PHARMACEUTICAL JURISPRUDENCE

UNIT 2 NOTES

DRUGS & COSMETICS ACT

- SCHEDULE G,H,M,N,P,T,U,V,W,X,Y, PART XII B, SCH F & DMR (QA)
- SALE OF DRUGS
- LABELLING OF DRUGS
- ADMINISTRATION OF THE ACT & RULES

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Detailed Study Of Schedules

Here, we have to study in detail about

- Schedule G
- Schedule H
- Schedule M
- Schedule N
- Schedule P
- Schedule T
- Schedule U
- Schedule V
- Schedule X
- Schedule Y
- Schedule F
- DMR (OA)

① Schedule G

- In this most drugs are hormonal preparations.
- Medicines listed as schedule G carry a caution on the label.
- The caution states: It is dangerous to take this preparation except under medical supervision.
- Examples: Mercaptopurin, Thiotepa, Primidone, Insulin, Metformin, Busulfan, Chlorambucil etc.

② SCHEDULE H

- This schedule contains prescription drugs.
- The drug label must display the texts "Rx" on the left top cooner of the label & warning : To be sold by retail on the prescription of a Registered Medical Practitioner only.
- Drugs under schedule H if comes under Narcotic Drugs & Psychotropic Substances Act, 1985 are labelled with symbol "NRx" & schedule H drug warning.
- Example: Acyclovir, Carbidopa, Diclofenac, Tretinoin etc.

③ SCHEDULE M

- Schedule M deals with 'Good Manufacturing Practices'
- It is defined as part of quality assurance which is aimed to ensure that the product are consistently manufactured to the quality appropriate to their intended use.
- It deals with requirment of premises, plant and equipment needed for setting up manufacturing unit.

Part 1 : Requirments for Premises & Materials

- Locations & Surroundings
- Building & Premises
- Water Supply
- Disposable of Waste
- Stores
- Working Space
- Sterile Products
- Container's Cleaning
- Machinery
- Raw- Materials

- Equipment
- Batch Manufacturing Record
- Sanitation
- Hygiene of Workers
- Medical Services
- Distribution Record
- Record of Market Complaints.
- Quality Control

Part 2: Requirment for Plant & Equipments

① Area :

(i) Basic Installation : Requires minimum of 30 sq. mt. (For tablet manufacturing upto 60 sq. mt.)

(ii) Ancillary Area : 10 sq. mt

② Equipment :

- Colloidal Mill
- Mixing & Storage Tanks
- Stainless Steel Containers.
- Planetary Mixer
- Triple Roller Mixer
- Air Conditioner
- Disintegration Test Apparatus
- Polishing Pan
- Leakage Test Apparatus

④ SCHEDULE N

It describes the minimum facilities and equipments for efficient running of a pharmacy.

It includes :

- A 'Pharmacy' logo in front
- Adequate storage & workspace
- Proper lighting & ventilation
- Refrigeration for temp. sensitive medications.
- Specific storage conditions
- Proper labelling of drugs
- Safety & Security
- Licensing.

⑤ SCHEDULE P

It describes the life period of drugs in months

- Example
  - Ampicillin : 36 Months
  - Adramycin : 30 Months
  - Ampicillin Sodium : 36 Months
  - Colistin Sulphate : 60 Months

- Schedule P_1 : Describe Pack size of drugs
  Example :
  - Aspirin : Tablets : 14 tabs
  - Glyceryl Trinitrate : Capsules : 25 Cap

⑥ SCHEDULE T

The schedule deals with GMP for Ayurvedic, Siddha & Unani Medicines.
It includes :

- Premises & Plant Requirements
- Quality Control
- Equipment & Machinery
- Personnel
- Storage & Packaging
- Documentation & Record

⑦ SCHEDULE U

Schedule U specifies the requirments related to records & documents that must be maintained by manufacturers of pharmaceutical products.
Key elements of schedule U includes :

- Batch Manufacturing Records
- Raw Material Records
- Quality Control Records
- Standard Operating Procedures
- Stability Testing Records
- Personnel & Equipment
- Distribution Records

⑧ SCHEDULE V

- This schedule deals with standards for Patent & Proprietary Medicines
- It basically outlines the standards for vitamin & mineral preparations.
- It includes.
  - Standardization of Dosage
  - Quality Requirments
  - Labelling Requirments
  - Therapeutic Use Standards.

⑨ SCHEDULE X

- Schedule X of Drugs & Cosmetics Act 1940, specifies the drugs that are classified as habit-forming or potentially addictive and therefore, require strict regulation in manufacturing, sale and distribution to prevent misuse & abuse.
- Schedule X drugs are primarily narcotics and psychotropic substances, which can have serious risk if misused.

(10) SCHEDULE Y

- Schedule Y deals with regulatory requirements for clinical trials of new drugs in India.
- It outlines standards and procedures for conducting clinical trials to ensure safety, efficacy & ethical treatment of trial participants.
- Schedule Y includes :
- Application for Clinical Trials
- Phases of Clinical Trials
- Ethical Guidelines & Informed Consent
- Good Clinical Practices
- Data Reporting & Record keeping
- Safety Reporting
- Import & Manufacture for Clinical Trials

(11) SCHEDULE F - PART XII B

- Schedule F Part XII - B of Drugs & Cosmetics Act provides regulatory standards & requirments specifically for blood banks and blood products in India.
- It outlines the necessary guidelines for establishing and operating blood banks, as well as for collecting, storing, testing and distributing blood & its component to ensure safety & quality.
- It includes :
- Licensing & Registration
- Infrastructure & Equipment
- Personnel Requirment
- Collection & Testing
- Storage & Shelf life
- Quality Control & Labelling Requirment.

(12) DRUGS & MAGIC REMEDIES (OBJECTIONAL ADUERTISEMENT)

The Drugs & Magic Remedies (Objectional Advertisement) Act, 1954 is an Indian law aimed at controlling misleading advertisement of drugs & 'Magic Remedies' that claims to have miraculous or exaggrated healing effect.

key features :

- Prohibition of false Advertising
- List of Disease & conditions
- Ban on 'Magic Remedies'
- Penalties for Violation

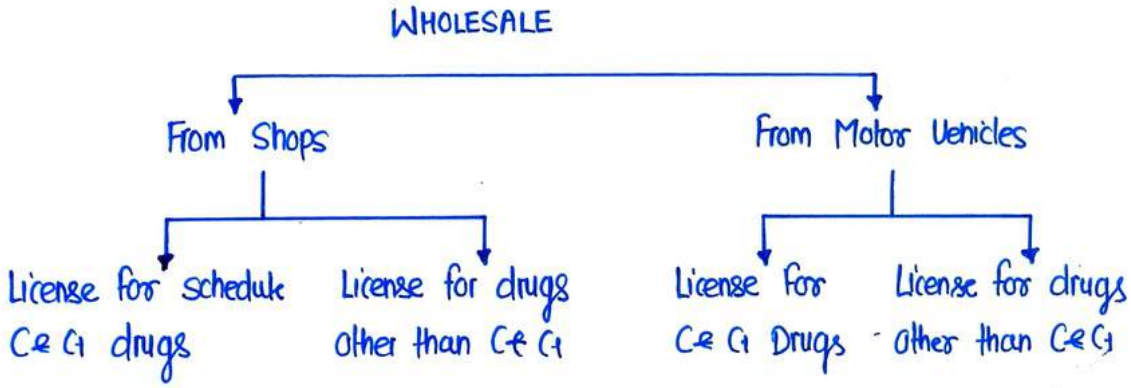
SALE OF DRUGS

- Sale is the process of passage of drugs from manufacturers to consumers.
- The sale license in India is acquired by wholesalers & retailers who are engaging in distribution of drugs in India
- There are 3 different type of drug license in India as follows :

① Wholesale drug License
② Retail Drug License
③ Restricted Drug License

① WHOLESALE OF DRUGS

The wholesale Drug License in India is issued by CDSCO to those wholesalers who are doing business in pharmaceuticals



@ Wholesale From Shops

Wholesale from shops refers to sale of drugs in bulk quantities from a fixed place, it requires two types of licenses.

- Wholesale of Schedule C & C1 Drugs
- Wholesale of drugs other than C & C1

Wholesale Of Schedule C & C1 Drugs

It requires following conditions:

- The licensee must have adequate area not less than 10 sq. mt. equipped with adequate facilities for storage of drugs in order to preserve their potency.
- The licensee must have detailed records of all purchases, sales and distribution, showing quantities, dates, suppliers & buyers.
- The records should be preserved from date of sale to a period of at least 3 years.
- License should be displayed in premises so that it is open to the public.
- The license may need periodic renewal, with updates on any changes in operations.
- If licensee desires to sell any other categories of drugs, he should seek permissions from licensing authority.

Wholesale Of Drugs Other Than Those Specified in C & C1

- The licensee must follow all the general conditions for whole of C and C1 drugs.
- The drug should not be sold to any person who does not possess a license for retail sale or distribution of drugs. However, this condition is not applicable to sale of drugs to hospitals, medical, educational or research institutions.

ⓑ Wholesale from Motor Vehicles

- At the present time, license are being granted for drug distribution from motor vehicles.
- Separate license are needed for wholesale of drugs under schedu C & G & other than those specified in C & G
- The conditions for those licenses are same as conditions from wholesale of drugs from shops
- Drug should be be bought from a licensed manufacturer or wholesaler & distributed to individuals having valid licenses for retail sale of drugs.
- The license should be displayed on the vehicle.
- In case any change is made in the ownership of the vehicle or constitution of the from that was granted license, the license authority should be informed within a week.

② RETAIL SALE OF DRUGS

- Retailing of drugs is done through shops or by vendors. In this drugs are directly sells to consumers.
- Retail Sale of drugs done from two ways.

ⓐ Retail sale from Shops
ⓑ Retail Sale from Vendors.

ⓐ Retail Sale From Shops

Following are the rules for the retail sale from shops
Facilities as per Schedule N

- Purchase only from licensed wholesales
- Separate licenses for schedule C, G & X drugs
- Sale under qualified supervision
- Records
- Inspection

Retail Sale of Drugs can be done from following shops :

(1) Chemist & Druggist Establishments

Chemist & Druggist Establishments, functioning under the supervision of 'Registered Pharmacist' but do not compound drugs.

(2) Pharmacies

Pharmacies, functions under supervision of a 'Registered Pharmacist' ~~but do not con~~ and engaged in compounding of drug.

(3) Drug Stores

Drug stores do not have a registered pharmacist & sell drugs specified as household remedies.

ⓑ Retail Sale From Vendors

- Sometimes drugs are sold by vendors who do not have a fixed place of business but have been granted a license by Licensing Authority to conduct business in particular area.
- For vendors license is issued only for drugs other than those specified in Schedules C & G.

③ RESTRICTED LICENSE

- A Restricted license for sale of drugs refers to a legal authorization that allows individuals or entities to sell certain controlled drugs or pharmaceuticals, but with specific limitations & conditions set by regulatory authorities.
- Restricted license is issued for drugs other than those specified in Schedule C, G & X & those specified in Schedule C & G but not in Schedule X.
- Following are required conditions :

- The licensee should have premises well-equipped with drug storage facilities.
- The license should be displayed in front of premises.
- The drug should be bought only from a licensed dealer or manufacturer.
- Drug should be sold in their original containes.

Classes Of Drugs Whose Sale Is Prohibited

- Misbranded, Spurious, Adulterated & Non-Standard Quality drugs.
- Patent or Proprietary drugs with undisclosed formulae.
- Drugs claimed to cure any disease specified in Schedule J.
- Drugs manufactured or imported in violation of provision of Act & Rules.
- Expired Drugs
- Drugs to be distributed as a free sample to the members of medical profession & bearing the words 'Physician's Sample. Not to be Sold'

Offences & Penalties

Offences	Penalties
• Sale, stocking or exhibition of drugs which may cause death or serious hurt as per section 320 of IPC.	Imprisonment from 5 year to life & fine > 10000
• Sale, Stocking, exhibitions for sale of spurious drugs	Imprisonment for 3-5 years & fine not less than 5,000 & imprisonment for 6-10 years & fine upto 10,000 on second conviction.
• Any adulterated but not containing toxic or harmful substances injurious to health.	Imprisonment 1-3 year & fine 5000
• Failure to keep records or disclose required information	Imprisonment 2-4 years & fine upto 10,000 on second conviction. Imprisonment for 1 year & fine upto ₹ 1,000.

LABELLING & PACKING OF DRUGS

- Labelling & Packaging of drugs are critical processes in the pharmaceutical industry.
- They ensure that medications are safe, effective and accessible to patients & healthcare providers
- Following are labelling requirments :

General Labelling Requirment

- Drug Name : The proper name of drug shall be printed.
- Net Content : Weight, Volume in metric system or units.
- Content of Active Ingredient :
  Oral liquids : Content per single dose
  Liquid parenterals : Content per ml
  Solid Parenteral : Content per mg
  Tablet, Capsules & Pills : Content per tab, capsule, pill.

- Name & Add of Manufacturer
- Manufacturing License Number
- Batch No
- Date of Manufacturing
- Date of Expiry
- Free samples to Medical Proffesion : Mention "Not to be Sold"
- Alcoholic Preparations : If Alcohol % > 3%, then it must be displayed.
- Information of Handling, use, Distribution, Storage etc.
- Maximum Retail Price
- Toothpaste containing fluoride : fluoride content in ppm.

SPECIAL LABELLING REQUIRMENTS

• Schedule G1	• Date of manufacture & expiry • Import license number
• Schedule F	• Prescribed Name
• Schedule G1	• Caution : It is dangerous to take this preparation except under Medical Supervision
• Schedule H	• Rx : To be sold by retail on prescription of a RMP only • NRx : " • XRx : To be sold by retail on prescription of RMP only.
• Schedule X	
• Schedule D	• Date of Manufacture • Date of Expiry
• Schedule G1	• Proper Name • Import License No • Batch No
• Schedule W • Prep. for Ext. Use • Pharmacopial Prep. • Patent & Proprietary Medicine • Medicines for Animals	• Proper Name (no trade name) • For External Use only • Labelling of 'IP', 'BP', 'USP' etc. • Quantities of Active Ingredients. • Name & Address of Manufacture • 'Not for Human Use, for Animal Treatment Only'

Specimen Labels

SCHEDULE H DRUG

Rx Erythromycin Estolate Tablets IP 500 MG

Each uncoated tablet contain :
Erythromycin Estolate IP
Equivalent to Erythromycin ..... 500 mg
Dosage : As directed by the Physician

Store in a cool, dark & dry place

WARNING : To be sold by retail on prescription of a Registered Medical Practitioner Only.

Mfg Lic. No 2/20
Batch No. 2019
Mfg. Date
Exp. Date

M.R.P. not to exceed ₹ .....
inclusive of all taxes

Manufactured by : XYZ Pharmaceuticals, India

For 100 Tablets of Phenobarbitone (Schedule X Drugs)

100 X 50 mg.
Tablets of Phenobarbitone

Schedule X drug.
Warning : To be sold by retailers on prescription of a registered medical practitioner only

JOHN & JOHN Ltd.
Chemists
75, Park Street, Culcutta

LIST OF PERMITTED COLOURS

No drug shall contain colour other than that specified below :

ⓐ **Natural Colours :** Annatto , Carotene , Chlorophyll , Cochineal , Curcumin , Red oxide of iron , Yellow oxide of iron . Titanium dioxide , Black oxide of iron

ⓑ **Artificial Colours :** Caromel , Riboflavin

ⓒ **Coal Tar Colours :** Quinizarine Green SS , Alizarin , Cyanine Green F , Fast Green FCF , Tartarazine , RED (Erythrosine) , Eosine YS or Eosin G , Toney Red or Sudan III . Indigo Carmine , Brilliant Blue FCF , Orange G , Resorcin Brown , Napthol Blue - Black .

OFFENCES & PENALTIES

- False or Misleading Labelling : Imprisonment upto 1 year / fine upto ₹ 5,000
- Failure To Comply with Labelling Requirements : Fine upto ₹ 2,000
- Sale with incorrect or incomplete labelling : Imprisonment upto 2 year / fine upto ₹ 10,000
- Non - compliance with packing regulations : ~~Imprisonment upto 2 years~~ / Fine upto ~~₹ 10,000~~ ₹ 2,000 .

ADMINISTRATION OF THE ACT & RULES

There are mainly 3 types of administrative agencies :

- Advisory
- Analytical
- Executive

① Advisory

- Drugs Technical Advisory Board (DTAB)
- Drugs Consultative Committee (DCC)

② Analytical

- Central Drugs Laboratory
- State Drug Control Laboratory
- Government Analyst

③ Executive

- Licensing Authorities
- Controlling Authorities
- Drug Inspectors
- Custom Collectors.

① DRUG TECHNICAL ADVISORY BOARD

- The Drug Technical Advisory Board (DTAB) is a key regulatory beardy in several countries, mainly India, where it plays a significant role in advising the government on drug regulations & policies.
- DTAB has following members :

ⓐ Ex- Officio Members (8)

(1) Director - General of Health Services, who is also the Chairman
(2) Drugs Controller of India
(3) Director, Central Drug Laboratory, kolkata
(4) Director, Central Research Institute, kasauli
(5) Director, Indian Veterinary Research Institute, Izzatnagar
(6) Poesident, Pharmacy Council of India.
(7) Poesident, Medical Council of India
(8) Director, Central Drug Research Institute, Lucknow

ⓑ Nominated Members (5)

- Two person nominated by central govt. amongst person who are incharge of drug control in India.
- 1 person from pharmaceutical industry nominated by central government.
- Two government analyst nominated by central government

© Elected Members

- A teacher in pharmacy or pharmaceutical chemistry or pharmacognosy elected by executive committee of PCI.
- A teacher in medicine or therapeutics eleded by executive committee of PCI.
- 1 Pharmacologist elected by governing body of Indian council of medical research.
- 1 person elected by council of central medical association.
- 1 person to be elected by council of Indian pharmaceutical association.

FUNCTIONS OF DTAB

- The DTAB advises the central & State Governments on technical matters of administration of act.
- It makes modifications & ammendments in the Act by consulting other Boards.
- It reviews data on drug's safety & efficacy, especially concerning adverse effect.
- It establishes & verifies quality standards for drugs, cosmetics and medical devices to ensure they meet safety & efficacy benchmarks.
- It recommends regulations related to manufacture, storage, distribution & sale of drugs.

② DRUG CONSULTATIVE COMMITTEE

- This agency comprises of two representatives nominated by Central Government & one nominee of each of the ~~Central~~ State Governments.
- This body has power to regulate its own procedure.

Functions

- It advises the Central Government, the State Governments & the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act.
- It can regulate its own procedure.

③ CENTRAL DRUGS LABORATORY

- The central Drugs Laboratory is established in Culcutta under the control of a director appointed by Central Gioverenment.
- It is the premier national laboratory for drug testing in ~~various countries~~ India, where it operates under the Ministry of Health & family welfare.
- It is established as central regulatory authority for drug quality control.
- It plays a crucial role in testing & certifying the quality, safety & efficacy of drugs, vaccines & diagnostics in the country.

Functions

- It analyses or tests the drug or cosmetics samples sent by customs collectors or courts.
- It carroles out the analytical Q.C. of imported samples.
- It collects, stores & distributes internal standards.
- It prepares reference standards & also maintains them.
- It maintains microbial cultures.
- It performs any other duties entrusted by Central Gioverenment
- It acts as an appellate authority in matter of disputes.
- It provides training of drug analysis.
- It advises the central drug control administration in respect of quality & toxicity.

④ GOVERNMENT DRUG ANALUST

- A Government Drug Analyst is a specialized role within the regulatory framework for drug quality control, typically employed by government health or regulatory agencies.
- Their main responsibility is to ensure the safety, efficacy & quality of drugs, cosmetics and medical devices within a country.
- They work in government laboratories such as Central Drugs Laboratory (CDL) or State Drug Testing Laboratories

Required Qualifications

- Government drug analysts must have masters in pharmacy, chemistry, pharmacology, microbiology or biotechnology & may require specific certifications depending on region.
- He/ She must have :
- Strong analytical & technical skills in laboratory settings.
- Familarity with GLP & GMP
- Efficiency in using lab equipment like HPLC & various spectrophotometers knowledge of regulatory standards & drug legislation.

Functioning

- Testing & Analysis of Drugs.
- Quality Control
- Sample Examination & Reporting
- Technical Support to Regulatory Authority
- Documentation & Record keeping
- Training & Mentorship

(S) STATE DRUG CONTROL LABORATORY

A State Drug Control Laboratory is a regional government facility responsible for testing & analyzing drugs, cosmetics & medical devices within a specific state.

Functions

- Testing & Quality Assurance
- Sample Analysis and Reporting
- Support for Regulatory Enforcement
- Public Health Research & Collaboration

⑥ LICENSING AUTHORITY

- The Central Government appoints the Licensing Authorities to issue licenses for drug import
- The State Government appoints them for their respective territories to issue licenses for the drug manufacture and sale & for cosmetic manufacture.
- It is the choice of Licensing Authorities to either issue or refuse licenses to the applicants, depending on whether or not they satisfy the prescribed rules.
- If the licensee fail to follow any conditions of licenses, the Licensing Authorities can cancel or suspend their licenses after providing them an opportunity of giving explanation.
- However, the decision of Licensing Authorities can be challenged in the court.

⑦ CONTROLLING AUTHORITIES

- Controlling Authority controls laws and standards related to manufacture, distribution, sale and quality control of drugs, cosmetics & medical devices
- They even controls the Drug Inspectors.

Qualifications

- He/She is a graduate in Pharmacy / Pharmaceutical Chemistry / Medicine with specialisation in Clinical Pharmacology / Microbiology from a recognised university
- He/She has experience in drug manufacturing and testing.

⑧ CUSTOM COLLECTORS

- Custom Collectors refer to specialized entities or individuals responsible for collecting & handling specific types of samples or products.
- These collectors are designated by the regulatory authorities to perform specific tasks related to enforcement of the Act.
- They are responsible for.
  - Collecting samples of drugs or cosmetics from manufacturers, wholesalers or retailers for laboratory testing & analysis.
  - Inspecting & seizing products that violate the Act or related regulations.
  - Gathering evidence & documentation related to non-compliance or illegal activities.

⑨ DRUG INSPECTORS

- A Drug- Inspector is a government - appointed officer responsible for enforcing drug laws & regulations to ensure safety, efficacy, & quality of drugs, cosmetics & medical devices.
- They typically work under the authority of national or state drug regulatory agencies.

Qualifications Of DI

- Person must have a degree in Pharmacy / Pharmaceutical Chemistry / Medicine with specialization in clinical pharmacology / Microbiology from a recognized Indian University.
- 18 months experience in manufacture / testing of atleast one of the substance specified in schedule C
- Gained experience of not less than 3 years in inspection of firms manufacturing any of the substance of Schedule C during their tenure as service as DI.

Power Of DI

- Inspect : Any premises where any drug or cosmetic is :
  - manufact & employed for standardization & testing.
  - Sold, Stocked, exhibited or offered for sale or distributed.

- Collection Of Samples : Any drug or cosmetic :
  - which is being manufactured, stocked, exhibited, sold or being distributed.
  - From any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to purchasers.

- **Enter & Search :** Any place in which he has reason to believe an offence relating to manufacture, sale or distribution of drugs or cosmetics has been or is being committed.

- **Stop & Search :** Vehicle, Vessel or other conveyance which he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence is being committed.

- **Examine Data :** Examine any record, register, document or any other material required.

DUTIES

- Inspection of manufacturing sites.
- Sampling & Testing
- Licensing & Registration
- Investigation & Enforcement
- Monitoring & Surveillance
- Provide guidance on regulatory compliance.
- Collaborate with regulatory authorities
- Seizure of unauthorized drugs
- Public Awareness.

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