Program Name	**:**	**B. Pharm**
Course Name	**:**	**Pharmaceutical Jurisprudence**
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Topic	**:**	**Drugs and Cosmetics Act, 1940 and Rules, 1945**
Sub-topic	**:**	

- Objectives
- Definitions
- Legal definitions of schedules to the Act and Rules
- Import of drugs- Classes of drugs and cosmetics prohibited from import
- Import under license or permit. Offences and penalties

DRUGS AND COSMETICS ACT, 1940 AND RULES, 1945

Introduction

Drugs Enquiry Committee appointed by Government in 1931 made various recommendations to have a control on the import, manufacture and sale of drugs. But Government was reluctant to implement these recommendations. Following the uprising in the country, Government passed Import of Drugs Bill in 1937 but that was not concerned with the manufacture, distribution and sale of drugs. Finally, to control the import, manufacture, distribution and sale of drugs and cosmetics, Drugs and Cosmetics Act was passed on10th April 1940 by the Indian Legislature. This Act was amended in1955 by the Indian Parliament and subsequently amended in 1960,1962, 1964, 1972, 1982, 1986, 1995, 2008, 2017, 2018 and 2019. In this Act, provision of license is made for the import, manufacture and sale of drugs and cosmetics. Central Government controls import of drugs and cosmetics while State Government appoints licensing authority to control manufacture, distribution and sale of drugs and cosmetics.

The Act consists of five chapters

Chapter I- Introductory

Chapter II - Administrative bodies

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

Objective

- This is an Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics.
- Manufacture, distribution and sale of drugs and cosmetics by qualified persons only.
- To prevent substandard in drugs.
- To regulate the manufacture and sale of Ayurvedic, Siddha, homeopathic and Unani drugs.
- To have regular inspection of licensed premises by drug inspectors.

Definitions

Drugs: 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.

Cosmetic: Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied 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.

Misbranded drugs: (A) If it is so coloured, 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 labelled in the prescribed manner.

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.

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.

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.

Schedules to the Act:

1. First Schedule: It prescribes the list of books specified in Ayurvedic, Siddha or Unani systems of medicine.

2. Second Schedule: It prescribes the standards to be complied with by imported drugs and by the drugs manufactured for sale, sold stocked or exhibited for sale or distributed.

Schedules to the Rules

Schedule A

It prescribes different forms required under Drugs and Cosmetic Act, for making the application to grant or issue of licences, sending memorandum, etc.

Schedule B

It prescribes the fees to be charged for test or analysis of samples of drugs by Central Drugs Laboratory and Government Analyst.

Schedule C& C (i)

It prescribes the list of the biological and other special products.

Schedule D

It prescribes classes of drugs which are exempted from the certain provisions applicable to the import of drugs.

Schedule E

It prescribes list of poisonous substances - omitted (22/6/1982).

Schedule E (i)

It prescribes list of Ayurvedic, Siddha and Unani poisonous substances.

Schedule F

It prescribes provisions applicable to the blood bank requirements and licensing to process the blood components.

Schedule F(i)

It prescribes provisions applicable to the production of bacterial as well as viral vaccines, sera and diagnostic antigens.

Schedule F(ii)

It prescribes the standards for surgical dressings.

Schedule F(iii)

It prescribes the standards for the umbilical tapes.

Schedule FF

It prescribes the standards for ophthalmic preparations.

Schedule G

It prescribes list of drugs which are required to be taken only under the supervision of a Registered Medical Practitioner. It is labelled with direction: 'Schedule G Drug' Caution "It is dangerous to take this preparation except under the supervision of Registered Medical Practitioner".

Schedule H

It prescribes list of drugs which are to be sold by retail only on the prescription of Registered Medical Practitioner. Schedule H drugs are labelled with direction Warning "To be sold by retail only on the prescription of Registered Medical Practitioner."

Schedule I

It prescribes calculation of proportion of poisons in certain cases -omitted (22/6/1982).

Schedule J

It prescribes the list of ailments or diseases for which drugs may not claim to prevent or cure.

Schedule K

It prescribes classes of drugs which are exempted from certain provisions applicable to manufacture of drug.

Schedule L

It prescribes list of drugs to be sold on prescription only - omitted (22/6/1982).

Schedule M

It prescribes the good manufacturing practices (GMP) and the requirements of factory premises, plant, equipment's, etc for manufacture of drugs.

Schedule M (i)

It prescribes requirements of factory premises, plant, equipment's, etc for manufacture of Homoeopathic drugs.

Schedule M (ii)

It prescribes requirements of factory premises, plant, equipment's, etc for manufacture of cosmetics.

Schedule M (iii)

It prescribes requirements of factory premises, plant, equipment's etc for manufacture of Medical devices.

Schedule N

It prescribes minimum equipment's to be possessed by pharmacy.

Schedule O

It prescribes provisions applicable to the black disinfectant fluids.

Schedule P

It prescribes life period of drugs.

Schedule P(i)

It prescribes the pack sizes of drugs.

Schedule Q

It prescribes the list of permitted coal tar colours for use in cosmetics and list of permitted colours for use in soaps.

Schedule R

It prescribes the standards for condoms made of rubber latex intended for single use.

Schedule R (i)

It prescribes standards for medical devices.

Schedule S

It prescribes standards for cosmetics

Schedule T

It prescribes the requirements of factory premises, plant, equipment's and hygienic conditions for manufacture of Ayurvedic, Siddha, and Unani Drug

Schedule U

It prescribes the particulars to be shown in the manufacturing records of drugs.

Schedule U (i)

It prescribes the particulars to be shown in the manufacturing records of cosmetics.

Schedule V

It prescribes standards for patent and proprietary medicines.

Schedule W

It prescribes the list of drugs which are marketed under generic name only.

Schedule X

It prescribes list of habit-forming narcotic drugs and psychotropic substances for the import, manufacture, distribution and sale of which requires a licence.

Schedule Y

It prescribes requirements and guideline on clinical trials for the import and manufacture of new drugs.

Classes of drugs which are prohibited for import in India

The following classes of drugs are prohibited for its import in India.

1. Adulterated, spurious, misbranded drugs or drugs which are not of standard quality.

2. Patent and proprietary medicine of which formula is not disclosed.

3. Drug imported in contravention of the provisions of theAct.

4. Drugs which may claim to cure any of the diseases as specified in the Schedule J.

5. Expired drugs.

6. Drugs which have not claimed therapeutic value.

7. Drugs which are likely to cause risk or injurious to human body or animal.

8. Drugs not intended for import.

Classes of drugs and cosmetics to be imported

1. Drugs which may be imported under licence

2. Drugs which may be imported without licence

Import Licence

Conditions of licence granted to a person for import of drugs for examination or test or analysis Import of drugs for personal use Conditions of import licence for Schedule C and Schedule X drugs Import licence is a licence granted to a person for the import of drugs specified in Schedule X, C and C(i). For the import of drugs specified in Schedule C, C(i) and X, the licence shall be granted in Form 10 and 10A respectively. For the import of small quantities of drugs, a licence is granted in Form 11.

Conditions of licence granted to a person for import of drugs for examination or test or analysis

Licence in Form 11 is granted by licensing authority to import small quantities of drugs, the import of which is otherwise prohibited, for the purpose of examination, test or analysis subjected to the following conditions-

1. The importer shall use the substances imported for the purpose of examination, test or analysis in the space specified in licence or at any other place authorized by licensing authority.

2. The licensee shall allow inspector to enter with or without notice at the premises where substances are kept and also, to inspect the premises and investigate manner in which substances are being used and to take sample thereof.

3. The importer shall keep the records of quantities of substances imported with date, name of manufacturer and shall report the same to licensing authority.

Import of drugs for personal use

Drugs may be imported for personal use under the following conditions even though the import of which is prohibited under section 10 of the Act.

1. If that drug shall form the part of passengers bonafied baggage and shall be the property of and be intended exclusively for personal use.

2. If customs authority directs and declares that drug is for personal use.

3. If the quantity of single dose so imported shall not exceed hundred doses. Even if the imported drug is not forming part of passengers bonafied baggage, it may be permitted for its import after getting permission from licensing authority in Form 12.

Conditions of import licence for Schedule C and Schedule X drugs

Import licence is granted under the following conditions-

1. The manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 9.

2. The licensee shall allow inspector to inspect the premises and check the records and take samples for test or analysis.

3. The licensee shall not sell any drug if the licensing authority directs so.

4. The licensee shall recall the batch as early as possible from sale if it does not comply with the prescribed standard.

Along with those conditions for Schedule C drugs the licensee shall maintain the following particulars for Schedule X drugs-

1. Name of drug
2. Batch No.
3. Name and address of manufacturer
4. Opening stock
5. Date of transaction
6. Quantity of drug received, if any
7. Name of purchaser with address and licence number
8. Balance quantity of drug at the end of business
9. Signature of person under whose supervision the drugs have been supplied.

The licensing authority has right to grant the licence or cancel or suspend the licence depending on conditions of licence. Any person who is aggrieved with the decisions of licensing authority may appeal to court of law within three months whose decision will be final.

Duration of Import Licence

Import licence is valid for three years from date of its issue unless it is suspended or cancelled. Provided that if application for a fresh registration is made three months before the expiry of existing licence the current licence shall deemed to continue in a force until orders are passed.

Offences and penalties

Offences	**Penalties**
Manufacture of any spurious drugs	a) 1-3 years imprisonment and Rs 5000 fine b) 2-6 years imprisonment and Rs 10000 fine on subsequent conviction.

Manufacture of adulterated drug	a) 1-year imprisonment and Rs 2000 fine b) 2 years imprisonment and Rs 2000 fine on subsequent conviction.
Manufacture of drugs in contravention of the provisions	a) imprisonment up to 3 months & Rs 500 fine imprisonment up to 6 months & Rs 1000 fine on subsequent conviction .

Reference:

Yadav, A., Remeth Dias, Vijay Havaldar, and Kailas Mali. *Pharmaceutical Jurisprudence*, 2012.