Name of Unit	Drugs and cosmetics act
Subject /Course name	Pharmaceutical Jurisprudence
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Class: B.Pharm. Semester	V
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Learning Outcome of Module 01

LO	Learning Outcome (LO)	Course Outcome Code
LO1	Discuss the Provisions related manufacture drugs and pharmaceuticals	BP505.2
LO2	Discuss the provisions for manufacture of new drugs	BP505.2
LO3	Explain the offences and penalties related to import of drugs and cosmetics	BP505.2

Content Table

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. • Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, • Conditions for grant of license and conditions of license for manufacture of drugs • Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

Objectives

- To regulate the **import, distribution and sale** of drugs & cosmetics through licensing in order to prevent substandard or harmful drugs and cosmetics.
- Excise control over the production of drugs and cosmetics in the country.
- To 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 and Unani drugs.**
- To establish **Drugs Technical Advisory Board (DTAB)** and **Drugs Consultative Committees (DCC)** for Allopathic and allied drugs and cosmetics.

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.

Ayurveda Sidha and Unani Drugs:

Include all medicines indented for internal or external use for or in diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals & manufactured exclusively in accordance with the formulae prescribed in authoritative books of Ayurvedic, siddha and Unani-Tibb systems of medicines.

Central License approving authority:

Means Drug Controller of India appointed by the Central Government.

Drug: Includes

a) all medicines used for the internal or external use of human beings or animals and all substances indented to be used for or in diagnosis, treatment , mitigation or prevention of any disease or disorder in human beings or animals including preparation applied for repelling mosquitoes

b) substances indented to affect the structure or any function of human body or indented to be used for the destruction of vermin or insects that cause disease in human beings or animals

c) all substances indented for use as components of drug including empty gelatin capsules

d) Devices indented for internal or external use in the diagnosis, treatment, mitigation or prevention of disease ordisorder in human beings or animals.

Import of Drugs

Classes of drugs prohibited to import

Import of drug under license

1) Specified in Schedule-C/C1
2) Specified in Schedule-X
3) Imported for Test/Analysis
4) Imported for personal use
5) Any new drugs

Offences and Penalties

Import & Registration of Drug & Cosmetics

Drugs/cosmetics may be imported to India under the authority of a license excepting those whose import is prohibited.

Some drugs/cosmetics can be imported without any permit, providing they are of standard quality & statement that they comply with the provisions relating to import has been given to the Customs Collector by manufacturer or importer.

Registration:

Requirement of registration of premises & drugs manufactured & meant for the import to India was introduced witheffect from 1.1.2003

Registration Certificate means a certificate issued by the LA for the registration of premises & drugs manufactured bythe manufacturer meant for import into & use in India.

An application for the issue of a registration certificate should be made to LA along with the information & undertaking specified in Schedule DI & DII. Registration certificate remains valid for a period of 3 years.

Requirements of Schedule D I are as follows

I. Particulars of manufacturer & manufacturing premises- i) name & address of manufacturing premises to be registered. Ii) name & address of partners/directors iii) name & address of authorized agents in India. Iv) brief profile of manufacturer's business & research activity v) copy of plant master file. vi) copy of plant registration/approval issued by authority of concerned foreign country.

II. Particulars of manufactured drugs to be registered under registration certificate- i) name of drug to be registered for import into & use in India. ii) a copy of approval list of above drugs showing permission for manufacturing/marketing in the country of origin. iii) a copy of GMP certificates as per WHO guidelines. iv) domestic prices of drugs to be imported in the currency of country of origin, v) names of drugs which are original products of the manufacturer.

III. Undertaking to declare that- i) that applicant shall comply with the conditions imposed under acts & rules, ii) applicant report from time to time any changes pertaining registration certificate or any administrative action taken due to ADR, iii) applicant shall allow LA to enter & inspect manufacturing premises & to examine process or procedures & allow to take samples of drugs concerned for test, analysis or examination, in respect to any drug manufactured for which application for registration certificate has been made.

Classes of Drugs Prohibited to Import

- **Any Misbranded** drugs
- Any drug of **substandard quality**
- Drugs claiming to cure diseases specified in Schedule-**J**
- **Adulterated** drugs
- **Spurious** drugs
- Drugs whose manufacture, sale/distribution are prohibited **in original country**, except for the purpose of test,examination and analysis.
- **Patent/Proprietary** medicines whose true formula is not disclosed.Import of the biological drugs(C/C1)
- Separate import licenses are granted for the import of biologicals and other special products and for drugsspecified in Schedule X.
- Conditions to be fulfillled:
- Licensee must have adequate and proper facility **for the storage.**

- Licensee must maintain a **record of the sale.**
- Licensee must **allow an inspector to inspect** premises and to check the records.
- Licensee must **furnish the sample** to the authority.
- Licensee must not sell drugs from which sample is withdrawn and he is advised **not to sale, and recall the batch** from the market.

Import of the Schedule-X drugs (Narcotic & Psychotropic drugs)

- Conditions to be fulfilled:
- Licensee must have adequate **storage facility.**
- Applicant must be **reputable** in the occupation, trade or business.
- The license **granted even** before should **not be suspended or cancelled.**
- The licensee has **not been convicted any offence** under the Drugs and Cosmetics Act or Narcotic andPsychotropic Substances Act.

Drugs Imported for examination, test or analysis

- Small quantities of drugs whose import is otherwise prohibited can be imported for the purpose of examination,test or analysis
- Conditions to be fulfilled:
- License is necessary under form**-11** from the licensing authority
- Must use imported **only for said purpose** and at the place specified in the license.
- Must keep the **record** with respect to quantities, name of the manufacturer and date of import.
- Must **allow an inspector** to inspect the premises and check the records.

Drugs imported for personal use

- Conditions to be fulfilled:
- **Up to 100 average doses** may be imported **without any permit**, provided it is part of passenger's luggage.
- More than 100 doses imported with license. Apply on form no***.-12-A,12-B***
- Drugs must be **bonafide personal use.**
- Drugs must be **declared** to the custom officers if so directed.

Import of drugs without license

- Substances **not used for medicinal purpose**
- Drugs in Sch-C1 required for manufacturing and not for medicinal use.
- Substances which are **both drugs and foods** such as:Condensed/Powdered Milk Malt Lactose Farex/Cerea Oats
- Predigested foods
- Ginger, Pepper, Cumin, Cinnamon

Penalties related to Import

OFFENCES	PENALTIES
Import of spurious OR adulterated drug OR Drug which involves risk to human beings or animals OR drug not having therapeutic Values	a) 3 years imprisonment and 5000 Rs. fine on first conviction b) b) 5 years imprisonment OR 10000 Rs. fine OR both for subsequent conviction
Any drug other than referred above, the import of which is prohibited	a) 6 months imprisonment OR 500 Rs. fine OR both for firstconviction b) 1 year imprisonment OR 1000 Rs. fine for subsequentoffence

Places through which drugs may be imported in India

Ferozpur cantonment & Amritsar Railway station	In respect to drugs imported by rail across the frontier with Pakistan
Ranaghat, Bongaon & Mohiassan Railway Stations	In respect to drugs imported by rail across the frontier with Bangladesh
Raxaul	In respect to drugs imported by road & rail connecting India & Nepal
Chennai, Kolkata, Mumbai, Cochin & Kandla	In respect to drugs imported by sea into India
Chennai, Kolkata, Mumbai, Delhi, Ahmedabad & Hyderabad	In respect to drugs imported by air into India

Cosmetics prohibited to import

- **Misbranded** cosmetics
- **Spurious** cosmetics
- Cosmetic containing **harmful** ingredients
- Cosmetics **not of standard quality**
- which contains more than-2 ppm **Arsenic**, 20 ppm **lead,** 100 ppm **heavy metals**

Application of laws relating to Sea & customs

The Customs Collector & other Officers authorized in this behalf by the Central Government may detain any imported packages which he suspects to contain any drug or cosmetic the import of which is prohibited under this act, and report such detention to the drugs Controller, India & if necessary forward any package or sample to Central Drugs Laboratory for analysis.

Manufacture:

Include any process or part of process for making, altering, ornamenting, finishing, packing, labeling, breaking up orotherwise 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 drugs or packing of any cosmetics or drug in ordinary course of retail process.

Patent or Proprietary Medicine:

In relation to Ayurveda, Sidha or Unani systems of medicine all formulations containing only such ingredients mentioned in the formulae described in authoritative books of Ayurveda, Sidha or Unani- Tibb systems of Medicine specified in the first schedule but does not include medicine which is administered by parenteral route also formulations included in authoritative books as mentioned in the first Schedule.

In relation to any other system of medicine, a drug which is a remedy or prescription presented in form ready for internal or external administration of human beings or animals and which is not included in edition of the Indian Pharmacopoeia for the time being or any Pharmacopoeia authorized in this behalf by the Central Government afterconstitution with the DTAB.

Misbranded drugs: A drug is deemed to be misbranded –

- If it is so colored, coated, powdered or polished that damage is concealed or if it is made to appear of better orgreat therapeutic value than it really is.

- If it is not labeled in prescribed manner; or
- If its label or container or anything accompanying the drugs bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

Adulterated Drugs: A drug is deemed to be adulterated –

- If it consists in whole or in part, of any filthy, putrid or decomposed substance; or
- If it has been prepared, packed or stored under insanitary conditions whereby it may have been renderedinjurious to health; or
- If its container is composed in whole or in part, of any poisonous or delirious substances which may render thecontents injurious to health.
- If it bears for purpose of coloring only a color other than one which is prescribed.
- If it contains any harmful or toxic substance which may render it injurious to health; o
- If any substance has been mixed there with so as to reduce its quality or strength.

Spurious Drugs: A drug is deemed to be spurious –

- If it is imported or manufactured under a name which belongs to another drug.; or
- If it is an imitation or is a substitute for, another drug or resembles another drug in a manner likely to deceive orunless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drugs; or
- If the label or container bears the name of an individual or company purporting to be the manufacture of thedrug, which company or individual is fictious or does not exist.
- If it has been substituted wholly or in part by another drug or substance; or
- If it purports to be the product of a manufacturer of whom it is not truly a product.

Misbranded Cosmetics: A cosmetic is deemed to be misbranded –

- If it contains color which is not prescribe; or
- If it is not labeled in prescribed manner; or
- If the label or container of anything accompanying the cosmetic bears any statement which is false or misleadingin particular.

Spurious Cosmetics: A cosmetic is deemed to be spurious –

- If it is imported under a name which belongs to another cosmetic; or
- If it is an imitation of, or a substitute for, or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another

cosmetic, unless it is

- plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or
- If the label of the container bears the name of an individual or company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious and does not exist; or
- If it purports to be the product of a manufacturer of whom it is not truly a product.

Schedule M Part II Plant & Equipment

Recommends the requirements of plant & equipment for the manufacture of drugs under the following sections.

i) Ointments, emulsions, lotions & suspensions,

ii) Syrups, elixirs & solutions,

iii) Pills, compressed tablets & hypodermic needles,

iv) Powders,

v) Hard gelatin capsules,

vi) Surgical dressings other than absorbent cotton,

vii) Eye ointments,, eye lotions & other preparations for external use,

viii) pessaries & suppositories,

ix) inhalers,

x) repacking of drugs,

xi) Parenteral preparations.

SALE OF DRUGS

- Classes of drugs prohibited to be sold
- Wholesale of biological (C/C1)
- Wholesale of other than those specified in C/C1 and X

Class of drug prohibited to sale

- Misbranded, spurious, adulterated and drugs not of standard quality
- Patent/Proprietary drugs with undisclosed formula
- Sch-J drugs
- Expired drugs.

- Drugs used for consumption by government schemes such as, Armed force.
- Physician's samples

Wholesale of biological (C/C1)

- Adequate premises, with **greater than 10 M^2 area**, with proper storage facility
- Drugs sold **only to retailer having license**
- Premises should be in charge of competent person who is **Reg. Pharmacist**.
- **Records** of purchase & sale
- Records preserved for 3 years from date of sale
- License should be **displayed on premises**
- All the conditions as discussed in for biological.
- Compounding is made by or under the direct and personal **supervision of a qualified person.**

Retail Sale

For retail sale, two types of licenses are issued:

i) General licenses

ii) Restricted licenses

Restricted license:

Granted to those dealers who do not engage the services of a qualified person and only deal with such classes of drugs whose sales can be effected without qualified person and vendors who do not have fixed premises

Labeling & Packaging

All the general and specific labeling and packaging specified to all classes of drugs and cosmetics should be as per theprovisions made under the act.

Labeling in India

All labels of a drug should conform as per the specifications under the Drugs and Cosmetics Rules 1945.

- That no person sell or distribute any drug unless it is labeled in accordance with the Rules (Rule 95 of D&C Act).

Labeling – is the norm in this context that provide comprehensive and concise statement of a drug's Quality Safety andEfficacy.

-it includes information regarding indications, effects, dosage form, frequency and duration of administration, warnings, hazards, contraindications, side effects, precautions and other relevant information.

Importance of labeling

The safe use of all medicines depends on users reading the labeling and packaging carefully and accurately and beingable to assimilate and act on the information presented.

All labels must be clear and concise and must bear all necessary information regarding the safe use of a product.

Prescription Drug Labeling

- These cannot be used safely by consumers without the diagnosis and supervision of a physician.
- These have unavoidably adverse effects, but the benefits of using such drugs outweigh the accompanying risks.
- It is the expert judgment of a practitioner to decide the use of a drugs for a particular patient.
- Thus, the manufacturer of a prescription drug is required to provide adequate labeling for
- practitioners to beable to administer or dispense the drug safely and for the purposes for which it is intended.

Components of Labeling

The prescription drug labeling consists of following components:-

- Container/ Carton Label
- Package Insert

A. Regulatory Requirements for Label :-

Rule 96 of the Drug and Cosmetic Rules (manner of labelling) mandates the minimum information which needs to be puton the label of all medicines.

- Misbranded drug if it is not labelled in the prescribed manner as in drug and cosmetic rules(chapter 3 section9(b) of D&C act).
- 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 which the container ispacked, namely :-

1) **Name of the drug:-**

- For drug included in the schedule F /F(1), the name given therein.
- For drugs included in the Indian Pharmacopoeia or the official pharmacopoeia and official compendia of drug standards prescribed in the rule 124, the name or synonym specified in the respective followed by letters 'I.P.'
- It entered on the label of the drug only for the purpose of indicating that the drug is in accordance withstandards set out in the Indian Pharmacopoeia.
- for drugs included in the National Formulary of India, the name or synonym specified therein followed by theletters 'N.F.I.'

2. **Net Quantity of contents**
3. **The content of active ingredients**
4. **Name and Address of manufacturer**
5. **Batch or lot number (Batch No.)**
6. **Manufacturing license number ("Mfg. Lic. No.")**
7. **Import License No.** (if applicable):- the no. of license under which the drug is imported, preceded by words"Import Lic. No."
8. **Manufacturing date, Expiry date and Storage conditions**
9. **Other Specific Requirements**

i. Physician Sample – 'Not to be sold'.

ii. Alcohol content

Package Inserts

- *The Package insert* is considered *"adequate direction for use".*

It is also directed to healthcare professional and help him in making correct decision regarding the prescribing ofdrug to a particular patient.

- In India, it is governed by the *'Drugs and Cosmetics Act(1940) and Rules(1945*)' .*Schedule D 11 (section 6)* of the rules including the heading to which information to be provided in the Package Inserts.
- It is divided into two parts:

  -Therapeutic indications

  -Pharmaceutical information

Drug Labeling Regulation in India

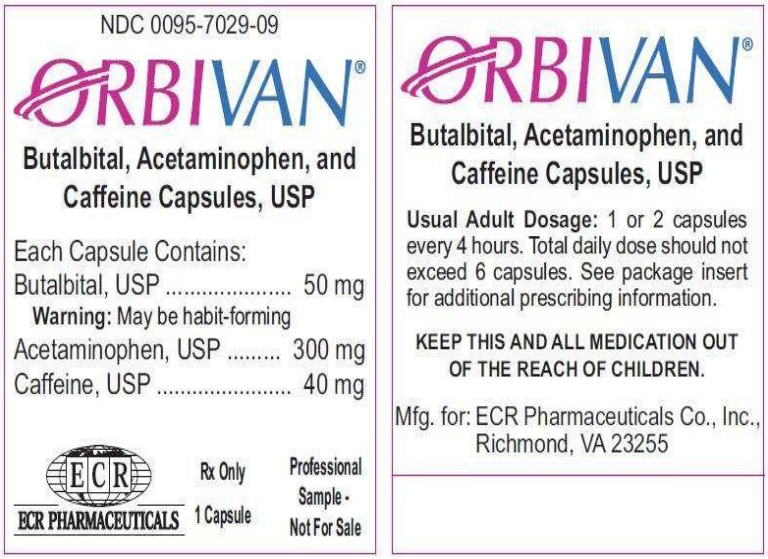
Rule 97 requires specific caution statements to be present on label for the different drug schedules.

Prescription drugs in India are those that fall under two schedules of the Drug and Cosmetics Rules, 1945 :

- ***Schedule H***
- ***Schedule X***

But drugs falling under **Schedule G** require the following mandatory text on the label: "Caution: It is dangerous to takethis preparation except under medical supervision".

For Allopathy



For Ayurvedic, Siddha, Unani, Homoepathy and Cosmetics

Question bank

Long essays (10 marks):

1. Explain the conditions to grant license for manufacture of drugs specified in schedule C, C1 and X.
2. Explain the conditions to grant license for manufacture of drugs specified other than schedule H and X.
3. What are the proceedents and subsequent conditions for grant of license to manufacture of drugs and cosmetics specified in schedule C, C1 and X?
4. Write the conditions to grant license for manufacture of:

   a). Drugs for purpose of examination, test and analysis.

   b). Loan licenses
5. Explain in detail about manufacture of new drug, loan license and repacking license.
6. Explain the various licenses issued under Drug and Cosmetics Act 1940.
7. Describe the classes of drugs and cosmetics which are prohibited from import and import under License.
8. Explain in detail about schedule M.
9. Discuss the penalties for manufacturing and sale of drugs in contravention of Drugs And Cosmetics Act 1940.
10. Explain in detail about prohibition of manufacture and sale of certain drugs under Drugs and Cosmetics Act 1940.

Short essays (5 marks):

1. What are the classes of drugs prohibited to import into India?
2. Discuss in detail about loan licenses.
3. Discuss in detail about repacking licenses.
4. Describe the classes of drugs to import under license or permit
5. Write a note on list of permitted colors as per Drugs and Cosmetics Act 1940.

Short answers (2 marks):

1. Give offences and penalties about import of drugs.
2. Write about import of drugs for personal use.
3. Write about import of new drugs.
4. Give two examples of permitted colors as per Drugs and Cosmetics Act 1940.

5. Write places from which drugs are imported in India.
6. Define drugs and cosmetics as per Drugs and Cosmetics Act
7. Write about manufacturing of new drugs.
8. Define spurious drugs as under Drugs and Cosmetics Act
9. Define misbranded and adulterated drugs
10. Mention the rules for drugs and cosmetics.