CONTENT

1. History
2. List Of Amending Acts And Adaptation Order
3. Objectives
4. Part I &II
5. Definitions
6. Administration Of The Act And Rules
7. Salient features of the Drugs and Cosmetics (Amendment) Act, 2008
8. Provision of the act for import, sale, manufacturing & labeling & packaging
9. Questions

HISTORY

- POSITIN TILL 1930 : India was largely dependent on import of modern medicines until after first word war.

- In August 1930 the government of India appointed a drug Enquiry Committee under the chairmanship of colonel R.N. Chopra, to go in to the question of adulterated & substandard drugs sold in country & to recommend step by which this menace could be control.

- The Drug Enquiry Committee submitted its report in 1931,the government of India could not give effect to its recommendation till 1937.

- After passing of the government of India Act,1935, drug became provincial subject & therefore center could pass law in respect of only imports.

- The drug import Bill was prepared & placed for consideration before the assembly in 1939. This was not acceptable to the public & provinces for uniform & comprehensive legislation. This led to the introduction of the Indian Drug Bill in the Central Legislature. It was passed & received assent of Governor General in Council & became Drug Act in 1940

LIST OF AMENDING ACTS AND ADAPTATION ORDER

1. The Repealing and Amending Act, 1949 (40 of 1949).
2. The Adaptation of Laws Order, 1950.
3. The Part B States (Laws) Act, 1951 (3 of 1951)
4. The Drugs (Amendment) Act, 1955 (11 of 1955)
5. The Drugs (Amendment) Act, 1960 (35 of 1960)
6. The Drugs (Amendment) Act, 1962 (21 of 1962)
7. The Drugs and Cosmetics (Amendment) Act, 1964 (13 of 1964)
8. The Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972).
9. The Drugs and Cosmetics (Amendment) Act, 1982 (68 of 1982)
10. The Drugs and Cosmetics (Amendment) Act, 1986 (71 of 1986)
11. The Drugs and Cosmetics (Amendment) Act, 1995 (22 of 1995)
12. The Drugs and cosmetics (Amendment) Act, 2008

OBJECTIVES

To prevent **substandard** in drugs, presumably for treatment. maintaining high standards of medical

To regulate the **import, manufacture, distribution and sale** of drugs & cosmetics through licensing.

Manufacture, distribution and sale of drugs and cosmetics by **qualified persons only**.

Act has nothing to do with the **Excise duty**

To regulate the manufacture and sale of **Ayurvedic, Siddha and Unani drugs.**

To establish **Drugs Technical Advisory Board(DTAB)** and **Drugs Consultative Committees(DCC)** for Allopathic and allied drugs and cosmetics.

Part I Drug & cosmetic act,1940

CHAPTER I : INTRODUCTORY

CHAPTER II : THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUG LABORATORY, THE DRUGS CONSULTATIVE COMMITTEE

CHAPTER III : IMPORT OF DRUGS AND COSMETICS

CHAPTER IV : MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

CHAPTER IV-A : PROVISIONS RELATING TO AYURVEDIC, SIDDHA AND UNANI DRUGS

CHAPTER V: MISCELLANEOUS

Part 2: Drug & Cosmetic Rules,1945

PART I : PRELIMINARY

PART II : THE CENTRAL DRUGS LABORATORY

PART III (Rules 9 to 20)

PART IV : IMPORT [AND REGISTERATION]

PART V: GOVERNMENT ANALYSTS, INSPECTORS, LICENCING AUTHORITIES AND CONTROLLING AUTHORITIES

PART VI : SALE OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

PART VI-A : SALE OF HOMEOPATHIC MEDICINES

PART VII : MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS OTHER THAN HOMOEOPATIC MEDICINES

PART VIII : MANUFACTURE FOR EXAMINATION, TEST OR ANALYSIS

PART IX : LABELLING AND PACKING OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

PART X : SPECIAL PROVISIONS RELATING TO BIOLOGICAL ANDOTHER SPECIAL PRODUCTS

PART XA : IMPORT OF MANUFACTURE OF NEW DRUG FOR CLINICAL TRIALS OR MARKETING

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

PART XI : EXEMPTIONS

PART XII : STANDARDS

PART XIII : IMPORT OF COSMETICS

PART XIV : MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

PART XV : LABELLING, PACKING AND STANDARDS OF COSMETICS

PART XV : MANUFACTURE FORSALE OF AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

PART XVII : LABELLING, PACKING AND LIMIT OF ALCOHOL IN] AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

PART XVIII-GOVERNMENT ANALYSIS AND INSPECTORS FOR AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

PART XIX : STANDARDS OF AYURVEDIC, SIDDHA AND UNANI DRUGS

DEFINITIONS

"COSMETIC" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applicated to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

DRUG

(I) All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(II) Such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette

(III) All substances intended for use as components of a drug including empty gelatin capsules; and

IV) Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board

Misbranded drugs :

(a) if it is so **colored, coated, powdered or polished** that damage is concealed or if it is made to appear of **better or greater therapeutic** value than it really is; or

(b) if it is **not labeled** in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any **false claim** for the drug or which is false or misleading in any particular.

Adulterated drug :

(a) if it consists, in whole or in part, of any **filthy, putrid** or **decomposed** substance; or

(b) if it has been prepared, packed or stored under **insanitary conditions** whereby it may have been contaminated with filth or whereby it may have been rendered **injurious to health**; or

(c) if its container is composed in whole or in part, of any **poisonous or deleterious substance** which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a **colour** other than one which is prescribed; or

(e) if it contains any **harmful or toxic substance** which may render it injurious to health; or

(f) if any substance has been **mixed** therewith so as to **reduce its quality or strength.**

Spurious drugs :

(a) if it is **imported** under a name which belongs to another drug; or

(b) if it is an **imitation** of, or a **substitute** for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the **name of another drug** unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if it has been **substituted wholly or in part** by another drug or substance; or

(d) if it purports to be the product of a manufacturer of whom it is not truly a product.

Manufacture :

In relation to any drug or cosmetic, it includes any process or part of a process for **making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting** any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

Patent or Proprietary medicine :

A drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is **not included in the edition of the Indian Pharmacopoeia** for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government.

Government Analysts.

(1) The State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the state and in respect of such drugs or [classes of drug or such cosmetics or classes of cosmetics] as may specified in the notification.

(2) The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or [classes of drugs or such cosmetics or classes of cosmetics] as may be specified in the notification

(3) Notwithstanding anything contained in sub-section (1) or sub-section (2), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

(4) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (1) or subsection (2) of this section.

Inspectors.

(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such person as it thinks fit, having the prescribed qualification, to be Inspectors for such areas as may be assigned to them by the Central Government or State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or [classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest [in the import, manufacture or sale of drugs or cosmetics] shall be appointed to be an Inspector under this section.

(4) Every Inspector shall be deemed to be public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860), and shall be officially subordinate to such authority [having the prescribed qualification] as the Government appointing him may specify in this behalf.

STANDARDS OF QUALITY

(a) in relation to a drug, that the drug complies with the standard set out in [the Second Schedule], and

(b) in relation to a cosmetic, that the cosmetic compiles with such standard as may be prescribed.

Administration of the act and rules

A) Advisory :

1)Drugs Technical Advisory Board-DTAB
2)Drugs Consultative Committee-D.C.C.

B) Analytical :

1)Central Drugs Laboratory - CDL
2)Drug Control Laboratory in states
3)Government Analysts

C) Executives :

1)Licensing authorities
2)Controlling authorities
3)Drug Inspectors

D) Schedule N
E) Schedule M
F) Schedule Y

Drugs Technical Advisory Board(DTAB)

Ex-Officio:

(i) Director General of Health Services (Chairman)
(ii) Drugs Controller, India

(iii)Director of the Central Drugs Laboratory, Calcutta
(iv) Director of the Central Research Institute, Kasauli

(v)Director of Indian Veterinary Research Institute, Izatnagar
(vi) President of Medical Council of India

(vii) President of the Pharmacy Council of India
(viii)Director of Central Drug Research Institute, Lucknow

Nominated:

1. Two persons by the Central Government from among persons who are in charge of drugs control in the **States**

2. One person by the Central Government from the **pharmaceutical industry**

3. Two persons holding the appointment of **Government Analyst** under this Act, to be nominated by the Central Government

Elected:

1. One person, to be elected by the Executive Committee of the **Pharmacy Council of India**, from among **teachers** in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;

2. One person, to be elected by the Executive Committee of the **Medical Council of India**, from among **teachers** in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;

3. One pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

4. One person to be elected by the Central Council of the **Indian Medical Association**;

5. One person to be elected by the Council of the **Indian Pharmaceutical Association**;

Functions:

I. To **advise** the Central Government and the State Governments on technical matters arising out of the administration of this Act.

II. Modification & Amendments in the Act with consultation of Board.

III. To carry out the other functions assigned to it by this Act.

(The nominated and elected members of the Board shall **hold office for three years**, but shall be eligible for re-nomination and re-election)

Drugs Consultative Committee(DCC)

- It is also an **advisory body** constituted by central government.

Constitution:

Two representatives of the **Central Government**

One representative of each **State Government**

Drugs Consultative Committee(DCC)

Functions:

- To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure **uniformity throughout India** in the administration of this Act.

- The Drugs Consultative Committee shall **meet when required** Has power to regulate its own procedure.

Central Drug Laboratory(CDL)

- Established in **Calcutta**, under the control of a director appointed by the Central Government.

Functions:

1. **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts.
2. Analytical **Q.C.** of the imported samples.

3. Collection, storage and distribution of **internal standards.**
4. Preparation of **reference standards** and their maintenance.

5. Maintenance of **microbial cultures.**
6. **Any other duties** entrusted by Central Government.

7. Acting as an **appellate authority** in matter of **DISPUTES.**
8. Training of drug analysis.

9. To advise the central drug control administration in respect of quality & toxicity.
10. To work out analytical specification of Monographs for IP & Homeopathic P.copoeia.

11. Analysis of cosmetics

Central drug testing Lab.(CDLT), CHENNAI, MUMBAI,GUWAHATI

N.B.:

- Biological & microbiological Test/Analysis are not carried out by C.D.L, sent to Directore of central Research Institute-Kasauli.
- Biological for Veterinary use sent to the Director, Indian Veterinary Research Institute, Izatnagar
- Test on condoms are carried out at the central Indian Pharmacopoeial laboratory, Ghaziabad

PROCEDURE

1. All samples of drugs/cosmetics sent to C.D.L. for analysis by court under registered post & sealed with copy of memorandum.

2. A copy of memorandum & specimen of impression of seal on packet sent separately by registration post.
3. On receipt of the packet, director/officer should record the conditions of seal on packet

4. On completion of test/analysis the director required to supply a report of the analysis.

Government analyst

- State government appoint persons as government analysts for the purpose of analysis/testing of samples of drugs & cosmetics.

- The central government may also appoint such person as a government analysts.

- Government analyst should have **NO** direct or indirect interest in Import, Manufacture OR Sale of drugs & cosmetics.

QUALIFICATION

A) For the analysis/testing of other than Biological(c/c1)

1. A graduate in Medicine OR Science OR Pharmacy OR Pharmaceutical chemistry & with at least 5 year post graduate experience in testing OR has completed two years training on testing of drugs, including in Sch.C in CDL.

2. A postgraduate degree in Medicine OR Science OR Pharmacy OR Pharmaceutical chemistry & with at least 3 year experience in testing OR has completed two years training on testing of drugs, including in Sch.C in CDL.

3. Holding associateship Diploma of the Instiution of Chemists with Analysis of drugs & Pharmaceuticals with at least 3 year experience in testing.OR has completed two years training on testing of drugs, including in Sch.C in CDL.

B) For the analysis/testing of Biological(Sch c/c1)

USED FOR HUMAN BEINGS

1. A graduate in Medicine OR Science OR Pharmacy OR Pharmaceutical chemistry. And trained either in physiology or bacteriology, Serology, pathology, pharmacology or Microbiology& with at least 5 year experience in testing of biological products & have at **least 6 months** training in Approvaled Laboratory.

2. A postgraduate degree in Medicine OR Science OR Pharmacy OR Pharmaceutical chemistry or assosiateship Diploma of the Institution of Chemists with Analysis of drugs & Pharmaceuticals.

3. And trained either in physiology or bacteriology, Serology, pathology, pharmacology or Microbiology& with at least 3 year experience in testing of biological products & have at least 6 months training in Approvaled Laboratory has completed two years training on testing of drugs, including in Sch.C in CDL.

C) For the analysis/testing of Biological for veterinary use

1. A graduate in veterinary Science OR General Science OR medicine OR Pharmacy.
   And atleast 5 year experience of testing.
2. A postgraduate in veterinary Science OR General Science OR medicine OR Pharmacy OR Pharmaceutical Chemistry.
   And atleast 3 year experience of testing.

DUTIES

1. To analyze & test sample of drugs & cosmetics sent by inspector or other persons & furnish reports.
2. To engage in any research work & forward the report to the government with a view to publication.

PROCEDURE

1. On receipt of samples the analyst should record the condition or the seal & compare it with the impression of the seal received separatly.

2. After completion of the analysis, a report in triplicate with full details should be supplied.

EXECUTIVES

i) LICENSING AUTHORITIES

❖FOR IMPORT: the central government appoints licensing authorities to issue licences for the import of drugs.

❖FOR MANUFACTURE & SALE: the state governments appoint licensing authorities for respective territories to issues licence for the respective & sale of drugs & for the manufacture & sale of drugs & for manufacture of cosmetic.

The licensing authorities are designated differently in different states. As

Drug controller

Director

Drug control Administration

Officer in charge, Drug control

Commissioner- FDCA

ii) CONTROLLING AUTHORITIES

All inspectors appointed shall be under the control of a controlling authority.

QUALIFICATION

- A graduate in Medicine OR Pharmacy OR Pharmaceutical chemistry (Clinical Pharmacology) OR Microbiology.

And at least 5 year experience in the manufacture or testing of drugs or enforcement of the Act.

DRUG INSPECTORS

- State government appoint persons as drug inspectors to inspect premises licensed for manufacture of drugs & cosmetics & sale of drugs.

- The central government may also appoint such persons.
- Drug inspectors should have no any financial interest in the import, manufacture or sale of drugs and cosmetics.

- All drug inspectors are public servant within the meaning of Indian Penal Code.

- Inspectors are required to keep all information's confidential & not to disclose

QUALIFICATION

A) TO INSPECT PREMISES MANUFACYURE OTHER THAN BIOLOGICAL & PREMISES ANUFACTURE BIOLOGICAL (C/G)

1. A degree in Pharmacy
2. Science or
3. Medicine (Clinical P.cology OR Microbiology)

Any qualification of above and-

A) Not less than 18 Months experience in manufacturing OR testing of the substances specified in Sch.C OR

B) Not less than 3 Years experience in the inspection of firm manufacturing any of the the substsnces specified in Sch.C

B) TO INSPECT PREMISES MANUFACYURE BIOLOGICAL (VETERINARY)

1. A graduate in veterinary Science OR General Science OR medicine OR Pharmacy. And 18 months experience in the manufacture OR testing of veterinary biological.

2. A graduate in veterinary Science OR General Science OR medicine OR Pharmacy OR Pharmaceutical Chemistry.
   And at least 3 year experience in the inspection of Firm Manufacturing veterinary biological.

DUTIES: classified under 2 heads

i) Inspection of premises, licensed for the sale of drugs.

ii) Inspection of premises licensed for the manufacture of drugs & cosmetics

Inspection of sale premises,

1. To inspect not less than once a year all shops within the area assigned to him

2. He checks whether the conditions of licences are being fulfilled or not.
3. To obtain & send sale samples for analysis.

4. To investigate any complaints
5. To institute prosecution
6. To maintain recored of all inspection.

7. To detain packages of imported drugs.
8. To enter & search where an offence is belived to be commited.
9. To exercise other duties as may be necessary

Inspection Of Manufacturing Premises

1. To inspect not less than once a year all shops within the area assigned to him. If manufacturer manufacturing biological drugs (C/C1), inspect plant, process, standardizing & testeing of drgs & method of storage & technical qualification of the staff.

2. To take sample & send for analysis
3. To check all record & registers.

4. To institute legal proceeding in case of breach of the Act.
5. To send detailed report of each inspection.

POWERS

1. Inspect any premises where drugs OR cosmetics being manufactured or sold or if biological product check plant, process & testing

2. Take samples of drugs OR cosmetics which are being manufactured or sold.
3. Enter and search any premises in which an offence is believed to be committed.

4. Examine & seize any records, registers & documents
5. Search any person, who he has reason to believe has secreted about any drug or cosmetic in respect of which an offence is being committed.

6. Stop & search any vehicle,vessel or other conveyance used for carring any drug or cosmaticin respect of which an offence being committed.
7. Exercise such other power as may be necessary

PROCEDURE

1. Whenever inspector take sample of drugs, he should inform the purpose in writing in the prescribed form.(No.17)

2. He shall tender the fair price in cash or credit.

3. If price is not accepted he should tender a receipt in prescribed form No.16

4. Divide the sample
   in four part if sample is taken from sales premises.
   in three part if sample is taken from manufacturing premises.
   If small container or likely to deteriorate, the inspector may take 3 or 4 such containers

5. Each part/container sealed & marked.
6. Allow the person to add his mark or seal to such part/containers.
7. Once part/container of the sample sent to the Govt. analyst, second is reserved for the court, third is sent to warrantor & fourth returned to person from whom sample is taken

8. Sample sent to Govt. Analyst by registration post or personally

9. Affter the report of analysis has been received from Gvt. Analyst. Drug inspector will decide any further action.

Salient features of the Drugs and Cosmetics (Amendment) Act, 2008

- Substantial **enhancement in punishment**
- **Life imprisonment** for offenders involved in manufacture, sale and distribution of spurious and adulterated drug likely to cause **grievous hurt**
- **Minimum** punishment of **seven years** which may extend to life imprisonment
- Provision for compensation to affected person

- Corresponding enhancement in punishment for **repeated offenders**
- **Cognizance** can be taken on the complaint of any gazette officer authorized by Central or State Government
- Cases to be tried by **Sessions Court**
- Designation of **special courts** for trial of offences in respect of adulterated and spurious drugs

- All offences relating to adulterated and spurious drugs made **cognizable and non bailable**
- Restrictions on bail – **Bail cannot be granted** unless public prosecutor is heard
- Certain offences made **compoundable**

Schedules to Drugs & Cosmetics Act

- To make available Standard Quality drug/ cosmetic to consumer.

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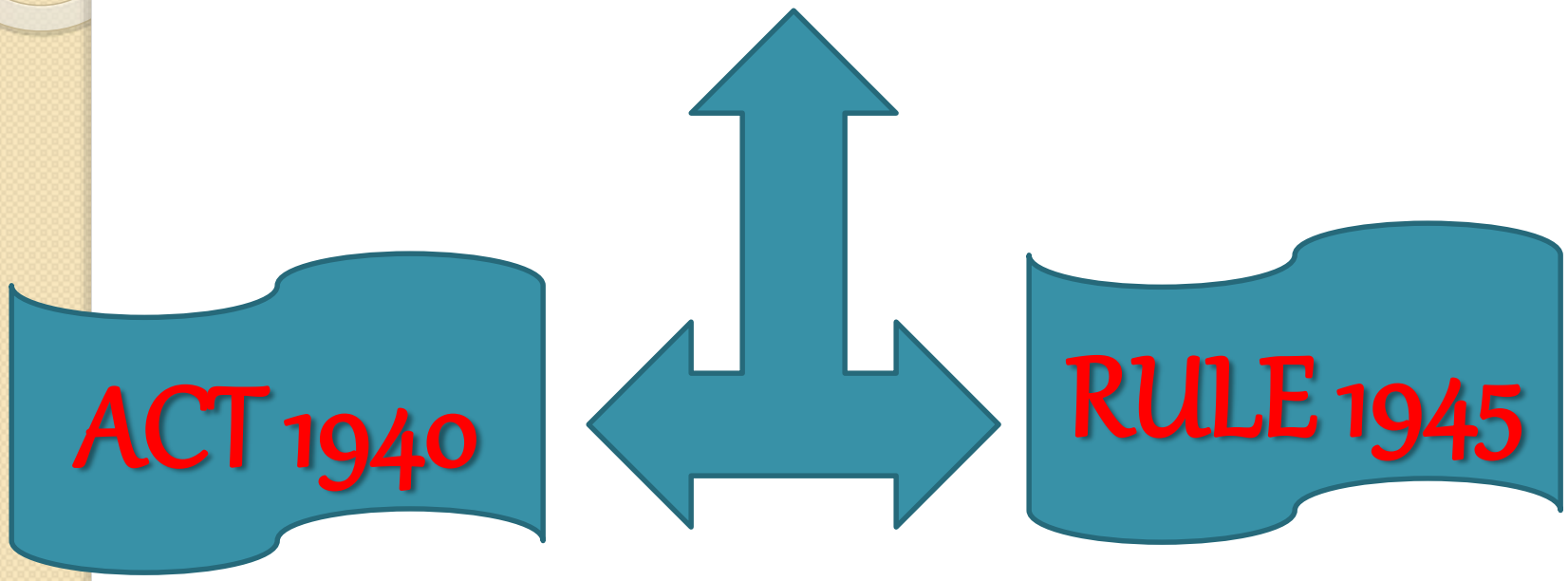
SCHEDULES



Schedules to the act

- **First schedule** – Names of **books** under **Ayurvedic** and **Siddha** systems

- **Second schedule** – **Standard to be complied** with by imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distribution

Name of few books under 1st Schedule: **AYURVEDA**

- Ayurvedic Formulary Of India (Part I)
- Arogya Kalpadruma
- Arka Prakasha
- Ayurveda Samgraha
- Bhaishajya Ratnavali
- Bhava Prakasha
- Charak Samhita
- Rasa Taringini
- Sahasrayoga
- Sushruta Samhita

Name of few books under 1st Schedule

SIDDHA

- Siddha Formulary Of India (Part I)
- Siddha Vaidya Thirattu
- Bhogar
- Pulippani
- Agasthiyar Paripuranam (400)
- Aga
- Nagamuni (200)
- Yogi Vatha Kaviyam (1500)

Name of few books under 1st Schedule

UNANI

- National Formulary Of Unani Medicine (Part I)
- Karabadin Qadri
- Karabadin Kabir
- Karabdain Azam
- Biaz Kabir Vol. II
- Kitab-ul-Taklis
- Mifta-ul-Aksir
- Al Karabadin

Schedules to the rules

SCHEDULE ‘A’

- *Proforma for application for the licenses, issue and renewal of licences, for sending memoranda under the act.*
- *There are total 50 forms or proforma.*

SCHEDULE ‘B’

- *Rates of fees for test or analysis by the Central Drug Laboratory or the Government Analyst.*

SCHEDULE ‘C’

- *List of **Biological and special products (Inject able)** applicable to special provisions.*
- *Examples are sera, vaccines, antigens, insulin, sterilized surgical ligature and suture, sterile disposable device for single use, antibiotics in injectable form etc.*
- *Prohibition of import after expiry of potency*
- *Labelled with the words ‘Caution: **It is dangerous to take this preparation except under medical supervision’***

SCHEDULE ‘C(1)’

- *List of Biological and special products **(non parentral)** applicable to special provisions.*
- *Examples are Drugs belonging to Digitalis and its preparation, Ergot and its preparation containing drugs,Vitamins and its preparation, Vaccines, In-vitro devices for HIV,HCV etc*
- *Prohibition of import after expiry of potency*
- *Labelled with the words ‘Caution: **It is dangerous to take this preparation except under medical supervision’***

SCHEDULE ‘D’

- ***Exemption of drugs from provision of import***

- ***Drugs come under Schedule D are:***

1) ***Substances not intended for medical use***
2) ***Substances which are used both as articles of food as well as drugs: -- All condensed or powdered milk. -- Farex, oats, latex and all other similar cereal preparations excepting those for parenteral use. -- Virol, bovril, chicken essence and all other similar predigested food. -- Ginger, Pepper, Cumin, Cinnamon and all other similar spices and condiments.***
3) ***Drugs and cosmetics imported for manufacture and export by units situated in “Special Economic Zone” as notified by the Govt. of India from time to time.***

SCHEDULE ‘D (I)’

- *Information required to be submitted by the manufacturer or his authorised agent with the application form for a registration certificate.*
- *The format shall be properly filled in and the detailed information, secret in nature,*
- *may be furnished on a Computer Floppy.*

SCHEDULE ‘D (II)’

- *Information required to be submitted by the manufacturer or his authorized agent with the Application Form for the registration of a bulk drug/formulation/special product for its import into India.*
- *The format shall be properly filled in and the detailed information, secret in nature,*
- *may be furnished on a Computer*

SCHEDULE ‘E’ (1)

- *List of poisonous substances under the **Ayurvedic , Siddha and Unani systems***

- *The container of a medicine for internal use made up ready for the 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 language.***

SCHEDULE ‘F’

(i) *Space, equipment and supplies required for a blood bank.*

(ii) *Minimum requirement for grant of license to procure blood components from whole human blood.*

SCHEDULE ‘F’ (1)

- *Part I - Provision applicable to the production of bacterial and viral vaccines.*
- *Part II - Provision applicable to the production of all sera from living animals.*
- *Part III - Provision applicable to the production and stand[illegible] diagnostic agents of*

SCHEDULE ‘F (II)’

- *Standards for Surgical Dressings*
- *Surgical dressings include bandage cloth, absorbent gauze, rolled bandage,etc*

SCHEDULE ‘F(III)’

- *Standards for Sterilised Umbilical tapes*

SCHEDULE ‘FF’

- *Standards for ophthalmic preparations*

- *Be sterile when dispensed or when sold except in case of those ophthalmic solutions and suspensions which are not specifically required to comply with the test for ‘Sterility’ in the Pharmacopoeia*
- *Labelled with words*

(a)Use within 1month of opening. Not for injection.

(b)Name and Concentration of Preservatives.

(c)Words like

(i) If irritation persist discontinue use and consult physician. Keep container tightly closed.

(ii)Do not touch the dropper tip/other dispensing tip to any surface

SCHEDULE ‘G’

- *List of substances required* ***to be used under medical supervision*** *and labelled accordingly*

- *Labelled with the words ‘Caution:* ***<u>It is dangerous to take this preparation except under medical supervision</u>’*** *– conspicuously printed and surrounded by a line within which there shall be no other words*

SCHEDULE ‘H’

- *List of substances **(prescription**) that should be sold by retail only on prescriptions of **R.M.P.***
- *Labelled with the symbol Rx and conspicuously displayed on the left top corner of the label.*
- *Labelled with the following words **‘To be sold by retail on the prescription of a Registered Medical Practitioner only.’***

SCHEDULE ‘J’

- *Diseases and ailments which a drug may not purport to prevent or cure or make claims to prevent or cure.*
- *Diseases under this schedule are*
  - *AIDS*
  - *Angina Pectoris*
  - *Diabetes*
  - *Cancer*
  - *Blindness*
  - *Deafness*
  - *Fairness of skin*
  - *Improvement in height of children/adults*
  - *Obesity etc*

SCHEDULE ‘K’

- *The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the Rules made there under to the extent and subject to the conditions specified in that Schedule.*
- *It include Quinine and other antimalarial drugs,*
- *Drugs supplied by RMP to his own patient,*
- *Drugs supplied by hospital or supported by government or local body,*
- *Substances which are used both as articles of food as well as drugs,*
- *Household remedies like aspirine tab,paracetamol tab,analgesic balm, gripe water for use of infants, etc.*

Schedule ‘M’

- *Requirements of manufacturing premises, **GMP requirements** of factory premises, plants and equipments.*
- *It includes:-*
- ***General requirements***

➢ *Location and surroundings- Free from open sewage,public lavatory, dust, smoke, excessive soot,obnoxious odour, chemical or biological emission*

➢ *Buildings and premises- Designs suitable for manufacturing operation and maintain hygiene.*

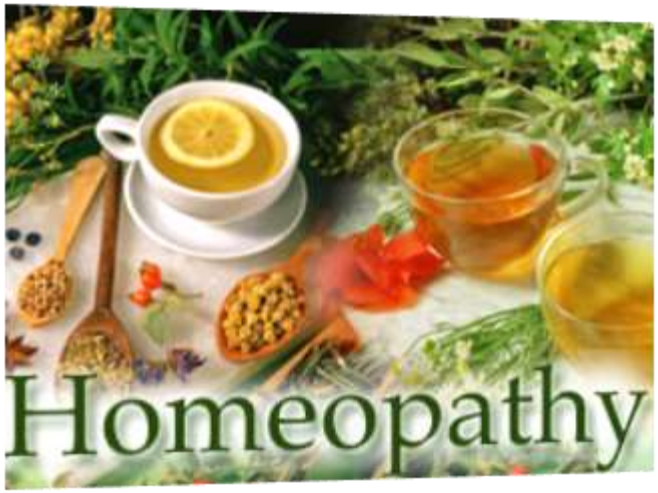
➢ *Water system- Validated system for water treatment to make it usable and free from microbial growth.*

➢ *Disposal of wastes- Disposal shall be according to Environment Pollution Control Board and as per*

- ***Warehousing area****- Designs allow sufficient and orderly warehousing of various categories of materials and products.*
- ***Production area****- Area shall be designed to allow the production preferably in uniflow with logical sequence of operation and avoiding the risk of cross contamination.*
- ***Ancillary area****- Rest and refreshment rooms shall be separate with changing storing clothes fascilities. Washing and toilet purposes shall be easily accessible.*
- ***Quality control area****- Lab independent of production area with separate and adequate space for each type of testing.*
- ***Manufacturing operation****- All operations shall be carried out under supervision of technical staff approved by Licensing Authority.*
- ***Documentation and record****- It shall specify the title, nature and purpose and laid out in orderly fashion.*

Schedule ‘M1’

- *Requirements of factory premises for manufacture of* ***Homeopathic medicines***



Schedule ‘M2’

- *Requirements of factory premises for manufacture of* ***cosmetics***

Schedule ‘M3’

- *Requirements of factory premises for manufacture of* ***medical devices***

SCHEDULE ‘N’

- *List of minimum equipment for the efficient running of a pharmacy*
- *Entrance shall bear an inscription “Pharmacy” in front*
- *Premises shall be separated from rooms for private use and it should be well built, dry,well lit and ventilated and of sufficient dimension to keep the goods separately.*

SCHEDULE ‘O’

- *Standard for disinfectant fluids*
- *The disinfectants shall be classified as follows:*

(A) ***Black fluids-*** *Homogeneous dark brown solution of coal tar acid or similar acids with or without hydrocarbons, and/or other phenolic compounds, and their derivatives.*

(B) ***White fluids-*** *Finely dispersed homogeneous emulsion of coal tar acid or similar acids with or without hydrocarbons, and/or other phenolic compounds, and their derivatives.*

SCHEDULE ‘P’

- *Life period of drugs*

- *Period in months (unless otherwise specified) between date of manufacture and date of expiry which the labelled potency period of the drug shall not exceed under the conditions of storage specified.*

SCHEDULE ‘P-1’

- *PACKING OF DRUGS*

- *The pack sizes of drugs meant for retail sale shall be as prescribed.*
- *Eg; The pack sizes for liquid Oral preparations shall be 30ml (paediatric only) 60 ml/100 ml/200 ml/450 ml.*

SCHEDULE ‘Q’

Part 1

- *List of dyes, colours and pigments permitted in cosmetics and soaps.*

Part 11

- *List of colours permitted in soaps.*

- *No Cosmetic and soaps shall contain Dyes, Colours and Pigments other than those specified by the Bureau of Indian Standards.*

SCHEDULE ‘R’

- *Standards for **mechanical contraceptives.***
- *The storage conditions necessary for preserving the properties of the contraceptives.*
- *Label contain:-*
- *The date of manufacture.*
- *The date up to which the contraceptive is expected to retain its properties.*

SCHEDULE ‘R-1’

- *Standards for Medical Devices*
- *The standards for the Medical Devices shall be laid down from time to time by the Bureau of Indian Standards*

SCHEDULE ‘S’

- *Standards for cosmetics in finished form*

- *Shall conform to the Indian Standards specifications laid down from time to time by the 3[Bureau of Indian Standards (BIS)].*

SCHEDULE ‘T’

- *Requirements (GMP) of factory premises for **Ayurvedic, Siddha, Unani** drugs.*

- *For getting a certificate of ‘Good Manufacturing Practices' of Ayurveda, Siddha-Unani drugs, the applicant shall made application on 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 26-E*

SCHEDULE ‘U’

- *Manufacturing, raw materials and analytical records of **drugs.***
- *Lot of the raw material used for the manufacture of products and also each batch of the final product and shall maintain records.*
- *The records or registers shall be retained for a period of 5 years from the date of manufacture.*

SCHEDULE ‘U(1)’

- *Manufacturing, raw materials and analytical records of **cosmetics***
- *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).*
- *Such records shall be retained for a period of three years.*

SCHEDULE ‘V’

- *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.*

SCHEDULE ‘W’

- *List of drugs marketed under generic names*
- *Its label contain the Names and quantities of active ingredients.*
- *If vitamins are present, the following words must be written*

  “For therapeutic use”

  “For prophylactic use”

  “For paediatric use” and age of child/infant

SCHEDULE ‘X’

- *List of **narcotic** drugs and **psychotropic** substances*
- *Symbol **XRX** in red on left hand top corner.*
- *Labelled with warnings:- **To be sold on prescription of RMPs only**.*
- *Drugs under this schedule may be imported under license or permit.*

SCHEDULE ‘Y’

- *Requirement and guidelines on **clinical trials** for import and manufacture of new drugs*
- *It include:*

  Application for permission

  Clinical trial

  Studies in special population

  Post Marketing Surveillance

Import and Registration as per D & C ACT

Import License :

1. **Form 10** --For import of drugs excluding those specified in Schedule X.
2. **Form 10-A** -- For import of drugs specified in Schedule X.

Form and manner of application for import license :

1. **Form 8** -- For drugs excluding those specified in Schedule X
2. **Form 8-A** -- For drugs specified in Schedule X.

3. Both application for import license shall be accompanied by a copy of Registration Certificate issued in **Form 41.**

4. Fees of 250 rupees -- For a duplicate copy of the license.

Form and manner of application for Registration Certificate :

1. Form 40 -- Application for registration certificate

2. Application made by manufacturer or by his authorized agent in India.

3. Authorization is documented by power of attorney and the certificate is attested by Indian Embassy

4. Fee of **US $1500** and **Form 40** – For premises meant for manufacturing drugs for import and use in India

5. Fee of **US $1000** and **Form 40** – For single drug

6. Fees paid through a challan in the Bank of Baroda, New Delhi.

7. Fee of **US $ 5000**—For inspection or visit of manufacturing premises or drugs

8. Testing fee – For testing , analysis and evaluation of drug to a testing laboratory approved by Central Govt.

9. Fee of **US $ 300** – For a duplicate copy of registration certificate.

A. License for import of drugs manufactured by one manufacture:

Single application for single drug.

Conditions to be satisfied before a license is granted :

1) License in Form 10 or in Form 10-A will be granted with regard to:

i. The premise: where imported substances are stocked.

ii. The occupation, trade or business carried out by applicant.

2) Any person aggrieved by the order may appeal to the Central Govt. within 30 days.

Registration Certificate for import of drugs manufactured by one manufacturer :

Form 41: Single application for single drug

Conditions of Import License:

1. Manufacturer will observe the undertakings given by him in **Form 9**
2. Inspector authorized by Licensing Authority may enter any premise with or without notice.
3. The licensee shall furnish specified samples from batch for examination to the Licensing authority.

4. Licensee shall not sell any batch until a certificate authorizing the sale of batch has been issued by authority.

5. The remainder of the batch be withdrawn if the batch does not confirm with the strength, quality and purity.

6. The licensee shall maintain a record of all sales of substances of import.

7. For sale and distribution of drugs specified in schedule X, a record is maintained

- Name of the drug
- Batch number
- Name and address of the manufacturer

- Date of transaction.
- Opening stock on business day.
- Quantity of drug received, if any and the source from which received.
- Name of the purchaser, his address and license number.
- Balance quantity at the end of the day.
- Signature of the person under whose supervision the drugs have been supplied.

Grant of import License and Registration certificate:

1. The licensing authority will issue the Import license in Form 10-A

2. Registration certificate in Form 41 on being satisfied that the conditions will be observed.

Duration of Import License and Registration certificate :

i. **3 years unless** suspended or cancelled.

ii. Application for **Import license** be made **3 months** before expiry of existing license

iii. **Registration certificate** be made **9 months** before expiry of existing certificate.

Suspension and cancellation of Import License and Registration certificate:

1. If Licensee fails to comply with any conditions.

2. Person aggrieved of the order may appeal to Central Govt. within 30 days of the receipt of the order.

Prohibition of Import after loss of potency:

Biological or other special product specified **in Schedule C or C(1)** will not be imported after the expiry date.

B) Import of new Homeopathic medicines:

1. New Homeopathic medicines will be imported only with the written permission of licensing Authority.

2. The Importer will produce documents and evidence for assessing the therapeutic efficacy of medicine

Prohibition of import of certain drugs:

The drug cannot be sold, manufactured or distributed in a country in which it is prohibited.

C) Import of Drugs of examination, test or analysis:

Small quantities of drugs prohibited under Section 10 can be imported.

1. Drugs can be imported only under license in **Form 11**.

2. The substances imported will be exclusively used for the purpose of testing, examination and analysis.

3. The licensee shall allow any Inspector to enter and inspect the premise where the substances are kept.

4. The licensee shall keep a record of the details of the substances imported.

Application for License for examination, test or analysis:

1. Application shall be made in **Form 12**
2. Countersigned by Head of institution, Director of the company or firm
3. Fee of Rs **100 (single drug) + Rs 50 (additional drug)**
4. Fees paid through Challan in Bank of Baroda, New Delhi

Cancellation of License:

1. Breach of Conditions of License.
2. The Licensee may appeal to the Central Govt within 3 months of the date of order

D) Import of drugs by Government hospital or Autonomous medical Institution for the treatment of patients:

1. Drugs that are defined in Rule 122-E

2. Imported for the treatment of patients suffering from:

   i) Life threatening disease
   ii) Disease causing serious permanent disability
   iii) Diseases requiring therapies for unmet medical needs

3. Imported by:
   i) Medical officer of a Govt. hospital or Medical Institution
   ii) Head of Autonomous medical Institution

The following conditions:

1. New drug can be imported only under license in **Form 11**.
2. Drug imported shall be used only for treatment of patients under supervision of Medical Officer.
3. The Licensee shall allow an inspector to enter and inspect the premise.
4. The licensee shall keep a record and submit it half yearly.
5. The licensee shall comply with other requirements as specified.
6. The dugs shall be stocked under proper conditions and dispensed under the supervision of registered pharmacist.
7. The quantity of single drug imported shall not exceed 100 avg doses/patient

Application for License for import of small quantities of new drug:

1. Application under **rule 122-E** for:
    i) Life threatening disease
    ii) Disease causing serious permanent disability

2. Application shall be made in **Form 12AA** .

3. Application in **Form 12AA** accompanied by fees of **Rs 100** (single drug) **+ Rs 50** (Additional drug)

4. Fees paid through Challan in Bank of Baroda, New Delhi

Cancellation of License:

E) Import of drugs for personal use :

Following conditions:

1. The drug shall form a part of passenger's bonafide baggage.

2. The drugs shall be declared to the Customs authorities.

3. The quantity of single drug shall not exceed 100 avg doses/patient.

PROVIDED that drug imported does not form a part of bonafide baggage if:

1. Application made in **Form 12-A** that drug is for baonafide personal use.
2. Quantity is reasonable and prescribed by medical practitioner.

3. The license for the said drug is granted in **Form 12-B**.

Manufacture of Drugs (Other than homeopathic for sale)

1. License is valid upto 5years from date of grant or renewal.
2. Application for renewal should be made within 6 months of its expiry
3. Following types of License can be granted:

   a) **License for manufacture of drug**
   b) **Loan licenses for manufacture of drugs**
   c) **Repacking Licenses**

Manufacturing license:

1. Issued to person/organization who have arrangements for manufacturing
2. Different license for different classes of drugs

Loan License:

1. Issued to person with no arrangement for manufacture.
2. Avails manufacturing facilities owned by another licensee.

Repacking License:

1. Granted for purpose of breaking up drug from bulk container into small packages.
2. Labelling of each package.
3. Issued for drugs other than those specified in **Schedule C, C1 and X.**

Manufacturing License

A)Conditions for grant or renewal of a license in Form 25 or 25-F (Other than those specified in C,C1 and X or those in X) :

1. Manufacture shall be under supervision of Competent technical staff consisting of at least one full time employee.

Competent technical staff is:

i. A graduate in pharmacy or eqvt. with 18 months experience in manufacturing **OR** 1 year if person has 6months training during his university course.

ii. Graduate in science (chemistry) + 3years experience

2. The factory premise should comply with Schedule M.

3. The applicant shall provide adequate space & equipment for manufacturing operation as in schedule M and GMP.

4. The applicant may provide staff, equipments and premises for testing of strength, quality and purity of substance and shall be separate from manufacturing unit.

5. The applicant must provide space for proper storage of drugs.

6. Application will justify that the medicines :

   i) Contains ingredients in therapeutic quantities
   ii) Safe for use
   iii) Stable under storage conditions

B) Conditions of License (For drugs Other than those specified in C,C1 and X):

1. The licensee shall maintain adequate staff, premises and equipment.
2. The licensee shall comply with provisions of act.
3. The licensee shall have facilities for testing of each batch of raw materials and finished products.
4. Licensee shall maintain records for a period of 5 years.
5. The licensee shall report any change in expert staff or any material alterations in the premises.
6. The licensee shall produce sufficient qty of drug for examination or test.

7. The licensee shall not sell any drug from a batch from which sample is supplied to licensing authority

8. The licensing authority may withdraw the remaining batch from sale if drug does not confirm with standard of strength, quality and purity.

9. The licensee shall maintain an Inspection book to enable an inspector to record his impressions.

10. The licensee shall maintain reference samples from each batch for performing all the tests.

C) For drugs specified in schedule X:

The licensee shall forward the statements concerning manufacture and supply of drugs to authority after every 3 months

D) For drugs specified In schedule C,C1(excluding X and XB) and those in Schedule C,C1 and X:

Drugs specified in:

Sch C,C1,X and XB other than Lvp, sera,vaccines : Form 28
Sch C,C1,X other than lvp, sera and vaccines : Form 28B
Lvp, sera and vaccines : Form 28D

E) For medicinal devices specified in Sch C:

1. The manufacture shall be done under supervision of person :

- A graduate in science with Physics/Chem/Microbiology
- A graduate in Pharmacy
- A degree/Diploma in Mechanical/Chemical/Plastic engineering.

2. Comply with conditions as in Sch M-III and GMP

Loan License
(Form-- 25-A, 28-A)

General Conditions:

1. The licensee shall comply with the provisions of the act.
2. The licensee shall test each batch of raw material and finished product manufactured .
3. Licensee shall maintain record for 5 years and 2 years after expiry.
4. The licensee shall allow an inspector to inspect all registers .
5. Adequate staff and lab shall be maintained .
6. Reference samples shall be maintained for 3 months after expiry.
7. The licensee shall furnish data on stability of drugs.
8. The licensee shall maintain inspection book as in Form 35 .

Repacking License:
(Form-- 25-B)

General Conditions :

1. Repacking operation shall be carried under hygienic condition under supervision
2. Factory shall comply with conditions as in Sch M.
3. Adequate arrangement for carrying out tests for strength, quality and purity of drugs

Competent persons:

1. Diploma in Pharmacy approved by PCI or is a registered pharmacist .
2. Passed Intermediate exam in chemistry or eqvt.
3. Passed matriculation or eqvt with minimum 4 years practical experience in manufacturing/repacking .

Information to be furnished by applicant:

1. Documentary evidence of ownership/occupation on rental or other basis of premise.

2. Constitution of the firm.

3. Any other relevant matter considered necessary

Cancellation and suspension of license:

Type of license	Class of Drugs	Forms		
		App	Grant of license	Renewal certificate
I) Manufacture of drugs for sale or distribution	(a) Drugs other than those specified in C,C1 & X part XB	24	25	26
	(a) Sale of drugs specified in X & Part XB	24-F	25-F	26-F
	(b) Drugs in C,C1 excluding those in X & part XB	27	28	26
	(c) Drugs in C,C1 & X	27-B	28-C	26-G
	(d) For operation of Blood Bank	27-C	28-C	26-G
	(e) Sale or distribution of LVPs & vaccines in Sch. X &part	27-D	28-D	26-H

II) Manufacture of homeopathic medicine	Grant or renewal of license	24-C	25-C	26-C
III) Manufacture of Cosmetics	(a) Grant or renewal of license	31	32	33
	(b) Grant or renewal of Loan license to manufacture cosmetics	31-A	32-B	33-C
(IV) Loan license	(a) Drugs other than those specified in Sch. C,C1and X	24-A	25-A	26-A
	(b) Sale of drugs specified in Sch. C and C1	27-A	28-A	26-A
(V) Repacking License	Drugs other than those specified in Sch. C,C1 and X	24-B	25-B	26-B