DRUGS AND COSMETICS RULES, 1945

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DRUGS AND COSMETICS RULES, 1945

In exercise of the powers conferred by 1[section 6(2), section 12, section 33 and section 33(N)] of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government is pleased to make the following Rules:-

PART 1 PRELIMINARY

1. Short title, extent and commencement :-

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(1) These Rules may be called the Drugs and Cosmetics Rules, 1945.

(2) They extend to the whole of India **1** [* * *].

Amended by G.S.R358, dt5.3.1975, w.e.f15.3.1975 (NotNoX-11011/3/72-D and: Ms, dt. 5.3.1975).

2. Definitions :-

2.1Adequate areas shall be designed to allow sufficient and orderly warehousing of various categories of materials and products like starting and packaging materials intermediates, bulk and finished products, products in quarantine, released, rejected returned or recalled, machine and equipment spare parts and change items

2.2Warehousing areas shall be designed and adapted to ensure good storage conditions They shall be clean, dry and maintained within acceptable temperature limits Where special storage conditions are required (eg., temperature, humidity) these shall be provided monitored and recorded Storage areas shall have appropriate house-keeping and rodent pests and vermin control

procedures and records maintained Proper racks, bins and platforms shall be provided for the storage of materials
2.3Receiving and dispatch bays shall protect materials and products from adverse weather conditions
24Where quarantine status is ensured by warehousing in separate earmarked areas in the same warehouse or store, these areas shall be clearly demarcated Any system replacing the physical quarantine, shall give equivalent assurance ot segregation Access to these areas shall be restricted to authorized persons
2.5There shall be a separate sampling areas in the warehousing area tor active law materials and excipients If sampling is performed in any other area, it shall be conducted in such a way as to prevent contamination, cross-contamination and mix-up
2 6 Segregation shall be provided tor the storage of rejected, recalled or relumed materials or products Such areas, materials or products shall be suitably marked and secured Access to these areas and materials shall be restricted
2.7 Highly hazardous, poisonous and explosive materials such as narcoticspsychotropic drugs and substances presenting potential risks ot abuse, fire or explosion shall be stored in safe and secure areas Adequate fire protection measures shall be provided in conformity with the rules of the concerned civic authority
2.8Printed packaging materials shall be stored in sate, separate and secure areas
2.9Separate dispensing areas for B (Beta)-Lactum, sex hormones and cytotoxic substances or any such special categories of products shall be provided with proper supply of filtered air and suitable measures tor dust control to avoid contamination Such areas shall be under differential pressure
210Sampling and dispensing of sterile materials shall be conducted under aseptic conditions conforming to Grade A, which can also be performed in a dedicated area within the manufacturing facility
211Regular checks shall be made to ensure adequate steps are taken against spillagebreakage and leakage of containers
212Rodent treatments (pest control) should be done regularly and at least once in a year and record maintained

PART 2 THE CENTRAL DRUGS LABORATORY

3. Functions :-

.The Tableting section shall be free from dust and floating particles and may be air-conditionedFor this purpose, each "tablet

compression machine" shall be isolated into cubicles and connected to a vacuum dust collector or an exhaust systemFor effective operations, the tablet production department shall be divided into four distinct and separate sections as follows: (a) Mixing, Granulation and Drying section. (b) Tablet compression section. (c) Packaging section (strip/blister machine wherever required). (a) Coating section (wherever required). 3.1The following electrically operated equipment are recommended for the manufacture of compressed tablets and hypodermic tablets, in each of the above sections, namely: (a) Granulation-cum-drying section (1) Disintegrator and sifter. (2) Powder mixer. (3) Mass mixer/Planetary mixer/Rapid mixer granulator. (4) "Granulator wherever required" . (5) Thermostatically controlled hot air oven with trays (preferably mounted on a trolley)/Fluid bed dryer. (6) Weighing machines. (b) Compression section (1) Tablet compression machine, single/multi punch/rotatory. (2) Punch and dyes storage cabinets. (3) Tablet de-duster. (4) Tablet Inspection unit/belt. (5) "Dissolution test apparatus wherever required" . (6) In-process testing equipment like single pan electronic balance, hardness tester, friability and disintegration test apparatus. (7) Air-conditioning and dehumidification arrangement (wherever necessary). (c) Packaging section (1) Strip/blister packaging machine. (2) Leak test apparatus (vacuum system). (3) Tablet counters (wherever applicable). (4) Air-conditioning and dehumidification arrangement (wherever applicable)Area.A minimum area of sixty square metres for basic installation and twenty square metres for Ancillary area is recommended for un-coated tablets. (d) Coating section (1) Jacketted kettle "stainless steel container or any other appropriate material" (steam, gas or electrically heated for preparing coating suspension). (2) Coating pan (stainless steel). (3) Polishing pan (where applicable). (4) Exhaust system (including vacuum dust collector). (5) Air-conditioning and dehumidification arrangement. (6) Weighing balance. The requirement for ancillary area in this part shall not apply to units registered before 1.1.2002 3.2The coating section shall be made dust free with suitable exhaust system to remove excess powder and fumes resulting from solvent evaporationIt shall be air-conditioned and dehumidified wherever considered necessary. Area.A minimum additional area of thirty square metres for coating section for basic installation and ten square metres for Ancillary area is recommendedSeparate area and equipment for mixing, granulation, drying, tablet compression, coating and

packing shall be provided for Penicillin group of drugs on the lines indicated aboveIn case of operations involving dust and floating particles, care shall be exercised to avoid cross-contamination. Note. The requirement for ancillary area in this part shall not apply to units registered before 1.1.2002." 3.3The manufacture of Hypodermic tablets shall be conducted under aseptic conditions in a separate air-conditioned roomthe walls of which shall be smooth and washableThe granulation, tableting and packing shall be done in this room. 3.4The manufacture of effervescent and soluble tablets shall be carried out in air-conditioned and dehumidified areas.

3A. . :-

14(1) The functions of the Laboratory in respect of the following drugs or classes of drugs shall be carried out at the Central Research Institute, Kasauli, and the functions of the Director in respect of the said drugs or classes of drugs shall be exercised by the Director of the said Institute:-
(1) Sera
(2) Solution of serum proteins intended for injection
(3) Vaccines
(4) Toxins
(5) Antigens
(6) Anti-toxins
(7) Sterilized surgical ligature and sterilized surgical suture
(8) Bacteriophages.
15[Provided that the functions of the Director in respect of Oral Polio Vaccine shall be exercised by the Deputy Director and Head of the Polio Vaccine Testing Laboratory in case of Central Research Institute, Kasauli only.]
16(1A) The functions of the Laboratory in respect of Oral Polio Vaccine shall be carried out by the following Institutes and the functions of the Director in respect of the said drugs shall be exercised by the Director of the respective Institutes:
(a) Pasteur Institute of India, Conoor.
(b) Enterovirus Research Centre (Indian Council of Medical Research), Haffkine Institute Compound, Parel, Bombay-400 012.]
17[(c) The National Institute of BiologicalsNOIDA]
18[(2) The functions of the Laboratory in respect of the following drugs or classes of drugs shall be carried out at the Indian Veterinary Research Institute, lzatnager or Mukteshwar and the

functions of the Director in respect of the said drugs or classes of drugs shall be exercised by the Director of either of the said institutes:

(1) Anti-sera for veterinary use.

(2) Vaccines for veterinary use.

(3) Toxoids for veterinary use.

(4) Diagnostic Antigens for veterinary use.]

[19][(3) The functions of the Laboratory in respect of condoms shall be carried out at the Central Indian Pharmacopoeia Laboratory, Ghaziabad and the functions of the Director in respect of the said condoms shall be exercised by the Director of the said Laboratory.]

[20][[21](4)] The functions of the Laboratory in respect of the following drug shall be carried out at the Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta and the functions of the Director in respect of the said drug shall be performed by the Serologist and Chemical Examiner of the said Laboratory. VDRL Antigen.]

[22][(5) The function of the Laboratory in respect of Intra-utrine Devices and Falope Rings shall be carried out at the Central Drugs Testing Laboratory, Thane, Maharashtra and the functions of the Director in respect of the said devices shall be exercised by the Director of the said laboratory.]

[23][(6) The functions of the Laboratory in respect of Homoeopathic medicines shall be carried out at the Homoeopathic Pharmacopoeia Laboratory, Ghaziabad and the functions of the Director in respect of the Homoeopathic medicines shall be exercised by the Director of the laboratory.]

(8) [24] The functions of the Laboratory in respect of Blood Grouping reagents and diagnostic kits for Human Immunodeficiency VirusHepatitis B Surface Antigen and Hepatitis C Virus shall be carried out at the National Institute of Biologicals, NOIDA and the functions of the Director in respect of the said drugs shall be exercised by the Director of the said laboratory.

Amended by NotNoF4-1/60-D, dt15.5.1961.

Substituted by G.S.R445(E), dt30.4.1992, w.e.f30.4.1992.

Insby G.S.R445(E), dt30.4.1992, w.e.f30.4.1992.

Rule 3A, sub-rule (1A), after Item (b), Item (c) shall be inserted by Drugs and Cosmetics (1st Amendment) Rules, 2002., NotiNoG.S.R249(E), dated April 4, 2002, published inthe Gazette of India, Extra., Part II, Section 3(i), dated 4th April, 2002, p2,

No158.

Added by NotNoF1-6/62-D, dt2.7.1969.

Added by S.O2139, dt5.6.1972 w.e.f12.8.1972.

Added by G.S.R2655, dt25.10.1975, w.e.f25.10.1975.

Sub-rule (4) omitted and (5), renumbered as (4) by G.S.R62(E), dt15.2.1982, w.e.f15.2.1982.

Substituted by G.S.R242(E), dt18.3.1998, w.e.f6.5.1998.

Insby G.S.R246(E), dt1.5.1991,w.e.f1.5.1991, (inadvertently mentioned as (7) in Gazette Notification).

Rule 3A, after sub-rule (7), sub-rule (8) shall be inserted by Drugs and Cosmetics (1st Amendment) Rules, 2002., NotiNoG.S.R249(E), dated April 4, 2002, published in the Gazette of India, Extra., Part II, Section 3(i), dated 4th April, 2002, p2, No158.

4. Despatch of samples for test or analysis :-

.The following equipment is recommended for the manufacture of powders namely: (1) Disintegrator. (2) Mixer (electrically operated). (3) Sifter. (4) Stainless steel vessels and scoops of suitable sizes. (5) Filling equipment . (6) Weighing balance. In the case of operation involving floating panicles of fine powder, a suitable exhaust system shall be providedWorkers should be provided with suitable masks during operation. Area.A minimum area of thirty square metres is recommended to allow for the basic installationsWhere the actual blending is to be done on the premises, an additional room shall be provided for the purpose. "Note. The requirement for additional room in this part shall not apply to units registered before 1.1.2002

5. Recording of condition of seals :-

.For the manufacture of capsules, separate enclosed area suitably air-conditioned and dehumidified with an airlock arrangement shall be providedThe following equipment is recommended for filling Hard Gelatin Capsules, namely: (1) Mixing and blending equipment (electrically or power driven). (2) Capsule filling units. (3) Capsules counters (wherever applicable) (4) Weighing balance. (5) Disintegration test apparatus. (6) Capsule polishing equipment. Separate equipment and, filling and packaging areas shall be

provided in penicillin and non-penicillin sectionsIn case of operations involving floating particles of fine powder, a suitable exhaust system shall be providedManufacture and filling shall be carried out in airconditioned areasThe room shall be dehumidified. Area.A minimum area of twenty-five square metres for basic installation and ten square metres for Ancillary area each for penicillin and non-penicillin sections is recommended. Note. The requirement for ancillary area in this part shall not apply to units registered before 1.1.2002

6. Report of result of test or analysis :-

.The following equipment is recommended for the manufacture of surgical dressings other than Absorbent Cotton Wool, namely, (1) Rolling machine. (2) Trimming machine. (3) Cutting equipment. (4) Folding and pressing machine for gauze. (5) Mixing tanks for processing medicated dressing. (6) Hot air dry oven. (7) Steam sterilizer or dry heat sterilizer or other suitable equipment. (8) Work tables/benches for different operationsArea.A minimum area of thirty square metres is recommended to allow for the basic installationsIn case medicated dressings are to be manufactured, another room with a minimum area of thirty square metres shall be provided.

7. Fees :-

.For the manufacture of Ophthalmic preparations, separate enclosed areas with air lock arrangement shall be providedThe following equipment is recommended for manufacture under aseptic conditions of Eye-Ointment, Eye-lotions and other preparations for external use, namely (1) Thermostatically controlled hot air ovens (preferably double ended). (2) Jacketted kettle/Stainless steel tanks (steam, gas or electrically heated). (3) Mixing and storage tanks of stainless steel/Planetary mixer. (4) Colloid mill or ointment mill. (5) Tube filling and crimping equipment (semi-automatic or automatic filling machines). (6) Tube cleaning equipment (air jet type). (7) Tube washing and drying equipment, if required. (8) Automatic vial washing machine. (9) Vial drying oven. (10) Rubber bung washing machine. (11) Sintered glass funnel, seitz filter or filter candle (preferably cartridge and membrane filters). (12) Liquid filling equipment (semi-automatic or automatic filling machines). (13) Autoclave (preferably ventilator autoclave). (14) Air-conditioning and dehumidification arrangement (preferably

centrally airconditioned and dehumidification system). (15) Laminar air flow units. Area.(1) A minimum area of twenty-five square metres for basic installation and ten square metres for Ancillary area is recommendedManufacture and tilling shall be carried out in air-conditioned areas under aseptic conditionsThe rooms shall be further dehumidified as considered necessary if preparations containing antibiotics are manufactured. (2) Areas for formulations meant for external use and internal use shall be separately provided to avoid mix up. "Note. The requirement for ancillary area in this part shall not apply to units registered before 1.1.2002."

8. Signature of certificates :-

.(i) The following equipment is recommended for manufacture of Pessaries and Suppositories, namely, (1) Mixing and pouring equipment. (2) Moulding equipment. (3) Weighing devices. Area.A minimum area of twenty square metres is recommended to allow for the basic installation. (ii) In the case of pessaries manufactured b y granulation and compression, the requirements as indicated under "Item 3 of Tablet", shall be provided.

PART 3 3

9. Section 9 :-

10. Section 10 :-

11. Section 11 :-

12. Section 12 :-

13. Section 13 :-

14. Section 14 :-

15. Section 15 :-

16. Section 16 :-

17. Section 17 :-

18. Section 18 :-

19. Section 19 :-

20. Section 20 :-

[Rules - Omitted by SRO 2136dt15.6.1957,NotNoF1-16/57-D,

dt15.6.1957.]

PART 4 "IMPORT AND REGISTRATION"

21. . :-

In this Part- [12][(a) import licence means either a licence in Form 10 to import drugs [3]excluding those specified in Schedule X, or a licence in Form 10-A to import drugs specified in Schedule X;]
(b) "licensing authority" means the authority appointed by the Central Government to perform the duties of the licensing authority under these Rules and includes any person to whom the powers of a licensing authority may be delegated under Rule 22;
(c) "licence for examination, test or analysis" means a licence in Form 11 to import small quantities of drugs the import of which is otherwise prohibited, for the purpose of examination, test or analysis.
[4](d) "manufacturer", includes a manufacturer of drugs, who may be a Company or a unit or a body corporate or any other establishment in a country other than India, having its drugs manufacturing facilities duly approved by the National Regulatory Authority of that country, and who also has a free sale approval of the drugs approved by the said authority in the concerned country, and/or in other major countries;
[4] (e) "Registration Certificate" means a certificate issued under Rule 27-A by the licensing authority in Form 41 for registration of the premises and the drugs manufactured by the manufacturer meant for import into and use in India

1. For the heading "IMPORT", the heading "IMPORT AND REGISTRATION" shall be substituted by Drugs and Cosmetics (5th Amendment) Rules, 2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

2. Substituted by G.S.R462(E), dt22.6.1982 (w.e.f22.6.1982).

3. The words, letters, brackets and figures "specified in Schedules C and C(I)" shall be omitted by Drugs and Cosmetics (5th Amendment) Rules, 2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

4. Clauses shall be inserted by Drugs and Cosmetics (5th

Amendment) Rules, 2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

22. . :-

The licensing authority may with the approval of the Central Government by an order in writing delegate the [1] "power to sign licences and Registration Certificates and" such other powers as may be specified in the order to any other person under his control.]

1. The words, "power to sign licences and", the words, "power to sign licences and Registration Certificates and" shall be substituted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

23. Import licences :-

[1]- An import licence in Form 10 shall be required for [2] "import of drugs" excluding those specified in Schedule X, and an import licence in Form 10-A shall be required for the import of drugs specified in Schedule X.]

1. Substituted by G.S.R462(E), dt22.6.1982 (w.e.f22.6.1982).

2. The words "import of any biological or other special product specified in Schedule C or C(I)", the words "import of drugs" shall be substituted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

24. Form and manner of application for import licence.- :-

[1] (1) An application for an import licence shall be made to the licensing authority in Form 8 for drugs excluding those specified in Schedule X, and in Form 8-A for drugs specified in Schedule X, either by the manufacturer himself having a valid wholesale licence for sale or distribution of drugs under these rules, or by the manufacturers agent in India either having a valid licence under

the rules to manufacture for sale of a drug or having a valid wholesale licence for sale or distribution of drugs under these rules, and shall be accompanied by a licence fee of one thousand rupees for a single drug and an additional fee at the rate of one hundred rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer: Provided that in the case of any subsequent application made by the same importer for import licence for drugs manufactured by the same manufacturer, the fee to accompany each such application shall be one hundred rupees for each drug.

(2) Any application for import licence in Form 8 or Form 8-A, as the case may be, shall be accompanied by a copy of Registration Certificate issued in Form 41 under Rule 27-A: Provided that in case of emergencies the licensing authority may, with the approval of the Central Government, issue an import licence in Form 10 or 10-A, as the case may be, without the issuance of Registration Certificate under Rule 27-A, for reasons to be recorded in writing.

(3) A fee of two hundred and fifty rupees shall be paid for a duplicate copy of the licence issued under this rule, if the original is defaced, damaged or lost.".

1. Rule shall be substituted by by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24,2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

<u>24A.</u> Form and manner of application for Registration Certificate.- :-

1 (1) An application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer himself, having a valid wholesale licence for sale or distribution of drugs under these rules, or by his authorised agent in India, either having a valid licence under the rules to manufacture for sale of a drug or having a valid wholesale licence for sale or distribution of drugs under these rules, and shall be accompanied by the fee specified in sub-rule (3) and the informations and undertakings specified in Schedules D-I and D-II duly signed by or on behalf of the manufacturer.

(2) The authorisation by a manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of

origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate.

(3) (i) A fee of one thousand and five hundred US dollars shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import into and use in India. (ii) A fee of one thousand US dollars shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional drug : Provided that in the case of any subsequent application for registration of additional drugs by the same manufacturer, the fee to accompany shall be one thousand US dollars for each drug.

(4) The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi - 110 001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04 - Public Health, 104 - Fees and Fines" : Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account "0210 - Medical and Public Health, 04 - Public Health, 104 - Fee and Fines", and the original receipt of the said transfer shall be treated as an equivalent to the bank challan, subject to the approval by the Bank of Baroda that they have received the payment.

(5) The applicant shall be liable for the payment of a fee of five thousand US dollars for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority under Rule 22.

(6) The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.

(7) A fee of three hundred US dollars shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

(8) No Registration Certificate shall be required under these rules in respect of an inactive bulk substance to be used for a drug formulation, with or without pharmacopoeial conformity.".

1. Rule shall be inserted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001,published in the Gazette of India, Extra., Part II, Section 3(i),dated 24th August, 2001, pp37-85, No424

25. Licences for import of drugs manufactured by one manufacturer :-

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(1) A single application may be made, and a single licence may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer.

[Provided that the drugs or classes of drugs are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit.

Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different drugs a separate licence shall be required in respect of the drugs manufactured by each such factory.]

(2) **1** [* * *]

1. Omitted under NotNoF1-16/57-D, dt. 15.6.1957.

25A. Conditions to be satisfied before a licence in Form 10 or Form 10-A is granted :-

1

(1) A licence in Form 10 or in Form 10-A shall be granted by the licensing authority having regard to-

2 (i) his conviction under the Act or these rules or the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) or the rules made thereunder.".

(ii) the occupation, trade or business ordinarily carried out by the applicant.

Provided that the licensing authority may refuse to grant a licence in Form 10-A in respect of any applicant where he is satisfied,-

(a) that the applicant has not complied with the provisions of the Act or these rules, or

(b) that by reasons of -
(i) his conviction under the Act or these rules or the Dangerous Drugs Act, 1930 or the rules made thereunder;
(ii) previous suspension or cancellation of the licence granted to him, he is not a fit person to whom licence shall be granted.
(2) Any person who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government and the Central Government may after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for making a representation in the matter, make such orders in relation thereto as it thinks fit.]

1. Substituted by G.S.R462(E),dt22.6.1982, w.e.f22.6.1982, previously added by NotNoF1-9/52-D, dt3.11.1958.

2. Clause (i)shall be substituted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24,2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424 (i) the premises, where the imported substances will be stocked are equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies; and

25B. Registration Certificate for import of drugs manufactured by one manufacturer.- :-

1 (1) A single application may be made, and a single Registration Certificate in Form 41 may be issued in respect of the import of more than one drug or class of drugs, manufactured by the same manufacturer :
Provided that the drug or classes of drugs, are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit:
Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different drugs, separate Registration Certificates shall be required in respect of the drugs manufactured by each such factory.".

1. Rule.25-B shall be inserted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24,2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

<u>26.</u> Conditions of import licence :-

- An import licence shall be subject to the following conditions-
(i) the manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 9;
(ii) the licensee shall allow any Inspector authorized by the licensing authority in that behalf to enter with or without notice any premises where the imported substance is stocked to inspect the means, if any, employed for testing the substance and to take samples;
(iii) the licensee shall on request furnish to the licensing authority from every batch of each substance or from such batch or batches as the licensing authority may from time to time specify a sample of such amount as the licensing authority may consider adequate for any examination required to be made, and the licensee shall, if so required, furnish full protocols of the tests, if any, which have been applied;
(iv) if the licensing 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-rule until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the licensing authority;
(v) The licensee shall, on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality and purity prescribed by Chapter 3 of the Act, or the Rules thereunder 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 the issues already made from that batch;
(vi) the licensee shall maintain a record of all sales by him of substances for the import of which a licence is required, showing particulars of the substance and of the person to whom sold and such further particulars, if any, as the licensing authority may specify and such record shall be open to the inspection of any Inspector authorized in that behalf by the licensing authority.
[Provided that in respect of the sale or distribution of drugs specified in Schedule X, the licensee shall maintain a separate record or register showing the following particulars, namely:-
1Name of the drug,
2Batch number,

3Name and address of the manufacturer,
4Date of transaction,
5Opening stock on the business day,
6Quantity of drug received, if any, and the source from which received,
7Name of the purchaser, his address and licence number,
8Balance quantity of drug at the end of the business day,
9Signature of the person under whose supervision the drugs have been supplied;]
(vii) the licensee shall comply with such further requirements, if any, applicable to the holders of import licences, as may be specified in

<u>27.</u> Grant of import licence :-

- On receipt of an application for an import licence in the form and manner prescribed in Rule 24, the licensing authority shall, on being satisfied that, if granted, the conditions of the licence will be observed, issue an import licence in Form 10 [or Form 10-A, as the case may be].

<u>27A.</u> Grant of Registration Certificate.- :-

1 (1) On receipt of an application for Registration Certificate in the Form and manner specified in Rule 24-A, the licensing authority shall, on being satisfied, that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form 41 : Provided further that if the application is complete in all respects and information specified in Schedules D-I and D-II are in order, the licensing authority shall, within nine months from the date of receipt of an application, issue such Registration Certificate, and in exceptional circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three months as the licensing authority, may deem fit.
(2) If the applicant does not receive the Registration Certificate within the period as specified in proviso to sub-rule (1), he may appeal to the Central Government and the Central Government may after such enquire into the matter, as it considers necessary, may pass such orders in relation thereto as it thinks fit.".

1. Rule shall be inserted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health),

NotiNoG.S.R604(E), dated August 24, 2001,published in the Gazette of India, Extra., Part II, Section 3(i),dated 24th August, 2001, pp37-85, No424

28. Duration of import licence :-

[- A licence, unless, it is sooner suspended or cancelled, shall be [1] "valid for a period of three years from the date of its issue"
Provided that if application for a fresh licence is made three months before the expiry of the existing licence the current licence shall be deemed to continue in force until orders are passed on the application.]

1. For the words, figures and letters, "valid up to the 31st December of the year following the year in which it is granted", the words "valid for a period of three years from the date of its issue" shall be substituted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001,published in the Gazette of India, Extra., Part II, Section 3(i),dated 24th August, 2001, pp37-85, No424

28A. Duration of Registration Certificate :-

.[1] -
A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue:
Provided that if the application for a fresh Registration Certificate is made nine months before the expiry of the existing certificate, the current Registration Certificate shall be deemed to continue in force until orders are passed on the application.".

1. Rule 28-A shall be inserted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24,2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

29. Suspension and cancellation of import licence :-

- If the manufacturer or licensee fails to comply with any of the conditions of an import licence, the licensing authority may after giving the manufacturer or licensee an opportunity to show cause

why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel it for such period as it thinks fit either wholly or in respect of some of the substances to which it relates.

[1] "Provided that a person who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as it considers necessary and after giving the said appellant an opportunity for representing his views, pass such orders in relation thereto as it thinks fit.".

1. The following proviso shall be substituted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

29A. Suspension and cancellation of Registration Certificate.- :-

[1] If the manufacturer fails to comply with any of the conditions of the Registration Certificate, the licensing authority may after giving him an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel the Registration Certificate for such period as it thinks fit either wholly or in respect of some of the substances to which it relates :

Provided that a person, who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, pass such orders in relation thereto as it thinks fit.".

1. Rule 29A shall be inserted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

30. Prohibition of import after expiry of potency :-

- No biological or other special product specified in Schedule C or C (1) shall be imported after the date shown on the label, wrapper or container of the drug as the date up to which the drug may be expected to retain a potency not less than, or not to acquire a toxicity greater than, that required, or as the case may be, permitted by the prescribed test.

30A. . :-

[* * * * * * * * * * *]

30AA. Import of New Homoeopathic medicines :-

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(1) No New Homoeopathic medicine shall be imported except under and in accordance with the permission in writing of the Licensing Authority.
(2) The importer of a New Homoeopathic medicine when applying for permission shall produce before the Licensing Authority 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.
[Explanation- For the purpose of this rule, New Homoeopathic medicine means,-
(i) a Homoeopathic medicine which is not specified in the Homeopathic Pharmacopoeia of India or the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia; or
(ii) which is not recognized in authoritative Homoeopathic literature as efficacious under the conditions recommended; or
(iii) a combination of Homoeopathic medicines containing one or more medicines which are not specified in any of the Pharmacopoeias referred to in clause (i) as Homoeopathic medicines and also not recognized in authoritative Homoeopathic literature as efficacious, under the conditions recommended.]

30B. Prohibition of import of certain drugs :-

- No drug, the manufacture, sale or distribution of which is prohibited in the country of origin, shall be imported under the same name or under any other name except for the purpose of examination, test or analysis.]

31. Standard for certain imported drugs.- :-

[1] No drug shall be imported unless it complies with the standard of strength, quality and purity, if any, and the test prescribed in the rules shall be applicable for determining whether any such imported drug complies with the said standards :

Provided that the drugs intended for veterinary use, the standards of strength, quality and purity, if any, shall be those that are specified in Schedule F(l) and the test prescribed in that Schedule shall be applicable for determining whether any such imported drug complies with the said standards and where no standards are specified in Schedule F(l) for any veterinary drug, the standards for such drug shall be those specified in the current edition, for the time being in force, of the British Pharmacopoeia Veterinary :

Provided further that the licensing authority shall not allow the import of any drug having less than sixty per cent residual shelf-life period as on the date of import:

Provided also that in exceptional cases the licencing authority may, for reasons to be recorded in writing, may allow, the import of any drug having lesser shelf-life period, but before the date of expiry as declared on the container of the drug.".

1. Rule shall be substituted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

<u>32.</u> Packing and labelling of imported drugs :-

- No drug shall be imported unless it is packed and labelled in conformity with the rules in Parts IX and X [* * *] and further conforms to the standards laid down in Part XII provided that in the case of drugs intended for veterinary use, the packing and labelling shall conform to the rules in Parts IX and X and Schedule F (1).]

<u>32A.</u> Packing and labelling of Homoeopathic medicine :-

- No Homoeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX-A.]

<u>33.</u> Import of drugs for examination, test or analysis :-

- Small quantities of drugs the import of which is otherwise

prohibited under Section 10 of the Act may be imported for the purpose of examination, test or analysis subject to the following conditions:-

(a) No drug shall be imported for such purpose except under a licence in Form 11;

(b) the licensee shall use the substances imported under the licence exclusively for purposes of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the licence, or in such other places as the licensing authority may from time to time authorize;

(c) the licensee shall allow any Inspector authorized by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances are kept, and to inspect the premises, and investigate the manner in which the substances are being used and to take samples thereof;

(d) the licensee shall keep a record of, and shall report to the licensing authority, the substances imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer;

(e) the licensee shall comply with such further requirements, if any, applicable to the holders of licences for examination, test or analysis as may be specified in any rules subsequently made under Chapter 3 of the Act and of which the licensing authority has given to him not less than one months notice.

33A. Import of drugs by a Government Hospital or Autonomous Medical Institution/or the treatment of patients.- :-

1 Small quantities of a new drug, as defined in Rule 122-E, the import of which is otherwise prohibited under Section 10 of the Act, may be imported for treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such disease requiring therapies for unmet medical needs, by a Medical Officer of a Government Hospital or an Autonomous Medical Institution providing tertiary care, duly certified by the Medical Superintendent of the Government Hospital, or Head of the Autonomous Medical Institution, subject to the following conditions, namely:-

(a) no new drug shall be imported for the said purpose except under a licence in Form 11-A, and the said drug has been approved for marketing in the country of origin;

(b) the licencee shall use the substances or drugs imported under the licence exclusively for the purpose of treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such diseases requiring therapies for unmet medical needs, under the supervision of its own Medical Officers at the place, specified in the licence or at such other places, as the licensing authority, may from time to time authorise;
(c) the licencee shall allow an Inspector authorised by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances or drugs are stocked, and to inspect the premises and relevant records and investigate the manner in which the substances or drugs are being used and to take, if necessary, samples thereof;
(d) the licencee shall keep a record of, and shall submit the said report half yearly to the licensing authority, the substances or drugs imported under the licence, together with the quantities imported and issued to the patients, the date of importation, the name of the manufacturer, the name and address of the patient for whom the drug is prescribed and the name of disease;
(e) the licencee shall comply with such other requirements, if any, applicable to the holders of import licences for import of new drugs for treatment of patients by Government Hospitals, as may be specified from time to time in any rule subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than one months notice;
(f) the drug shall be stocked under proper storage conditions and shall be dispensed under the supervision of a registered pharmacist;
(g) the quantity of any single drug so imported shall not exceed 100 average dosages per patient: Provided that the licensing authority may, in exceptional circumstances, sanction the import of drug a larger quantity.".

1. Rule 33A shall be inserted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E),dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

34. Application for licence for examination, test or analysis :-

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(1) An application for a licence for examination, test or analysis shall be made in Form 12 and shall be made or countersigned by the head of the institution in which, or by a proprietor or director of the company or firm by which the examination, test or analysis will be conducted.

(2) The licensing authority may require such further particulars to be supplied as he may consider necessary.

[1](3) Every application in Form 12 shall be accompanied by a fee of one hundred rupees for a single drug and an additional fee of fifty rupees for each additional drug.

[1] (4) The fees shall be paid through a challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi - 110 001 or any other branch or branches of Bank of Baroda, or any other Bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210 - Medical and Public Health, 04 - Public Health, 104 - Fees and Fine"..

1. For sub-rule(3)and(4)shall be substituted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E),dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i),dated 24th August, 2001, pp37-85, No424

<u>34A.</u> Application for licence to import small quantities of new drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patients.- :-

[1] (1) An application for an import licence for small quantities of a new drug, as defined in Rule 122-E for the purpose of treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such diseases requiring therapies for unmet medical needs, shall be made in Form 12-AA, by a Medical Officer of the Government Hospital or Autonomous Medical Institution, which shall be certified by the Medical Superintendent of the Government Hospital or Head of the Autonomous Medical Institution, as the case may be.

(2) The licensing authority may require such further particulars to be supplied, as he may consider necessary.

(3) Every application in Form 12-AA shall be accompanied by a fee of one hundred rupees for a single drug and an additional fee of fifty rupees for each additional drug.

(4) The fees shall be paid through a challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi - 110 001 or any other branch or

branches of Bank of Baroda, or any other Bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210 - Medical and Public Health, 04 - Public Health, 104 - Fees and Fine"..

1. Rules 34A shall be inserted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E),dated August 24,2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 24th August, 2001, pp37-85, No424

35. Cancellation of licence for examination, test or analysis :-

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(1) A licence for examination, test or analysis may be cancelled by the licensing authority for breach of any of the conditions subject to which the licence was issued.

(2) A licensee whose licence has been cancelled may appeal to the Central Government within three months of the date of the order.

35A. Cancellation of licence for import of small quantities of new drugs.- :-

1 (1) A licence for import of small quantities of a new drug, defined in Rule 122-E, for the purpose of the treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such diseases requiring therapies for unmet medical needs, by a Government Hospital or an Autonomous Medical Institution may be cancelled by the licensing authority for breach of any of the conditions subject to which the licence was issued or for contravention of any of the provisions of the Act and rules made thereunder.

(2) A licencee whose licence has been cancelled may appeal to the Central Government within three months from the date of the receipt of the order, and the Central Government may after such enquiry into the matter, as it considers necessary and after giving the appellant an opportunity for representing his views, may pass such orders in relation thereto, as it thinks fit.".

1. Rule 35A shall be inserted by Drugs and Cosmetics (5th Amendment) Rules,2001 Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R604(E), dated August 24, 2001, published in the Gazette of India, Extra., Part II, Section 3(i),

dated 24th August, 2001, pp37-85, No424

36. Imports of drugs for personal use :-

- Small quantities of drugs, the imports of which is otherwise prohibited under Section 10 of the Act, may be imported for personal use subject to the following conditions-
(i) The drugs shall form part of a passengers bona fide baggage and shall be the property of, and be intended for, the exclusive personal use of the passenger;
(ii) the drugs shall be declared to the Customs authorities if they so direct;
(iii) the quantity of any single drug so imported shall not exceed one hundred average doses.
Provided that the licensing authority may in an exceptional case in any individual case sanction the unports of a larger quantity.
[Provided further that any drug, imported for personal use but not forming part of bona fide personal baggage, may be allowed to be imported subject to the following conditions, namely-
(i) the licensing authority, on an application made to it in Form 12-A is satisfied that the drug is for bonafide personal use;
(ii) the quantity to be imported is reasonable in the opinion of the licensing authority and is covered by prescription from a registered medical practitioner; and
(iii) the licensing authority grants a permit in respect of the said drug in Form 12-B.]

37. Packing of patent or proprietary medicines :-

- Patent or proprietary medicine shall be imported in containers intended for retail sale.
[Provided that such medicine may be imported in bulk containers by any person who holds a licence to manufacture, if such person has obtained permission in writing to unport such medicines from the licensing authority at least three months prior to the date of import and the imports are made within a period of twelve months from the date of issue of such permission].]

38. Statement to accompany imported drugs :-

- All consignments of drugs sought to be imported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of

the drugs.

39. Documents to be supplied to the Customs Collector :-

- Before drugs for the import of which a licence is not required are imported a declaration signed by or on behalf of the manufacturer or by or on behalf of the importer that the drugs comply with the provisions of Chapter 3 of the Drugs and Cosmetics Act, 1940 and the Rules thereunder shall be supplied to the Customs Collector.

40. Procedure for the import of drugs :-

-
(1) If the Customs Collector has reason to doubt whether any drugs comply with the provisions of Chapter III of the Act and Rules thereunder he may, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the director of the laboratory appointed for this purpose by the Central Government and may detain the drugs in the consignment of which samples have been taken until the report of the director of the said laboratory or any other officer empowered by him on this behalf, subject to the approval of the Central Government on such samples is received.
Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the Customs Collector and to return the consignment or such portion thereof as may be required, the Customs Collector shall make over the consignment to the importer.
(2) If an importer who has given an undertaking under the proviso to sub- rule (1) is required by the Customs Collector to return the consignment or any portion thereof he shall return the consignment or portion thereof within ten days of receipt of the notice.]

41. :-

(1) If the director of the laboratory appointed for the purpose by the Central Government or any other officer empowered by him on this behalf subject to the approval of the Central Government reports to the Customs Collector that the samples of any drug in a consignment are not of standard quality, or that the drug contravenes in any other respect the provisions of Chapter III of

the Act or the Rules thereunder and that the contravention is such that it cannot be remedied by the importer, the Customs Collector shall communicate the report forthwith to the importer who shall, within two months of his receiving the communication either export all the drugs of that description in the consignment, to the country in which they were manufactured or forfeit them to the Central Government which shall cause them to be destroyed.]

Provided that the importer may within fifteen days of receipt of the report make a representation against the report to the Customs Collector, and the Customs Collector shall forward the representation with a further sample to the licensing authority, who after obtaining, if necessary, the report of the Director of the Central Drugs Laboratory, shall pass orders thereon which shall be final.

(2) If the director of the laboratory appointed for the purpose by the Central Government or any other officer empowered by him on this behalf, subject to the approval of the Central Government reports to the Customs Collector that the samples of any drug contravene in any respect the provisions of Chapter III of the Act or the Rules thereunder and that the contravention is such that it can be remedied by the importer, the Customs Collector shall communicate the report forthwith to the importer and permit him to import the drug on his giving an

42. . :-

Omitted by NotNoF1-9/52-D.S., dt3.11.1953.

43. . :-

The drugs specified in Schedule D shall be exempt from the provisions of Chapter III of the Act and of the Rules made thereunder to the extent, and subject to the conditions specified in that Schedule.

43A. . :-

No drug shall be imported into India except through one of the following places, namely:- Firozepur Cantonment and Amritsar Railway Stations : In respect of drugs imported by rail across the frontier with Pakistan. Ranaghat, Bongaon and Mohiassan Railway Stations : In respect of drugs imported by rail across the frontier with Bangladesh, [Raxaul: in respect of drugs imported by road and

railway lines connecting Raxaul in India and Birganj in Nepal] ["Chennai, Kolkata, Mumbai, Cochin and Nhava Sheva and Kandla"] In respect of drugs imported by sea into India. [Chennai, Kolkata, Mumbai, Delhi, Ahmedabad and Hyderabad]; In respect of drugs imported by air into India.]

43B. . :-

Drugs, consignments of which are in transit through India to foreign countries and which shall not be sold or distributed in India shall be exempted from the requirements of Chapter 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder.
Provided that if the Government of the countries to which the drugs are consigned regulate their import by the grant of import licences, the importer shall at the time of import into India, produce such import licences.]

PART 5 [GOVERNMENT ANALYSTS, INSPECTORS, LICENSING AUTHORITIES AND CONTROLLING AUTHORITIES]

44. Qualifications of Government Analyst :-

- A person appointed as a Government Analyst under the Act shall be a person who-
(a) is a graduate in Medicine or Science or Pharmacy or Pharmaceutical chemistry of a [University established in India by the law or has an equivalent qualification recognised and notified by the Central Government for such purpose] and has had not less than five years post-graduate experience in the testing of drugs in a laboratory [or has completed two years training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory], or
(b) possesses a post-graduate degree in Medicine or Science or Pharmacy or Pharmaceutical Chemistry of a [University established in India by the law or has an equivalent qualification recognised and notified by the Central Government for such purpose] or possesses the Associate- ship Diploma of the Institution of Chemists (India) obtained by passing the said examination with Analysis of Drugs and Pharmaceuticals as one of the subjects and has had after obtaining the said postgraduate degree or diploma not less than three Years experience in the testing of drugs in a laboratory under the control of (i) a Government Analyst appointed under the Act, or (ii) the head of an Institution or testing

laboratory approved for the purpose by the appointing authority [or has completed two years training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory].

Provided that-

[(i) for the purpose of examination of items in Schedule C,-

(ia) the persons appointed under clause (a) or (b) and having degree in Medicine, Physiology, Pharmacology, Microbiology, Pharmacy should have experience or training in testing of said items in an institution or laboratory approved by the appointing authority for a period of not less than six months;

(ib) the person appointed under clause (a) or (b) but not having degree in the above subjects should have experience or training in testing of the said Schedule C drugs for a period of not less than three years in an institution or laboratory approved by the appointing authority or have completed two years training on testing of drugs including item stated in Schedule C in Central Drugs Laboratory;]

(ii) for a period of four years from the date on which Chapter IV of the Act takes effect in the States, persons, whose training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be considered necessary, a reasonable guarantee of adequate knowledge and competence may be appointed as Government AnalystsThe persons so appointed may, if the appointing authority so desires, continue in service after the expiry of the said period of four years;

(iii) no person who is engaged directly or indirectly in any trade or business connected with the manufacture of drugs shall be appointed as a Government Analyst for any area.

Provided further that for the purpose of examination of Antisera, Toxoid and Vaccines and Diagnostic Antigens for Veterinary use, the person appointed shall be a person who is a graduate in Veterinary Science, or general science, or medicine or pharmacy and has had not less than five years experience in the standardization of biological products or a person holding a post-graduate degree in Veterinary Science, or general science, or medicine or pharmacy or pharmaceutical chemistry with an experience of not less than three years in the standardisation of biological products.

Provided also that persons, already appointed as Government Analysts may continue to remain in service, if the appointing authority so desires, notwithstanding the fact that they do not fulfil the qualifications as laid down in clause (a), clause (b) or the

preceding proviso.)

45. Duties of Government Analysts :-

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(1) The Government Analyst shall cause to be analysed or tested such samples of drugs [and cosmetics] as may be sent to him by Inspectors or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these Rules.

(2) A Government Analyst shall from time to time forward to the Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government.

46. Procedure on receipt of sample :-

- On receipt of a package from an Inspector containing a sample for test or analysis, the Government Analyst shall compare the seals on the packet[or on portion of sample or container] with the specimen impression received separately and shall note the condition of the seals on the [packet or on portion of sample or container]After the test or analysis has been completed, he shall forthwith supply to the Inspector a report in triplicate in Form 13 of the result of the test or analysis, together with full protocols of the tests or analysis applied.

[Explanation- It shall be deemed to be full and sufficient compliance with the requirement of the rule in respect of the supply of "protocols of the tests or analysis applied", if-

(1) for pharmacopoeial drug, where the tests or methods of analysis prescribed in the official pharmacopoeia are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report;

(2) for patent or proprietary medicines for which the tests and methods prescribed in any of the official pharmacopoeias are applicable and are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report;

(3) for patent or proprietary medicines containing pharmacopoeial drugs for which the official tests or analysis or methods of assays are modified and applied, a description of the actual tests or, as the case may be, analysis or methods of assays so applied is given in the report;

(4) for patent or proprietary medicines for which no pharmacopoeial

tests or methods of analysis are available or can be applied but for which tests or methods of analysis given in standard books or journals are followed, a description of such tests or methods of analysis applied together with the reference to the relevant books or journals from which the tests or methods of analysis have been adopted, is given in the report;
(5) for those drugs for which methods of test are not available and have been evolved by the Government Analyst, a description of tests applied is given in the report.]

47. Report of result of test or analysis :-

- An application from a purchaser for test or analysis of a drug under Section 26 of the Act shall be made in Form 14-A and the report of test or analysis of the drug made on such application shall be supplied to the applicant in Form 14-B.

48. Fees :-

- The fees to be paid by a person submitting to the Government Analyst under Section 26 of the Act for test or analysis of a drug [or cosmetic] purchased by him shall be those specified in Schedule B.

49. Qualifications of Inspectors :-

- A person who is appointed an Inspector under the Act shall be a person who has a degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialisation in Clinical Pharmacology or Microbiology from a University established in India by law.
Provided that only those Inspectors-
(i) who have not less than 18 months experience in the manufacture of at least one of the substances specified in Schedule C, or
(ii) who have not less than 18 months experience in testing of at least one of the substances in Schedule C in a laboratory approved for this purpose by the licensing authority, or
(iii) who have gained experience of not less than three years in the inspection of firm manufacturing any of the substances specified in Schedule C during the tenure of their services as Drugs Inspectors;
[Provided further that the requirement as to the academic qualification shall not apply to persons appointed as Inspectors on or before the 18th day of October 1993.]

49A. Qualification of a Licensing Authority :-

- No person shall be qualified to be a Licensing Authority under the Act unless :
(i) he is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialisation in Clinical Pharmacology or Microbiology from a University established in India by law; and
(ii) he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years.
[Provided that the requirements as to the academic qualification shall not apply to those Inspectors and the Government Analysts who were holding those positions on the 12th day of April, 1989.]]

50. Controlling Authority :-

-
(1) All Inspectors appointed by the Central Government shall be under the control of an officer appointed in this behalf by the Central Government.
(2) All Inspectors appointed by the State Government shall be under the control of an officer appointed in this behalf by the State Government.
(3) For the purposes of these rules an officer appointed by the Central Government under sub-rule (1), or as the case may be, an officer appointed by the State Government under sub-rule (2) shall be a controlling authority.]

50A. Qualification of a Controlling Authority :-

-
(1) No person shall be qualified to be a Controlling Authority under the Act unless :
(i) he is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialisation in Clinical Pharmacology or Microbiology from a University established in India by law; and
(ii) he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years.
[Provided that the requirements as to the academic qualification shall not apply to those Inspectors and the Government Analysts who were holding those positions on the 12th day of April, 1989.]]

51. Duties of Inspectors of premises licensed for sale :-

- Subject to the instructions of the controlling authority, it shall be the duty of an Inspector authorized to inspect premises licensed for the sale of drugs-

(1) to inspect ["not less than once a year"] all establishments licensed for the sale of drugs within the area assigned to him;

(2) to satisfy himself that the conditions of the licences are being observed;

(3) to procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain drugs being sold or stocked or exhibited for sale in contravention of the provisions of the Act or Rules thereunder;

(4) to investigate any complaint in writing which may be made to him;

(5) to institute prosecutions in respect of breaches of the Act and Rules thereunder;

(6) to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks, and to submit copies of such record to the controlling authority;

(7) to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act;

(8) when so authorized by the State Government, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

52. Duties of inspectors specially authorised to inspect the manufacture of drugs :-

- Subject to the instructions of the controlling authority it shall be the duty of an Inspector authorized to inspect the manufacture of ["drugs and cosmetics"]-

(1) to inspect ["not less than once a year"], all premises licensed for manufacture of drugs within the area allotted to him and to satisfy himself that the conditions of the licence and provisions of the Act and Rules thereunder are being observed;

(2) in the case of establishments licensed to manufacture products specified in Schedules C and C (1) to inspect the plant and the process of manufacture, the means employed for standardizing and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and all details of location,

construction and administration of the establishment likely to affect the potency or purity of the product;
(3) to send forthwith to the controlling authority after each inspection a detailed report indicating the conditions of the licence and provisions of the Act and Rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed;
(4) to take samples of the drugs manufactured on the premises and send them for test or analysis in accordance with these Rules;
(5) to institute prosecutions in respect of breaches of the Act and Rules thereunder.

53. Prohibition of disclosure of information :-

- Except for the purposes of official business or when required by a Court of law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties.

54. Form of order not to dispose of stock :-

- An order in writing by an Inspector under clause (c) of Section 22 of the Act requiring a person not to dispose of any stock in his possession shall be in Form 15.

54A. Prohibition of sale :-

- No person in possession of a [drug or cosmetic] in respect of which an Inspector has made an order under clause (c) of sub-section (i) of Section 22 of the Act shall in contravention of that order sell or otherwise dispose of any stock of such [drug or cosmetic].]

55. Form of receipts for seized drug, cosmetic, record, register, documents or any other material objects :-

- A receipt by an Inspector for the stock of any drug or cosmetic or for any record, register, document or any other material object seized by him under clause (c) or clause (cc) of sub-section (1) of Section 22 of the Act shall be in Form 16.]

55A. Manner of certifying copies of seized documents :-

- The Drugs Inspector shall return the documents, seized by him

under clause (cc), or produced before him under clause (cca), of sub-section (1) of Section 22 of the Act, within a period of twenty days of the date of such seizure or production, to the person from whom they were seized or, as the case may be, the person who produced them, after copies thereof of extracts therefrom have been signed by the concerned Drugs Inspector and the person from whom they were seized, or as the case may be, who produced such records.]

56. Form of intimation of purpose of taking samples :-

.- When an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.

56A. Form of receipt for samples of drugs where fair price tendered is refused :-

- Where the fair price, for the samples of drugs taken for the purpose of test or analysis, tendered under sub-section (1) of section 23 has been refused, the Inspector shall tender a receipt therefor to the person from whom the said samples have been taken as specified in Form 17-A.]

57. Procedure for despatch of sample to Government Analyst :-

-
(1) The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under sub-section (4) of Section 23 of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form 18, in an outer cover addressed to the Government Analyst.
(2) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.

58. Confiscation of drugs, implements, machinery, etc. :-

-
(1) Where any person has been convicted for contravening any of the provisions of Chapter IV of
(2) Where any person has been convicted for the manufacture, of any drug deemed to be misbranded under clause (a), clause (b),

clause (c), clause (d), clause (f) or clause (g) of Section 17 of the Act, or adulterated drug under Section 17B of the Act, or for manufacture for sale, or stocking or exhibiting for sale or distribution of any drug without a valid licence as required under clause (c) of Section 18 of the Act, any implements or machinery used in such manufacture, sale or distribution and any receptacle, packages, or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.]

58A. Procedure for disposal of confiscated drugs :-

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(1) The Court shall refer the confiscated drugs to the Inspector concerned for report as to whether they are of standard quality or contravene the provisions of the Act or the Rules in any respect.
(2) If the Inspector, on the basis of Government Analysts report finds the confiscated drugs to be not of standard quality or to contravene any of the provisions of the Act or the rules made thereunder, he shall report to the Court accordingly. The Court shall thereupon order the destruction of the drugsThe destruction shall take place under the supervision of the Inspector in the presence of such authority, if any, as may be specified by the Court.
(3) If the Inspector finds that the confiscated drugs are of standard quality and do not contravene the provisions of the Act or the rules made thereunder, he shall report to the Court accordingly[The Court may then order the Inspector to give the stocks of confiscated drugs to hospital or dispensary maintained or supported by the Government or by Charitable Institutions.]]

PART 6 SALE OF DRUGS OTHER THAN HOMEOPATHIC MEDICINES

59. . :-

(1) The State Government shall appoint licensing authorities for the purpose of this Part for such areas as may be specified.
[(2) Application for the grant or renewal of a licence [to sell, stock, exhibit or offer for sale or distribute] drugs, other than those included in Schedule X, shall be made in Form 19 or Form 19-A, as the case may be, or in the case of drugs included in Schedule X shall be made in Form 19-C, to the licensing authority and shall be accompanied by a fee of rupees forty.

Provided that in the case of an itinerant vendor or an applicant who desires to establish a shop in a village or town having population of 5,000 or less, the application in Form 19-A shall be accompanied by a fee of rupees ten.

(3) A fee of rupees six shall be paid for a duplicate copy of a licence to sell, stock, exhibit for sale or distribute drugs, other than those included in Schedule X, or for a licence to sell, stock, exhibit for sale or distribute drugs included in Schedule X, if the original is defaced, damaged or lost.

Provided that in the case of itinerant vendor or an applicant who desires to establish a shop in a village or town having a population of 5,000 or less, the fee for a duplicate copy of a licence if the original is defaced, damaged or lost, shall be rupees two.

(4) Application for renewal of a licence to [sell, stock, exhibit or offer for sale or distribute] drugs, after its expiry but within six months of such expiry shall be accompanied by a fee of rupees forty, plus an additional fee at the rate of rupees thirty per month or part thereof.

Provided that in the case of an itinerant vendor or an applicant desiring to open a shop in a village or town having a population of 5,000 or less, the application for such renewal shall be accompanied by a fee of rupees ten, plus an additional fee at the rate of rupees eight per month or part thereof.]

60. . :-

A licensing authority may with the approval of the State Government by an order in writing delegate the power to sign licences and such other powers as may be specified in the order to any other person under his control.]

61. Forms of licences to sell drugs :-

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(1) A licence [to sell, stock, exhibit or offer for sale or distribute] drugs other than those specified in Schedules C, C(1) and X and by retail on restricted licence or by wholesale, shall be issued in Form 20, Form 20-A or Form 20-B, as the case may be.

Provided that a licence in Form 20-A shall be valid for only such drugs as are specified in the licence.

(2) A licence to sell, stock, exhibit for sale or distribute drugs specified in Schedules C and C(1) excluding those specified in Schedule X, by retail on restricted licence or by wholesale shall be

issued in Form 21, Form 21-A or Form 21-B, as the case may be.
[Provided that a licence in Form 21-A shall not be granted for drugs specified in Schedule C and shall be valid for only such Schedule C(1) drugs as are specified in the licence.]
(3) A licence to sell, stock or exhibit for sale or distribute drugs specified in Schedule X by retail or by wholesale shall be issued in Form 20-F or Form 20-G as the case may be.]

62. Sale at more than one place :-

- If drugs are sold or stocked for sale at more than one place, separate application shall be made, and a separate licence shall be issued, in respect of each such place.
[Provided that this shall not apply to itinerant vendors who have no specified place of business and who will be licensed to conduct business in a particular area within the jurisdiction of the licensing authority.]

62A. Restricted licences in Forms 20-A and 21-A :-

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(a) Restricted licences in Forms 20-A and 21-A shall be issued, subject to the discretion of the licensing authority, to dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person.
(b) Licences to itinerant vendors shall be issued only in exceptional circumstances for bonafide travelling agents of firms dealing in drugs or for a vendor who purchases drugs from a licensed dealer for distribution in sparsely populated rural areas where other channels of distribution of drugs are not available.
(c) The licensing authority may issue a licence in Form 21-A to a travelling agent of a firm but to no other class of itinerant vendors for the specific purpose of distribution to medical practitioners or dealers, samples of biological and other special products specified in Schedule C.
Provided that travelling agents of licensed manufacturers, agents of such manufacturers and of importers of drugs shall be exempted from taking out licence for the free distribution of samples of medicines among members of the medical profession, hospitals, dispensaries and the medical institutions or research institutions.]

62B. Conditions to be satisfied before a licence in Form 20-A or Form 21- A is granted :-

-

(1) A licence in Form 20-A or Form 21-A shall not be granted to any person, unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs to which the licence applies.

Provided that this condition shall not apply in the case of licence granted to itinerant vendors.

(2) In granting a licence under Rule 62A the authority empowered to grant it shall have regard to-

(i) the number of licences granted in the locality during one year immediately preceding; and

(ii) the occupation, trade or business carried on by such applicant.

Provided that the licensing authority may refuse to grant or renew a licence to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or these Rules or the previous cancellation or suspension of any licence granted thereunder, he is not a fit person to whom a licence should be granted under this Rule.

(3) Any person who is aggrieved by the order passed by the licensing authority in sub-rule (1) may, within 30 days from the date of the receipt of such order appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, make such order in relation thereto as it thinks fit.]

62C. Application for licence to sell drugs by wholesale or to distribute the same from a motor vehicle :-

-

(1) Application for the renewal of a licence to sell by wholesale or to distribute from a motor vehicle shall be made to the licensing authority in Form 19-AA and shall be accompanied by a fee of rupees twenty.

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 rupees twenty plus an additional fee at the rate of rupees twenty per month or part thereof.

(2) A fee of rupees five shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

62D. Form of licences to sell drugs by wholesale or distribute drugs from a motor vehicle :-

- A licence shall be issued for sale by wholesale or for distribution from a motor vehicle of drugs other than those specified in Schedule C and Schedule C(1) in Form 20-BB and of drugs specified in Schedule C and Schedule C(1) in Form 21-BB.
Provided that such a licence shall not be required in a case where a public carrier or a hired vehicle is used for transportation or distribution of drugs.]

63. Duration of licence :-

- An original licence or a renewed licence to sell drugs, unless sooner suspended or cancelled, shall be valid up to the 31st December of the year following the year in which it is granted or renewed.
[Provided that if the application for renewal of 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 applicationThe licence shall be deemed to have expired if application for its renewal is not made within six months after its expiry.]]

63A. Certificate of renewal of a sale licence :-

- The certificate of renewal of a sale licence in Forms 20, 20-A, 20-B, [20-F, 20-G], 21, 21-A and 21-B shall be issued in Form 21-C.]

63B. Certificate of renewal of licence :-

- A certificate of renewal of a licence in Form 20-BB or Form 21-BB shall be issued in Form 21-CC.]

64. Conditions to be satisfied before a licence in 2[Form 20, 20-B, 20-F, 20- G, 21 or 21-B] is granted 3[or renewed] :-

-
(1) A licence in [Form 20, 20-B, 20-F, 20-G, 21 or 21-B] [to sell,

stock, exhibit or offer for sale or distribute] drugs shall not be granted [or renewed] to any person unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted [or renewed] are adequate, equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies and are in charge of a person competent in the opinion of the licensing authority to supervise and control the sale, distribution and preservation of drugs.

Provided that in the case of a pharmacy a licence in Form 20 or 21 shall not be granted [or renewed] unless the licensing authority is satisfied that the requirements prescribed for a pharmacy in Schedule N have been complied with.

[Provided further that licence in Form 20-F shall be granted [or renewed] only to a pharmacy and in areas where a pharmacy is not operating, such licence may be granted [or renewed] to a chemist and druggist.]

Explanation- For the purpose of this rule the term pharmacy shall be held to mean and include every store or shop or other place- (1) Where drugs are dispensed, that is, measured or weighed or made up and supplied; or (2) where prescriptions are compounded; or (3) where drugs are prepared; or (4) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "Pharmacy", "Pharmacist, "Dispensing Chemist", or "Pharmaceutical Chemist", or (5) which, by sign, symbol or indication within or upon it gives the impression that the operations mentioned at (1), (2) and (3) are carried out in the premises; or (6) which is advertised in terms referred to in (4) above.

(2) In granting [or renewing] a licence under sub-rule (1) the authority empowered to grant it shall have regard-

(i) to the average number of licences granted [or renewed] during the period of 3 years immediately preceding, and

(ii) to the occupation, trade or business ordinarily carried on by such applicant during the period aforesaid.

Provided that the licensing authority may refuse to grant or renew a licence to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or these rules, or the previous cancellation or suspension of any licence granted [or renewed] thereunder, he is not a fit person to whom a licence should be granted [or renewed] under this ruleEvery such order shall be communicated to the licensee as soon

as possible.
[Provided further that in respect of an application for the grant of a licence in Form 20-B or Form 21-B or both, the licensing authority shall satisfy himself that the premises in respect of which a wholesale licence is to be granted [or renewed] are-
(i) of an area of not less than ten square meters; and
"(ii) in the charge of a competent person, who- (a) is a Registered Pharmacist, or; (b) has passed the matriculation examination or its equivalent examination from a recognised Board with the four years experience in dealing with sale of drugs, or; (c) holds a degree of a recognised University with one years experience in dealing with drug;"
[Provided also that-
(i) in respect of an application for the grant of a licence in Form 20 or Form 21 or both, the licensing authority shall satisfy itself that the premises are on an area of not less than 10 square meters, and
(a) In Form 20 or Form 21 or both, and
(b) In Form 20-B or Form 21-B or both. the licensing authority shall satisfy itself that the premises are of an area not less than 15 square meters.
Provided also that the provisions of the preceding proviso shall not apply to the premises for which licences have been issued by the licensing authority before the commencement of the Drugs and Cosmetics (1st Amendment) Rules, 1997.]
[(3) Any person who is aggrieved by the order passed by the licensing authority in sub-rule (1) may, within 30 days from the date of the receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, make such order in relation thereto as it thinks fit.]

65. Condition of licences :-

- Licences in [Forms 20,20-A, 20-B, 20-F, 20-G, 21 and 21-B] shall be subject to the conditions stated therein and to the following general conditions-
[(1) Any drug shall, if compounded or made on the licensees premises, be compounded or made by or under the direct and personal supervision of a [registered pharmacist].]
(2) The supply, otherwise than by way of wholesale dealing [* * *] of any drug supplied on the prescription of a Registered Medical

Practitioner [registered pharmacist].

[(3)

(1) The supply of any drug [other than those specified in Schedule X] on a prescription of a Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of entry in the register shall be entered on the prescriptionThe following particulars shall be entered in the register-

(a) serial number of the entry,

(b) the date of supply,

(c) the name and address of the prescriber,

[(d) the name and address of the patient, or the name and address of the owner of the animal if the drug supplied is for veterinary use,]

(e) the name of the drug or preparation and the quantity or in the case of a medicine made up by the licensee, the ingredients and quantities thereof,

(f) in the case of a drug specified in [Schedule C or Schedule H] the name of manufacturer of the drug, its batch number and the date of expiry of potency, if any,

(g) the signature of the [Registered Pharmacist] by or under whose supervision the medicine was made up or supplied.

Provided that in the case of drugs which are not compounded in the premises and which are supplied from or in the original containers the particulars specified in items (a) to (g) above may be entered in a cash or credit memo book, serially numbered and specially maintained for this purpose.

Provided further that if the medicine is supplied on a prescription on which the medicine has been supplied on previous occasion and entries made in the prescription register it shall be sufficient if the new entry in the register includes a serial number, the date of supply, the quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on the previous occasion.

Provided further that it shall not be necessary to record the above details in the register or in the cash or credit memo particulars in respect of-

(i) any drugs supplied against prescription under the Employees State Insurance Scheme if all the above particulars are given in that prescription, and

(ii) any drugs other than that specified in [Schedule C or Schedule H] if it is supplied in the original unopened container of the

manufacturer and if the prescription is duly stamped at the time of supply with the name of the supplier and the date on which the supply was made and on condition that the provisions of sub-rule (4) (3) of this rule are complied with.

(2) The option to maintain a prescription register or a cash or credit memo book in respect of drugs and medicines which are supplied from or in the original container, shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of the licence to sell by retail.

Provided that the Licensing Authority may require records to be maintained only in prescription register if it is satisfied that the entries in the carbon copy of the cash or credit memo book are not legible.]

[(4)

(1) The supply by retail, otherwise than on a prescription of a drug specified in Schedule C [* * *] shall be recorded at the time of supply either-

(i) in a register specially maintained for the purpose in which the following particulars shall be entered-

(a) serial number of the entry,

(b) the date of supply,

(c) the name and address of the purchaser,

(d) the name of the drug and the quantity thereof,

(e) in the case of a drug specified in Schedule C, the name of the manufacturer, the batch number and the date of expiry of potency,

(f) the signature of the person under whose supervision the sale was effected, or

(ii) in a cash or credit memo book, serially numbered containing all the particulars specified in items (b) to (f) of sub-clause(i) above.

Note- The entries in the carbon copy of the cash or credit memo which is retained by the licensee shall be maintained in a legible manner.

(2) The option to maintain a register or cash or credit memo book shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of a licence to sell by retail.

Provided that the Licensing Authority may require records to be maintained in a register if it is satisfied that the entries in the carbon copy of the cash/credit memo book are not legible.

(3)

(i) The supply by retail of any drug shall be made against a cash/credit memo which shall contain the following particulars-

(a) Name, address and sale licence number of the dealer,

[(b) Serial number of the cash/credit memo,
(c) the name and quantity of the drug supplied.]
(ii) Carbon copies of cash/credit memos shall be maintained by the licensee as record.
[(4)
(i) Records of purchase of a drug intended for sale or sold by retail shall be maintained by the licensee and such records shall show the following particulars, namely-
(a) the date of purchase,
(b) the name and address of the person from whom purchased and the number of the relevant licence held by him,
(c) the name of the drug, the quantity and the batch number, and
(d) the name of the manufacturer of the drug.
(ii) Purchase bills including cash or credit memos shall be serially numbered by the licensee and maintained by him in a chronological order.]]
[(5)
(1) Subject to the other provisions of these rules the supply of a drug by wholesale shall be made against a cash or credit memo bearing the name and address of the licensee and his licence number under the Drugs and Cosmetics Act in which the following particulars shall be entered-
(a) the date of sale,
(b) the name, address of the licensee to whom sold and his sale licence numberIn case of sale to an authority purchasing on behalf of Government, or to a hospital, medical, educational or research institution or to a Registered Medical
(c) the name of the drug, the quantity and the batch number,
(d) the name of the manufactuer;
[(e) the signature of the competent person under whose supervision the sale was effected.]
(2) Carbon copies of cash or credit memos specified in clause (1) shall be preserved as records for a period of three years from the date of the sale of the drug.
[(3)
(i) Records of purchase of a drug intended for resale or sold by wholesale shall be maintained by the licensee and such records shall show the following particulars, namely-
(a) the date of purchase,
(b) the name, address and the number of relevant licence held by the person from whom purchased,
(c) the name of the drug, the quantity and the batch number, and

(d) the name of the manufacturer of the drug.
(ii) Purchase bills including cash or credit memos shall be serially numbered by the licensee and maintained by him in a chronological order.]]
(6) The licensee shall produce for inspection by an Inspector appointed under the Act on demand 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 Rules thereunder have been observed.
(7) Except where otherwise provided in these Rules, all registers and records maintained under these Rules shall be preserved for a period of not less than two years from the date of the last entry therein.
(8) Notwithstanding anything contained in this Rule it shall not be necessary to record any particulars in a register specially maintained for the purpose if the particulars are recorded in any other register specially maintained under any other law for the time being in force.
[(9)
(a) Substances specified in Schedule H or Schedule X shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner and in the case of
(b) The supply of drugs specified in Schedule H or Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years.]
(10) For the purposes of clause (9) a prescription shall-
(a) be in writing and be signed by the person giving it with his usual signature and be dated by him;
[(b) specify the name and address of the person for whose treatment it is given, or the name and address of the owner of the animal if the drug is meant for veterinary use;]
(c) indicate the total amount of the medicine to be supplied and the dose to be taken.
(11) The person dispensing a prescription containing a drug specified in Schedule H [and Schedule X] shall comply with the following requirements in addition to other requirements of these Rules-
(a) the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more

than once;
(b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions;
(c) at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.
[(11A) No person dispensing a prescription containing substances specified in [Schedule H or X] may supply any other preparation, whether containing the same substances or not in lieu thereof.]
[(12) Substances specified in Schedule X kept in retail shop or premises used in connection therewith shall be stored-
(a) under lock and key in cupboard or drawer reserved solely for the storage of these substances; or
(b) in a part of the premises separated from the remainder of the premises and to which only responsible persons have access.]
(13)[* * *]
(14) [* * *]
[(15)
(a) The description "Drugstore" shall be displayed by such licensees who do not require the services of a [Registered Pharmacist].
(b) The description "Chemists and Druggists" shall be displayed by such licensees who employ the services of a [Registered Pharmacist] but who do not maintain a "Pharmacy" for compounding against prescriptions.
(c) The description "Pharmacy", "Pharmacist", "Dispensing Chemist" or "Pharmaceutical Chemist" shall be displayed by such licensees who employ the services of a [Registered Pharmacist] and maintain a "Pharmacy" for compounding against prescriptions.
[Explanation- For the purpose of this rule-
(i) Registered Pharmacist means a person who is a registered pharmacist as defined in clause (i) of Section 2 of the Pharmacy Act, 1948 . Provided that the provisions of sub-clause (i) shall not apply to those persons who are already approved as "qualified person" by the Licensing authority on or before the 31st December, 1969.
(ii) "Date of Expiry of Potency" means the date that is recorded on the container label or wrapper as the date upto which the substance may be expected to retain a potency not less than or not to acquire a toxicity greater than that required or permitted by the prescribed test.]]

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

[(17) No drug shall be sold or stocked by the licensee after the date of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper.

Provided that any such drugs in respect of which the licensee has taken steps with the manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, may be stocked after the date of expiration of potency pending such withdrawal, [and all such drugs shall be kept in packages or cartons, the top of which shall display prominently, the words "Not for sale"].]

[(18) No drug intended for distribution to the medical profession as free sample which bears a label on the container as specified in clause [(ix)] of sub rule (1) of Rule 96, and no drug meant for consumption by the Employees State Insurance Corporation, the Central Government Health Scheme, the Government Medical Stores Depots, the Armed Forces Medical Stores or other Government institutions, which bears a distinguishing mark or any inscription on the drug or on the label affixed to the container thereof indicating this purpose shall be sold or stocked by the licensee on his premises.]

[Provided that this sub-rule shall not be applicable to licensees who have been appointed as approved chemists, by the State Government in writing, under the Employees State Insurance Scheme, or have been appointed as authorised agent or distributor, by the manufacturer in writing, for drugs meant for consumption under the Central Government Health Scheme, the Government Medical Stores Depots, the Armed Forces Medical Stores or other Government Institutions for drugs meant for consumption under those schemes "or have been appointed as authorised Depots or Carrying and Forwarding agent by the manufacturer in writing, for storing free samples meant for distribution to medical profession" that the stock shall be stored separately from the trade stocks and shall maintain separate records of the stocks received and distributed by them.]

[(19) The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug, shall be made only by dealers who employ the services of a [Registered Pharmacist) and such supply shall be made under the direct

supervision of the [Registered Pharmacist] in an envelope or other suitable wrapper or container showing the following particulars on the label-
(a) name of the drug,
(b) the quantity supplied,
(c) the name and address of the dealer.
[(20) The medicines for treatment of animals kept in a retail shop or premises shall be labelled with the words "Not for human use-for treatment of animals only" and shall be stored-
(a) in a cupboard or drawer reserved solely for the storage of veterinary drug, or
(b) in a part of the premises separated from the remainder of the premises to which customers are not permitted to have access.]
[(21)
(a) The supply of drugs specified in Schedule X shall be recorded at the time of supply in a register (bound and serially page numbered specially maintained for the purpose and separate pages shall be allotted for each drug.
(b) The following particulars shall be entered in the said register, namely-
(i) Date of transaction;
(ii) Quantity received, if any, the name and address of the supplier and the number of the relevant licence held by the supplier;
(iii) Name of the drug;
(iv) Quantity supplied;
(v) Manufacturers name;
(vi) Batch Noor Lot No.;
(vii) Name and address of the patient/purchaser;
(viii) Reference Number of the prescription against which supplies were made;
(ix) Bill Noand date in respect of purchases and supplies made by him;
(x) Signature of the person under whose supervision the drugs have been supplied.]

65A. 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.]

66. Cancellation and suspension of licences :-

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(1) The licensing authority may, after giving the licensee an opportunity to show cause why such an order should not be passed b y an order in writing stating the reasons therefore, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either

[Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the licence shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority-

(a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or

(b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission, the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or

(c) if the act or omission was a continuing act or omission, he had not or could not reasonably have had knowledge of that previous act or omission, or

(d) that he had used due diligence to ensure that the conditions of the licence or the provisions of the Act or the rules thereunder were observed.]

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

66A. Procedure for disposal of drugs in the event of cancellation of licence :-

[-
(1) In case a licensee, whose license has been cancelled, desires to dispose of the drugs he has in his possession in the premises in respect of which the licence has been cancelled, he shall apply in writing to the licensing authority for this purpose, giving the following particulars, namely:-
(a) the name and address of the person to whom the drugs are proposed to be sold or supplied together with the number of the licence for sale or manufacture, as the case may be held by him,
(b) the names of drugs together with their quantities, batch numbers, the names and addresses of their manufacturers and the dates of their expiry, if any, proposed to be sold to the person mentioned in clause (a).
(2) The licensing authority may, after examination of the particulars referred to in sub-rule (1) and, if necessary, after inspection by an Inspector of the premises where the drugs are stocked, grant the necessary permission for their disposal.]

67. . :-

Omitted by S.O289, dt20.12.1972, w.e.f3.2.1973.

PART 6A SALE OF HOMOEOPATHIC MEDICINES

67A. . :-

(1)The State Government shall appoint Licensing Authorities for the purpose of this Part for such areas as may be specified.
(2) Application for the grant or renewal of a licence [to sell, stock, exhibit or offer for sale or distribute] Homoeopathic medicines shall be made in Form 19-B to the Licensing Authority and shall be accompanied by [a fee of rupees ten].
[Provided that if the applicant applied for renewal of licence after its expiry but within six months of such expiry the fee payable for renewal of such licence shall be [rupees ten plus an additional fee at the rate of rupees eight per month or part thereof]].
[(3) If the original licence is either defaced, damaged or lost, a duplicate copy thereof may be issued on payment of a fee of one rupee and twenty-five paise.]

67B. . :-

A Licensing Authority may, with the approval of the State

Government, by an order in writing, delegate the power to sign licences and such other powers, as may be specified, to any other person under his control.

<u>67C.</u> Forms of licences to sell drugs :-

-
(1) A licence [to sell, stock, exhibit or offer for sale or distribute] Homoeopathic medicines by retail or by wholesale shall be issued in Form 20-C or Form 20-D as the case may be.

<u>67D.</u> Sale at more than one place :-

- If drugs are sold or stocked for sale at more than one place, a separate application shall be made and a separate licence shall be obtained in respect of each place.

<u>67E.</u> Duration of licences :-

.- An original licence or a renewed licence unless it is sooner suspended or cancelled shall be valid up to the 31st December of the year following the year in which it is granted or renewed.
[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 after its expiry.]

<u>67EE.</u> Certificate of renewal :-

- The certificate of renewal of a sale licence in Forms 20-C and 20-D shall be issued in Form 20-E.]

<u>67F.</u> Conditions to be satisfied before a licence in Form 20-C or Form 20- D is granted :-

-
(1) A licence in Form 20-C or Form 20-D [to sell, stock exhibit or offer for sale or distribute] Homoeopathic medicines shall not be granted to any
[Provided that no registered Homoeopathic medical practitioner who is practising Homoeopathy in the premises where

Homoeopathic medicines are sold shall deal in Homoeopathic medicines.]

(2) Any person who is aggrieved by the order passed by the Licensing Authority under sub-rule (1) may within 30 days from the date of the receipt of such order appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his case, make such order in relation thereto as it thinks fit.

67G. Conditions of licence :-

- Licence in Form 20-C or 20-D shall be subject to the conditions stated therein and to the following further conditions, namely-

(1) The premises where the Homoeopathic medicines are stocked for sale or sold are maintained in a clean condition.

(2) The sale of Homoeopathic medicines shall be conducted under the supervision of a person, competent to deal in Homeopathic medicines.

(3) The licensee shall permit an Inspector to inspect the premises and furnish such information as he may require for ascertaining whether the provisions of the Act and the Rules made thereunder have been observed.

(4) The licensee in Form 20-D shall maintain records of purchase and sale of Homoeopathic medicines containing alcohol together with names and addresses of parties to whom sold.

[(5) The licensee in Form 20-C shall maintain records of purchase and sale of Homoeopathic medicines containing alcoholNo records of sale in respect of Homeopathic potentised preparations in containers of 30 mlor lower capacity and in respect of mother tinctures made up in quantities up to 60 mlneed be maintained.]

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

67GG. 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 or 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.]

67H. Cancellation and suspension 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 therefore, cancel a licence issued under this Part or suspend it for such period as he thinks fit, 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.

[Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the licence shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority-

(a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or

(b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission, the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or

(c) if the act or omission was a continuing act or omission, that he had not or could not reasonably have had knowledge of that previous act or omission, or

(d) that he had used due diligence to ensure that the conditions of the licence or the provisions of the Act or the rules thereunder were observed.

[(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 7 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.

68A. Grant or Renewal of Licences by the Central Licence Approving Authority :-

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(1) Notwithstanding anything contained in this Part, on and from the commencement of the Drugs and Cosmetics (9th Amendment) Rules, [vide 1992 GSR 923 (E), dt14.12.1992], 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 alongwith the application [and the licence (in triplicate) to be granted or 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

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.]

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 power 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.]

69. Application for licence to manufacture drugs other than those specified in Schedules C and C(1) to the Drugs and Cosmetics Rules :-

[(1) Application for grant or renewal of licence to manufacture for sale [or for distribution] of drugs, other than those specified in Schedules C and C(1) 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 24-B;
(b) in the case of manufacture of drugs included in Schedule X in Form 24-F;
(c) in any other case, in Form 24.
(2)
(a) Every application in Form 24-B shall be accompanied by a fee of rupees eighty plus an inspection fee of rupees twenty for the first inspection and rupees ten in the case of the second or every subsequent inspection or for purposes of renewal of the licence.
(b) Every application in Form 24-F shall be accompanied by a fee of rupees eight hundred and an inspection fee of rupees one hundred for the first inspection and rupees one hundred in the case of second or every subsequent inspection or for purposes of renewal

of the licence.
(c) Every application in Form 24 shall be accompanied by a fee of rupees four hundred and an inspection fee of rupees one hundred for the first inspection and rupees fifty in the case of the second or every subsequent inspection or for purposes of renewal of the licence.
(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
(i) in the case of Form 24-B rupees eighty plus an additional fee at the rate of rupees thirty per month or part thereof in addition to the inspection fee;
(ii) in the case of Form 24-F rupees eight hundred plus an additional fee at the rate of rupees four hundred per month or part thereof in addition to the inspection fee.
(iii) in the case of Form 24 rupees four hundred plus an additional fee at the rate of rupees one hundred and fifty per month or part thereof in addition to the inspection fee.
(4) A fee of rupees fifteen, two hundred or sixty-five shall be paid respectively 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.]
1 "(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 24-F shall be accompanied by an additional fee at the rate of rupees three hundred for each additional item of drugApplications in Form 24-B for licence to manufacture for sale and distribution for repacking for more than 10 items of each category or for manufacture of additional items of drugs shall be accompanied by additional fee of rupees one hundred for each additional item of drugs as categorized in Schedule M and M-III.".
Explanation- For the purpose of these rules, the term repacking means the process of breaking up any drug from a bulk container into small packages and the labelling of each such package with a view to its sale and distribution, but does not include the compounding or dispensing or the packing of any drug in the ordinary course of the retail business.]
"(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 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. In the Drugs and Cosmetics Rules, 1945,(hereinafter referred to as the said rules), in Rule 69, for sub-rule (5), the following shall be substituted, namely:- "(5) Applications by licensees to manufacture additional items of drugs shall, in the case of a licence to manufacture for sale and distribution other than repacking, be made to the Licensing AuthoritySuch applications shall, if the additional items of drugs applied for belong to categories which are not already included in the licence, be accompanied by a fee of [rupees fifty] for each additional category of drugs specified in Schedule M." "by the Drugs and Cosmetics Act, 1940 (23 of 1940)"

69A. Loan licences :-

-

(1) Applications for the grant or renewal of loan [license to the manufacture for sale or for distribution] of drugs other than those specified in [Schedules C, C(1) and X] shall be made in Form 24-A to the licensing authority and shall be accompanied by [a fee of rupees two hundred].

[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 rupees [two hundred] plus [an additional fee at the rate of rupees seventy-five] per month or part thereof.]

Explanation- For the purpose of this rule a loan licence means a licence which a 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) Subject to the provisions of sub-rule (2) applications for manufacture of additional items on a loan licence shall be accompanied by a fee of [rupees fifty] for each category of items.]

[(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 fee of rupees thirty] issue a duplicate licence.]]

69B. . :-

* * *]

<u>70.</u> 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 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.]

<u>70A.</u> Form of loan licence to manufacture for sale 4[or for distribution] of drugs other than those 2[specified in Schedules C, C(1) and X] :-

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

<u>71.</u> Conditions for the grant or renewal of a licence in Form 25 2[or Form 25-F] :-

- Before a licence in Form 25 [or form 25-F] 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 awhole time employee and who is-
(a) a graduate in Pharmacy or Pharmaceutical Chemistry of [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 [a University established in India by law or has an equivalent qualification recognised 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 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 [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

[(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 [or Form 25-F] as it existed before that date shall be deemed to be qualified for the purposes of this rule.

[Provided further that for drugs other than those specified in Schedule C, C(1) and X and meant for veterinary use, the wholetime 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 recognised by the Central Government and who has had atleast three years practical experience in the manufacture of drugs excluding graduate in Pharmacy who shall have atleast eighteen months practical experience in the manufacture of drugs.]

[Provided [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 clauses (a), (b) or (c) of this rule, has, in the opinion of the Licensing Authority, adequate experience in the manufacture of such substance.]

(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.

[(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 the testing unit, which shall be separate from the manufacturing unit and 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 [under Part XV(A) of these Rules] for this purpose.]

[(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 recognised 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.]

[(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;

(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 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.]

"(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 122-E, from the licensing authority as defined in clause (b) of Rue 21."

(7) The licensee shall comply with the requirements of Good

Manufacturing Practices as laid down in Schedule M.]

71A. Conditions for the grant or renewal of a licence in Form 25-B :-

- Before a licence in Form 25-B 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;

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

[(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.

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 arrangement up to the 31st July, 1977;

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 71-A or 74- A 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 (8 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 recognised by the licensing authority as equivalent to it, or

(c) a person who has passed the Matriculation examination or an examination recognised 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.]

71B. Conditions for the grant or renewal of a licence in Form 25-A :-

- Before a licence in Form 25-A 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 patentor 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 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.]

<u>72.</u> Duration of licence :-

- An original licence or a renewed licence in Form 25, [Form 25-B or Form 25-F] unless sooner suspended or cancelled shall be valid up to the 31st December of the year following the year in which it is granted or renewed.

[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.]]

<u>73.</u> Certificate of renewal :-

.- The certificate of renewal of a licence in Form 25 or Form 25-F shall be issued in Form 26 or Form 26-F respectively.]

<u>73A.</u> A certificate of renewal of loan licence :-

- The certificate of renewal of a loan licence in Form 25-A shall be issued in Form 26-A.

<u>73AA.</u> Duration of loan licence :-

- An original loan licence in Form 25-A or a renewed loan licence in Form 26-A, unless sooner suspended or cancelled, shall be valid up

to the 31st December, of the year following the year in which it is granted or renewed.
[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 fees, 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.]]

73B. Certificate of renewal of licence in Form 25-B :-

- The certificate of renewal of a licence in Form 25-B shall be issued in Form 26-B.]

74. Conditions of licence in 2[Form 25 and Form 25-F] :-

- A licence in [Form 25 and Form 25-F] shall be subject to the conditions stated therein and to the following further conditions, namely-
(a) the licensee shall provide and maintain staff, 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 [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 UThe 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 [Inspector authorised by the Act] to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture and the means employed in standardising and testing the drugs;

(f) the licensee shall allow an [Inspector authorised by the Act] to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs and shall supply to such Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the rules thereunder have been observed;

(g) the licensee shall, from time to time, report to the licensing authority any changes in the expert staff responsible for the manufacture or testing of the drugs and any material alterations in the premises or plant used for the purpose which have been made since the date of the last inspection made on behalf of the licensing authority;

[(h) the licensee shall, on request, furnish to the licensing authority, the controlling authority or to such authorities as the licensing authority or the controlling authority may direct, from every batch or batches of drugs as the licensing authority or the controlling authority may from time to time specify, a sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish full protocols of tests which have been applied;]

(i) if the licensing authority [or the controlling authority] so directs and if requested by the licensee who had also furnished 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 authorising the sale of the batch has been issued to him by or on behalf of the licensing authority [or the controlling authority];

(j) the licensee shall on being informed by the licensing authority [or the controlling authority] that any part of any batch of the drug has been found by the licensing authority [or the controlling authority] not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch;

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

[(1) 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 batchIn 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 potencyIn case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture;]

[(m) the licensee, who has been granted a licence in Form 25-F, shall-

(i) forward to the licensing authority of the concerned States of manufacture and supply of the drug a statement of the sales effected to the manufacturers, wholesalers, retailers, hospitals, dispensaries and nursing homes and Registered Medical Practitioners every three months.

(ii) maintain accounts of all transactions giving details as indicated below in a register bound and serially page numbered and such records shall be retained for a period of five years or one year after the expiry of potency, whichever is later-

AAccounts of the drugs specified in Schedule X used for the manufacture-

1Date of issue.

2Name of the drug.

3Opening balance of stock on the production day.

4Quantity received, if any, and source from where received.

5Quantity used in manufacture.

6Balance quantity on hand at the end of the production day.

7Signature of the person in charge.

BAccounts of production-

1Date of manufacture.

2Name of the drug.

3Batch Number.

4Quantity of raw material used in manufacture.

5Anticipated yield.

6Actual yield.

7Wastage.

8Quantity of the manufactured goods transferred.

CAccounts of the manufactured drugs-

1Date of manufacture.

2Name of the drug.

3Batch Number.

4Opening Balance.

5Quantity manufactured.

6Quantity sold.

7Name of the purchaser and his address.

8Balance quantity at the end of the day.
9Signature of the person in charge.
(n) The licensee shall store drugs specified in Schedule X in bulk form and when any of such drug is required for manufacture in a place other than its place of storage it shall be kept in a separate place under the direct custody of a responsible person.]
[(o) The licensee shall comply, with the requirements of Good Manufacturing Practices as laid down in Schedule M.]]

74A. Conditions for licence in Form 25-B :-

- A licence in Form 25-B 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 [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;
[(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 [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;
[(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 UThe records or register shall be retained for a period of five years from the date of repackingThe 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;]

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

[(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 batchIn 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 potencyIn 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.]

74B. Conditions of licence in Form 25-A :-

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(1) The licence in Form 25-A 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 UThe records or registers shall be retained for a period of five years from the date of manufactureThe licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

(4) The licensee shall either-

(i) provide and maintain to the satisfaction of the licensing authority adequate staff and adequate laboratory facilities for carrying out tests of strength, quality and purity of the substances

manufactured by him; or
(ii) make arrangements with some institution approved by the licensing authority [under Part XV(A) of these Rules] for such tests to be regularly carried out on his behalf by the institution.]
(5) The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batchIn 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 potencyIn case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.]
[(6) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.]]

75. Forms of application for licence to manufacture for sale or distribution of drugs specified in Schedules C and C(1) 6[excluding those specified in Part X- B and Schedule X] :-

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(1) Applications for the grant or renewal of licence to manufacture for sale or distribution of drugs specified in Schedules C and C (1) [excluding those specified in Part X-B and Schedule X], shall be made to the licensing authority in Form 27, and shall be accompanied by a fee of rupees six hundred and an inspection fee of rupees four hundred for the first inspection or rupees two hundred in the case of second or every subsequent inspection or for the purpose of renewal of the licence.
Provided that if the application for the renewal of licence is made after its expiry but within six months of such expiry the fee payable for renewal of the licence shall be rupees six hundred plus an additional fee or rupees three hundred per month or a part thereof in addition to the inspection fee.
(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 shall be accompanied by a fee of rupees twelve hundred and an inspection fee of rupees four hundred for the first inspection or rupees two hundred in the case of second or every subsequent inspection or for the purposes of renewal of the licence.

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 rupees twelve hundred plus an additional fee of rupees six hundred per month or a part thereof in addition to the inspection fee.
[(3) The application for grant or renewal of licences to manufacture for sale or for distribution of drugs in [1] "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 27-D and shall be accompanied by licence fee of rupees six hundred and an inspection fee of rupees four hundred for the first inspection or rupees two hundred in the case of second or every subsequent inspection or for the purpose of renewal of the licence.
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 shall be rupees six hundred plus an additional fee of rupees three hundred per month or a part thereof in addition to the inspection fee.]
[(4)] A fee of rupees one hundred or two hundred shall be paid respectively, for a duplicate copy of licence issued under sub-rule (1) or sub-rule (2) [or sub- rule (3)], if the original is defaced, damaged or lost.
[(5)] Application for including any additional drug in the licence for its manufacture shall be accompanied by a fee of rupees fifty for "each drug subject to a maximum of rupees six hundred".]
"(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 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. In the Drugs and Cosmetics Rules, 1945,(hereinafter referred to as the said rules), IN Rule 75, sub-rule (3) of, for the words "Large Volume Parenterals and Sera and Vaccines", the words "Large Volume Parenterals, Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs", shall be substitutedby the" Drugs and Cosmetics Act, 1940 (23 of 1940)"

<u>75A.</u> Loan Licences :-

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(1) Applications for the grant or renewal of loan [licences to manufacture for sale or for distribution] of drugs specified in Schedules [excluding those specified in Part X-B and Schedule X] shall be made in Form 27-A to the licensing authority and shall be accompanied by a fee of rupees [six hundred].

[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 rupees [six hundred] plus an additional fee at the rate of rupees [three hundred] per month or a part thereof.]

Explanation- For the purpose of this rule a loan licence means a licence which a 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 another licensee in Form 28.

(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) Subject to the provisions of sub-rule (2) application for manufacture of additional items on a loan licence shall be accompanied by [a fee of rupees fifty for each item subject to a maximum of rupees six hundred].

[(4) If the licensing authority is satisfied that a loan licence is defaced, damaged or otherwise rendered useless, he may, on payment of a fee of rupees [one hundred] issue a duplicate licence.]]

75B. . :-

* * * * *]

76. Forms of licences to manufacture drugs specified in Schedules C and C(1), excluding those specified in 7[Part X-B and] Schedule X, or drugs specified in Schedules C, C (1) and X and the conditions for the grant or renewal of such licences :-

- [A licence to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) other than [1]"Large Volume Parenterals, Sera and Vaccines and Recombinant DNA (r-DNA) derived drugs",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 Schedule C and C(1) (other t h a n [2]"Large Volume Parenterals, Sera and Vaccines and Recombinant DNA (r-DNA) derived drugs" drugsspecified in Part X-B) and Schedule X shall be issued in Form 28-B A licence to manufacture for sale or for distribution of [3] "Large Volume Parenterals, Sera and Vaccines and Recombinant DNA (r-DNA) derived drugs" shall be issued in Form 28-DBefore a licence in Form 28 or Form 28-B or Form 28-D 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 [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 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 [a University established in India by law or has an equivalent qualification recognised and notified by the Central Government for such purpose] who for the purpose of his degree has studied Chemistry [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 [a University established in India by law or has an equivalent qualification recognised 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

[(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.]

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.

[Provided further 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 recognised by the Central

[Provided further also that for the medical devices specified in Schedule C, the whole time employee under whose supervision the manufacture is conducted may be a Graduate in Science with Physics or Chemistry or Microbiology as one of the subjects; or graduate in Pharmacy; or Degree/Diploma holder in Mechanical or Chemical or Plastic Engineering of a University recognised by the Central Government for such purposes.]

(2) The factory premises shall comply with the conditions prescribed in Schedule M [and Schedule M-III in respectof Medical devices].

(3) The applicant shall provide adequate space, plant and equipment for any or all the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M [and Schedule M-III].

[(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, were making arrangements with institutions approved by the Licensing Authority for such tests to be carried out on their behalf may continue such arrangement 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 [under Part XV (A) of

these Rules for this purpose].

[(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 recognised 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.

[(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 date so furnished.]

[(7) The applicant shall, while applying fora 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 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.]

"(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 122-E, from the licensing authority as defined in clause (b) of Rule 21."

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

[Explanation- For the purpose of this rule, "Large Volume Parenterals" shall mean the sterile solutions intended for parenteral administration with a volume of 100 mlor more (and shall include anti-coagulant solutions) in one container of the finished dosage form intended for single use.]

1. In the Drugs and Cosmetics Rules, 1945,(hereinafter referred to as the said rules), in Rule 76 for the words, "Large Volume Parenterals, Sera and Vaccines", the word "Large Volume Parenterals, Sera and Vaccines and Recombinant DNA (r-DNA)

derived drugs", shall be substituted by the Drugs and Cosmetics Act, 1940 (23 of 1940)

2. In the Drugs and Cosmetics Rules, 1945,(hereinafter referred to as the said rules), in Rule 76 for the words, "Large Volume Parenterals, Sera and Vaccines", the word "Large Volume Parenterals, Sera and Vaccines and Recombinant DNA (r-DNA) derived drugs", shall be substituted by the Drugs and Cosmetics Act, 1940 (23 of 1940)

3. In the Drugs and Cosmetics Rules, 1945,(hereinafter referred to as the said rules), in Rule 76 for the words, "Large Volume Parenterals, Sera and Vaccines", the word "Large Volume Parenterals, Sera and Vaccines and Recombinant DNA (r-DNA) derived drugs", shall be substituted by the Drugs and Cosmetics Act, 1940 (23 of 1940)

76A. Form of loan licence to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) 5[excluding the drugs specified in Schedule X] and conditions for the grant or renewal of such licence :-

- A loan licence to manufacture for sale [or for distribution] drugs specified in Schedules C and C (1) [excluding the drugs specified in Schedule X] shall be issued in Form 28-A, 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.]

77. Duration of licence :-

- An original licence in [Form 28, Form 28-B and Form 28-D or renewed licence in Form 26, 26-F, and Form 26-H], unless sooner suspended or cancelled shall be valid up to the 31st December of

the year following the year in which it is granted or renewed.
[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.]]

78. Conditions of licence :-

- A licence in [Form 28, Form 28-B or Form 28- D] shall be subject to the special conditions, if any, set out in Schedule F or Schedule F(1), as the case may be, which relate to 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 microorganisms shall provided to the satisfaction of the Licensing Authority separate laboratories and utensils and apparatus required for the culture or manipulation of such microorganisms, the laboratories, utensils and apparatus so provided not being used for the manufacture of any other substance.
[(b) The licensee shall provide and maintain staff, premises and equipment as specified in Rule 76.
[(c)
(i) The licensee shall maintain records of manufacture as per particulars given in Schedule U.
(ii) The license shall either in his own laboratory or in any laboratory approved by the Licensing Authority [under Part XV (A) to these Rules] test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing
[(d) The licensee shall allow an Inspector appointed under the Act, to enter, with or without prior notice, any premises where the manufacture is carried on and to inspect the premises, and in the case of substances specified in Schedules C and C(1), to inspect the plant and the process of manufacture and the means employed for

standardizing and testing the substance.]

[(e) The licensee shall allow an Inspector, appointed under the Act to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to 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.

[(g) The licensee shall on request furnish to the Licensing Authority, controlling authority or to such authorities as the Licensing Authority or the controlling authority may direct, from every batch of drugs as the Licensing Authority or the controlling authority may from time to time specify, a sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish full protocols of the tests which have been applied.]

[(h) If the Licensing Authority or the controlling authority so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is, or protocols are furnished under the last preceding sub- paragraph until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the Licensing Authority or the controlling authority.]

[(i) The licensee shall on being informed by the Licensing Authority or the controlling authority that any part of any batch of the substance has been found by the Licensing Authority or the controlling authority not to conform with the standards of strength, quality or purity specified in these Rules and on being directed so to do, withdraw the

(j) No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture.

[(k) The licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.]

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

[(m) The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batchIn case of drugs bearing and expiry date on the label the reference samples shall be maintained for a period of three months beyond the date of expiry of potencyIn case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.]

[(n) The licensee, who has been granted a licence in Form 28-B shall-

(i) forward to the Licensing Authority of the concerned States of manufacture and supply of drug a statement of the sales effected to the manufacturers, wholesalers, retailers, hospitals, dispensariesNursing Homes and Registered Medical Practitioners every three months;

(ii) maintain accounts of all transactions giving details as indicated below in a register bound and serially page numbered, and such records shall be retained for a period of five years or one year after the date of expiry of potency, whichever is later.

AAccounts of the drugs specified in Schedule X used for the manufacture-

1Date of issue.

2Name of the drug.

3Opening balance of stock on the production day.

4Quantity received, if any, and source from where received.

5Quantity used in manufacture.

6Balance quantity on hand at the end of the production day.

7Signature of the person in charge.

BAccounts of Production-

1Date of manufacture.

2Name of the drug.

3Batch number.

4Quantity of raw material used in manufacture.

5Anticipated yield.

6Actual yield.

7Wastage.

8Quantity of the manufactured goods transferred to stock.

CAccounts of manufactured drugs-

1Date of manufacture.

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

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

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(1) The licence in Form 28-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 28 whose manufacturing facilities have 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, 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 URecords 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 manufactureThe 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.]

[(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 date so furnished.

(6) 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 batchIn 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 potencyIn case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.]

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

79. Inspection before grant or renewal of licence :-

[- Before a licence under 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 the Act with or without an expert in the field concernedThe 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 standardising and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the Technical Staff to be employedHe 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.]

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 :-

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(1) If the Licensing Authority [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 shall issue a licence [under this Part].
(2) If the Licensing Authority [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.

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 [or Central Licence Approving Authority as the case may be,] that the conditions laid down have been satisfied and deposits an inspection fee of rupees fifty the Licensing Authority [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, [in respect of drugs notified under Rule 68A] issue a licence in Form 28 [or Form 28-B].

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 [he shall prepare a report to that effect in respect of those drugs which have been notified by the Central Government under Rule 68A and forward it along with the application to the Central Licence Approving Authority], and shall issue a certificate of renewal [under this part].

83A. Certificate of renewal of a loan licence :-

- The certificate of renewal of a loan licence in Form 28-A shall be issued in Form 26-A.]

83AA. Duration of loan licence :-

- An original loan license in Form 28-A or renewed loan licence in Form 26-A, unless sooner suspended or cancelled, shall be valid up to the 31st December of the year following the year in which it is granted or renewed.
[Provided that if the application for the renewal of 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.

84A. Provisions 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 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.]]

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.]

84B. Prohibition for the manufacture for sale of cyclamates and preparations containing cyclamates :-

[- No persons shall manufacture for sale cyclamates and preparations containing cyclamates.]

85. Cancellation and suspension of licences :-

[-
(1) The Central Licence Approving Authority may, after giving the licensee an opportunity to show cause, [or direct the licensee to stop manufacture, sale or distribution of the said drugs and [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.
(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 any of the drugs to which it relates [or direct the licensee to stop manufacture, sale or distribution of the said drugs and [thereupon order the destruction of drugs and] the stocks 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.]

[(3) A licensee whose licence has been suspended or cancelled by the Central Licence Approving Authority or Licencing 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 oppotunity of being heard, confirm, reverse or modify such order.]

PART 7A 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 :-

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(1) Application for grant or renewal of licences 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.

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

(a) by a fee of [rupees eighty] for the manufacture of Homoeopathic mother tinctures and potentised preparations and an inspection fee of [rupees twenty] for the first inspection or [rupees ten] in case of inspection for renewal of licence;

(b) by a fee of [rupees forty] for the manufacture of Homoeopathic potentised preparations only, and an inspection fee of [rupees ten] for the first inspection or [rupees five] in case of inspection for renewal of licence;

(c) by a fee of [rupees forty] 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 [rupees ten] for the first inspection or [rupees five] in case of inspection for renewal of licence.

(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) [rupees eighty] plus an additional fee at the rate of [rupees thirty] per month or part thereof and an inspection fee of [rupees ten] for the manufacture of Homoeopathic mother tinctures and potentised preparations;
[(b) rupees forty plus an additional fee at the rate of rupees thirty per month or part thereof and an inspection fee of rupees five for the manufacture of Homoeopathic potentised preparations only];
(c) [rupees forty] plus an additional fee at the rate of [rupees fifteen] per month or part thereof and an inspection fee of [rupees five] for the manufacture of potentised preparations from back potencies by pharmacies who are already licensed to sell Homoeopathic medicines by retail.]
(4) A fee of [rupees fifteen] shall be paid for a duplicate copy of the licence for the manufacture of Homoeopathic mother tincture 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 [rupees ten].
[(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 rupees five 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 documents 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;
(3) while applying for a licence to manufacture a New Homoeopathic medicine an applicant shall produce alongwith 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.

<u>85D.</u> Form of licence to manufacture Homoeopathic medicines :-

[-Licence for manufacturer of Homoeopathic medicines is a license t o manufacture potentised preparations from back potencies by Pharmacies who are already licensed to sell Homoeopathic medicines by retail shall be granted in Form 25-C.]

<u>85E.</u> Conditions for the grant or renewal of a licence in Form 25-C :-

- Before a licence in Form 25-C 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 [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 S.2 of Homoeopathy Central Council Act, 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 25-C for manufacture of different classes of Homoeopathic medicines included in them shall be deemed to be qualified for the purpose of this rule.]

[(2) The factory premises shall comply with the requirements and conditions specified in Schedule M-1.

Provided that where the Licensing Authority considers it necessary o r 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 [under Part XV(A) of these Rules] forsome 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.

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

85EA. Inspection before grant or renewal of licence :-

[- Before a licence under this Part is granted or renewed in Form 25-C or Form 26-C, 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 appointed under the ActThe 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 alongwith the means to be employed or being employed for standardising 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 Schedule M-I read with the requirements of maintenance of records as laid down in Schedule U.

85EB. Report by Inspector :-

- The Inspector or Inspectors shall forward a detailed descriptive report giving his or their findings on each aspect of inspection alongwith 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 25-C or Form 26-C.
(2) If the licence 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 rupees 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 25-C or Form 26-C.

85EE. Appeal to the State Government :-

- Any person who is aggrieved by the order passed by the Licencing 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 valid up to the 31st December of the year following the year in which it is granted or renewed.
[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.

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 85E;
(b) the licensee shall allow an [Inspector appointed under the Act] t o enter, with or without prior notice, any premises where the manufacture of a Homoeopathic medicine in respect of which the
(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;
[(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 [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 [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 [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 of adhering matterThe 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;

[(ea) no colour shall be added to any Homoeopathic medicines; Provided that caramel may be added to combinations 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[Such records shall be maintained for a period of five years.]

85HH. Additional information to be furnished by an applicant for 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 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.]

85I. Cancellation and suspension 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 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.
[(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 8 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.

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.
[Provided that in the case of a drug the composition of which is such that the drug is not generally recognised 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 :-

-
(1) An application for a licence in Form 29 shall be made to the Licensing Authority appointed by the State Government for the purposes 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.
[(2) Every application in Form 29 shall be accompanied by a fee of rupees fifteen.]

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 [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 months 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 .
[(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 9 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.
[Provided that where a drug, not classified under Schedule F, Schedule F(1) and Schedule X, blood productsNarcotic and Psychotropic Substances 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.]
[(2) The provisions of rule 96- Rule 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 medical 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;
(d) the dose, if the medicine is for internal use;
[(e) the words Tor External use only shall be printed on the label if the medicine is for external application;]
(ii) Condition (3) of the conditions in Rule 65 is satisfied.]

95. Prohibition of sale or distribution unless labelled :-

- Subject to the other provisions of these Rules, no person shall sell

or distribute any drug (including a patent or proprietary medicine) unless it is labelled in accordance with these Rules.

96. Manner of Labelling :-

[-
(1) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely-
(i) The name of the drug:
[(A) For this purpose], [the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any which shall be shown immediately after or under the proper name and shall be]-
(a) for drugs included in Schedule F or Schedule F(1), the name given therein;
(b) for drugs included in the Indian Pharmacopoeia or the official Pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters I.P. or, as the case may be, by the recognised abbreviations of the respective official pharmacopoeia and official compendia of drug standards;
(c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters N.F.I.;
(d) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.]
[(B) Ommitted vide the Drugs and Cosmetics (First Amendment) Rules, 2000
(ii) A correct statement of the net contents in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in Metric system.
(iii) The content of active ingredients- This shall be expressed-
(a) for oral liquid preparations in terms of the content per single dose, the dose being indicated in 5 millilitres [* * *];
Provided that where the dose is below 5 millilitres the contents of active ingredients may be expressed in terms of one millilitre [or

fraction thereof];
[Provided further that where the single dose is more than 5 millilitre, the content of active ingredients shall be expressed in terms of minimum single dose as approved by the Licensing Authority,]
(b) for liquid parenteral preparations ready for administration, in terms of 1 millilitre or percentage by volume or per dose in the case of a single dose container.
Provided that if the preparation is contained in an ampoule it will be enough if the composition is shown on the label or wrapper affixed to any package in which such ampoule is issued for sale;
(c) for drugs in solid form intended for parenteral administration in terms of units or weight per milligramme or gramme;
(d) for tablets, capsules, pills and the like, in terms of the content in each tablet, capsule, pill or other unit, as the case may be;
(e) for other preparations, in terms of percentage by weight or volume or in terms of unitage per gram or millilitre as the case may be.
Provided that clause (iii) shall not apply to a pharmacopoeial preparation where the composition of such preparation is specified in the respective pharmacopoeia and to a preparation included in the National Formulary of India;
(iv) [The name of the manufacturer and the address of the premises of the manufacturer where the drug has been manufactured.] Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the manufacturer and his principal place of [manufacture] is shown.
(v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words Batch No. or BNo. or Batch or Lot No. or Lot.
(vi) Every drug manufactured in India shall bear on its label the number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words Manufacturing Licence Number or MfgLicNo. or M.L.
(vii) Drugs specified in Schedule P and their preparations including combinations with other drugs shall bear on their labels the date of manufacture and the date of expiry of potency, and the period

between the date of manufacture and the date of expiry shall not exceed that laid down in the said Schedule [under the conditions of storages specified therein[Drugs and their] preparations not included in Schedule P, shall bear on their labels the date of their manufacture and also the date of their expiry which shall not exceed sixty months from the date of manufacture].

Provided that this period may be extended by the Licensing Authority specified in clause (b) of Rule 21 in respect of any specified drug if satisfactory evidence is produced by the manufacturer to justify such an extension.

(viii) Drugs specified in Schedule C(1) and their preparations including combinations with other drugs shall bear on the labels (a) the date of manufacture, (b) date of expiry of potency fixed by the manufacturer, and (c) where such drugs are imported, also the number of licence under which the drug is imported, preceded by the words Import Licence.

[Provided that drugs in bulk form included in Schedule C(1) which are not ready for use and not included in Schedule P need not bear on the label the date of expiry of potency.]

Provided further that no reference shall be made to any other licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter or advertisement enclosed therewith.

(ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words Physicians sample - Not to be sold which shall be overprinted.

[(x) If any preparation contains not less than 3 per cent by volume of alcohol the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished products.]

[(xi) In addition to the other particulars which are required to be printed or written under these rules, the label of innermost container of the following categories of drugs and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which should not be less than I mm in width and without disturbing the other conditions printed on the label under these rules, namely- Narcotic analgestics, hypnotics, sedatives, tranquillisers, corticosteriods, hormones, hypoglycemics, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-

Cancer drugs and all other drugs falling under Schedules G, H and X whether covered or not in the above list.

Provided that the provisions of this clause shall not apply to-

(a) preparations intended for animal treatment;

(b) preparations intended for external use;

(c) Ophthalmic preparations and ear drops; and

(d) Sterile preparations such as sutures, surgical dressings and preparations intended for parenteral use.]

(2)

(i)The particulars to be printed or written on the label of a mechanical contraceptive shall be as specified in Schedule R.

(ii)The following particulars, in addition to those specified under sub- rule (1) shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container and on every other covering in which the container of a contraceptive, other than a mechanical contraceptive, is packed, namely-

(a) the date of manufacture;

(b) the date up to which the contraceptive is expected to retain its properties;

(c) the storage conditions necessary for preserving the properties of the contraceptive up to the date indicated in sub-clause (b).

Provided that for oral contraceptives it shall be sufficient to display on the label of the container the date of manufacture only.

(3)

(i)The particulars prescribed in sub-rule (1) shall be printed or written in indelible ink either on the label borne by a container or vaccine

(ii) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.

(4) Where by any provision of these rules any particulars are required to be displayed on a label on the container such particulars may, instead of being displayed on a label, be etched, painted or otherwise indelibly marked on the container.

Provided that, except where otherwise provided in these rules, the name of the drug or any distinctive letters intended to refer to the drug shall not be etched, painted or otherwise indelibly marked on any glass container other than ampoules.

Explanation- For the purpose of this rule, the date of expiry shall be in terms of month and year and it shall mean that the drug is recommended till the last day of the monthThe date of expiry shall

be preceded by the words Expiry date.

97. Labelling of medicines :-

-

[(1) The container of a medicine for internal use shall-
(a) if it contains a substance specified in Schedule G, be labelled with the words Caution: it is dangerous to take this preparation except under medical supervision - conspicuously printed and surrounded by a line within which there shall be no other words;
(b) if it contains a substance specified in Schedule H be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and be also labelled with the following words. Schedule H drug - Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only;
(c) if it contains a substance specified in Schedule H and comes within the purview of the [Narcotic Drugs and Psychotropic Substances Act, 1985] be labelled with the symbol NRx which shall be in red and conspicuously displayed on the left top corner of the label, and be also labelled with the following words. Schedule H drug - Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only;
(d) if it contains a substance specified in Schedule X, be labelled with the symbol XRx which shall be in red conspicuously displayed on the left top corner of the label, and be also labelled with the following words. Schedule X drug - Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.
(2) The container of an embrocation, liniment, lotion, [ointment, antiseptic cream,] liquid antiseptic or other liquid medicine for external application shall be labelled with the words in capital Tor External use only.]
[(3)The container of a medicine made up ready only for treatment of an animal shall be labelled conspicuously with the words Not for human use; for animal treatment only, and shall bear a symbol depicting the head of a domestic animal.]
[(4) The container of a medicine prepared for treatment of human ailments shall if the medicine contains industrial methylated spirit, indicate this fact on the label and be labelled with the words- "FOR EXTERNAL USE ONLY".]
[(5) Substances specified in Schedule X in bulk form shall bear a label wherein the symbol as specified in sub-rule (1) shall be given conspicuously in red letters.]

98-101. . :-

[* * *]

102. Non-Sterile Surgical Ligature and Suture :-

[- Every container of, and wrapper enclosing surgical ligature or suture other than a ligature or suture offered or intended to be offered for sale as sterile, shall bear a label on which are printed or written in a conspicuous manner in indelible red ink the words "Non-sterile surgical ligature (suture)- not to be used for operations upon the human body unless efficiently sterilized".]

103. . :-

(1) [* * *]
(2) The name and address of the manufacturer shall be printed on the label of the container of a patent or proprietary medicine.
(3) The true formula or list of the ingredients shall be printed or written in indelible ink on the outer label of every package containing patent or proprietary medicine.

104. Use of letters IPetc :-

[.- The letters IP. and recognised abbreviations of pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognised under the Rules.]

104A. Prohibition against altering inscriptions on containers, labels or wrappers of drug :-

[- No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug.
Provided that nothing in this rule shall apply to any alteration, any inscription or mark made on the container, label or wrapper of any drug at the instance or direction or with the permission of the Licensing Authority.]

105. Packing of drugs :-

[-
(1) The pack sizes of drugs meant for retail sale shall be as prescribed in Schedule P-1 to these rules.
(2) The pack sizes of drugs not covered by the Schedule P-1 shall be as given below: Unless specified otherwise in Schedule P-1,
(i) The pack sizes for Tablets/Capsules shall be- Where the number of Tablets (coated or uncoated)/Capsules (hard or soft gelatine) is less than 10, such packing shall be made by the integral numberFor numbers above 10, the pack sizes of Tablets/ Capsules shall contain multiples of 5.
(ii) The pack sizes for liquid Oral preparations shall be 30 ml(paediatric only) 60 ml./100 ml./200 ml./450 ml.
(iii) The pack sizes for Paediatric Oral Drops shall be 5 ml/10 ml/15 ml.
(iv) The pack sizes for Eye/Ear/Nasal drops shall be 3 ml./5 ml./10 ml.
(v) The pack sizes for Eye Ointment shall be 3 gm./5 gm/10 gm.
Provided that the provisions of the pack sizes covered under this rule shall not apply to-
1Pack sizes or dosage forms not covered by the foregoing provisions of this rule.
2The imported formulations in finished form.
3Preparations intended for Veterinary use.
4Preparations intended for Export.
5Vitamins/Tonics/Cough Preparations/Antacids/Laxatives in Liquid Oral formsUnit dose (including applicaps).
6Pack sizes of dosage forms meant for retail sale to Hospitals, Registered Medical Practitioners , Nursing Homes.
7Physicians Samples.
8Pack sizes of Large Volume intravenous Fluids.
Provided also that pack sizes of any of the new drug as and when approved by the Licensing Authority appointed under Rule 21 and if not covered under this rule, shall be examined for the purpose of approval with specific justification by the said Licensing Authority.]
Provided further that Oxytocm injection meant for sale shall be in single unit blister pack only

<u>105A.</u> Packing of drugs specified in Schedule X :-

[- The drugs specified in Schedule X shall be marketed in packings not exceeding-

(i) 100 unit doses in the case of tablets/capsules;
(ii) 300 mlin the case of oral liquid preparation;
(iii) and 5 mlin the case of injections.
Provided that nothing in this rule shall apply to packings meant for use of a hospital or a dispensary subject to the conditions that-
(i) such supplies are made by the manufacturers or distributors direct to the hospital/dispensaries; and
(ii) hospital packs shall not be supplied to a retail dealer or to a Registered Medical Practitioner.]

106. Diseases which a drug may not purport to prevent or cure :-

[-
(1) No drug may purport or claim to prevent or cure or may convey to the intending user thereof any idea that it may prevent or cure, one or more of the diseases or ailments specified in Schedule J.
(2) No drug may purport or claim to procure or assist to procure, or may convey to the intending user thereof any idea that it may procure or assist to procure, miscarriage in women.
Explanation- [* * *]]

PART 9 A LABELLING AND PACKING OF HOMOEOPATHIC MEDICINES

106A. Manner of labelling of Homoeopathic medicines :-

-
(A) The following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Homoeopathic medicine and on every other covering in which the container is packed:-
(i) The words Homoeopathic medicine.
(ii) The name of the medicine-
[(a) For drugs included in the Homoeopathic Pharmacopoeia of India or the United States of America or the United Kingdom, or the German Homoeopathic Pharmacopoeia, the name specified in that Pharmacopoeia.]
(b) For other drugs, the name descriptive of the true nature of the drugs.
(iii) The potency of the Homoeopathic medicine- For this purpose the potency shall be expressed either in decimal, centesimal or millisimal systems.

[(iiiA) In case of a Homoeopathic medicine containing two or more ingredients, the name of each ingredient together with its potency and proportion expressed in metric system shall be stated on the label.]

[(iv) Name and address of the manufacturer when sold in original containers of the manufacturerIn case a Homoeopathic medicine is sold in a container other than that of the manufacturer - the name and address of the seller.]

(v) In case the Homoeopathic medicine contains alcohol, the alcohol content in percentage by volume in terms of ethyl alcohol shall be stated on the label.

[Provided that in case that the total quantity of the pharmacopoeial Homoeopathic medicine in the container is 30 millilitres or less, it will not be necessary to state the content of alcohol in the label.]

(B) In addition to the above particulars the label of a Homoeopathic mother tincture shall display the following particulars-

(i) a distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the words "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot" or any distinguishing prefix;

(ii) manufacturing licence number, the number being preceded by the words "Manufacturing Licence Number" or "MfgLicNo." or "M.L.".

[Explanation- This clause shall not apply to a Homoeopathic mother tincture manufactured outside India.]

(C) No Homoeopathic medicine containing a single ingredient shall bear a proprietary name on its label.]

106B. Prohibition of quantity and percentage :-

[- No homoeopathic medicine containing more than 12% alcohol v/v (Ethyl Alcohol) shall be packed and sold in packing or bottles of more than 30 millilitres, except that it may be sold to hospitals/ dispensaries in packings or bottles of not more than 100 millilitres.]

PART 10 SPECIAL PROVISIONS RELATING TO BIOLOGICAL AND OTHER SPECIAL PRODUCTS

107. Name of substance :-

[- If any substance specified in Schedule C is advertised or sold as

a proprietary medicine or is contained in a medicine so advertised or sold, the proper name of the substance shall appear on the label in the manner prescribed in this Part.

[Explanation- For the purpose of this rule the expression "Proper name" means the proper name stated in Schedule For if no such name is stated, the name descriptive of the true nature and origin of the substanceProvided that in the case of veterinary biological product the expression "proper name" means the proper name stated in Schedule F(1) or if no such name is stated, the name or synonym given in the current edition for the time being of the [British Pharmacopoeia (Veterinary)], or, if no such name is stated either in Schedule F(1) or the [British Pharmacopoeia (Veterinary)], the name descriptive of the true nature and origin of the substance approved by the Licensing Authority.]

108. Container :-

[-

(1) No substance specified in Schedule C shall be sold or offered for sale unless it has been sealed in a previously sterilised container made of glass or any other suitable material approved for the purpose by the Licensing Authority appointed under Rule 21, in such manner as may, in the opinion of the Licensing Authority, suffice to preclude the access of bacteria.

Provided that it shall not be necessary to use a previously sterilised container if the filled and sealed container is to be sterilised after the sealing and such sterilising procedure would render the products sterileHowever, the Licensing Authority may, for any special reasons, direct the licensee to pre-sterilise such containers.]

(2) When any such substance is issued in liquid form in containers which are sealed in such a manner that portions of the contents can be withdrawn for use on different occasions, the liquid shall contain a sufficient proportion of some antiseptic to prevent the growth of any organism which may be accidentally introduced in the process of removing a portion of the contents of the container.

Provided that nothing in this sub-rule shall apply to a penicillin suspension in oil and wax.

[(3) The container shall comply with such further requirements, if any, as are specified in Schedule F or Schedule F(1) as the case may be, in that behalf.]

[(4) The Licensing Authority may in the case of any particular preparation of any such substance dispense with any of the

requirements of this Rule or of Schedule F or Schedule F(1) asthe case may be, and may make such additional requirements, as having regard to the nature of the preparation, they may deem necessary.]

109. Labelling :-

[-
(1) The following particulars and such further particulars, if any, as are specified in Schedule F or Schedule F(1), as the case may be, shall be printed or written in indelible ink on the label of every phial, ampoule or other container of a substance specified in Schedule C and on every other covering in which such phial, ampoule or container is packed-
(a) Where a drug is imported, the number of licence under which it is imported, preceded by the words "Import Licence".
Provided that no referene shall be made to any other import licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter of advertisement enclosed therein.
(b) Where a test for potency in units is required by these rules, a statement of the potency in units defined in terms of relating to the standard preparation specified in Schedule F or F(1), as the case may be.
Provided that this clause shall not apply in the case of vaccine lymph.
(c) Where a test for potency of maximum toxicity is required the date up to which the substance if kept under suitable conditions may be expected to retain a potency not less than that stated on the label of the container or not to acquire a toxicity greater than that permitted by the test, as the case may beThe date of expiry shall be in terms of month and year and it shall mean that the drug is recommended for use till the last day of the monthThe date of expiry shall be preceded by the words Expiry date.
Provided that nothing in these rules shall be deemed to require the labelling of any transparent cover or any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.
(2) The particulars prescribed in clause (a) of the preceding sub-rule shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for saleThe

said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.

(3) The following particulars, and such further particulars, if any, as are specified in Schedule F or Schedule F(1), as the case may be, shall be printed or written in indelible ink either on the label borne by the container of any substance specified in Schedule Corona label or wrapper affixed to any package in which any such container is issued for sale, namely-

(a) the date on which the manufacture of the particular batch from which the substance in the container is taken was completed as defined in Schedule F or Schedule F(1) or if there is no definition in Schedule F or F(1) as hereafter defined in this rule and in the case of vaccine prepared from concentrates, the date of completion of the final products and the bottling for issue;

(b) where an antiseptic substance has been added, the nature and the percentage proportion introduced;

(c) the precaution necessary for preserving the properties of the contents up to the date indicated in clause (c) of sub-rule (1).

(4) For the purpose of clause (a) of sub-rule (3), the date of which the manufacture of a batch is completed shall be-

(a) in cases where a test for potency or toxicity is required, by these rules not being so required, is accepted by the Licensing Authority as sufficient for the purpose of fixing the date of completion of manufacture, the date on which the substance was removed from cold storage after having been kept at a temperature not exceeding 5C continuously for a period not exceeding two years from the time when the last test was completed;

(b) in cases where no such test is required or accepted-

(i) if the substance is a serum obtained from a living animal, the earliest date on which any material contributing to the batch was removed from the animal;

(ii) if the substance was obtained by the growth of organisms on artificial media, the earliest date on which growth was terminated in any of the material contributing to the batch.

Provided that if a batch of the substance (including all material contributing to this batch) has for a period of not more than three years been kept in cold storage at a temperature not exceeding 5C continuously from the earliest practicable date after that on which growth was terminated in the material as the case may be, the date of removal from cold storage shall be treated as the date on which the manufacture of the batch is completed;

(c) in all other cases, the date on which the substance is filled in the container.]

109A. Labelling of Medical Devices :-

[- The labelling of Medical devices shall confirm to the Indian Standards Specifications laid down from time to time by the Bureau of Indian Standards in addition to any other requirement prescribed under the said rules.]

110. Prohibition of sale of substance after prescribed date :-

- No person shall sell, or exhibit for sale any substance specified in Schedule C after the date recorded on the container, label or wrapper as the date up to which the substance may be expected to retain a potency not less than, or not to acquire a toxicity greater than that required or permitted by the prescribed test as the case may be.

110A. . :-

[* * * * * * * * * *]

111. Standards :-

[- Every substance specified in Schedules C and C(1) intended for sale shall conform with the standards of strength, quality and purity specified in these Rules and in Schedule F or F(1) as the case may be, and the tests for determining such conformity shall be applied to samples taken from the final product after every manufacturing process has been completed.]

112. Tests for strength and quality :-

[- The tests, if any, required for determining the strength and quality of each of the substances specified in Schedules C and C (1) shall be those set out in Schedule F or Schedule F(1) [or as specified] as the case may be.]

113-114. . :-

[* * * * * * * * * *]

115. Application of tests for sterility :-

- The tests shall be applied-
(a) to samples taken from each batch of the substance before the operation of filling and sealing the containers in which it is to be issued has commenced except preparations, which after being sealed in the containers are to be sterilized by heat, in a manner satisfactory to the Licensing Authority; and
(b) to the contents of sample containers when ready for issue.

116-118. . :-

[* * * * * * * * *]

119. . :-

(1) If at this examination no growth of micro-organisms is found in any tube, the sample may be treated as having passed the test.
(2) If at the examination a growth of micro-organisms is visible, further samples may be taken and the tests may be repeated on the further samples taken; but no container the contents of which form part of the batch shall be issued until such further samples have passed the testThe process of taking samples from the batch for a test may be repeated twice.
Provided that if the same organism is visible in more than one test the batch shall be treated as not sterile and the material contained in the batch shall not be issued or used as part of a further batch unless and until it has been resterilized and has passed the tests.

120. Notwithstanding anything contained in the last preceding Rule, in any case where :-

-
(a) a substance is required in any emergency by a registered medical practitioner, but the licensee has no filled containers in stock, or
(b) a substance which in the opinion of the Licensing Authority is so unstable in solution that the delay occasioned by the completing of the sterility test on filled containers would render its issue in active form impossible, the licensee may issue the substance from a batch which has already passed the tests for sterility and freedom from abnormal toxicity, without completing the sterility test on the filled containers, provided that he complies with the following conditions-

(i) the licensee shall before the issue take samples in the required proportions from the containers into which the batch is filled, and after the required inoculation and incubation shall examine the tubes every day for five days;
(ii) if at any examination any growth is visible in any of the tubes, he shall immediately notify the Licensing Authority;
(iii) he shall keep available for inspection a record of all issues made under this Rule containing such particulars of the circumstances in which the issue is made as the Licensing Authority may require.

121. Test for freedom from abnormal toxicity :-

.-The test for freedom from abnormal toxicity shall be carried out as per the current edition of Indian Pharmacopoeia in the case of each batch of the serum tested by the licensee or by an institution approved by the licensing authority for the purpose of carrying out the test on its behalf"

121A. Test for pyrogens :-

[- Solution of substances intended for parenteral administration in large volumes (10 mlor more at a time) shall be pyrogen-free and tested for pyrogensIf water or any other aqueous solvent is supplied along with the substances for preparing such solutions, it shall also be pyrogen-free and tested for pyrogens.]

122. Substances specified in Schedule C(1) :-

- The following provisions shall apply in the case of a substance specified in Schedule C(1)-
(a) The container shall comply with the requirements, if any specified in Schedule F or Schedule F(1) [or as specified] as the case may be.
(b) [* * *]
(c) The substance shall conform to the standards of strength, quality and purity specified in Schedule F or Schedule F(1), [or as specified] as the case may be and the tests for determining the strength, quality and purity of the substance shall be those specified in Schedule F or Schedule F (1) [or as specified] as the case may be.
(d) The test for determining the strength, quality and purity of a substance specified in Schedule F or Schedule F(1) [or as specified]

as the case may be shall be applied to samples taken from the final product after each manufacturing process has been completed.
(e) The substance should be stored in a cool place and away from light.

PART 10A IMPORT OR MANUFACTURE OF NEW DRUG FOR CLINICAL TRIALS OR MARKETING

122A. Application for permission to import New Drug :-

[1]"(1)
(a) No new drug shall be imported, except under, and in accordance with, the permission granted by the Licensing Authority as defined in clause (b) of Rule 21;
(b) An application for grant of permission to import a new drug shall be made in Form 44 to the Licensing Authority, accompanied by a fee of fifty thousand rupees :
Provided further that where a subsequent application by the same applicant for that drug, whether in modified dosage form or with new claims, is madethe fee to accompany such application shall be fifteen thousand rupees :
Provided further that any application received after one year of the grant of approval for the import and sale of new drug, shall be accompanied by a fee of fifteen thousand rupees and such information and data as required by Appendix 1 or Appendix I-A of Schedule Y, as the case may be.";
(2) The importer of a new drug when applying for permission under sub-rule (1), shall submit data as given in Appendix I to Schedule Y including the results of local clinical trials carried out in accordance with the guidelines specified in that Schedule and submit the report of such clinical trials in the format given in Appendix II to the said Schedule.
Provided that the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such a nature that the Licensing Authority may, in public interest decide to grant such permission on the basis of data available from other countries.
Provided further that the submission of requirements relating to Animal Toxicology, Reproduction studies, Teratogenic studies, Perinatal studies, Mutagenicity and Carcinogenicity may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate published evidence regarding the safety of the drug, subject to the other provisions of these rules.

[2] (3) The Licensing Authority, after being satisfied that the drug if permitted to be imported as raw material (bulk drug substance) or as finished formulation shall be effective and safe for use in the country, may issue an import permission in Form 45 and/or Form 45-A, subject to the conditions stated therein :
Provided that the Licensing Authority shall, where the data provided or generated on the drug is inadequate, intimate the applicant in writing, and the conditions, which shall be satisfied before permission, could be considered."

1. In Rule 122A, sub-rule (1), shall be substituted, by Drugs and Cosmetics (9th Amendment) Rules, 2001Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R900(E), dated December 12, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 12th December, 2001, pp13-24, No622

2. In Rule 122A, after sub-rule (2), sub-rule (3) shall be inserted, by Drugs and Cosmetics (9th Amendment) Rules, 2001Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R900(E), dated December 12, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 12th December, 2001, pp13-24, No622

<u>122B.</u> Application for approval to manufacture New Drug [***] :-

[12]"(1)
(a) No new drug shall be manufactured for sale unless it is approved by the Licensing Authority as defined in clause (b) of Rule 21.
(b) An application for grant of approval to manufacture the new drug and its formulations shall be made in Form 44 to the Licensing Authority as defined in clause (b) of Rule 21 and shall be accompanied by a fee of fifty thousand rupees:
Provided that where the application is for permission to import a new drug (bulk drug substance) and grant of approval to manufacture its formulation/s, the fee to accompany such application shall be fifty thousand rupees only :
Provided further that where a subsequent application by the same applicant for that drug, whether in modified dosage form or with new claims, is made, the fee to accompany such subsequent application shall be fifteen thousand rupees :
Provided further also that any application received after one year of the grant of approval for the manufacture for sale of the new drug,

shall be accompanied by a fee of fifteen thousand rupees and such information and data as required by Appendix I or Appendix I-A of Schedule Y, as the case may be.":

(2) The manufacturer of a new drug under sub-rule (1) when applying for approval to the Licensing Authority mentioned in the said sub-rule, shall submit data as given in Appendix I to Schedule Y including the results of clinical trials carried out in the country in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in the format given in Appendix II to the said Schedule;

[3]"(2A) The Licensing Authority as defined in clause (b) of Rule 21 after being satisfied that the drug if approved to be manufactured as raw material (bulk drug substance) or as finished formulation shall be effective and safe for use in the country, shall issue approval in Form 46 and/or Form 46-A, as the case may be, subject to the conditions stated therein :

Provided that the Licensing Authority shall, where the data provided or generated on the drug is inadequate, intimate the applicant in writing, and the conditions, which shall be satisfied before permission could be considered."

.

(3) When applying for approval to manufacture of a new drug under sub-rule (1) or its preparations, to the State Licensing Authority, an applicant shall produce along with his application, evidence that the drug for the manufacture of which application is made has already been approved [4]"in the name of the applicant" by the Licensing Authority mentioned in Rule 21.

Provided that the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such a nature that the [5] "Licensing Authority in Rule 21 " may, in public interest decide to grant such permission on the basis of data available from other countries.

Provided further that the submission of requirements relating to Animal Toxicology, Reproduction studies, Teratogenic studiesPerinatal studies, Mutagenicity and Carcinogenicity may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate published evidence regarding the safety of the drug, subject to the other provisions of these rules.

1. In the Drugs and Cosmetics Rules, 1945,(hereinafter referred to as the said rules), in the said rules, in Rule 122B, in the marginal

note, the words, letters and figures "other than the drugs classifiable under Schedule C and C (1)" shall be omitted, by the Drugs and Cosmetics Act, 1940 (23 of 1940)"

2. In Rule 122B, sub-rule (1), shall be substituted, by Drugs and Cosmetics (9th Amendment) Rules, 2001Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R900(E), dated December 12, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 12th December, 2001, pp13-24, No622

3. In Rule 122B, after sub-rule (2), sub-rule (2A) shall be inserted, by Drugs and Cosmetics (9th Amendment) Rules, 2001Ministry of Health and Family Welfare (Depttof Health), NotiNoG.S.R900(E), dated December 12, 2001, published in the Gazette of India, Extra., Part II, Section 3(i), dated 12th December, 2001, pp13-24, No622

4. In the Drugs and Cosmetics Rules, 1945,(hereinafter referred to as the said rules), in the said rules, in Rule 122B, in the marginal note, the words, letters and figures "other than the drugs classifiable under Schedule C and C (1)" shall be omitted, by the Drugs and Cosmetics Act, 1940 (23 of 1940)"

5. In the Drugs and Cosmetics Rules, 1945,(hereinafter referred to as the said rules), in the in Rule 122B, in sub-rule (3), in the first provisio ,the words "Licensing Authority", the words and figures ,Licensing Authority in Rule 21" shall be substituted by the " Drugs and Cosmetics Act, 1940 (23 of 1940)"

122C. Application for approval to manufacture new drug classifiable under Schedules C and C (1) :-

[***]

122D. Permission to import or manufacture fixed dose combination. :-

(1) An application for permission to import or manufacture fixed dose combination of two or more drugs as defined in clause (c) of Rule 122-E shall be made to the Licensing Authority as defined in clause (b) of Rule 21 in Form 44, accompanied by a fee of fifteen thousand rupees and shall be accompanied by such information and data as is required in Appendix VI of Schedule Y.

(2) The Licensing Authority after being satisfied that the fixed dose combinationif approved to be imported or manufactured as finished formulation shall be effective and safe for use in the country, shall

issue permission in Form 45 or Form 46, as the case may be, subject to the conditions stated therein :
Provided that the Licensing Authority shall where the data provided or generated on the fixed dose combination is inadequate, intimate the applicant in writing, and the conditions which shall be satisfied before grant of approval/permission could be considered :

122DA. Application for permission to conduct clinical trials for New Drug/ Investigational New Drug. :-

(1) No clinical trial for a new drug, whether for clinical investigation or any clinical experiment by any institution, shall be conducted except under, and in accordance with, the permission, in writing, of the Licensing Authority defined in clause (b) of Rule 21.
(2) An application for grant of permission to conduct,
(a) human clinical trials (Phase-1) on a new drug shall be made to the Licensing Authority in Form 44 accompanied by a fee of fifty thousand rupees and such information and data as required under Schedule Y;
(b) exploratory clinical trials (Phase-11) on a new drug shall be made on the basis of data emerging from Phase-1 trial, accompanied by a fee of twenty-five thousand rupees;
(c) confirmatory clinical trials (Phase-111) on a new drug shall be made on the basis of the data emerging from Phase-11 and where necessary, data emerging from Phase-1 also, and shall be accompanied by a fee of twenty-five thousand rupees:
Provided that no separate fee shall be required to be paid along with application for import/manufacture of a new drug based on successful completion of phases clinical trials by the applicant:
Provided further that no fee shall be required to be paid along with the application by Central Government or State Government Institutes involved in clinical research for conducting trials for academic or research purposes.
(3) The Licensing Authority after being satisfied with the clinical trials, shall grant permission in Form 45 or Form 45-A or Form 46 or Form 46-A, as the case may besubject to the conditions stated therein :
Provided that the Licensing Authority shall, where the data provided on the clinical trials is inadequate, intimate the applicant in writing, within six months, from the date of such intimation or such extended period, not exceeding a further period of six

months, as the Licensing Authority may, for reasons to be recorded in writing, permit, intimating the conditions which shall be satisfied before permission could be considered.
Explanation.For the purpose of these rules Investigational New Drug means a new chemical entity or a product having therapeutic indication but which have never been earlier tested on human being.

122DAA. Definition of Clinical trial :-

For the purpose of this Part, "Clinical trial" means a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and/or adverse effects with the objective of determining safety and/or efficacy of the new drug.".

122DB. Suspension or cancellation of Permission/Approval :-

If the importer or manufacturer under this Part fails to comply with any of the conditions of the permission or approval, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel it.

122DC. Appeal. :-

Any person aggrieved by an order passed by the Licensing Authority under this Pan, may within sixty days from the date of such order, appeal to the Central Government, and the Central Government may after such enquiry into the matter as is considered necessary, may pass such order in relation thereto as it thinks fit."

122E. Definition of new drug :-

- For the purpose of this part, new drug shall mean and include-
[(a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognised as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims. Provided that the limited use, if any, has been

with the permission of the licensing authority.]
(b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form in an already marketed combination is proposed to be changed, with certain claims, vizindications dosage, dosage form (including sustained release dosage form) and route of administration(See items (b) and (c) of Appendix VI to Schedule Y).
Explanation- For the purpose of this rule-
(i) all vaccines shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;
(ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia whichever is earlier.]

PART 10B REQUIREMENTS FOR THE COLLECTION, STORAGE, PROCESSING AND DISTRIBUTION OF WHOLE HUMAN BLOOD, HUMAN BLOOD COMPONENTS BY BLOOD BANKS AND MANUFACTURE OF BLOOD PRODUCTS

122EA. Definitions :-

[-
(1) In this Part and in the Forms contained in Schedule A and in Part XIIB and Part XIIC of ScheduleF, unless there is anything repugnant in the subject of context,-
(a) "apheresis" means the process by which blood drawn from a donor, after separating plasma or platelets or leucocytes, is retransfused - simultaneously into the said donor;
(b) "autologous blood" means the blood drawn from the patient for retransfusion into himself later on;
(c) "blood" means and includes whole human blood, drawn from a donor and mixed with an anti-coagulant;
(d) "blood bank" means a place or organisation or unit or institution or other arrangements made by such organisation, unit or institution for carrying out all or any of the operations for collection, apheresis, storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components;
(e) "blood component" means a drug prepared, obtained, derived or separated from a unit of blood drawn from a donor;
(f) "blood product" means a drug manufactured or obtained from

pooled plasma of blood by fractionation, drawn from donors;
(g) "donor" means a person who voluntarily donates blood after he has been declared fit after a medical examination, for donating blood, on fulfilling the criteria given hereinafter, without accepting in return any consideration in cash or kind from any source, but does not include a professional or a paid donor;
Explanation- For the purposes of this clause, benefits or incentives like pins, plaques, badges, medals, commendation certificates, time-off from, membership of blood assurance programme, gifts of little or intrinsic monetary value shall not be construed as consideration.
(h) "leucapheresis" means the process by which the blood drawn from a donor, after leucocyte concentrates have been separated, is re-transfused simultaneously into the said donor.
(i) "plasmapheresis" means the process by which the blood drawn from a donor, after plasma has been separated, is re-transfused during the same sitting into the said donor;
(j) "plateletpheresis" means the process by which the blood drawn from a donor, after platelet concentrates have been separated, is re-transfused simultaneously into the said donor;
(k) "professional donor" means a person who donates blood for a valuable consideration, in cash or kind, from any source, on behalf of the recipient- patient and includes a paid donor or a commercia donor;
(m) "replacement donor" means a donor who is a family friend or a relative of the patient - recipient.]

122F. Form of application for licence for operation of Blood Bank/processing of whole human blood for components /manufacture of Blood Products for sale or distribution :-

-

(1) Application for the grant and/or renewal of licence for the operation of a Blood Bank/processing of Human Blood for components/manufacture of Blood Products shall be made to the Licensing Authority appointed under Part VII in [2][Form 27-C or Form 27-E, as the case may be,] and shall be accompanied by licence fee of [1][rupees six hundred and an inspection fee of rupees four hundred for first inspection or rupees two hundred in the case of second or every subsequent inspection or for the purposes of renewal of licence].
Provided that if the applicant applies for renewal of licence after its

expiry but within six months of such expiry the fee payable for the renewal of the licence shall be rupees six hundred plus an additional fee at the rate of rupees [1][three] hundred per month or a part thereof in addition to the inspection fee.

Provided further that a licensee holding a licence in [2][Form 28-C or Form 28- E, as the case may be,] for operation of blood bank/processing of whole human blood for components/manufacture of blood products shall apply for grant of licence under sub-rule (1) before the expiry of the said licence on [3][Form 27-C or Form 27-E, as the case may be,] and he shall continue to operate the same till the orders on his application are communicated to him.

[465466][***]

(2) A fee of rupees one hundred shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

(3) Application by a licensee to manufacture additional drugs listed in the application shall be accompanied by fee of rupees fifty for each drug listed in the application.

(4) On receipt of the application for the grant or renewal of such licence, the Licensing Authority shall,-

(i) verify the statements made in the application form.

(ii) cause the manufacturing and testing establishment to be inspected in accordance with the provision of Rule 122(I); and

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

(5) If the Licensing Authority is satisfied that the applicant is in a position to fulfil the requirements laid down in the rules, he shall prepare a report to that effect and forward it alongwith the application [467][and the licence (in triplicate) to be granted or 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.

(6) If, on receipt of the application and the report of the Licensing Authority referred to in sub-rule [468] [(5)] and after taking such measures including inspection of the premises, by the Inspector, appointed by the Central Government under section 21 of the Act, and/or along with the Expert in the field concerned if deemed necessary, the Central Licence Approving Authority, is satisfied that

the applicant 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 and shall supply the applicant with a copy of the inspection report.

Part X-A insby G.S.R944(E), dt21.9.1988, w.e.f21.9.1988.

In the Drugs and Cosmetics Rules, 1945, in Rule 122-F, in sub-rule (1), Explanation shall be omitted; by the Drugs and Cosmetics Act, 1940 (23 of 1940). Omitted Explanation is : [Explanation- For the purpose of this rule, "Blood Bank" means a place or organisational unit or an institution, or other arrangement made by such organisational unit or institution for carrying out all or any of the operations of manufacture of Human Blood Components or Blood Products or Whole Human Blood for its collection, storage, processing, distribution from selected human donors.]

Substituted by G.S.R788(E), dt10.10.1985, w.e.f10.10.1985.

Substituted by G.S.R779, dt18.7.1980, w.e.f26.7.1980.

122G. Form of licence for the operation of a Blood Bank/Processing of Whole Human Blood for components and manufacture of blood products and the conditions for the grant or renewal of such licence :-

2"(1)"A licence for the operation of a Blood Bank or for processing whole Human Blood for components and manufacture of blood products shall be issued in **2**[Form 28-C or Form 28-E or Form 26-G or Form 26-I, as the case may be]Before a licence in **471**[Form 28-C or Form 28-E or Form 26- G or Form 26-I, as the case may be] is granted or renewed the following conditions shall be complied with by the applicant-

472[(i) The operation of Blood Bank and/or processing of whole human Blood for components shall be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person who is whole time employee and who is Medical Officer, and possessing-

(a) Post-graduate degree in Medicine-M.D(Pathology/Transfusion

Medicines); or
(b) Degree in Medicine (M.B.B.S.) with Diploma in Pathology or Transfusion Medicines having adequate knowledge in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components; or
(c) Degree in Medicine (M.B.B.S.) having experience in Blood Bank for one year during regular service and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components, the degree or diploma being from a University recognised by the Central Government.
Explanation- For the purposes of this condition, the experience in Blood Bank for one year shall not apply in the case of persons who are approved by the Licensing Authority and/or Central Licence Approving Authority prior to the commencement of the Drugs and Cosmetics (Amendment)* Rules, 1999.]
(ii) The applicant shall provide adequate space, plant and equipment for any or all the operations of blood collection or blood processingThe space, plant and equipment required for various operations is given in Schedule F, Part XII-B and/or XII-C.
(iii) The applicant shall provide and maintain adequate technical staff as specified in Schedule T, Part XII-B and/or XII-C.
(iv) The applicant shall provide adequate arrangements for storage of Whole Human Blood, Human Blood components and blood products.
(v) The applicant shall furnish to the Licensing Authority, if required t o do so, data on the stability of Whole Human Blood, its components or blood products which are likely to deteriorate, for fixing the date of expiry which shall be printed on the labels of such products on the basis of the data so furnished.
473 "(2) Application for grant or renewal of a licence for operation of Blood Bank or processing of human blood components shall be made by the Blood Bank run by the Government, Indian Red Cross Society, hospital, charitable trust or voluntary organization approved by a State/ Union Territory Blood Transfusion Council only.
Explanation.- For the purpose of this sub-rule, "renewal" shall include renewal of any licence issued prior to the commencement of the drugs and cosmetics (6th Amendment) Rules, 2005.".

. In the Drugs and Cosmetics Rules, 1945, Rule 122-G shall be

numbered as sub-rule (1) , by the Drugs and Cosmetics Act, 1940 (23 of 1940).

Part X-A insby G.S.R944(E), dt21.9.1988, w.e.f21.9.1988.

In the Drugs and Cosmetics Rules, 1945,Rule 122-G after sub-rule (1) as so renumbered, the following shall be inserted by the Drugs and Cosmetics Act, 1940 (23 of 1940). "(2) Application for grant or renewal of a licence for operation of Blood Bank or processing of human blood components shall be made by the Blood Bank run by the Government, Indian Red Cross Society, hospital, charitable trust or voluntary organization approved by a State/ Union Territory Blood Transfusion Council only. Explanation.- For the purpose of this sub-rule, "renewal" shall include renewal of any licence issued prior to the commencement of the drugs and cosmetics (6th Amendment) Rules, 2005.".

122H. Duration of licence :-

- An original licence in [Form 28-C or Form 28- E or a renewed licence in Form 26-G or Form 26-1] unless sooner suspended or cancelled shall be valid up to the 31st December of the year following the year in which it is granted or renewed.

122I. Inspection before grant or renewal of licence for operation of Blood Bank, processing of Whole Human Blood for Components and Manufacture of Blood Products :-

- Before a licence in [Form 28-C or Form 28-E is granted or a renewal of licence in Form 26-G or Form 26-I is made, as the case may be,] the Licensing Authority or the Central Licence Approving Authority, as the case may be, shall cause the establishment in which Blood Bank is proposed to be operated/ whole human blood for component is processed [/] blood products are manufactured to be inspected by one or more inspectors, appointed under the Act and/or alongwith the Expert in the field concernedThe Inspector Or Inspectors shall examine all portions of the premises and appliances/equipments and inspect the process of manufacture intended to be employed or being employed alongwith the means to be employed or being employed for operation of blood bank/ processing of whole human blood for components/manufacture of blood products together with their [testing] facilities and also enquire into the professional qualification of the expert staff and other technical staff to be employed.

122J. Report by Inspector :-

.- The Inspector or Inspectors shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendation in accordance with the provisions of Rule 122(I) to the Licensing Authority or to the Central Licence Approving Authority.

122K. Further application after rejection :-

- If within a period of six months from the rejection of application for a licence the applicant informs the Licensing Authority that the conditions laid down have been satisfied and deposits an inspection fee of rupees fifty the Licensing Authority may, if after causing further inspection to be made is satisfied that the conditions for the [grant or renewal of a licence have been complied with, shall grant or renew the licence in Form 28-C or Form 28-E.
Provided the in the case of a drug notified by the Central Government under rule 68A, the application, together with the inspection report and the Form of licence (in triplicate to be granted or renewed), duly completed shall be sent, to be Central Licence Approving Authority, who may approve the same and return it to the Licensing Authority for issue of the licence.]

122L. 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 power under rules to persons 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.

122M. Provision for appeal to the State Government by a Party whose licence has not been granted or renewed :-

- Any person who is aggrieved by the order passed by the Licensing Authority or Central Licence Approving Authority, as the case may be, 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, after such enquiry, into the matter as it considers necessary and after giving the said person an opportunity for

representing his view in the matter may pass such order in relation thereto as it thinks fit.

122N. Additional information to be furnished by an 1[applicant] for licence or by a licensee to the Licensing Authority :-

- The applicant for the grant of licence or any person granted a licence under the 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, 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 statement made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.

122O. Cancellation and suspension of licences :-

-
(1) The Licensing Authority or Central Licence Approving Authority may for such licences granted or renewed by him after giving the licensee an opportunity to show cause by such an order should not be passed by an order in writing stating the reason thereof, 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, [or direct the licensee to stop collection, storage, processing, manufacture and distribution of the said substances and [thereupon order the destruction of substances and] stocks 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 provision of the Act or Rules thereunder.
(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 or Central Government, which shall decide the same.

122P. Conditions of licence :-

- [A licence in Form 28-CForm 28-E, Form 26-G or Form 26-I shall be subject to the special conditions set out in Schedule F, Part XIIB and Part XIIC, as the case may be, which relate to the substance in

respect of which the licence is granted or renewed and to the following general conditions, namely-]

(i)

(a) The licensee shall provide and maintain adequate staff, plant and premises for the proper operation of a Blood Bank for processing whole human blood, its components and / or manufacture of blood products.

(b) The licensee shall maintain staff, premises and equipment as specified in Rule 122GThe licensee shall maintain necessary records and registers as specified in Schedule F, Parts XII-B and XII-C.

(c) The licensee shall test in his own laboratory whole human blood, its components and blood products and [maintain records and] registers in respect of such tests as specified in Schedule F, Parts

(d) The licensee shall maintain/preserve reference [sample and] supply to the Inspector the reference sample of the whole human blood collected by him in an adequate quantity to conduct all the prescribed testsThe licensee shall supply to the Inspector the reference sample for the purpose of testing.

(ii) The licensee shall allow an Inspector appointed under the Act to enter, with or [without] prior notice, any premises where the activities of the Blood Bank are being carried out, for the processing of Whole Human Blood and/or Blood Products, toinspect the premises and plant and the process of manufacture and the means employed for standardising and testing the substance.

(iii) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(iv) The licensee shall from time to time report to the Licensing Authority any changes in the expert staff responsible for the operation of a Blood Bank/processing of whole human blood for components and/ or manufacture of blood products and any material alterations in the premises or plant used for that purpose which have been made since the date of last inspection made on behalf of the Licensing Authority before the grant of the licence.

(v) The licensee shall on request furnish to the Licensing Authority, or Central Licence Approving Authority or to such Authority as the Licensing Authority, or the Central Licence Approving Authority may direct, from any batch unit of drugs as the Licensing Authority or Central Licence Approving Authority may from time to time specify,

sample of such quantity as may be considered adequate by such Authority for any examination and, if so required, also furnish full protocols of the test which have been applied.

(vi) If the Licensing Authority or the Central Licence Approving Authority so directs, the licensee shall not sell or offer for sale any batch/ unit in respect of which a sample is, or protocols are furnished under the last preceding sub-paragraph until a certificate authorising the sales of batch/unit has been issued to him by or on behalf of the Licensing Authority or the Central Licence Approving Authority.

(vii) The licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch/unit of the substance has been found by the Licensing Authority or the Central Licence Approving Authority not to conform with the standards of

(viii) No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufactureFurther no batch/unit manufactured under this licence shall be supplied/distributed to any person without prescription of Registered Medical Practitioner.

(ix) The licensee shall comply with the provisions of the Act and of these Rules and with such further requirements, if any, as may be specified in any Rules subsequently made under Chapter IV of the Act,

provided that Where such further requirements are specifed in the-Rules, these would come in force four months after publication in the Official Gazette.

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

(xi) The licensee shall destroy the stocks of batch/unit which does not comply with standard tests in such a way that it would not spread any disease/infection by way of proper disinfection method.]

[(xii) All bio-medical waste shall be treated, disposed off or destroyed as per the provisions of The Bio-Medical Wastes (Management and Handling) Rules, 1996.

(xiii) The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components and/or manufacture blood products from the blood drawn from such a donor.]

PART 11 EXEMPTIONS

123. . :-

The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule.

PART 12 STANDARDS

124. Standards of drugs :-

[-
(1) For drugs included in the Indian Pharmacopoeia:
(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force.
(b) In case the standards for identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian
(2) For other drugs:
(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the official pharmacopoeia, or the time being in force, of any country to which the drug claims to comply with.
(b) In case the standards for identity, purity and strength for drugs are not specified in the edition of such official pharmacopoeia, for the time being in force, but are specified in the edition immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of such official pharmacopoeia to which the drug claims to comply with.
(c) For drugs for which standards are not included in the edition of the official pharmacopoeia, for the time being in force, of any country or in its edition immediately preceding but included in the official compendia of drugs standards, namely, the British Pharmaceutical Codex or the National Formulary of the United States, for the time being in force, to which the drug claims to comply with.]

124A. Standards for veterinary drugs :-

[- For drugs intended for veterinary use, the standards shall be those given in the current edition for the time being in force of the [British Pharmacopoeia (Veterinary)].]

124B. Standards for patent or proprietary medicines :-

[- The standards for patent or proprietary medicines shall be those laid down in Schedule V and such medicines shall also comply with the standards laid down in the Second Schedule to the Act.]

124C. Standards for Surgical Dressings :-

[- The standards for Surgical Dressings shall be such as are laid down in Schedule F (II).]

124D. Standards for Sterilised Umbilical tapes :-

[- The standards for Sterilised Umbilical tapes shall be as laid down in Schedule F (III).]

125. Standards for substances (other than food) intended to affect the structure or any function of human body-contraceptives :-

[-
(1) The standards for mechanical contraceptives shall be such as are laid down in Schedule R.
(2) The standards which other contraceptives will have to comply with shall be in conformity with the formulae approved as safe and efficacious by the Central GovernmentSuch formula shall be displayed on the label of every container of such contraceptive.]

125A. Standards for Medical Devices :-

[- The standards for the Medical Devices shall be such as are laid down in Schedule R-1.]

126. . :-

[Standards for substances intended to be used for the destruction of vermin or insects which cause discase in human beings or animals.] Disinfectants The standards for disinfectants shall be such as are laid down in Schedule O.

126A. Standards for ophthalmic preparations 3[including Homoeopathic ophthalmic preparations] :-

[- The standards for ophthalmic preparations including Homoeopathic Ophthalmic preparations shall be those laid down in Schedule FF, and such preparations shall also comply with the

standards set out in the Second Schedule to the Act.]

127. List of colours permitted to be used in drugs :-

[-
(1) No drug shall contain a colour other than that specified below:
(1) Natural Colours Annatto Carotene Chlorophyll Cochineal Curcumin Red Oxide of iron Yellow Oxide of iron [Titanium Oxide] [Black Oxide of Iron]
(2) Artificial Colours Caramel [Riboflavin]
(3) Coal Tar Colours

(4) Lakes The aluminium or calcium salts (lakes) of any of the water-soluble colours listed above.
(2) The label on the container of a drug containing a permitted colour shall indicate the common name of the colour.)

128. . :-

The following rules are hereby repealed except as respects things done or omitted to be done under those rules, namely:- Andhra Pradesh Drugs Rules, 1945Assam Drugs Rules, 1945. Bihar Drugs Rules, 1945. Bombay Drugs Rules, 1946. East Punjab DrugsRules, 1945. C.Pand Berar Drugs Rules, 1945. Madras Drugs Rules,1945. Orissa Drugs Rules, 1945. Rajasthan Drugs Rules, 1953. Saurashtra Drugs Rules, 1953. Travancore-Cochin Drugs Rules, 1953. United Provinces Drugs Rules, 1945. West Bengal Drugs Rules, 1946. [Mysore Drugs Rule s, 1954.]

PART 13 IMPORT OF COSMETICS

129. Statement to accompany imported cosmetics :-

- All consignments of cosmetics sought to be imported shall be accompanied by an invoice or statement showing the name and quantities of each article of cosmetic included in the consignment and the name and address of the manufacturer.

130. Documents to be supplied to the Collector of Customs :-

- Before any cosmetics are imported, a declaration signed by or on behalf of the manufacturer or by or on behalf of the importer that

the cosmetics comply with the provisions of Chapter III of the Act, and the rules made thereunder, shall be supplied to the Collector of Customs.

131. Procedure for the import of cosmetics :-

-

(1) If the officer appointed at the post of entry by the Central Government has reason to believe that any cosmetic contravenes any of the provisions of the Act or the rules made thereunder he may take sample of the cosmetic from the consignment for inspectionIf on examination of the sample defects are noticed the officer shall advice the Commissioner of Customs for further action to be taken. If the suspected contravention of the provisions of the Act or the rules is such as may have to be determined by test, the officer shall send the sample to the laboratory established for the purpose for performing such testsThe consignment of the said cosmetic shall be detained till such time that the test report on such sample is received from the Director of the said laboratory or any other officer of the laboratory empowered by him in this behalf with the approval of the Central Government.

Provided that if the importer gives an undertaking in writing not to dispose of the cosmetic without the consent of the Commissioner of Customs and to return the consignment or such portion thereof as may be required, the Commissioner of Customs shall make over the consignment to the importer.

(2) If the importer who has given an undertaking under the proviso to sub- rule (1) is required by the Collector of Customs to return the consignment or portion thereof, he shall return the consignment or portion thereof within ten days of receipt of the notice.

Further Procedure on receipt of the report of analysis

(3) If the Director of the laboratory established for the purpose by the Central Government or any other officer of the laboratory empowered by him in this behalf with the approval of the Central Government, reports to the Commissioner of Customs or to the officer mentioned in sub-rule (1) above that the sample of any cosmetic in a consignment contravenes the provisions of Chapter III of the Act or the rules made thereunder and that the contravention is such that it cannot be remedied by the importer, the Commissioner of Customs shall communicate the report forthwith to the importer who shall within two months of receiving

such a communication either send back all the cosmetic of that description in the consignment to the country in which it was manufactured or to the country from which it was imported or hand it over to the Central Government which shall cause it to be destroyed.

Provided that the importer may within thirty days of receipt of the report make a representation against the report to the Commissioner of Customs who shall forward the representation with a fresh sample of the cosmetic to the Drugs Controller, India, who after obtaining, if necessary, the report of the Director of the Central Drugs Laboratory shall pass orders thereon which shall be final.

(4) If the Drugs Controller or any other officer empowered by him in this behalf with the approval of Central Government reports to the Commissioner of Customs after inspection of the sample of cosmetic and if necessary, after obtaining a test report thereon that the sample of the said cosmetic contravenes in any respect the provisions of Chapter III of the Act or the rules made thereunder but that the contravention is such that it can be remedied by the importer, the Commissioner of Customs shall communicate the report forthwith to the importer and permit him to import the cosmetic on his giving an undertaking in writing not to dispose of the cosmetic without the permission of the officer authorised in this behalf by the Central Government.

<u>132.</u> Exemption of cosmetics :-

- Cosmetics as may be specified in Schedule D shall be exempted from the provisions of Chapter III of the Act and the rules made thereunder to the extent and subject to the conditions specified in that Schedule. 133Import through points of entry- No cosmetic shall be imported into India except through the points of entry specified in Rule 43A.

<u>134.</u> Cosmetic to contain Dyes, Colours and Pigments :-

[- No Cosmetic shall contain Dyes, Colours and Pigments other than those specified by the Bureau of Indian Standards (IS: 4707 Part I as amended) and Schedule Q. The permitted Synthetic Organic Colours and Natural Organic colours used in the Cosmetic shall not contain more than-

(i) 2 parts per million of Arsenic calculated as Arsenic Trioxide.

(ii) 20 parts per million of Lead calculated as Lead.

(iii) 100 parts per million of Heavy Metals other than Lead calculated as the total of the respective metals.]

134A. Prohibition of import of cosmetic containing hexachlorophene :-

[- No cosmetic containing hexachlorophene shall be imported.]

135. Import of cosmetics containing lead or arsenic compound prohibited :-

- No cosmetic shall be imported in which a lead or arsenic compound has been used for purposes of colouring.

135A. Import of cosmetics containing mercury compounds prohibited :-

[- No cosmetic shall be imported which contains mercury compounds.]

136. Import of cosmetics for personal use :-

- Small quantities of cosmetics the import of which is otherwise prohibited under Section 10 of the Act, may be imported for personal use subject to the following conditions-
(i) The cosmetics shall form part of a passengers baggage and shall be the property of, and be intended for, the bona fide use of the passenger; and
(ii) The cosmetics shall be declared to the Customs authorities if they so direct.

PART 14 MANUFACTURE OF COSMETICS FOR SALE 3[OR FOR DISTRIBUTION]

137. Manufacture on more than one set of premises :-

- If cosmetics are manufactured on more than one premises, a separate application for each such premises shall be made and a separate licence obtained for each such premises.

138. Application for licence to manufacture cosmetics 3[for sale or for distribution] :-

-
[(1) Application for grant or renewal of [licence to manufacture

cosmetics for sale or for distribution] 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) in Form 31 and shall be accompanied by a fee of [rupees four hundred] and an inspection fee of [rupees one hundred] for the first inspection or [rupees fifty] in case of inspection for renewal of licence. [* * * * * * * * * * *]

(2) If a person applies for the renewal of licence after expiry but within six months of such expiry, the fee payable for the renewal of such licence shall be [rupees four hundred] plus an additional fee at the rate of [rupess two hundred] per month or a part thereof and an inspection fee of [rupees fifty]. [* * * * * * * * * * *]

(3) Application by a licensee to manufacture additional items of cosmetics shall be accompanied by a fee of rupees five for each item. [* * * * * * * * * * * *]

[(4) A fee of rupees fifty shall be paid for duplicate copy of a licence issued under sub-rule (1), if the original is defaced, damaged or lost.]

<u>138A.</u> Application for loan licence to manufacture cosmetics :-

[-

(1) Application for grant or renewal of a loan licence for the manufacture for sale of cosmetics shall be made in Form 31-A to the Licensing Authority and shall be accompanied by a fee of [rupees two hundred].

Explanation- For the purpose of this rule a loan licence means a licence which a 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 32.

(2) If a person applies for the renewal of a loan licence after its expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be [rupees two hundred] plus an additional fee at the rate of [rupees seventy five] per month or part thereof.

(3) 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 to undertake the manufacture on behalf of the applicant for a loan licence.

(4) The loan licence shall be granted by the Licensing Authority to only such applicants who propose to avail of the facilities of manufacture of cosmetics in the premises of a manufacturer located in the same State where the applicant is locatedIn case the manufacture of cosmetics involves any special process of manufacture or use of equipments which are not available in the State where the applicant is located, the Licensing Authority, after consulting the Licensing Authority where the manufacturing unit is located, may grant the loan licence.

(5) Subject to the provisions of sub-rule (2), application for manufacture of additional items on a loan licence shall be accompanied by a fee of rupees five for each item.

(6) A fee of [rupees thirty] shall be paid for a duplicate copy of a licence issued under sub-rule (1) if the original is defaced, damaged or lost.]

139. Condition for the grant or renewal of a licence in Form 32 :-

.- Before a licence in Form 32 is granted or renewed, the following conditions shall be complied with by the applicant.

(1) The manufacture shall be conducted under the direction and personal supervision of a competent technical staff consisting of at least one person who is a whole time employee and who possesses any one of the following qualifications-

(a) holds a Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948, or

(b) is registered under the Pharmacy Act, 1948 , or

(c) has passed the Intermediate Examination with Chemistry as one of the subjects or an examination recognised by the Licensing Authority as equivalent to it.

(d) [* * * * * * * * * *]

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

(3)-(4) [* * * * * * * * * *]

(5) The applicant shall either-

(i) provide and maintain adequate staff, premises and laboratory equipment for testing the cosmetic manufacture, and the raw materials used in the manufacture, or

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

139A. Form of licence to manufacture cosmetics for sale 6[or for distribution] :-

[- A licence to manufacture cosmetics for sale [or for distribution] against application in Form 31, shall be granted in Form 32.]

139AA. Inspection before grant or renewal of licence :-

[- Before a licence under this Part is granted or renewed in Form 32, Form 32-A or Form 33, 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 appointed under the ActThe 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 alongwith the means to be employed or being employed for standardising and testing the substances to be manufactured and inquire into the professional qualifications of the technical staff to be employedHe 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 o f competent technical staff, manufacturing plants, testing equipments and the requirements of plant and equipment as laid down in Schedule M-II read with the requirements of maintenance of records as laid down in Schedule U-I.

139AB. Report by Inspector :-

- The Inspector or Inspectors shall forward a detailed descriptive report giving his or their findings on each aspect of inspection alongwith his or their recommendations after completion of his or their inspection to the Licensing Authority.

139AC. Grant or refusal of licence :-

-
(1) If the Licencing 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 the conditions of the licence and the rules under the Act shall be observed, he shall grant or renew a licence in Form 32, Form 32A or Form 33.
(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.

139AD. 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 rupees fifty, the Licencing 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 32, Form 32A or Form 33.

139AE. Appeal to the State Government :-

- Any person who is aggrieved by the other 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.]

139B. Form of loan licence to manufacture cosmetics for sale 2[or for distribution] :-

[- A loan licence to manufacture cosmetics for sale [or for distribution] against application in Form 31-A shall be granted in Form 30-A.]

140. Duration of licence :-

- An original licence or a renewed licence shall unless sooner suspended or cancelled be valid up to the 31st December of the year following the year in which it is granted or renewed.
[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.]

141. Certificate of renewal :-

- The certificate of renewal of a licence in Form 32 shall be issued in Form 33.

141A. Certificate of renewal of loan licence :-

[- The certificate of renewal of a licence in Form 32-A shall be issued in Form 33-A.]

141AA. Duration of a loan licence :-

[.- An original loan licence in Form 32-A or a renewed loan licence in Form 33-A, unless sooner suspended or cancelled, shall be valid upto the 31st December of the year following the year in which it is granted or renewed.
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 applicationThe licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.]

142. Conditions of licence :-

- A licence in Form 32 shall be subject to the conditions stated therein and to the following other conditions, namely-
(a) The licensee shall provide and maintain staff, premises and equipment as specified in Rule 139.
(b) The licensee shall comply with the provisions of the Act and the rules made thereunder and with such further requirements, if any, as may be specified in any rules to be made hereafter under Chapter IV of the Act.
[(b-1) The licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in Schedule U(1) and such records shall be retained for a period of three years.]
(c) The licensee shall test each batch or lot of the raw materials used by him for the manufacture of the cosmetics and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests.The records or registers shall be retained for a period of three years from the date

of manufacture.
(d) The licensee shall allow any [Inspector appointed under the Act] to enter with or without prior notice any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured products under a receipt.
(e) 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 complied.
(f) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and the defects noticed.
[Provided that clauses (b-1) and (c) shall not apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by amanufacture of soap shall be such as are approved by the "Licensing Authority".]

142A. 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.]

142B. Conditions of licence in Form 32-A :-

[-
(a) A licence in Form 32-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee, in Form 32, whose manufacturing facilities, is cancelled or suspended, as the case may be under these rules.
(b) The licensee shall comply with the provisions of the Act and

these rules and with such further requirements, if any, as may be specified from time to time in 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.

[(b-1) The licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in Schedule U(1) and such records shall be retained for a period of three years.]

(c) The licensee shall test each batch or lot of the raw materials used by him for the manufacture of the cosmetics and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests. The records or registers shall be retained for a period of three years from the date of manufacture.

(d) The licensee shall allow an Inspector appointed under the Act to enter with or without prior notice any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured products under a receipt.

(e) 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 complied.

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

143. Cancellation and suspension of licence :-

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(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 therefore, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either

(2) A licensee whose licence has been suspended or cancelled may appeal within a period of three months from the date of the order to the State Government which shall after considering the appeal, pass orders, and such orders shall be final.

144. Prohibition of manufacture of Cosmetics containing

colours other than those prescribed :-

[-
(1) No Cosmetics shall be manufactured which contain Dyes, Colours and Pigments other than the one specified by the Bureau of Indian Standards (IS : 4707 Part I as amended) and Schedule Q.
(2)The permitted Synthetic Organic colours and Natural Organic Colours used in the Cosmetic shall not contain more than-
(i) 2 parts per million of Arsenic calculated as Arsenic Trioxide.
(ii) 20 parts per million of lead calculated as lead.
(iii) 100 parts per million of Heavy Metals other than lead calculated as the total of the respective metals.]

144A. Prohibition of manufacture of cosmetic containing hexachlorophene :-

[- No cosmetic containing hexachlorophene shall be manufactured.)
[Provided that in the case of soaps hexachlorophene may be used in concentrations not exceeding one per cent weight by weight.
Provided further that the following cautionary note shall be printed and shall appear in a conspicuous manner on the wrapper of package of each soap, namely- "Contains hexachlorophene-not to be used on babies".]

145. Use of Lead and Arsenic compounds for the purpose of colouring cosmetics prohibited :-

- The use of Lead and Arsenic compounds for the purpose of colouring cosmetics is prohibited.

145A. Form of intimation for purposes of taking samples of cosmetics :-

[- Where an Inspector takes a sample of a cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.]

145AA. Form of receipt of samples of Cosmetics where fair price tendered is refused :-

[- Where the fair price, for the samples of Cosmetics taken for the purpose of test or analysis, tendered under sub-section (1) of section 23 has been refused, the Inspector shall tender a receipt therefor to the person from whom the said samples have been

taken as specified in Form 17-A.]

145B. Form of receipt for seized cosmetics :-

[- A receipt by an Inspector for the stock of any cosmetics seized under clause (c) of sub-section (1) of Section 22 of the Act, shall be in Form 16.]

145BA. Manner of certifying copies of seized documents :-

[- The Drugs Inspector shall return the documents, seized by him under clause (cc), or produced before him under clause (cca), of sub-section (1) of Section 22 of the Act, within a period of twenty days of the date of such seizure or production, to the person from whom they were seized or, as the case may be, the person who produced them, after copies thereof or extracts therefrom have been signed by the concerned Drugs Inspector and the person from whom they were seized, or, as the case may be, who produced such records.]

145C. Form of order not to dispose of stocks of cosmetics :-

[- An order in writing by an Inspector under clause (c) of sub-section (1) of Section 22 of the Act requiring a person not to dispose of any stock of cosmetics in his possession shall be in Form 15.]

145D. Prohibition of manufacture of cosmetic containing mercury compounds :-

[-No cosmetic containing mercury compounds shall be manufactured.]

P A R T 1 5 [LABELLING, PACKING AND STANDARDS OF COSMETICS]

146. Prohibition of sale or distribution :-

- Subject to the other provisions of these rules, no person shall sell or distribute any cosmetic unless the cosmetic, if of Indian origin, is manufactured by a licensed manufacturer and labelled and packed in accordance with these rules.

147. Exemption of Cosmetics not manufactured for consumption or sale in India from the provisions of this

Part :-

[- Labels on packages or containers of cosmetics not manufactured for consumption or sale in India shall be adapted to meet the specific requirements, if any, of the consignee.
Provided that where a cosmetic 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.]

148. Manner of labelling :-

- Subject to other provisions of the rules, a cosmetic shall carry-
(1) on both the inner and outer labels:
(a) the name of the cosmetics,
"(b) the name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured: Provided that if the cosmetic is contained in a very small size container where the address of the manufacturer cannot be given, the name of the manufacturer and his principal place of manufacture shall be along with pin code"
(2) on the outer label- A declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, weight for semi-solids, combined with numerical count if the content is sub-divided. Provided that this statement need not appear in case of a package of perfume, toilet water or the like, the net content of which does not
(3) on the inner label; where a hazard exists:
(a) Adequate direction for sale use,
(b) Any warning, caution or special direction required to be observed by the consumer,
(c) A statement of the names and quantities of the ingredients that are hazardous or poisonous.
[(4) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the letter "B": Provided that this clause shall not apply to any cosmetic containing 10 grams or less if the cosmetic is in solid or semisolid state, and 25 millilitres or less if the cosmetic is in a liquid state.]
[Provided further that in the case of soaps, instead of the batch

number, the month and year of manufacture of soap shall be given on the label.]

[(5) Manufacturing licence number, the number being preceded by the letter M.]

(6) Where a package of cosmetic has only one label such label shall contain all the information required to be shown on both the inner and the outer labels, under these rules.

148A. Prohibition against altering inscriptions on containers, labels or wrappers of cosmetic. :-

- No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any cosmetic: Provided that nothing in this rule shall apply to any alteration, any inscription or mark made on the container, label or wrapper of any cosmetic at the instance or direction or with the permission of the licensing authority."

149. [Labelling of Hair Dyes containing Dyes, Colours and Pigments- Hair dyes containing Para :-

-Phenylenediamine or other Dyes, Colours and Pigments] shall be labelled with the following legend in English and local languages and these shall appear on both the inner and the outer labels. " Caution-This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying directions should first be madeThis product should not be used for dyeing the eyelashes or eyebrows; as such a use may cause blindness." Each package shall also contain instructions in English and local languages on the following lines for carrying out the test. "This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity existsTo make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcoholApply a small quantity of the hair dye as prepared for use to the area and allow it to dryAfter twenty-four hours, wash the area gently with soap and waterIf no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result."

149A. Special provisions relating to toothpaste containing fluoride :-

[-
(i) Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton.
(ii) Date of expiry should be mentioned on tube and carton.]

150. Report of result of test or analysis of cosmetics :-

.- Test reports on samples of cosmetics taken for test or analysis under these rules shall be supplied in Form 34.]

150A. Standards for cosmetics :-

[- Subject to the provisions of these rules, the standards for cosmetics shall be such as may be prescribed in Schedule S.]

PART 15A APPROVAL OFINSTITUTIONS FOR CARRYING OUT TESTS ON DRUGS, COSMETICS AND RAWMATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS/COSMETICS

150B. Application for grant of approval for testing drugs/cosmetics :-

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(1) Application for grant or renewal of approval for carrying out tests for identity, purity, quality and strength of drugs or cosmetics or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs or cosmetics, shall be made in Form 36 to the Licensing Authority appointed by the State Government for the purposes of Part VII, VII(A) or XIV of these rules, as the case may be and referred to as the "approving authority" under this Part and shall be accompanied by an inspection fee of rupees five hundred in the case of testing of drugs specified in Schedules C and C(1) and rupees three hundred in the case of testing of drugs other than those specified in Schedules C and C(1), homoeopathic drugs and cosmetics.
Provided that the applicant shall furnish to the approving authority such additional information as may be required by him in connection with the application in Form 36.
Provided further that if the applicant applies for renewal of approval

after its expiry but within six months of such expiry, the inspection fee payable shall be rupees five hundred plus an additional inspection fee at the rate of rupees four hundred per month in the case of testing of drugs specified in Schedules C and C(1) and rupees three hundred plus an additional inspection fee of rupees two hundred per month in the case of testing of drugs other than those specified in Schedules C and C(1), homoeopathic drugs and cosmetics.

(2) A separate application shall be made for grant of approval for carrying out tests on additional categories of drugs or items of cosmetics.

Explanation- For the purpose of this Part, the words drugs and cosmetics shall also mean and include the raw materials used in the manufacture of drugs including homoeopathic drugs or cosmetics, as the case may be.

150C. Form in which approval to be granted for carrying out tests on drugs/cosmetics on behalf of licensees for manufacture of drugs/cosmetics and conditions for grant or renewal of such approval :-

-

(1) Approval for carrying out such tests of identity, purity, quality and strength of drugs or cosmetics as may be required under the provisions of these rules, on behalf of licensee for manufacture of drugs or cosmetics shall be granted in Form 37.

(2) Before approval in Form 37 is granted or renewed, the following conditions shall be complied with by the applicant:-

(1) The premises where the tests are being carried on shall be well lighted and properly ventilated except where the nature of tests of any drug or cosmetic warrants otherwiseWherever necessary, the premises shall be air-conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests, microbiological tests, etc.

(2) The applicant shall provide adequate space having regard to the nature and number of samples of drugs or cosmetics proposed to be tested.

Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate.

(3) If it is intended to carry out tests requiring the use of animals, the applicant shall provide for an animal house and comply with the

following requirements:-

(a) The animal house shall be adequate in area, well lighted and properly ventilated and the animals undergoing tests shall be kept in air-conditioned area.

(b) The animals shall be suitably housed in hygienic surroundings and necessary provision made for removal of excreta and foul smell.

(c) The applicant shall provide for suitable arrangements for preparation of animal feed.

(d) The applicant shall provide for suitable arrangements for quarantining of all animals immediately on their receipt in the institution.

(e) The animals shall be periodically examined for their physical fitness.

(f) The applicant shall provide for isolation of sick animals as well as animals under test.

(g) The applicant shall ensure compliance with the requirements of the Prevention of Cruelty to Animals Act, 1960 .

(h) The applicant shall make proper arrangements for the disposal of the carcasses of animals in a manner as not to cause hazard to public health.

(4) The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of drugs or cosmetics intended to be tested which shall be adequate in the opinion of the approving authority.

(5) The testing of drugs or cosmetics, as the case may be, shall be under the active direction of a person whose qualifications and experience are considered adequate in the opinion of the approving authority and who shall be held responsible for the reports of test or analysis issued by the applicant.

(6) The testing of drugs or cosmetics, as the case may be, for identity, purity, quality and strength shall be carried out by persons whose qualifications and experience of testing are adequate in the opinion of the approving authority.

(7) The applicant shall provide books of standard recognised under the provisions of the Act and the rules made thereunder and such books of reference as may be required in connection with the testing or analysis of the products for the testing of which approval is applied for.

<u>150D.</u> Duration of approval :-

- An approval granted in Form 37 or renewed in Form 38 unless sooner suspended or withdrawn, shall be valid up to the 31st December of the year following the year in which it is granted or renewed.

Provided that if an application for the renewal of an approval in Form 37 is made before its expiry or if the application is made within six months of its expiry after the payment of the additional inspection fee, the approval shall continue to be in force until orders are passed on the application and the approval shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.

150E. Conditions of approval :-

- An approval in Form 37 shall be subject to the following general conditions:

(a) The institution granted approval under this Part (hereinafter referred to as the approved institution) shall provide and maintain a n adequate staff and adequate premises and equipment as specified in Rule 150C.

(b) The approved institution shall provide proper facilities for storage so as to preserve the properties of the samples to be tested by it.

(c) The approved institution shall maintain records of tests for identity, purity, quality and strength carried out on all samples of drugs, or cosmetics and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of substances for which an expiry date is assigned for a period of two years from the expiry of such date and in the case of other substances for a period of six years.

(d) The approved institution shall allow the Inspector appointed under this Act to enter with or without prior notice the premises where the testing is carried on and to inspect the premises and the equipment used for test and the testing procedures employedThe instution shall allow the Inspectors to inspect the registers and records maintained under these rules and shall supply to such Inspectors such information as they may require for the purpose of ascertaining whether the provisions of the Act and rules made thereunder have been observed.

(e) The approved institution shall from time to time report to the approving authority any changes in the person-in-charge of testing

of drugs or cosmetics or in the expert staff responsible for testing as the case may be and any material alterations in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant of renewal of approval.
(f) The approved institution shall furnish reports of the results of tests or analysis in Form 39.
(g) In case any sample of a drug or a cosmetic is found on test to be not of standard quality, the approved institution shall furnish the approving authority [and the licensing authority of the State where the manufacturer and/or sender of the drug or cosmetic is located] with a copy of the test report on the sample with the protocols of tests applied.
(h) The approved institution shall comply with the provisions of the Act and rules made thereunder and with such further requirements, if any, as may be specified in the rules subsequently made under Chapter IV of the Act of which the approving authority has given the approved institution not less than four months notice.
(i) The approved institution shall maintain an Inspection Book to enable the Inspector to record his impressions or defects noticed.

150F. Inspection before grant of approval :-

- Before an approval in Form 37 is granted, the approving authority shall cause the institution at which the testing of drugs or cosmetics, as the case may be, is proposed to be carried out to be inspected jointly by the Drugs Inspectors of the Central Drugs Standard Control Organisation and the State Drugs Control Organisation who shall examine the premises and the equipment intended to be used for testing of drugs or cosmetics and inquire into the professional qualifications of the expert staff to be employed.

150G. Report of Inspection :-

- The Drugs Inspector mentioned in Rule 150F shall forward to the approving authority a detailed report of the results of the inspection.

150H. Procedure of approving authority :-

.-
(1) If the approving authority after such further enquiry, if any, as

he may consider necessary, is satisfied that the requirements of the rules made under the Act have been complied with and that
(2) If the approving 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 an approval could be granted.

150I. Further application after rejection :-

- If within a period of six months from the rejection of an application for approval, the applicant informs the approving authority that the conditions laid down have been satisfied and deposits inspection fee of rupees fifty, the approving authority may, if, after causing a further inspection to be made, he is satisfied that the conditions for grant of approval have been complied with, grant the approval in Form 37.

150J. Renewal :-

- On an application being made for renewal the approving authority may cause an inspection to be made and if satisfied that the conditions of the approval and the rules made under the Act are and shall continue to be observed shall issue a certificate of renewal in Form 38.

150K. Withdrawal and suspension of approvals :-

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(1) The approving authority may, after giving the approved institution an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, withdraw an approval granted under this Part or suspend it for such period as he thinks fit either wholly or in respect of some of the categories of drugs or items of cosmetics to which it relates, if in his opinion the approved institution had failed to comply with any of the conditions of the approval or with any provision of the Act or the rules made thereunder.
(2) Any approved institution whose approval has been suspended or withdrawn may within three months of the date of the order, appeal to the State Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by it in this behalf and notified in the Official Gazette.]

PART 16 MANUFACTURE FOR SALE OF AYURVEDIC (INCLUDING

SIDDHA) OR UNANI DRUGS

151. Manufacture on more than one set of premises :-

- If Ayurvedic (including Siddha) or Unani drugs are manufactured on 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.

152. Licensing authorities :-

- For the purpose of this Part the State Government shall appoint such licensing authorities and for such areas as may be specified in this behalf by notification in the Official Gazette.

153. Application for licence to manufacture Ayurvedic (including Siddha) or Unani drugs :-

(i) An application for the grant or renewal of a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 24-D to the licensing authority along with "a fee of rupees one thousand".
Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry.
Provided further that the applicant may apply for renewal after the expiry of one month but within three months of such expiry in which case "the fee payable for renewal of such license shall be rupees one thousand and two hundred plus an additional fee of rupees six hundred".
(ii) "a fee of rupees three hundred" shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.

153A. Loan Licence :-

(i) An application for the grant or renewal of a loan licence to manufacture for sale of any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 25-E to the licensing authority along with "a fee of rupees six hundred".
Explanation- For the purpose of this rule, a loan licence means a licence which a licensing authority may issue to an applicant who

does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licensee in Form 25-D.
Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry.
Provided further that the applicant may apply for renewal after the expiry of one month, but within three months of such expiry in which case "the fee payable for renewal of such license shall be rupees six hundred plus an additional fee of rupees three hundred".
(ii) "A fee of rupees one hundred and fifty" shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.]

154. Form of licence to manufacture Ayurvedic (including Siddha) or Unani drugs :-

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(1) Subject to the conditions of Rule 157 being fulfilled, a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25-DThe licence shall be issued within a period of three months from the date of receipt of the application.
(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic (including Siddha) or Unani systems of medicine, as the case may be, which the State Government may approve in this behalf.

154A. Form of loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani drugs :-

[-
(1) A loan licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25-E.
(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic (including Siddha) or Unani systems of medicine, as the case may be, which the State Government may approve in this behalf.
(3) 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.]

155. Certificate of renewal :-

.- The certificate of renewal of a licence in Form 25-D shall be issued in Form 26-D.

155A. Certificate of renewal of a loan licence :-

- The certificate of renewal of a loan licence in Form 25-E shall be issued in Form 26-E.]

155B. Certificate of award of G.M.Pof Ayurveda, Siddha and Unani Drugs. :-

The certificate of Good Manufacturing Practices (GMP) to manufacturers of Ayurved-Siddha or Unani drugs shall be issued to licensee who comply with the requirements of Good Manufacturing Practices (GMP) of Ayurveda, Siddha and Unani drug as laid down in Schedule T.

156. Duration of licence :-

An original licence in Form 25-D or a renewed licence in Form 26-D, unless sooner suspended or cancelled shall be "Valid for a period of three years from the date of its issue" or renewed.
Provided that if the application for the renewal of a licence is made before its expiry or within one month of its expiry, or if the application is made within three months of its expiry after payment of the "additional fee of rupees five hundred", the licence shall continue to be in force until orders are passed on the applicationThe licence shall be deemed to have expired, if application for its renewal is not made within three months of its expiry.

156A. Duration of loan licence :-

An original loan licence in Form 25-E or a renewed loan licence in Form 26-E, unless sooner suspended or cancelled, shall be "valid for a period of three years from the date of its issue" or renewed. \
Provided that if the application for the renewal of a loan licence is made in accordance with Rule 153A, the loan licence shall continue to be in force until orders are passed on the applicationThe licence shall be deemed to have expired, if application for its renewal is not made within three months of its expiry.]

157. Conditions for the grant or renewal of a licence in Form 25-D :-

- Before a licence in Form 25-D is granted or renewed in Form 26-D, the following conditions shall be complied with by the applicant, namely-

(1) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be carried out in such premises and under such hygienic conditions as are specified in Schedule T.

"(1-A) For getting a certificate of Good Manufacturing Practices of Ayurveda Siddha-Unani drugs, the applicant shall make an application on a plain paper, providing the information on existing infrastructure of the manufacturing unit, and the licensing authority shall after verification of the requirements as per Schedule T", issue the certificate within a period of 3 months in Form 26E-I",

(2) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole-time employee and who possesses the following qualifications, namely-

(a) a degree in Ayurveda or Ayurvedic Pharmacy, Siddha or Unani system of medicine, as the case may be, conferred by a University, a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognised by the Central Government or a State Government for this purpose, or

(b) a diploma in Ayurveda, Siddha or Unani system of medicine granted by a State Government or an Institution recognised by the Central Government for this purpose, or

(c) a graduate in Pharmacy or Pharmaceutical Chemistry or Chemistry or Botany of a University recognised by the Central Government with experience of at least two years in the manufacture of drugs pertaining to the Ayurvedic or Siddha or Unani system of medicine, or

(d) a Vaid or Hakim registered in a State Register of Practitioners of indigenous systems of medicines having experience of at least four years in the manufacture of Siddha or Unani drugs, or

(e) a qualification as Pharmacist in Ayurvedic (including Siddha) or Unani systems of medicine, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani drugs as may be recognised by the Central Government.

(3) The competent technical staff to direct and supervise the manufacture of Ayurvedic drugs shall have qualifications in

Ayurveda and the competent technical staff to direct and supervise the manufacture of Siddha drugs and Unani drugs shall have qualifications in Siddha or Unani, as the case may be.

158. Conditions of licence :-

- A licence in Form 25-D shall be subject to the conditions stated therein and to the following further conditions, namely-
(a) The license shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw materials and finished products.
(b) The licensee shall allow an Inspector appointed under the Act to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises, to take samples of the raw materials as well as the finished products, and to inspect the records maintained under these rules.
[(c) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.]

158A. Conditions of loan licence :-

[- A licence in Form 25-E shall be subject to the following further conditions, namely;
(a) The licence in Form 25-E shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25-D whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.
(b) The licensee shall comply with the provisions of the Act and of the rules and with such further requirements if any, as may be specified
(c) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or any other person on his behalf, of the raw materials and finished products.
(d) The licensee shall allow an Inspector appointed under the Act 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 have been observed.]
[(e) The licensee shall maintain an Inspection Book in Form 35 to

enable an Inspector to record his impressions and the defects noticed.]

159. Cancellation and suspension of licences :-

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(1) The licensing authority may, after giving the licensee an opportunity to show cause, within a period which shall not be less than fifteen days from the date of receipt of such notice, 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 drugs 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 the rules made thereunder.
(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within a period of three months from the date of receipt of the order which shall, after considering the appeal, decide the same.

160. Identification of raw materials :-

- Raw materials used in the preparation of Ayurvedic (including Siddha) or Unani drugs shall be identified and tested, wherever tests are available for their genuineness, and records of such tests as are carried out for the purpose and the methods thereof shall be maintained.

PART 16A APPROVAL OFINSTITUTIONS FOR CARRYING OUT TESTS ON AYURVEDIC, SIDDHA AND UNANI DRUGS AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA AND UNANI DRUGS

160A. Application for grant of approval for testing Ayurvedic, Sidciha and Unani drugs :-

.- Application for grant or renewal of approval for carrying out tests for identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of the said Ayurvedic, Siddha and Unani drugs, shall be made in Form 47 to the Licensing Authority appointed by the State Government for the purposes of Part XVI, XVII or XVIII ofthese rules, as the case may

beand referred to as the "approving authority" under this part and shall be accompanied by an inspection fee of six thousand rupees in respect of the Ayurvedic, Siddha, Unani drugs specified in the books prescribed in First Schedule to the Act: Provided that the applicant shall furnish to the approving authority such additional information as may be required by it in connection with the application in Form 47 : Provided further that if the applicant applies for renewal of approval after its expiry but within six months of such expiry, the inspection fee payable shall be six thousand rupees plus an additional inspection fee at the rate of one thousand rupees per month in the case of testing of Ayurvedic, Siddha and Unani drugs specified in First Schedule to the Act.
Explanation.-For the purpose of this Part, the words "Ayurvedic, Siddha and Unani drugs" shall also mean and include the raw materials used in the manufacture of Ayurvedic, Siddha and Unani drugs, as the case may be.

160B. Form in which approval to be granted for carrying out texts on Ayurvedic, Siddha and Unani drugs on behalf of licensees for manufacture of Ayurvedic, Siddha and Unani drugs and conditions for grants or renewal of such approval :-

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(1) Approval for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs shall be granted in Form 48.
(2) Before approval in Form 48 is granted or renewed, the following conditions shall be complied with by the applicants, namely:-
(i) The premises where the tests are carried out shall be well lighted and properly ventilated except where the nature of tests of any AyurvedicSiddha and Unani drug warrants otherwiseWherever necessary, the premises shall be air-conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests and microbiological tests.
(ii)
(a) The applicant shall provide adequate space having regard to the nature and number of samples of drugs proposed to be tested : Provided that the approving authority shall determine from time to

time whether the space provided continues to be adequateProvided further that separate section shall be provided for (i) Chemistry, (ii) Pharmacognosy, (iii) Ayurveda, Siddha and Unani(iv) Microbiology, (v) Sample Room, (vi) Office-cum-Record Room, with proper partitions and minimum required area of 800 square feet.

(b)[564] "(i) Expert in Ayurveda or Siddha or Unani medicine who possesses a degree qualification recognized under Schedule II of Indian Medicine Central Council Act, 1970;

(ii) Chemist, who shall possess at least Bachelor Degree in Science or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University; and

(iii) Botanist (Pharmacognosist), who shall possess at least Bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University."

(c) \The applicant shall provide adequate equipments essential for carrying out tests for identity, purity, quality and strength Ayurvedic. Siddha and Unani drugs as per pharmacopoeial standards or other available standards.

1. \Alcohol determination apparatus complete set.
2. \Volatile oil determination apparatus.
3. \Boiling point determination apparatus.
4. \Melting point determination apparatus.

5Refractometer.

6Polarimeter.

7Viscometer (Ostwalds, Redwood viscometer).

8Tablet disintegration apparatus.

9Moisture determination apparatus (1C filtrator).

10U.VSpectrophotometer.

11Muffle furnace.

12Electronic Balance.

13Hot air oven(s) different range of temperature/vacuum oven.

14Refrigerator.

15Glass distillation apparatus/plant.

16Water supply demineralised exchange equipment/ Distillation equipment.

17Air conditioner.

18LPG Gas Cylinder with burners.

19Water bath (temperature controlled).

20Heating mantle (4) or as required.

21TLC apparatus with all accessories.

22Sieves 10 to 120 with sieve shaker.

23Centrifuge machine.

24Dehumidifier (where necessary).
25pH meter.
26G.L.Cwith F.Idetector.
27Silica crucible.
28Tablet friability tester.
29Tablet dissolution tester.
30. \Other related equipment, reagents, chemicals and glasswares.
1Microscope binocular.
\ 2Dissecting Microscope.
\ 3Microtome.
4Chemical balance.
5Microslide cabinet.
6Aluminium slide trays.
7Hot air oven.
8Occular Micrometer.
9Stage Micrometer.
10Camera Lucida Prism type and mirror type.
\ 11Hotplates.
12Refrigerator.
13LPG Cylinder with burners.
14Other related equiments, reagents, glasswares etc.
\ Note.-Instruments like HPLC, HPTLC, Atomic Absorption Spectrophotometer could be arranged by tie up with other laboratories. MICROBIOLOGY SECTION
1Laminar air flow bench (L.A.F)
2B.O.DIncubator.
3Plain Incubator.
4Serological water bath.
5Oven.
6Autoclave/Sterilizer.
7Microscope (high power).
8Colony counter.
9. \Other related equipment and reagents.
(3) \The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of Ayurvedic, Siddha and Unani drugs intended to be tested which shall be adequate in the opinion of the approving authority.
(4) \The testing of Ayurvedic, Siddha and Unani drugs, as the case may be. for identity, purity, quality and strength shall be carried out under the active direction of one of the experts stated in clause (b) of sub-rule (2) who shall be the person-in-charge of testing and shall be held responsible for the reports of test issued by the

applicant.
(5) The testing of Ayurvedic, Siddha and Unani drugs, as the case may be. for identity, purity, quality and strength shall be carried out by persons whose qualifications and experience of testing are adequate as stated in clause (b) of sub-rule (2).
(6) The applicant shall provide books of standard recognized under the provisions of the Act and the rules made thereunder and such books of reference as may be required in connection with the testing or analysis of the products for the testing of which approval is applied for.
(7) \The applicant shall provide list of standard AyurvedicSiddha and Unani drugs (Reference samples) recognized under the provisions of the Act and rules made thereunder and such reference samples kept in the laboratory may be required in connection with the testing or analysis of the products of which approval is applied for.

In the Drugs and Cosmetics Rules, 1945, in Rule 160B of sub-rule (2), in clause (ii), for sub-clause (b), the given clause shall be substituted for testing and analysis of Ayurveda, Siddha and Unani drugs namely in place of old clause as :- "(b) The applicant shall provide a list of persons who may be employed with him as experts, such as Chemist, Botanist and expert in Ayurveda/Siddha/Unani or Pharmacist who shall possess a degree i n Chemistry, Botany, Atyurved/Siddha/Unani/ Bachelor in Pharmacy from a recognized University or equivalent, with experience for 2 years for carrying out tests or analysis as per the AyurvedicSiddha and Unani pharmacopoeias." by the Drugs and Cosmetics Act, 1940 (23 of 1940)

160C. Duration of approval :-

.- An approval granted in Form 47 or renewed in Form 49 unless sooner suspended or withdrawn, shall be valid for a period of three years from the date on which it is granted or renewed : Provided that if an application for the renewal of an approval in Form 40 is made before its expiry or if the application is made within six months of its expiry after the payment of the additional inspection fee, the approval shall continue to be in force until orders to be contrary are passed on the application and the approval shall be deemed to have expired if the application for renewal is not made within six months of expiry.

160D. Conditions of approval :-

.- An approval in Form 48 shall be subject to the following conditions, namely:-

I. \The Institution granted approval under this Part (hereinafter referred to as the approved laboratory) shall provide and maintain adequate staff and adequate premises and equipment as specified in Rule 160-B.

II. \The approved laboratory shall provide proper facilities for storage so as to preserve the properties of the samples to be tested by it.

III. \The approved laboratory shall maintain records of tests for identity, purity, quality and strength carried out on all samples of Ayurvedic, Siddha and Unani drugs and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of substances for which date of expiry date is assigned; for a period of two years from such date of expiry and in the case of other substancesfor a period of three years.

IV. \The approved laboratory shall allow the Inspector appointed under this Act to enter with or without prior notice the premises where t he testing is carried out and to inspect the premises and t h e equipment used for test and the testing procedures employedThe laboratory shall allow the Inspectors to inspect the registers and records maintained under these rules and shall supply to such Inspectors such information as they may require for the purpose of ascertaining whether the provisions of the Act and rules made thereunder have been observed.

V. \The approved laboratory shall from time to time report to the approving authority any changes in the person-in-charge of testing of Ayurvedic, Siddha and Unani drugs or the expert staff responsible for testing, as the case may be, and any material alterations in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant or renewal of approval.

VI. \The approved laboratory shall furnish reports of the results of tests or analysis in Form 50.

VIIIn case any sample of Ayurvedic, Siddha and Unani drug is found on test to be not of standard quality, the approved laboratory shall furnish to the approving authority and the licensing authority of the State where the manufacturer and/or sender of the Ayurvedic, Siddha and Unani drugs is located, a copy of the test

report on the sample with the proiocols of tests applied.
VIIIThe approved laboratory shall comply with the provisions of the Act and rules made thereunder and with such further requirements, if any. as may be, specified in the rules made from time to time under Chapter IV- A of the Act of which the approving authority has given the approved laboratory not less than four months notice.
IX. \The approved laboratory shall maintain an inspection book to enable the Inspector to record his impression or defects notices.

160E. Inspection before grant of approval :-

.-Before an approval in Form 48 is granted, the approving authority shall cause the laboratory at which the testing of Ayurvedic, Siddha and Unani drugs, as the ease may be, is proposed to be carried out to be inspected jointly by the Inspectors appointed or designated by the Central Government and State Government for this purpose, who shall examine the premises and the equipment intended to be used for testing of drugs and verify into the professional qualifications of the expert staff who are or may be employed by the laboratory.

160F. Report of inspection :-

.-The Inspectors appointed by the Central Government as stated in Rule 160-E shall forward hi the approving authority a detailed report of the results of the inspection.

160G. Procedure of approving auturity :-

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(1) If the approving authority after such further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules made under the Act have been complied with and that the conditions of the approval and the rules made under the Act have been observed, it shall grant approval in Form 48.
(2) If the approving authority is not so satisfied, it shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which shall be satisfied before approval could be granted.

160H. Application after rejection :-

. -If within a period of six months from the rejection of an

application for approval, the applicant informs the approving authority that the conditions laid down have been satisfied and deposits inspection fee of two thousand rupees, the approving authority may, if, after causing a further inspection to be made and after being satisfied that the conditions for grant of approval have been complied with, grant the approval in Form 48.

160I. Renewal :-

. -On an application being made for renewal, the approving authority shall, after causing an inspection to be made and if satisfied that the conditions of the approval and the rules made under the Act have been complied with, shall issue a certificate of renewal in Form 49.

160J. Withdrawal and suspension of approvals :-

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(1) The approving authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, withdraw an approval granted under this part or suspend it for such period as it thinks fit either wholly or in respect of testing of some of the categories of Ayurvedic, Siddha and Unani drugs to which it relates, if in his opinion the approved laboratory had failed to comply with any of the conditions of the approval or with any provision of the Act or the rules made thereunder.
(2) Any approved laboratory, whose approval has been suspended or withdrawn, may, within three months of the date of the order of suspension or withdrawal, appeal to the State Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by the Department of Indian Systems of Medicine and Homoeopathy, Government of India in this behalf and notified in the Official Gazette;".

PART 17 [LABELLING, PACKING AND LIMIT OF ALCOHOL IN] AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

161. Labelling, packing and limit of alcohol :-

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(1) There shall be conspicuously displayed on the label of the container or package of an Ayurvedic (including Siddha) or Unani drug, the true list of all the ingredients used in the manufacture of

t h e preparation together with the quantity of each of the ingredients incorporated therein and a reference to the method of preparation thereof as detailed in the standard text and Adikarana, as are prescribed in the authoritative books specified in the First Schedule of the Act.

Provided that if the list of ingredients contained in the medicine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with the packing and reference be made to this effect on the label.

(2) The container of a medicine for internal use made up ready for t h e treatment of human ailments shall, if it is made up from a substance specified in Schedule E(1), be labelled conspicuously with the words Caution: to be taken under medical supervision both in English and Hindi languages.

(3) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Ayurvedic (including Siddha) or Unani drug and on any other covering in which the container is packed, namely:

(i) The name of the drugFor this purpose the name shall be the same as mentioned in the authoritative books included in the First Schedule of the Act.

(ii) A correct statement of the net content in terms of weight, measure or number as the case may beThe weight and volume shall be expressed in metric system.

(iii) The name and address of the manufacturer.

(iv) The number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words Manufacturing Licence Number or Mfg. Lic.No. or "M.L.".

(v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot" or any distinguishing prefix.

(v i) The date of manufactureFor this purpose the date of manufacture shall be the date of completion of the final products, or the date of bottling or packing for issue.

(vii) The words "Ayurvedic medicine" or "Siddha medicine" or "Unani medicine" as the case may be.

(viii) The words "FOR EXTERNAL USE ONLY" if the medicine is for

external application.
(ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) or (viii), further bear on the label of the container the words "Physicians sampleNot to be sold" which shall be overprinted.
[(ix)
(a) Preparation (Asavas) with high content of alcohol as base.

(b) Preparations containing self-generated alcohol.

	Name of the drug	Maximum content of	Maximum size
		alcohol (Ethylalcohol v/v)	of packing
(i)	Mritsanjivani Sura	16 per cent	30 ml.
(ii)	Mahadrakshava	16 per cent	120 ml.]

(4) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper-case or other covering used solely for the purpose of packing, transport in delivery.

161A. Exemption in labelling and packing provisions/or export of Ayurvedic (including Siddha) and Unani Drugs. :-

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(1) Label and packages or containers of Ayurvedic, Siddha and Unani Drugs for export may be adapted to meet the specific requirements of the law of the country to which the said drug is to be exported, but the following particulars shall appear in conspicuous position on the container in which drug is packed and on every other covering in which that container is packed, namely: (a) name of the Ayurvedic, Siddha and Unani drug (Single or compound formulations); (b) the name, address of the manufacturer and the number of licence under which the drug has been manufactured; (c) batch or lot number; (d) date of manufacture, along with date for "Best for use before"; (e) main ingredients, if required by the importing country; (f) for EXPORT: Provided that where Ayurvedic, Siddha and Unani single or compound drug not classified under the First Schedule or Schedule E-(l), 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 152.
(2) The provisions of Rule 161 shall not apply to a medicine made up "ready for treatment," whether after, or without, alteration, which is supplied on the prescription of a registered medical practitioner, if the medicine is labelled with the following particulars; namely:- (a) the name and address of the suppliers; (b) the words "For External Use Only", if the medicine is for external application."

PART 18 GOVERNMENT ANALYSTS AND INSPECTORS FOR AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

162. Duties of inspectors specially authorised to inspect the manufacture of Ayurvedic (including Siddha) or Unani drugs :-

- Subject to the instructions of the controlling authority, it shall be the duty of an Inspector authorised to inspect the manufacture of Ayurvedic (including Siddha) or Unani drugs-
(i) to inspect not less than twice a year, all premises licensed for manufacture of Ayurvedic (including Siddha) or Unani drugs within the area allotted to him and to satisfy himself that the conditions of the licence and the provisions of the Act and the rules made thereunder are being observed;
(ii) to sent forthwith to the controlling authority after each inspection a detailed report indicating whether or not the conditions of the licence and the provisions of the Act and the rules made thereunder are being observed;
(iii) to take samples of the drugs manufactured on the premises and send them for test or analysis in accordance with these rules;
(iv) to institute prosecutions in respect of violation of the Act and the rules made thereunder.

162A. 162A :-

Qualifications for State Drug Licensing Authority for licensing uf Ayurvedu, Siddha and Unani drugs:
(a) The Ayurvedic/Siddha/LJnani qualifications as per Schedule II of CCIM Act, 1970/BPharma (Ayurveda) of a recognized University.
(b) At least 5 years experience in the Ayurveda/Siddha/Unani drug manufacturing or testing of Ayurvedic, Siddha and Unani drugs or enforcement of provisions of Chapter IV-A of the Drugs and Cosmetics Act, 1940 and rules made thereunder or

teaching/research on clinical practice of Ayurveda/Siddha/Unani System.

163. Procedure for despatch of sample to Government Analyst and its receipt by the Government Analyst :-

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(1) Sample for test or analysis shall be sent to the Government Analyst by registered post or by hand in a sealed package, enclosed together with a memorandum in Form 18-A in an outer cover addressed to the Government Analyst.

(2) The package as well as the outer cover shall be marked with a distinguishing number.

(3) A copy of the memorandum and a specimen impression of the seal used to seal the package shall be sent by registered post or by hand to the Government Analyst.

(4) On receipt of the package from an Inspector, the Government Analyst or an Officer authorised by him in writing in this behalf shall open the package and shall also record the conditions of the seals on the package.

(5) After the test or analysis has been completed, one copy of the results of the test or analysis shall be supplied forthwith to the sender in Form 13-AA copy of the result in Form 13-A shall be sent simultaneously to the controlling authority and to the Drugs Controller, India.

164. Method of test or analysis to be employed in relation to Ayurvedic (including Siddha) or Unani drugs :-

.- The method of test or analysis to be employed in relation to an Ayurvedic (including Siddha) or Unani drug shall be such as may be specified in the Ayurvedic (including Siddha) or Unani Pharmacopoeia, or if no such pharmacopoeias are available or if no tests are specified in such pharmacopoeias, such tests as the Government Analyst may employ, such tests being scientifically established to determine whether the drug contains the ingredients as stated on the label.

165. Qualifications of Government Analyst :-

.- A person who is appointed a Government Analyst under Section 33F of the Act shall be a person possessing the qualifications prescribed in Rule 44 or a degree in Ayurveda, Siddha or Unani

system, as the case may be, conferred by a University, a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognised by the Central or State Government, as the case may be, for this purpose and has had not less than three years post-graduate experience in the analysis of drugs in a laboratory under the control of (i) a Government Analyst appointed under the Act, or (ii) a Chemical Examiner to Government, or (iii) the head of an institution specially approved for the purpose by the appointing authority.

166. Duties of Government Analyst :-

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(1) The Government Analyst shall analyse or test or cause to be analysed or tested such samples of Ayurvedic (including Siddha) or Unani drugs as may be sent to him by Inspectors or any other persons or authority authorised by the Central Government or a State Government under the provisions of Chapter IVA of the Act and shall furnish reports of the results of test or analysis in accordance with these rules.

(2) A Government Analyst appointed under Section 34F shall from tune to time forward to the Government reports giving the results of analytical work and research with a view to their publication at the discretion of the Government.

167. Qualifications of Inspector :-

[- A person who is appointed an Inspector under Section 33G shall be a person who-

(a) has the qualifications laid down under Rule 49 and shall have undergone practical training in the manufacture of Ayurvedic (including Siddha) or Unani drug, as the case may be; or

(b) has a degree in Ayurvedic or Siddha or Unani system or a degree in Ayurveda Pharmacy, as the case may be, conferred by a University or a State Government or a Statutory Faculty, Council or Board of I Indian Systems of Medicine recognised by the Central Government or the State Government for this purpose; or

(c) has a diploma in Ayurveda, Siddha or Unani Systems, as the case may be, granted by a State Government or an Institution recognised by the Central Government or a State Government for this purpose.]]

PART 19 STANDARDS OF AYURVEDIC SIDDHA AND UNANI DRUGS

168. Standards to be complied with in manufacture for sale or for distribution of Ayurvedic, Siddha and Unani Drugs :-

169. Permitted Excipients :-

. Permitted Excipients, i.eadditives, preservatives, antioxidants, coloring agents, flavouring agents, alternate sweeteners specified in column (2) of the Table below are permitted in Ayurveda or Siddha or Unani drugs as per reference standards or grade under the prevention of Food Adulteration Act (PFA), Indian Pharmacopoeia (IP), British Pharmacopoeia (UP), United States National Formulary (USNF) and others as mentioned in column (3) of the Table, namely :

1Additives used in various processes and to formulate dosage form shall be mentioned clearly with quantity in the flow sheet and the record shall be maintained by the manufacturing unit.

2 Manufacturers shall be responsible to ensure rationality, safety and quantity of various additives used in the formulationThis will be as per IP/BP/USP/PFA/or other standard reference book."