PART VII

[1][MANUFACTURE FOR SALE OR FOR DISTRIBUTION] OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

68. *Manufacture on more than one set of premises.* — If drugs are manufactured on more than one set of premises a separate application shall be made and a separate licence shall be issued in respect of each such set of premises.

[2][**68-A.** *Grant or Renewal of Licences by the Central Licence Approving Authority.*— *(1)* Notwithstanding anything contained in this Part, on and from the commencement of the Drugs and Cosmetics (Amendment) Rules,1992, a licence for the manufacture for sale or distribution of drugs as specified from time to time by the Central Government by notification in the Official Gazette, for the purpose of this rule, shall be granted or renewed, as the case may be, by the Central Licence Approving Authority (appointed by the Central Government):]

Provided that the application for the grant or renewal of such licence shall be made to the Licensing Authority.

(2) On receipt of the application for grant or renewal of a licence, the licensing authority shall,-

(i) verify the statement made in the application form;

(ii) cause the manufacturing and testing establishment to be inspected in accordance with the provisions of rule 79; and

(iii) in case the application is for the renewal of licence, call for the information(s) of the past performance of the licensee.

(3) If the licensing authority is satisfied that the applicant is in a position to fulfil the requirements laid down as in these Rules, he shall prepare a report to that effect and forward it along with the application [3][and the licence (in triplicate) to be granted and renewed, duly completed] to the Central Licence Approving Authority:

Provided that if the licensing authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these Rules, he may, by order, for reasons to be recorded in writing, refuse to grant or renew the licence, as the case may be.

(4) If on receipt of the application and the report of the licensing authority referred to in sub-rule *(3)* and after taking such measures including inspection of the premises by the Inspector, appointed by the Central Government under section 21 of the Act, with or without an expert in the concerned field if deemed necessary, the Central Licence Approving Authority, is satisfied that the applicant

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1. Subs. by G.S.R 788 (E), dt. 10-10-1985.
2. Ins. by G.S.R 923 (E), dt. 14-12-1992.
3. Subs. by G.S.R 89 (E), dt. 14-2-1996.

is in a position to fulfil the requirements laid down in these Rules, he may grant or renew the licence, as the case may be:

Provided that if the Central Licence Approving Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules, he may, notwithstanding the report of the licensing authority, by order, for reasons to be recorded in writing, reject the application for grant or renewal of licence, as the case may be.]

[1][**68B.** *Delegation of Powers by the Central Licence Approving Authority.*—The Central Licence Approving Authority may with the approval of the Central Government, by notification delegate his powers of signing licences and any other powers under the rules to any person under his control having same qualifications as prescribed for controlling authority under Rule 50A for such areas and for such periods as may be specified.]

[2][**69.** *Application for licence to manufacture drugs other than those specified in Schedules C and C(I) to the Drugs and Cosmetics Rules.*—[3][*(1)* Application for grant or renewal of [4][licence to manufacture for sale or for distribution] of drugs, other than those specified in Schedules C and C(I) shall be made to the licensing authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the licensing authority) and shall be made —

(a) in the case of repacking of drugs excluding those specified in Schedule X for sale or distribution in, Form 24B;

(b) in the case of manufacture of drugs included in Schedule X, in Form 24F;

(c) in any other case, in Form 24.]

[5][(2)*(a)* Every application in Form 24B shall be made up to ten items for each category of drugs categorised in Schedule M and shall be accompanied by a licence fee of rupees five hundred plus and an inspection fee of rupees two hundred for every inspection or for the purpose of renewal of the licence.

1. Ins. by G.S.R 89 (E), dt. 14-02-1996.
2. Amended by Notfn. F. 1-22/59-D, dt. 9-4-1960.
3. Subs. by G.S.R 462 (E), dt. 22-06-1982.
4 Subs. by G.S.R.788 (E), dt. 10-10-1985.
5. Subs. by G.S.R 601(E), dt. 21-8-2001.

(b) Every application in Form 24F shall be made up to ten items for each category of drugs categorised in Schedule M 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 subsequent inspection or for the purpose of renewal of licence.

(c) Every application in Form 24 shall be made up to ten items for each category of drugs [3][referred to in Schedule M relating to pharmaceuticals products and Schedule MIII 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 one thousand and five hundred for every inspection or for the purpose of renewal of the licence.]

[1][*(3)* If a person applies for the renewal of a licence after the expiry thereof but within six months of such expiry the fee payable for the renewal of such licence shall be–]

[2][*(i)* in the case of Form 24B a licence fee of rupees five hundred plus an additional fee at the rate of rupees two hundred and fifty per month or part thereof in addition to an inspection fee of rupees two hundred;

(ii) in the case of Form 24F a licence fee of rupees six thousand plus an additional fee at the rate of rupees one thousand per month or part thereof in addition to an inspection fee of rupees one thousand;

(iii) in the case of Form 24 a licence fee of rupees six thousand plus an additional fee at the rate of rupees one thousand per month or part thereof in addition to an inspection fee of rupees one thousand and five hundred.]

[1][*(4)* A fee [2][rupees one thousand shall be paid] for a duplicate copy of the licence issued under clause *(a)*, clause *(b)* or clause *(c)* of sub-Rule *(1)* if the original is defaced, damaged or lost.]

[2][*(5)* Applications for manufacture of more than ten items of each category of drugs as categorized under Schedule M and M-III or for manufacture of additional items of drugs by licensees in Form 24 or Form 24F shall be accompanied by an additional fee at the rate of rupees three hundred for each additional item of drug. Applications in Form 24B for licence to manufacture for sale and distribution for repacking for more than 10 items of each category or for manufacture of additional item of drug shall be accompanied by additional fee of rupees one hundred for each additional item of drugs as cetegorized in Schedule M and M-III].

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1. Subs. by G.S.R 462 (E), dt. 22-6-1982.
2. Subs. by G.S.R 26 (E), dt. 19-1-2006.
3. Subs. by G.S.R 640 (E), dt. 29-6-2016.

[1][*(6)* Where an application under this Rule is for the manufacture of drug formulations falling under the purview of new drug as defined in rule 122E, such application shall also be accompanied with approval, in writing in favour of the applicant, from the licensing authority as defined in clause *(b)* of rule 21.]

[2][**69A.** *Loan Licences.*—[3][*(1)* Application for the grant or renewal of loan licences to manufacture for sale or for distribution of drugs other than those specified in Schedule C, Schedule C (1) and Schedule X shall be made up to ten items for each category of drugs [5][referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics] and shall be made in Form 24A accompanied by a licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred to the licensing authority:

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 such licence shall be accompanied by a licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred plus an additional fee at the rate of rupees one thousand per month or part thereof.]

[4][*Explanation.*- For the purpose of this rule a loan licence means a licence which the Licensing Authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by a licensee in Form 25.]

(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.

[3][*(3)* Subject to the provisions of sub-rule *(2)*, application for manufacture of more than ten items for each category of drug on a loan licence shall be accompanied by an additional fee of rupees three hundred per additional item specified [5][referred to in Schedule M relating to pharmaceuticals products and Schedule MIII relating to medical devices and *in-vitro* diagnostics].

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1. Ins. by G.S.R 311 (E), dt. 1-5-2002.
2. Amended by Notfn. No. F. 1-16/57-D, dt. 15-6- 1957.
3. Subs. by G.S.R 601(E) dt. 24-8-2001.
4. Subs. by G.S.R 724(E) dt. 07-11-2013.
5. Subs. by G.S.R 640 (E), dt. 29-6-2016.

[1][(4) If the Licensing Authority is satisfied that a loan licence is defaced, damaged or lost or otherwise rendered useless, he may, on payment of a [2][fee of rupees one thousand] issue a duplicate licence.]

[3][* * * * *]

[4][**70.** *Form of licence to repack or manufacture drugs other than those specified in Schedules C and C(1).*-

Licences for repacking of drugs against application in Form 24-B shall be granted in Form 25-B, licences for manufacture of drugs included in Schedule X and against application in Form 24-F shall be granted in Form 25-F and licences for manufacture of drugs against application in Form 24 shall be granted in Form 25.]

[5][**70A.** *Form of loan* [6][*licence to manufacture for sale or for distribution*] *of drugs other than those* [7][*specified in Schedules C, C(1) and X*].—

A loan [6][licence to manufacture for sale or for distribution] or drugs other than those [7][specified in Schedules C, C(1) and X] shall be issued in Form 25A.]

[8][**71.** *Conditions for the grant or renewal of a licence in Form 25* [9][*or Form 25F*].—

Before a licence in Form 25 [9][or Form 25F] is granted or renewed, the following conditions shall be complied with by the applicant.-

(*1*) The manufacture shall 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 [10][a University established in India by law or has an equivalent qualification recognised 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. This period of experience may, however, be reduced by six months if the person has undergone training in manufacture of drugs for a period of six months during his University course; or

(*b*) a graduate in Science of [10][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 as a principal subject and has

1. Ins. by Notfn. No. F.1-20/64-D, dt. 26.10.1968.
2. Subs. by Notfn. No. G.S.R. 601 (E), dt. 24.8.2001.
3. Rule 69 omitted by G.S.R. 944 (E), dt. 21-9-1988.
4. Subs. by Notfn. No. G.S.R. 462 (E), dt. 22.6.1982.
5. Ins. by Notfn. No. F.1-16/57 D, 15-6-1957 & No. F.1/22/59-D, dt. 9.4.1960.
6. Subs. by Notfn. No. G.S.R. 788 (E), dt. 10-10-1985.
7. Subs. by Notfn. No. G.S.R. 462 (E), dt. 22-6-1982.
8. Subs. by Notfn. No. F.1-16/57-D, dt. 15-6-1957.
9. Ins. by G.S.R. 462(E), dt. 22-6-1982.
10. Subs. by Notfn. No. G.S.R. 71 (E), dt. 30-1-1987.

had at least three years practical experience in the manufacture of drugs after his graduation; or

(c) a graduate in Chemical Engineering or Chemical Technology or Medicine of [1][a University established in India by law or has an equivalent qualification recognised and notified by the Central Government for such purpose] with general training and practical experience, extending over a period of not less than three years in the manufacture of drugs, after his graduation; or

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

Provided that any person who was immediately before the 29th June, 1957, actively directing and personally supervising the manufacture of drugs and whose name was accordingly entered in any licence granted in Form 25 [3][or Form 25F] as it existed before the date shall be deemed to be qualified for the purposes of this rule:

[4][Provided further that for drugs other than those specified in Schedules C, C(1) and X and meant for veterinary use, the whole-time employee under whose supervision the manufacture is conducted shall be a graduate in Veterinary Science or Pharmacy or General Science or Medicine of a University recognized by the Central Government and who has had at least three years practical experience in the manufacture of drugs excluding graduate in Pharmacy who shall have at least eighteen months practical experience in the manufacture of drugs:]

[5][Provided [6][also] that the Licensing Authority may, in the matter of manufacture of disinfectant fluids, insecticides, liquid paraffin, medicinal gases, non-chemical contraceptives, plaster of Paris and surgical dressings, for the manufacture of which the knowledge of Pharmaceutical Chemistry or Pharmacy is not essential, permit the manufacture of the substance under the active direction and personal supervision of the competent technical staff, who, although not having any of the qualifications included in clause (a), (b) or (c) of this rule, has, in the opinion of the Licensing Authority, adequate experience in the manufacture of such substance.]

1. Subs. by G.S.R. 71(E), dt. 30-1-1987.
2. Added by Notfn. NO. F. 1-19/59-D, dt. 13-6-1961.
3. Ins. by. G.S.R. 462 (E), dt. 22-6-1982.
4. Ins. by. G.S.R. 93 (E), dt. 24-2-1999.
5. Added Notfn. No. F. 1-14/68-D, dt. the 26-10-1968.
6. Sub. by. G.S.R. 93 (E), dt. 24-2-1999.

(2) The factory premises shall comply with the conditions prescribed in Schedule M.

(3) The applicant shall provide adequate space, plant and equipment for the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M.

[1][(4) The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out tests of the strength, quality and purity of the substances at a testing unit, which shall be separate from the manufacturing unit and the head of the testing unit shall be 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, were making arrangements with institutions approved by the Licensing Authority for such tests to be carried out on their behalf may continue such arrangements up to 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 [4][under Part XV(A) of these rules] for this purpose.]

[2][(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.

[3][(6) 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;

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1. Subs. by G.S.R. 926 dt. 16-7-1977.
2. Ins. by G.S.R. 681(E), dt. 5-12-1980.
3. Ins. by G.S.R. 515 dt. 10-4-1976.
4. Ins. by G.S.R. 1172 dt. 23-8-1977.

(ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulation and under the conditions in which the formulation 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]

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

[2][(7) The licensee shall comply with the requirements of Good Manufacturing Practices as laid down in Schedule M.]

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

[3][**71A.** Conditions for the grant or renewal of a licence in Form 25B. Before a licence in Form 25B is granted or renewed the following conditions shall be complied with by the applicant :-

(1) the repacking operation shall be carried out under hygienic conditions and under the supervision of a competent person;

[4][(2) the factory premises shall comply with the conditions prescribed in Schedule M; and]

[5][(3) the applicant shall have adequate arrangements in his own premises for carrying out tests for the strength, quality and purity of the drugs at a testing unit which shall be separate from the repacking unit:]

[6][(4) The application for grant of licence for a drug formulation containing single active ingredient shall be made only in proper name:]

Provided that the repacking units, which before the commencement of the Drugs and Cosmetics (Second Amendment) Rules, 1977, were making arrangements with institutions approved by the licensing authority for such tests to be carried out on their behalf, may continue such arrangements up to the 31st July, 1977:

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1. Ins. by G.S.R. 311 (E), dt. 1-5-2002.
2. Ins. by G.S.R. 735 (E), dt. 24-6-1988.
3. Ins. by No. F.1-22/59-D, dt. 9-4-1960.
4. Amended by S.O. 2139 dt. 12-8-1972.
5. Amended by G.S.R. 926 dt. 16-7-1977.
6. Ins. by G.S.R. 570 (E), dt. 7-8-2014.

Provided further that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods the licensing authority may permit such test to be conducted by institutions approved by it under Part XV(A) of these Rules for this purpose.]

Explanation.–A person who satisfies the following minimum qualifications shall be deemed to be a "competent person" for the purposes of rule 71A or 74A of these rules, namely: –

(a) a person who holds the Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 (VIII of 1948) or a person who is registered under the said Act, or

(b) a person who has passed the Intermediate examination with Chemistry as one of the principal subjects or an examination equivalent to it or an examination recognized by the Licensing Authority as equivalent to it; or

(c) a person who has passed the Matriculation examination or an examination recognized by the Licensing Authority as equivalent to it and has had not less than four years' practical experience in the manufacture, dispensing or repacking of drugs.]

[1][**71B. Conditions for the grant of renewal of a licence in Form 25A.**– Before a licence in Form 25A is granted or renewed, 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, recipients, additives and pharmaceutical aids used in the formulations and under 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.

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

1. Ins. by G.S.R. 515 (E), dt. 24-3-1976.
2. Ins. by G.S.R. 570 (E), dt. 7-8-2014.

[1][72. ***Duration of licence.***–An original licence or a renewed licence in Form 25, [2][Form 25B or Form 25F] unless sooner suspended or cancelled shall be [3][valid for a period of five years on and from the date on which] it is granted or renewed:

[4][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][73. *Certificate of renewal.*– The certificate of renewal of a licence in Form 25 or Form 25F shall be issued in Form 26 or Form 26E respectively].

[5][73A. *A certificate of renewal of loan licence.*- The certificate of renewal of a loan licence in Form 25A shall be issued in Form 26A.]

[5][73AA. *Duration of loan licence.*– An original loan licence in Form 25A or a renewed loan licence in Form 26A, unless sooner suspended or cancelled, shall be [3][valid for a period of five years on and from the date on which] it is granted or renewed:]

[6][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.]

[7][73B. *Certificate of renewal of licence in Form 25B.*–The certificate of renewal of a licence in Form 25B shall be issued in Form 26B.]

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1. Subs. by Notfn. No. F.1-10/62-D, dt. 10-4-1964.
2. Subs. by G.S.R. 462 (E), dt. 22-6-1982.
3. Subs. by G.S.R. 601 (E), dt. 24-8-2001.
4. Amended by S.O. 2139 dt. 12-8-1972.
5. Amended by Notfn. No. F.1-10/62-D, dt. 10-4-1964.
6. Amended by S.O. 2139 dt. 12-8-1972.
7. Ins. by S.O. 1196, dt. 6-5-1960.

[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;

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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.

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]:

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.

Provided that the applicant shall possess a licence in Form 28 to manufacture such drugs:

Provided further that if the application for renewal of a licence is made after its expiry but within six months of such expiry, the fee payable for renewal of the licence shall be [1][rupees six thousand plus an additional fee of rupees one thousand per month or part thereof in addition to an inspection fee of rupees one thousand five hundred.]

[2][(3) The application for grant or renewal of licence to manufacture for sale or for distribution of drugs in [4][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 27D and [1][shall be made up to ten items for each category of drugs categorized in Schedule M 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 purposes of renewal of licences:]

Provided that if the application for renewal of a licence is made after its expiry but within six months of such expiry, the fee payable for renewal of the licence [1][shall be rupees six thousand plus an additional fee of rupees one thousand per month or a part thereof in addition to the inspection fee of rupees one thousand and five hundred.]

[1][(4) A fee of rupees one thousand shall be paid for duplicate copy of the licence issued under sub-rule (1), sub-rule (2) or sub-rule (3), as the case may be, if the original licence is defaced, damaged or lost.

(5) If the licensee applies for manufacture of more than ten items of each category of drugs, the application shall be accompanied by an additional fee at the rate of rupees three hundred for each additional item of drugs [5][referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics].]

[3][(6) Where an application under this Rule is for the manufacture of drug formulations falling under the purview of new drugs as defined in Rule 122-E, such application shall also be accompanied with approval, in writing, in favour of the applicant, from the licensing authority as defined in clause (b) of Rule 21.]]

1. Subs. by G.S.R. 601 (E), dt. 24-8-2001.
2. Ins. by G.S.R. 119 (E), dt. 11-3-1996.
3. Ins. by G.S.R. 311 (E), dt. 1-5-2002.
4. Subs. by G.S.R. 26 (E), dt. 19-1-2006.
5. Subs. by G.S.R. 640 (E), dt. 29-6-2016.

[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;]

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.

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.

this Part is granted or renewed the Licensing Authority or Central Licence Approving Authority, as the case may be, shall cause the establishment in which the manufacture is proposed to be conducted or being conducted to be inspected by one or more Inspectors appointed under this Act with or without an expert in the concerned field. The Inspector or Inspectors shall examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the 'Requirements of Good Manufacturing Practices' and the 'Requirements of Plant and Equipment' as laid down in Schedule M read with the Requirements of Maintenance of Records as laid down in Schedule U.]

[1][**80.** ***Report by Inspector.***–The Inspector shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the provisions of Rule 79, to the Licensing Authority or Central Licence Approving Authority, as the case may be.]

81. ***Procedure of Licensing Authority.***–(1) If the Licensing Authority [5][or Central Licence Approving Authority, as the case may be,] after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the Rules under the Act have been complied with and that the conditions of the licence and the Rules under the Act will be observed, he [2][shall issue a licence under this Part].

(2) If the Licensing Authority [5][or Central Licence Approving Authority, as the case may be,] is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence can be granted and shall supply the applicant with a copy of the inspection report.

[3][**82.** ***Further application after rejection.*** –If within a period of six months from the rejection of an application for a licence the applicant informs the Licensing Authority [5][or Central Licence Approving Authority, as the case may be,] that the conditions laid down have been satisfied and deposits an inspection [4][fee of rupees two hundred and fifty] the Licensing Authority [5][or Central Licence Approving Authority, as the case may be,] may, if after causing a further inspection to be made, he is satisfied that the conditions for the grant of a licence have been complied with, [5][in respect of drugs notified under Rule 68-A] issue a licence in Form 28 [2][or Form 28-B].

1. Subs. by G.S.R. 923 (E), dt. 14-12-1992.
2. Ins. by G.S.R. 462 (E), dt. 22-6-1982.
3. Ins. by F.1-16/57-D, dt. 15-6-1957.
4. Subs. by G.S.R. 601 (E), dt. 24-8-2001.
5. Ins. by G.S.R. 923 (E), dt. 14-12-1992.

83. Renewal.–On application being made for renewal, the licensing authority may cause an inspection to be made and, if satisfied that the condition of the licence and the Rules under the Act are, and will continue to be observed, [1][he shall prepare a report to that effect in respect of those drugs which have been notified by the Central Government under Rule 68-A and forward it along with the application to the Central Licence Approving Authority], and shall issue a certificate of renewal [3][under this Part].

[3][**83-A.** ***Certificate of renewal of a loan licence.***–The certificate of renewal of a loan licence in [8][Form 28A or Form 28DA] shall be issued in Form 26A or Form 26J respectively.]

[4][**83-AA.** ***Duration of loan licence.***–An original loan licence in [8][Form 28A or Form 28DA] or a renewed loan licence in [8][Form 26A or Form J], 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:

[6][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 the 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].]

84. The provisions of this Part shall apply to the manufacture of drugs for sale notwithstanding that such drugs are manufactured for sale outside India.

[7][[6][**84-A.** ***Provision for appeal to the State Government or Central Government by party whose licence has not been granted or renewed.–***

Any person who is aggrieved by the order passed by the Licensing Authority or the Central Licence Approving Authority, as the case may be, refusing to [2][grant or renew a licence under this Part], may within thirty days from the date of receipt of such order, appeal to the State Government or Central Government, as the case may be, and the State Government or the Central Government may, after such enquiry into the matter,] as is considered necessary and after giving the said person an opportunity for representing his views, may pass such order in relation thereto as it thinks fit.]

1. Ins. by G.S.R. 923 (E), dt. 14-12-1992.
2. Subs. by G.S.R. 119 (E), dt. 11-3-1996..
3. Ins. by F1-16/57-B, dt. 15-6-1957.
4. Ins. by Notfn. No. F. 1-10/62-D, dt. 10-4-1964.
5. Subs. by G.S.R. 601 (E), dt. 24-8-2001.
6. Subs. by S.O. 2139, dt. 12-8-1972.
7. Subs. by G.S.R. 923 (E), dt. 14-12-1992 as corrected by G.S.R. 373 (E), dt. 13-4-1993.
8. Subs. by G.S.R. 574 (E), dt. 17-5-2012.

[6][**84AA.** *Additional information to be furnished by an applicant for licence or a licensee to the licensing authority.*— The applicant for the grant of a licence or any person granted a licence under this Part shall, on demand, furnish to the Licensing Authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation on rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm or any other relevant matter which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.]

[1][**84B.** *Prohibition for the manufacture for sale of cyclamates and preparations containing cyclamates.*—No person shall manufacture for sale cyclamates and preparations containing cyclamates.]

[2][**85.** *Cancellation and suspension of licences.*—(1) The Central Licence Approving Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates [3][or direct the licensee to stop manufacture, sale or distribution of the said drugs and [4][thereupon order the destruction of drugs and] the stock thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of the licencee or with any provisions of the Act or rules made thereunder.

(2) The Licensing Authority may, for such licences granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, [3][or direct the licensee to stop manufacture, sale or distribution of the said drugs and [4][thereupon order the destruction of drugs and] the stock thereof in the presence of an Inspector] if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.]

[5][(3) A licensee whose licence has been suspended or cancelled by the Central Licence Approving Authority or Licensing Authority under sub-rule (1) or sub-rule (2), as the case may be, may within ninety days of the receipt of a copy of the order by him prefer an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government may after giving the licensee an opportunity of being heard, confirm, reverse or modify such order.]

1. Ins. by S.O.2358, dt. 26-8-1972.
2. Subs. by G.S.R. 923 (E), dt. 14-12-1992 as corrected by G.S.R. 373 (E), dt. 13-4-1993.
3. Ins. by G.S.R. 20 (E), dt. 11-1-1996.
4. Ins. by (Corrigenda) G.S.R. 514 (E), dated 5.11.1996.
5. Ins. by 615 (E), dt. 9-8-1994 as corrected by G.S.R. 55 (E), dt. 7-2-1995.
6. Ins. by S.O. 2139, dt. 5-6-1972.

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[1][PART VIIA
[2][MANUFACTURE FOR SALE OR FOR DISTRIBUTION] OF HOMOEOPATHIC MEDICINES

85A .*Manufacture on more than one set of premises.*—If Homoeopathic medicines are manufactured in more than one set of premises a separate application shall be made and a separate licence shall be obtained in respect of each such set of premises.

85B. *Application for licence to manufacture Homoeopathic medicines.*—(1) Application for grant or renewal of [2][licence to manufacture for sale or for distribution] of Homoeopathic medicines shall be made to the Licensing Authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the Licensing Authority) and shall be made in Form 24-C.

[3][(2) The application in Form 24-C shall be accompanied–

(*a*) by a fee of [4][rupees two hundred] for the manufacture of Homoeopathic mother tinctures and potentised preparations and an inspection fee of [4][rupees one hundred] for the first inspection or [4][rupees fifty] in case of inspection for renewal of licence;

(*b*) by a fee of [4][rupees two hundred] for the manufacture of Homoeopathic potentised preparations only, and an inspection fee of [4][rupees one hundred] for the first inspection or [4][rupees fifty] in case of inspection for renewal of licence;

(*c*) by a fee of [4][rupees two hundred] for the manufacture of potentised preparations from back potencies by pharmacies which are already licensed to sell Homoeopathic medicines by retail and an inspection fee of [4][rupees one hundred] for the first inspection or [4][rupees fifty] in case of inspection for renewal of licence.

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1. Ins. under G.S.R. 1185 (E), dt. 18-8-1964.
2. Sub. by G.S.R. 788 (E), dt. 10-10-1985.
3. Sub. by G.S.R. 245, dt. 11-2-1976.
4. Subs. by G.S.R. 601 (E), dt. 24-8-2001.

[1][(3) If a person applies for renewal of a licence after its expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be-

(*a*) [2][rupees two hundred] plus an additional fee at the rate of [2][rupees one hundred] per month or part thereof and an inspection fee of [2][rupees fifty] for the manufacture of Homoeopathic mother tinctures and potentised preparations;

[4][(*b*)[2][rupees two hundred] plus an additional fee at the rate of [2][rupees one hundred] per month or part thereof and an inspection fee of [2][rupees fifty] for the manufacture of Homoeopathic potentised preparations only;]

(c) [2][rupees two hundred] plus an additional fee at the rate of [2][rupees one hundred] per month or part thereof and an inspection fee of [2][rupees fifty] for the manufacture of Homoeopathic mother tinctures and potentised preparations from back potencies by pharmacies who are already licensed to sell Homoeopathic medicines by retail.]

(4) A fee of [2][rupees fifty] shall be paid for a duplicate copy of the licence for the manufacture of Homoeopathic mother tinctures and potentised preparations issued under sub-rule (1) if the original is defaced, damaged or lost, while the fee to be paid for such a duplicate copy of the licence for the manufacture of Homoeopathic potentised preparations only shall be [2][rupees fifty].

[3][(5) Applications by licensee to manufacture additional items of Homoeopathic medicines shall be made to the Licensing Authority and such applications shall be accompanied by a fee of [2][rupees fifty] for each additional item.]

85C. *Application to manufacture 'New Homoeopathic medicines.'*—Subject to the other provisions of these Rules

(1) no 'New Homoeopathic medicine' shall be manufactured unless it is previously approved by the Licensing Authority mentioned in Rule 21;

(2) the manufacturer of 'New Homoeopathic medicine', when applying to the Licensing Authority mentioned in sub-rule (1) shall produce such documentary and other evidence as may be required by the Licensing Authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it.

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1. Subs. by G.S.R. 245, dt. 3-2-1976.
2. Subs. by G.S.R. 601 (E), dt. 24-8-2001.
3. Ins. by G.S.R. 13 (E), dt. 7-1-1983.
4. Subs. by G.S.R. 779 (E), dt. 18-7-1980.

(3) While applying for a licence to manufacture a 'New Homoeopathic medicine' an applicant shall produce along with his application evidence that the 'New Homoeopathic medicine' for the manufacture of which application is made has already been approved.

Explanation.—The term 'New Homoeopathic medicine' in this rule shall have the same meaning as in rule 30AA.

[1][**85D.** *Form of licence to manufacture Homoeopathic medicines.*—Licence for manufacture of Homoeopathic medicines is a licence to manufacture potentised preparations from back potencies by Pharmacies who are already licensed to sell Homoeopathic medicines by retail and shall be granted in Form 25C.]

85E. *Conditions for the grant or renewal of a licence in Form 25C.*—Before a licence in Form 25C is granted or renewed the following conditions shall be complied with by the applicant:—

(1) The manufacture of Homoeopathic medicines shall be conducted under the direction and supervision of competent technical staff consisting at least of one person who is a whole time employee [2][and who is—

(a) a graduate in Science with Chemistry as one of the subjects with three years' experience in manufacture of Homoeopathic Medicines; or

(b) a graduate in Pharmacy with 18 months of experience in the manufacture of Homoeopathic medicines; or

(c) holds qualification as defined under sub-clause (g) of clause (1) of section 2 of Homoeopathy Central Council Act, 1973 (59 of 1973) with 18 months of experience in the manufacture of Homoeopathic medicines:

Provided that the persons who are already in employment with five years' experience in the manufacture of Homoeopathic medicines and whose name was accordingly entered in any licence granted in Form 25C for manufacture of different classes of Homoeopathic medicines included in them shall be deemed to be qualified for the purpose of this rule.]

[3][(2) The factory premises shall comply with the requirements and conditions specified in Schedule M-I:

1. Amended by F.1-59/68-D (SO 4816), dt. 19-11-1969.
2. Subs. by G.S.R. 812 (E), dt. 14-11-1994 as corrected by G.S.R. 517 (E), dt. 26-6-1995.
3. Subs. by G.S.R. 570 (E), dt. 12-6-1987.

Provided that where the Licensing Authority considers it necessary or expedient so to do, it may having regard to the nature and extent of manufacturing operations, relax or suitably alter the said requirements or conditions in any particular case for reasons to be recorded in writing.]

(3) The applicant for manufacture of Homoeopathic mother tinctures shall either (i) provide and maintain adequate staff, premises and laboratory equipment for identifying the raw materials and for testing the mother tinctures wherever possible, or (ii) make arrangements with some institution approved by the Licensing Authority [2][under Part XV(A) of these rules] for such tests, wherever possible, to be regularly carried out on his behalf by that institution.

(4) The premises where Homoeopathic medicines are manufactured shall be distinct and separate from the premises used for residential purposes.

(5) Homoeopathic medicines shall not be manufactured simultaneously with drugs pertaining to other systems of medicine.

(6) The applicant shall make arrangements for proper storage of Homoeopathic medicines manufactured by him:

[1][Provided that in case potentised preparations are made in a Pharmacy holding licence in Form 20-C, the conditions (2) and (3) shall not apply. The licensee shall ensure to the satisfaction of the Licensing Authority that the products manufactured by it, conform to the claims made on the label.]

[3][**85-EA.** *Inspection before grant or renewal of licence.*-- Before a licence under this Part is granted or renewed in Form 25C or Form 26C, the Licensing Authority shall cause the establishment, in which the manufacture is proposed, to be conducted or being conducted, to be inspected by one or more Inspectors shall examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the substances to be manufactured and inquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the requirements of plant and equipment as laid down in Part I of Schedule M read with the requirements of maintenance of records as laid down in Schedule U.

1. Amended by F.1-59/68-D (SO 4816), dt. 19-11-1969.
2. Ins. by G.S.R. 1172 (E), dt. 23-8-1977.
3. Ins. by G.S.R. 493 (E), dt. 9-6-1995.

85EB. *Report by Inspector.*—The Inspector or Inspectors shall forward a detailed descriptive report giving his or their findings on each aspect of inspection along with his or their recommendations after completion of his or their inspection to the Licensing Authority.

85EC. *Grant or refusal of licence.*— (1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary is satisfied that the requirements of the rules under the Act have been complied with and that conditions of the licence and the rules under the Act shall be observed, he shall grant or renew a licence in Form 25C or Form 26C.

(2) If the Licensing Authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence can be granted or renewed and shall supply the applicant with a copy of inspection report.]

85ED. *Further application after rejection.* .—If within a period of six months from the rejection of an application for a licence, the applicant informs the Licensing Authority that the conditions laid down have been fulfilled and deposits an inspection fee of [1][rupees two hundred and fifty], the Licensing Authority may, if, after causing further inspection to be made, he is satisfied that the conditions for the grant of licence have been complied with, issue a licence in Form 25C or Form 26C.

85EE. *Appeal to the State Government.*—Any person who is aggrieved by the order passed by the Licensing Authority refusing to grant or renew a licence under this Part may within ninety days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as is considered necessary and after giving the said person an opportunity for representing the case, pass such order as it thinks fit.]

85F. *Duration of licence.*—An original licence or a renewed licence unless it is sooner suspended or cancelled shall be [1][valid for a period of five years on and from the date on which] it is granted or renewed:

[2][Provided that if the application for renewal of a licence in force 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 application for its renewal is not made within six months of its expiry.]

85G. *Certificate of renewal.*—The certificate of renewal of a licence in Form 25-C shall be issued in Form 26-C.

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1. Subs. by G.S.R. 601 (E), dt. 24-8-2001.
2. Subs. by S.O. 2139, dt. 12-8-1972.

85H. *Conditions of licence.*—A licence in Form 25-C shall be subject to the conditions stated therein and to the following further conditions, namely :—

(a) the licensee shall provide and maintain staff and premises as specified in Rule 85-E;

(b) the licensee shall allow an [1][Inspector appointed under the Act] to enter, with or without prior notice, any premises where the manufacture of a Homoeopathic medicine in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured Homoeopathic medicines;

(c) 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 the rules made thereunder have been observed;

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

(e) the licensee shall comply with the following conditions in respect of mother tinctures manufactured by him-

(i) the crude drug used in the manufacture of the mother tincture shall be identified and records of such identification shall be kept [3][for a period of five years];

(ii) the total solids in the mother tincture shall be determined and records of such tests shall be kept [3][for a period of five years];

(iii) the alcohol content in the mother tincture shall be determined and records of the same shall be maintained [3][for a period of five years];

(iv) the containers of mother tinctures shall preferably be of glass and shall be clean and free from any sort of impurities or adhering matter. The glass shall be neutral as far as possible;

(v) in the process of manufacture of mother tinctures hygienic conditions shall be scrupulously observed by the licensee. Storage and handling conditions shall also be properly observed by the licensee according to Homoeopathic principles;

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1. Amended by G. S. R. 444, dt. 28-4-1973.
2. Amended by F-1-14/ 68-D, dt. 26-10-1968.
3. Ins. by G.S.R. 13(E), dt. 7-1-1983.

[1][(ea) no colour shall be added to any Homoeopathic medicines :

Provided that caramel may be added to combination of Homoeopathic preparations with syrup base;]

(f) records shall be maintained of Homoeopathic medicines containing alcohol and the quantities sold together with names and addresses of parties to whom sold.[2] [Such records shall be maintained for a period of five years.]

[3][**85HH.** *Additional information to be furnished by an applicant for the licence or a licensee to the Licensing Authority.*–The applicant for the grant of licence or any other person granted a licence under this Part shall, on demand, furnish to the Licensing Authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation in rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm or any other relevant matters which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.]

85-I. *Cancellation and suspension of licences.*– (1) The Licensing Autority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules made thereunder.

[4][(2) A licensee whose licence has been suspended or cancelled may, within three months of the date of the order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.]

PART VIII

MANUFACTURE FOR EXAMINATION, TEST OR ANALYSIS

86. *Conditions relating to manufacture for examination, test or analysis.*–The provisions of Section 18 of the Act shall not apply to the manufacture of any drug in small quantities for the purpose of examination, test or analysis if the conditions prescribed in this Part are fulfilled.

87. *Labelling.*–Any drug manufactured for the purpose of examination, test or analysis shall be kept in containers bearing labels indicating the purpose for which it has been manufactured.

88. *Labelling of drugs supplied to other persons.*—If any drug manufactured for the purpose of examination, test or analysis is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the substance if known, or if not known a reference which will enable the substance to be identified and the purpose for which it has been manufactured.

1. Ins. by G.S.R. 680 (E), dt. 5-12-1980.
2. Ins. by G.S.R. 13 (E), dt. 7-1-1983.
3. Ins. by S. O. 2139, dt. 12-8-1972.
4. Subs. G.S.R. 926, dt. 16-7-1977.

Note: Sample testing charges will be determined / revised by the Director or Government Analyst of the Pharmacopoeial laboratory for Indian Medicine, as the case may be, in consultation with the Department of Ayurveda, Yoga, Unani, Siddha and Homoeopathy, Ministry of Health and Family Welfare.

[1][SCHEDULE C

(See rules 23, 61 and 76 and Part X)

Biological and Special Products

1. Sera.
2. Solution of serum proteins intended for injection.
[2][3. Vaccines for parenteral injections.
4. Toxins.
5. Antigen.
6. Antitoxins.
7. Neo-arsphenamine and analogous substances used for the specific treatment of infective diseases.
8. Insulin.
9. Pituitary (Posterior Lobe) Extract.
10. Adrenaline and Solutions of Salts of Adrenaline.
[3][11. Antibiotics and preparations thereof in a form to be administered parenterally.]
[4][12 Any other preparation which is meant for parenteral administration as such or after being made up with a solvent or medium or any other sterile product and which-
(a) requires to be stored in a refrigerator; or
(b) does not require to be stored in a refrigerator.]
13. Sterilized surgical ligature and sterilized surgical suture.
[2][14. Bacteriophages.
[5][15 Ophthalmic preparations.]
[6][16 Sterile Disposable Devices for single use only.]

1. Amended by Notfn. No. F. 1-30/47-A, dt. 5-1-1950
2. Amended by Notfn. No. F. 1-8/60-D, dt. 31-8-1960
3. Subs. by No. G.S.R. 487(E) ,dt. 2.7.1984.
4. Amended by Notfn. No. F. 1-14/68-D, dt. 26-10-1968
5. Ins. by Notfn. No. G.S.R. 1242(E) ,dt. 17.9.1979
6. Ins. by Notfn. No. G.S.R. 109(E) ,dt. 22.2.1994.

[1][SCHEDULE C (1)

(*See* Rule 23, 61 and 76)

Other Special Products

1 Drugs belonging to the Digitalis group and preparations containing drugs belonging to the Digitals group not in a form to be administered parenterally.

2 Ergot and preparations containing Ergot not in a form to be administered parenterally.

3 Adrenaline and preparations containing Adrenaline not in a form to be administered parenterally.

4 Fish Liver Oil and preparations containing Fish Liver Oil.

5 Vitamins and preparations containing any vitamins not in a form to be administered parenterally.

6 Liver extract and preparations containing liver extract not in a form to be administered parenterally.

7 Hormones and preparations containing Hormones not in a form to be administered parenterally.

8 Vaccine not in a form to be administered parenterally.

[2][9. Antibiotics and preparations thereof not in a form to be administered parenterally.]

[3][10. In-vitro Blood Grouping Sera.

11. In-vitro Diagnostic Devices for HIV, HbsAg and HCV.]

1. Amended by. Notfn. No. F. 1-22/59-D, dt. 9-4-1960
2. Subs. by.G.S.R.487(E) ,dt. 2-7-1984.
3. Ins. By G.S.R. 601(E), dt. 27.8.2002.

89. *Licence.*—If the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a licence in Form 25 or Form 28 in respect of such drugs he shall, before commencing such manufacture, obtain a licence in Form 29:

[1][Provided that in the case of a drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use, no licence in Form 29 shall be granted unless the applicant produces a certificate from the "Licensing Authority" mentioned in Rule 21, to the effect that there would be no objection to such licence being granted.

90. *Form of application.*— [2][(1)] An application for a licence in Form 29 shall be made to the Licensing Authority appointed by the State Government for the purpose of this Part (hereafter in this Part referred to as the Licensing Authority) in Form 30 and shall be made by or countersigned by the head of the institution in which, or a director of the firm or company by which, the substance will be manufactured.

[4][(2) Every application in Form 29 shall be accompanied by a fee of [3][rupees two hundred fifty].

91. *Duration of licence.*—A licence in Form 29 shall, unless sooner cancelled, be in force for a period of one year from the date of issue, and may thereafter be renewed for periods of one year at a time.

92. *Conditions of licence.* —A licence in Form 29 shall be subject to the following conditions—

(a) the licensee shall use the drugs manufactured under the licence exclusively for purpose of examination, test or analysis, and shall carry on the manufacture and examination, test or analysis at the place specified in the licence;

(b) the licensee shall allow any [3][inspector appointed under the Act] to enter, with or without notice, the premises where the drugs are manufactured and to satisfy himself that only examination, test or analysis work is being conducted;

(c) the licensee shall keep a record of the quantity of drugs manufactured for examination, test or analysis and of any person or persons to whom the drugs have been supplied;

(d) the licensee shall comply with such further requirements, if any, applicable to the holders of licences in Form 29 as may be specified in any rules subsequently made under the Act and of which the Licensing Authority has given him not less than one month's notice;

(e) the licensee shall maintain an Inspection Book to enable an Inspector to record his impressions and defects noticed.

93. *Cancellation of licences.*-

(1) The Licensing Authority may after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part, either wholly or in respect of some of the substances to which it relates, if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provision of the Act or Rules thereunder

1. Ins. under F. 1-19/59-D (SO 1449), dt. 13-6-1961.
2. Re-numbered by S.O. 903, dt. 28-2-1976.
3. Subs. by G.S.R. by 444, dt. 31.3.1973.
4. Ins. by S.O 903, dt. 28-2-1976.

[1][(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within three months of the date of the order.]

PART IX
LABELLING AND PACKING OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

94. *Exemption of certain drugs from certain provisions of this Part.*— (1) Labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the country to which the drug is to be exported but the following particulars shall appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed:

(a) name of the drug;

(b) the name, address of the manufacturer and the number of the licence under which the drug has been manufactured;

(c) batch or lot number;

(d) date of expiry, if any:

[2][Provided that where a drug, not classified under Schedule F, Schedule F(1) and Schedule X, [5][or blood products defined under rule 122EA] is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the Licensing Authority mentioned in Rule 21.]

[4][Provided further that where a drug classified as Narcotic Drug or Psychotropic Substance is to be exported under a code number, the same may be permitted by the said licensing authority on the following conditions, namely:-

(i) Each consignment of export shall be accompanied with requisite import license from the importing country;

(ii) The applicant shall obtain a no objection certificate from the Drugs Controller, India for manufacture of such formulations to be exported with code number against each export order along with certificate from the regulatory authority of the importing country controlling Narotic Drugs and Psychotropic Substances that they do not have any objection for the import of the drug with code number;

(iii) The State Licensing Authority shall issue the manufacturing license for these formulations on each export order on the basis of a No Objection Certificate from Drugs Controller, India;

(iv) A no objection certificate shall be obtained from the drugs Controller, India for export of each consignment; and

(v) A no objection certificate shall be obtained from the Narcotic Commissioner of India, Gwalior for export of each consignment of the drug.]

[3][(2) The provisions of Rules 96 to 101 inclusive, shall not apply to a medicine made up ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered practitioner provided that:

(*i*) the medicine is labelled with the following particulars : —

(*a*) the name and address of the supplier;

(*b*) the name of the patient and the quantity of the medicine;

(*c*) the number representing serial number of the entry in the prescription register;

1. Subs. by F.1-10/68-D (S.O 2482), dt. 17-6-1969.
2. Ins. by G.S.R. 676 (E), dt. 2-6-1988.
3. Subs. by F.1-19/59-D, dt. 13-6-1961.
4. Ins. by G.S.R. 592 (E), dt. 13-8-2008.
5. Subs. by 592 (E), dt. 13-8-2008.