicant proposing to manufacture pharmaceutical products shall comply with the provisions referred to in Schedule M.

(2A) The applicant proposing to manufacture medical devices and in-vitro diagnostics shall comply with the quality management system as referred to in Schedule M-III.

(3) The applicant shall provide adequate space, plant and equipment for pharmaceutical products as referred to in Schedule M and for Medical devices and in-vitro diagnostics as referred to in Schedule M-III.]

[3][(4) The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out such tests of the strength, quality and purity of the substances as may be required to be carried out by him under the provisions of Part X of these rules including proper housing for animals used for the purposes of such tests, the testing unit being separate from the manufacturing unit and the head of the testing unit being independent of the head of the manufacturing unit:

Provided that the manufacturing units which before the commencement of the Drugs and Cosmetics (Amendment) Rules, 1977[4], were making arrangements with institutions approved by the Licensing Authority for such tests to be carried out on their behalf may continue such arrangements upto the 30th June, 1977 :

Provided further that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods other than sterility the Licensing Authority may permit such tests to be conducted by institutions approved by it [2][under Part XV (A) of these rules] for this purpose.

1. Ins. by F.1-6/62-D (SO 2889), dt. 2-7-1969.
2. Ins. by G.S.R 1172 (E), dt. 23-8-1977.
3. Sub. by G.S.R 926 (E), dt. 24-6-1977.
4. These rules came in to force on 28th May, 1977 vide G.S.R 665 (E), dt. 6-5-1977.
5. Sub. by G.S.R 690 (E), dt. 25-9-2014. Earlier Ins. by G.S.R 109 (E), dt. 22-2-1994.
6. Sub. by G.S.R 640 (E), dt. 29-6-2016.

[1][(4A) The head of the testing unit referred to in condition (4) shall possess a degree in Medicine or Science or Pharmacy or Pharmaceutical Chemistry of a University recognized for this purpose and shall have experience in the testing of drugs, which in the opinion of the Licensing authority is considered adequate.]

(5) The applicant shall make adequate arrangements for the storage of drugs manufactured by him.

[2][(6) The applicant 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 shall be printed on the labels of such drugs on the basis of the data so furnished.]

[3][(7) The applicant shall, while applying for licence to manufacture patent or proprietary medicines, furnish to the Licensing Authority evidence and data justifying that the patent or proprietary medicines−

(i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;

(ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulations and under the conditions in which the formulations for administration and use are recommended;

(iii) are stable under the conditions of storage recommended;

(iv) contain such ingredients and in such quantities for which there is therapeutic justification.;] and

[4][(v) have the approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug as defined in Rule 122E, from the licensing authority as defined in clause (b) of rule 21.]

[5][(8) The licensee of pharmaceutical products shall comply with the requirements of 'Good Manufacturing Practices' as laid down in Schedule M and the licensee of Medical Devices and in-vitro diagnostics shall comply with the requirements of "Quality Management System" as laid down in Schedule M-III..]

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1. Ins. by G.S.R 681 (E), dt. 5-12-1980.
2. Ins. by G.S.R 444 dt. 31-3-1973.
3. Ins. by G.S.R 515 dt. 24-3-1976.
4. Ins. by G.S.R 311 (E), dt. 1-5-2002.
5. Subs. by G.S.R 640 (E), dt. 29-06-2016. Previously Ins. by G.S.R 735 (E), dt. 24-6-1988.

[1][*Explanation*:- For the purpose of this rule, [6]["Large Volume Parenterals" sera and vaccines and recombinant DNA (r-DNA) derived drugs,] shall mean the sterile solutions intended for parenteral administration with a volume of 100 ml. or more (and shall include anti-coagulant solutions) in one container of the finished dosage form intended for single use.]

[7][(9) The applicant shall make application for grant of licence for a drug formulation containing single active ingredient only in proper name.]

[2]**[76A. Forms of loan licenses to manufacture for sale or for distribution drugs specified in Schedule C and C(1) excluding drugs specified in Schedule X or of Large Volume Parenterals, Sera and Vaccine and recombinant DNA (r-DNA) derived drugs, and conditions for the grant or renewal of such license.—** A loan license to manufacture for sale or for distribution of drugs specified in Schedules C and C(1), excluding drugs specified in Schedule X, and Large Volume Parenterals, Sera and Vaccine and Recombinant DNA(r-DNA) derived drugs specified in Part XB shall be issued in Form 28A and a loan license to manufacture for sale or for distribution of Large Volume Parenterals, Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs shall be issued in Form 28DA, and the applicant shall, while applying for a licence to manufacture patent or proprietary medicines, furnish to the Licensing Authority evidence and data justifying that the patent or proprietary medicines-

(i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;

(ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulations, and under the conditions in which the formulations for administration and use are recommended;

(iii) are stable under the conditions of storage recommended; and

(iv) contain such ingredients and in such quantities for which there is therapeutic justification.]

[7][Provided that the application for grant of a licence for a drug formulation containing single active ingredient shall be made only in proper name.]

[3][**77**. *Duration of licence*. —An original licence in [4][Form 28, Form 28B and Form 28D or renewed licence in Forms 26, 26F, and Form 26H], unless sooner suspended or cancelled shall be [5][valid for a period of five years on and from the date on which] it is granted or renewed:

1. Ins. by G.S.R. 119 (E), dt. 11-3-1996.
2. Subs. by G.S.R. 574 (E), dt. 17-7-2012.Earlier Subs. by G.S.R. 788 (E), dt. 10-10-1985 and Subs. by G.S.R. 462 (E), dt. 22-6-1982.
3. Amended by No. G.1-10/62-D, dt. 10-4-1964.
4. Subs. by G.S.R. 119 (E), dt. 11-3-1996.
5. Subs. by G.S.R. 601 (E), dt. 24-8-2001.
6. Subs. by G.S.R. 26 (E), dt. 19-1-2006.
7. Ins. by G.S.R. 570 (E) dt. 7-8-2014.

[1][Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.]]

[2][**78**. Conditions of licence.−A licence in [3][Form 28, Form 28B or Form 28D] shall be subject to the special conditions, if any, set out in Schedule F or ScheduleF(1), as the case may be, which relate to the 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 requirement, 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;

[4][(b) The licensee shall provide and maintain staff, premises and equipment as specified in Rule 76;]

[5][(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 [6][under Part XV (A) of 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 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;]

(d) The licensee shall allow an [7][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 Schedules C and C(1), to inspect the plant and the process of manufacture and the means employed for standardizing and testing the substance;]

1. Amended by S.O. 2139 dt. 12-8-1972.
2. Amended by F.1-6/62-B, dt. 2-6-1969.
3. Subs. by G.S.R. 119 (E), dt. 11-3-1996.
4. Amended by F.1-16/57-D (SO 2136), dt. 15-6-1957.
5. Amended by F.1-20/64-D (SO 3868), dt. 26-10-1968.
6. Ins. by G.S.R. 1172 (E), dt. 23-8-1977.
7. Subs. by G.S.R. 444 (E), dt. 31-3-1973.

(e) The licensee shall allow an [1][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 such 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 substance 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;

[1][(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 drug 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;]

[2][(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 sub-paragraph until a certificate authorising the sale of the batch has been issued to him by or on behalf of the Licensing Authority or the Controlling Authority;]

[1][(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 that 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;]

(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;

[3][(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;]

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1. Subs. by G.S.R 444, dt. 28-4-1973.
2. Amended by F.1-16/57-D, dt. 15-6-1957.
3. Amended by F.1-14/68-B (SO 3868), dt. 26-10-1968.

[1][(l) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and defects noticed.]

[2][(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 is specified on the label the reference samples shall be maintained for a period of three years from the date of manufacture.]

[3][(n) The licensee, who has been granted a license in Form 28B 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 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.

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1. Subs. by F.1-14/68-B (SO3868), dt. 26-10-1968.
2. Ins. by G.S.R. 444, dt. 28-4-1973.
3. Ins. by G.S.R. 462 (E), dt. 22-6-1982.

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.

(o) 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.]

[1][(p) The licensee shall comply with the requirements of [3]['Good Manufacturing Practices' as laid down in Schedule L-1 and Good Manufacturing Practices' as laid down in Schedule M.]

[4][(q) 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.]

[2][78A. Conditions of license in [5][Form 28A or Form 28DA]- (1) The license in [5][Form 28A of Form 28DA] shall be deemed to be cancelled or suspended, if the licence owned by the licensee in [6][[5][Form 28 or Form 28D] whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.

1. Ins. by G.S.R. 735 (E), dt. 24-6-1998.
2. Amended by F.1-14/68-D (S.O. 3868), dt. 26-10-1968.
3. Ins. by G.S.R. 780 (E), dt. 10-9-2008.
4. Ins. by G.S.R. 289 (E), dt. 15-4-2015.
5. Subs. by G.S.R. 574 (E), dt. 17-7-2012.
6. Subs. by G.S.R. 592 (E), dt. 13-8-2008.

(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 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 (i) provide and maintain to the satisfaction of the Licensing Authority adequate staff and adequate laboratory facilities for carrying out tests of the strength, quality and purity of the substances manufactured by him, or (ii) make arrangements with some institution approved by the Licensing Authority for such tests to be regularly carried out on his behalf by the institution.]

[1][(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.]

[2][(6) The licensee shall maintain reference samples from each batch of the drug 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 labels, 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.]

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

[4][(8) 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.

[5][**79. Inspection before grant or renewal of licence**.–Before a licence under

1. Ins. by G.S.R. 444, dt. 28-4-1973.
2. Subs. by G.S.R. 574 (E), dt. 17-7-2012.
3. Ins. by G.S.R. 331 (E), dt. 8-5-1984.
4. Ins. by G.S.R. 289 (E), dt. 15-4-2015.
5. Subs. by G.S.R. 923 (E), dt. 14-12-1992.