ONE shot

COMPLETE CONCEPT

PHARMACY INDIA

B.PHARMA | 5 SEMESTER

PHARMACEUTICAL JURISPRUDENCE

DRUGS AND COSMETIC ACT

UNIT-2

- DETAILED STUDY OF SCHEDULES
- LABELLING AND PACKING OF DRUGS
- SALES OF DRUGS
- ADMINISTRATION OF THE ACT AND RULES

B. PHARMA 5TH SEM ONE SHOT NOTES

UNIT-2

DRUGS AND COSMETICS ACT 1940 & RULES 1945

Unit	Syllabus
2	• Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) • Sale of Drugs: Wholesale, Retail sale and Restricted license. Offences and penalties • Labeling & packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. • Administration of the Act and Rules - Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, licensing authorities, controlling authorities, Drugs Inspectors

DETAILED STUDY OF SCHEDULE

Schedule	Description
G	List of substances that are required to be used only **under medical supervision** and which are to be **labeled accordingly.** ❑ It is compulsory to make proper bill of sale of Schedule & drugs. ❑ Also Compulsory to regulate all records of purchase and sale of Schedule G drugs for 2 years. ❑ **Examples-** Aminopterin, Busulphan, Carbutamide, Daunorubicin etc.
H	List of prescription drugs. **Examples-** Verapamil, Diclofenac, Barbital, Ketamine, etc.
M	**Good** manufacturing practice (GMP) requirement of factory premises, plants and equipment. **Ex- mixing tanks, storage tanks, oven etc.** **M_1 -** Requirement of factory premises etc. for manufacture of homoeopathic preparation. **M_2 -** Requirement of factory premises etc. for manufacture of cosmetics. **M_3 -** Requirements of factory premises for the manufacture of medical devices.
N	List of minimum equipment for efficient running of a pharmacy. (Navyug Pharmacy).
P	Life period of drug.
P_1	Pack sizes of drugs.
T	Good manufacturing practice for Ayurvedic Siddha, Unani medicines.

	It also includes- ❑ factory premises ❑ Location & surroundings ❑ Building ❑ Water supply ❑ Disposable of waste. ❑ Container's cleaning ❑ Stores ❑ Raw materials
U	Particulars to be shown in manufacturing records.
U_1	Particulars to be shown in manufacturing, raw material and analytical records of cosmetic.
V	Standard for patent or proprietary medicines (Victory). **It includes-** ❑ Tablets ❑ Capsules ❑ Liquid oral dosage forms. ❑ Injections ❑ Ointments
X	List of drugs whose import, manufacture and sale, labeling and packaging are governed by special provision. **Ex- Barbital, Phenobarbital etc.**
Y	Requirement and guideline for permission to import and manufacture of new drugs for sale or to undertake clinical trial. **It includes-** ❑ Application for permissions. ❑ Clinical trials (I-IVth phase) ❑ Human pharmacology (Phase I) ❑ Therapeutic exploratory trials (Phase I) ❑ Therapeutic confirmatory trials (Phase I) ❑ Post marketing trials (Phase IV).
Schedule F-Part XII B	This schedule deals with the requirements for the functioning and operation of a blood banks and preparation of blood components. **It Includes-** ❑ General Requirements ❑ Location and surrounding ❑ Buildings ❑ Health, Clothing, & Sanitation of staff ❑ Accommodation for a blood bank ❑ Personnel ❑ Maintenance ❑ equipment's
F_1	**Part I-** Provisions applicable to the production of all bacterial and viral vaccine.

	Part II- Provisions applicable to the production of all sera from living animal of blood components. **Part III-** Provisions applicable to the manufacture and standardization of diagnostic agent (Bacterial origin)
F_2	Standards for surgical dressings.
F_3	Standards for sterilized umbilical tapes.
FF	Standards of ophthalmic preparations.

SALES OF DRUGS

- Sale may be defined as the process of passage of articles from the manufacturer to the consumer.
- **There are two general types of sale:**

1. **Whole sale of drugs**
   I. Drugs other than those specified in Schedule C, C1 and X
   II. Other than Schedule C, C1 drugs from Motor Vehicle
   III. Schedule X drugs
   IV. Drugs specified in Schedule C and C1 but not included in Schedule X drugs
   V. Drugs specified in Schedule C and C1 from Motor Vehicle
2. **Retail sale of drugs**
   I. General licenses
   II. Restricted licenses

Wholesale of drugs other than those specified in Schedule C, C1 and X

- The License is issued in Form 20B.
- Following conditions are to be satisfied by the licensee:
  - The license should be displaced in a prominent part of premises opened to the public.
  - The licensee must have adequate premises which should not be less than 10 sq. meters, equipped with facilities for the proper storage of drugs.

Wholesale of drugs other than Schedule C, and C1 drugs from Motor Vehicle

- The License is issued in Form 20BB.
- Following conditions are to be satisfied by the licensee:
  - The license should be displaced in a prominent part of the vehicle.
  - Drug should be purchased only from a duly licensed dealer or manufacturer.

Wholesale of Schedule X

- The license is issued in Form 20G
- Following conditions are to be satisfied by the licensee:

- The license should be displaced in a prominent part of premises opened to the public.
- The licensee must have adequate premises which should not be less than 10 sq. meters, equipped with facilities for the proper storage of drugs.

Wholesale of drugs specified in Schedule C and C1 but not included in Schedule X

- The license is issued in Form 21B
- Following conditions are to be satisfied by the licensee:
  - The license should be displaced in a prominent part of premises opened to the public.
  - The licensee should observe precautions prescribed for stocking or sale of drugs.

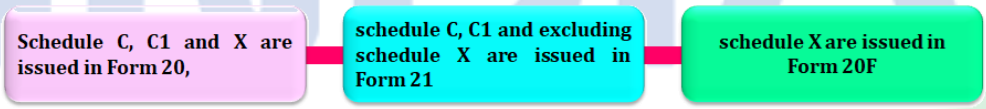
Wholesale of drugs specified in Schedule C and C1 from motor vehicle

- The license is issued in Form 21BB
- Following conditions are to be satisfied by the licensee:
  - The license should be displaced in a prominent part of premises opened to the public.
  - The licensee should observe the precautions prescribed for the storage of drugs.

Retail sale

For retail sale two types of licenses are issued

1. **General license:** Granted to a person who have premises for business and who have engage the services of qualified person to supervise the sale of drug and do the compounding and dispensing.
   - Retail sale license for drugs other than those specified in



2. **Restricted license:** Granted to those dealers who do not engage the services of qualified person.

Restricted license

- Restricted licenses for sale of drugs other than those specified in schedule C, C1 and X are issued in Form 20A.
- Restricted licenses for sale of drugs specified in schedule C, C1 and excluding schedule X are issued in Form 21A
- Restricted licenses are granted to:

- Dealers or person in respect of drugs whose sale does not require the supervision of qualified person.
- Vendors who purchase drugs from a licensed dealer for distribution in sparsely populated areas where other channels of distribution of drugs are not available.

Offences and Penalties for Manufacture and Sale of Drugs

Offences	Penalties for first conviction	Penalties for subsequent conviction
Anyone who sells any adulterated or spurious drugs or drugs which likely to cause death	Imprisonment for a minimum of 5 Years extend up to life time imprisonment and fine of not less than Rs.10,000	Imprisonment up to 10 Years or fine up to Rs. 20,000 or both
Seles of any adulterated or spurious drugs or drugs which is not likely to cause death.	Imprisonment for 1 -3 Years and fine of not less than Rs. 5,000	Imprisonment for 2 -4 Years and fine of not less than Rs. 10,000
Sale of drug in contravention of any other provision	1-2 years imprisonment and fine	2-4 years imprisonment and fine not less than Rs. 5,000
Not disclosing the name of manufacturer or the place where the manufactured drug are kept	Imprisonment up to 3 Years or fine up to Rs.1,000 or both	Imprisonment up to 3 Years or fine up to Rs.1,000 or both
Failure to keep records of manufacture or sale of drugs	Imprisonment up to 3 Years or fine up to Rs.1,000 or both	Imprisonment up to 3 Years or fine up to Rs.1,000 or both
Use of govt. analyst report for advertising any drug	Fine up to Rs. 500	Imprisonment up to 10 Years or fine or both

LABELLING & PACKING OF DRUGS

Labelling of Drugs

- The containers of all the drugs should be labeled as per the provisions of Drug and Cosmetics Rules 1945.
- Following general particulars should be appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed:
  - **Name of drug (official name, trade name)**

- ✓ Net content in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be.

- **The content of active ingredients–**
  - ✓ For oral liquid preparations in terms of the content per single dose, being indicated in 5 ml or multiple thereof.
  - ✓ For liquid parenteral preparations ready for administration in terms of 1 ml or percentage by volume or per dose in the case of single dose container.
- **Name and address of the manufacturer**
  - ✓ Manufacturing license number (Mfg. Lic. No.) under which the drug has been manufactured
  - ✓ A distinctive batch number, lot number (preceded by words "Batch No.", "B. No.:, "Lot No.")
  - ✓ Manufacturing and expiry date.
  - ✓ Precautionary information related to care in handling, usage etc.
  - ✓ Information related to storage.

➢ **General information such as:**
- ✓ Shake well before use (Suspension, Emulsion, lotion)
- ✓ For external use only (if external preparation)
- ✓ Not to be sold (if physician sample)
- ✓ For animal use only (for veterinary products)

Class of drug	Nature of Medicine	Particulars which should appear on label
Schedule C	In original form	1) Proper name of the substance in addition to any patent or proprietary name 2) License No. 3) Batch or Lot No. 4) Potency in units 5) Name & address of manufacturer 6) Date of manufacture 7) Date of expiry 8) Precaution necessary for preserving the properties of drug
Schedule G	Medicines made up ready for internal use	The words "Caution: it is dangerous to take this preparation except under medical supervision" – conspicuously printed and surrounded by a line within which there shall be no other words;
Schedule G	Any drug (External use)	No caution required

Class of drug	For internal use and not comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985)	1) Symbol Rx displayed on left top corner of the label 2) Schedule H drugs-Warning: to be sold by retail on the prescription of a R.M.P. only
Schedule H	For internal use and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985	1) Symbol NRx displayed on left top corner of the label 2) Schedule H drugs- Warning: to be sold by retail on the prescription of a R.M.P. only
Schedule X	For internal use	1) Symbol NRx in red ink displayed on left top corner of the label 2) Schedule X drugs- Warning: to be sold by retail on the prescription of a R.M.P. only
Schedule P	Any drug	1) Date of manufacturing 2) Date of expiry of the potency
Schedule W	Single ingredient	Proper name (no trade name)
Patent and proprietary	-----	1) Quantities of the active ingredient 2) Name and address of manufacturer
Ophthalmic ointments	-----	1) special instructions regarding storage, wherever applicable 2) Warning: If irritation persist or increase discontinue the use and consult the physician
Mechanical contraceptive	-----	1) Particulars specified in schedule R 2) Date of manufacture 3) Storage condition

Packing of drugs

- The pack sizes of drugs meant for retail sale shall be as prescribed in Schedule P_1 to the rules and for other drugs.
- **The pack sizes for Tablets/Capsules shall be–**
  - ✓ Where the number of Tablets (coated or uncoated)/Capsules (hard or soft gelatin) is less than 10 :- *Packing shall be made by the integral number.*
  - ✓ Where the number of Tablets (coated or uncoated)/Capsules (hard or soft gelatin) is more than 10: *Pack size of Tablets/Capsules shall contain multiples of 5.*

- ✓ The pack sizes for liquid Oral preparations shall be: *30 ml (pediatric only)/60 ml/100 ml/200 ml/450 ml.*
- ✓ The pack sizes for Pediatric Oral Drops shall be: *5 ml/10 ml /15 ml.*
- ✓ The pack sizes for Eye/Ear/Nasal drops shall *be: 3 ml/5 ml /10 ml.*
- ✓ The pack size for Eye Ointment shall be: *3 gm/5 gm/10 gm*

➢ **Provided that the provisions of the pack sizes covered under this rule shall not apply to: –**

- ✓ The imported formulations in finished form.
- ✓ Preparations intended for Veterinary use.
- ✓ Preparations intended for Export.
- ✓ Vitamins/Tonics/Cough preparations/Antacids/Laxatives in liquid oral forms, Unit dose forms.

ADMINISTRATION OF THE ACT & RULES

Advisory	Analytical	Executives
▪ Drugs Technical Advisory Board-DTAB ▪ Drugs Consultative Committee-D.C.C.	1) Central Drugs Laboratory - CDL 2) Drug Control Laboratory in states 3) Government Analysts	1) Licensing authorities 2) Controlling authorities 3) Drug Inspectors

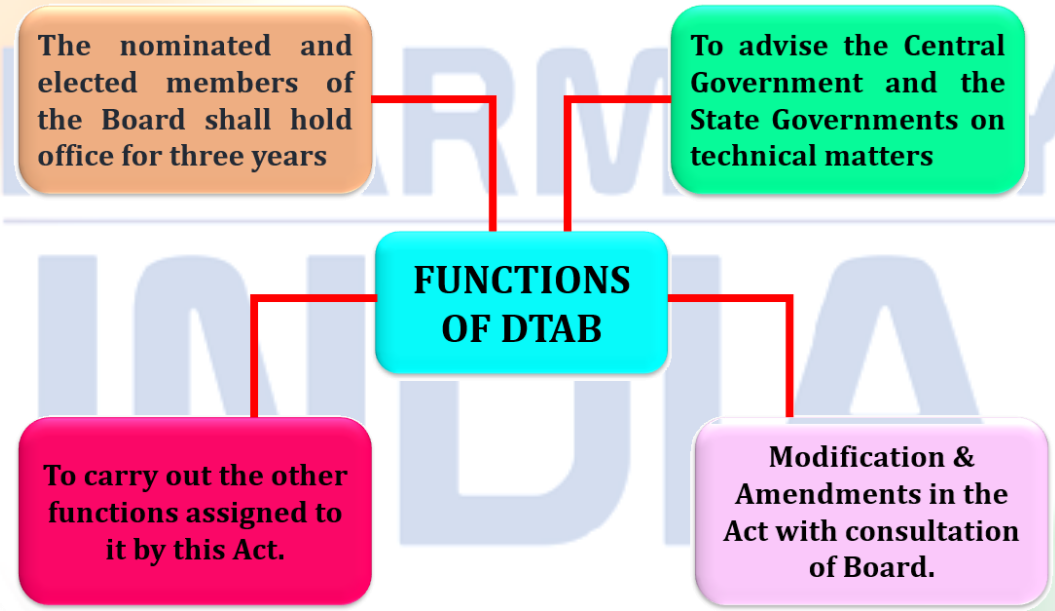
Drug Technical Advisory Board

DTAB is constitute by Central government.

❖ It consist of 18 members, of whom 8 are ex-officio members, 5 nominated and 5 elected members.

Ex-officio Members (8)	a. Director General of Medical and Central b. Health Services, Government of India (Chairman). c. Drugs Controller General of India (Member secretary) d. Director, Central Drug Research Institute (CDRI), Lucknow, U. P. e. Director, Central Drug Laboratory, Kolkatta. f. Director, Indian Veterinary Research Institute (IVRI), Izzatnagar, U.P. g. Director, Central Research Institute (CRI), Kasauli, H.P. h. President, Pharmacy Council of India (PCI) i. President, Medical Council of India (MCI)
Elected Members (5)	a. 1 professor → in pharmaceutics or pharmaceutical chemistry or pharmacognosy → elected by the Executive Committee of PCI from any University or affiliated pharmacy college. b. 1 professor → in medicine or therapeutics in any of the Government or affiliated medical College → elected by

	Executive Committee of Medical Executive Committee of Medical Council of India. c. 1 professor → in pharmacology and toxicology → elected by the Governing Body of Indian Council of Medical Research d. (ICMR). e. 1 member → elected by the Central Council of Indian Pharmaceutical Association (IPA). f. 1 member → elected by the Indian Medical Association (IMA).
Nominated Members (5)	a. 2 members → nominated by Central Government who are incharge of Drugs Control Department of the State or Union Territory. b. 2 Government Analysts → nominated by Central Government anywhere from the country. c. 1 Industrialist → representing pharmaceutical industry to be nominated by Central Government.

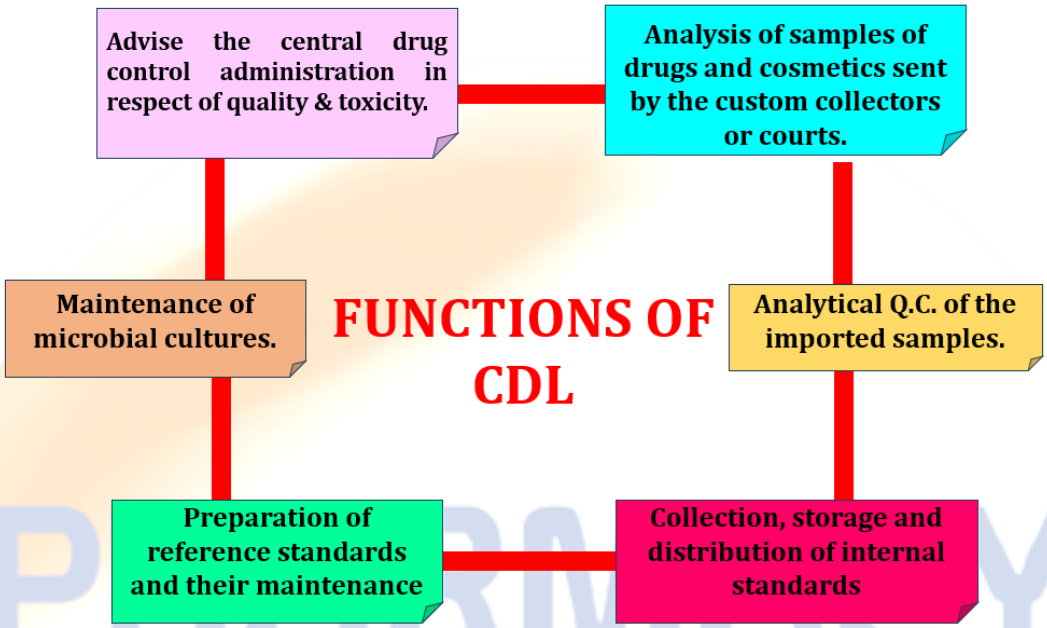


Drugs Consultative Committee (DCC)

- It is also an advisory body constituted by central government.
- **Constitution:** Two representatives of the Central Government.
- One representative of each State Government.
- DCC advise the Central Government and 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.

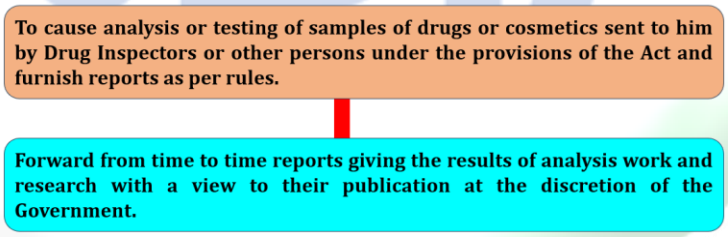
Central Drug Laboratory (CDL)

- Establishment of Central Drug Laboratory under the control of a director appointed by the Central Government.

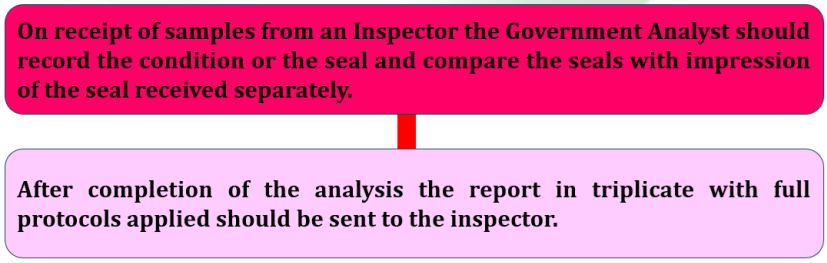


Government Analyst

- State Government may appoint such persons, having prescribed qualification as Government Analysts for the purpose of analysis/testing of samples of drugs and cosmetics.
- The central government may also appoint such person as a Government Analysts.
- Person who is directly or indirectly engaged in any trade connected with manufacture or sale of drugs & cosmetics can not be appoint as Government Analyst
- **Duties of Government Analyst:**



- **Procedure**



Licensing Authorities

- **For import:** The central government appoints licensing authorities to issue or renewal of licenses for the import of drugs.
- **For manufacture and sale:** The state governments appoint licensing authorities for respective territories to issues license for the sale of drugs and for the manufacture and sale of drugs and for manufacture of cosmetic.
- The Drug Controller of India has been notified as the Central License Approving Authority.

Drug Inspector

- Central and State Government are empowered to appoint a qualified persons as Drug Inspectors to inspect premises licensed for manufacture of drugs & cosmetics & sale of drugs.
- Drug Inspectors should have no any financial interest in the import, manufacture or sale of drugs and cosmetics.
- Drug Inspectors are deemed to be public servant.
- Drug Inspectors are required to keep all information's confidential & not to disclose.

POWERS OF DRUG INSPECTOR

INSPECT

- Any premises wherein any drug or cosmetic is-
  1.manufactured and the means employed for standardizing and testing.
  2.Sold,stocked,exhibited or offered for sale, or distributed.

COLLECTION OF SAMPLES

Any drug or cosmetic-

1. which is being manufactured stocked exhibited, sold, offered for sale, or is being distributed;
2. from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee

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

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