Unit-IV Pharmaceutica Jurisprudence

(Compiled by: Mr. Shmmon Ahmad, Faculty of Pharmacy, Glocal University Saharanpur, email: shmmon@theglocaluniversity.in)

Topic : Drug and Cosmetic Act 1940

Drugs Enquiry Committee appointed by Government in 1931 under the chairmanship of Colonel R.N.Copra to have a control on the import, manufacture and sale of drugs. But it not have strict rule. thus 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.

Schedules to the Act-(List of drug and equipment)

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

Schedule L: It prescribes list of drugs to be sold on prescription only- omitted

Schedule M: It prescribes the good manufacturing practices (GMP) and the requirements of factory premises, plant, equipments, etc for manufacture of drugs.

Schedule P: It prescribes life period of drugs

Schedule R: It prescribes the standards for condoms made of rubber latex intended for single use**.**

Schedule S: It prescribes standards for cosmetic

Schedule T: It prescribes the requirements of factory premises, plant, equipments and hygienic conditions for manufacture of Ayurvedic, Siddha, and Unani

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 **(NRx)**.

SORT DEFINITIONS

Ayurvedic, Siddha or Unani Drug

It includes all medicines intended for internal or external use for or in diagnosis, treatment, prevention, mitigation or cure of diseases in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative(standard) books of Ayurvedic, Siddha and Unani systems of medicines specified in First Schedule.

Cosmetic

Cosmetic means any article intended to be rubbed, sprayed, poured, sprinkled on or introduced into or otherwise applied to the human body thereof, for cleansing, beautifying or promoting the attractiveness or altering the appearance and also includes any article intended to be used as a component of cosmetic but does not include soap.

Loan Licence [Rule 69A]

It means a licence granted to a person who do not have his own arrangements of manufacture but who intends to avail himself of the manufacturing facilities owned by another manufacturer.

Adulterated Drug

- A drug shall be deemed to be adulterated if-
- it contains in whole or in parts of filthy, putrid or decomposed substances; or
- it is prepared, packed or stored under unsanitary conditions whereby it may have been contaminated with filth or which may render the contents injurious to the health, or
- its container is composed in whole or in parts of poisonous or deleterious substance which may render the contents injurious to the health; or
- it contains or bears for the purpose of colouring only, a color other than those prescribed or it contains harmful or toxic substances which may render it injurious to health; or
- any substance has been mixed therewith so as to reduce its quality or strength.

Manufacture : Manufacture in relation to any drug or cosmetic includes any process or part of process for making, altering, ornamenting, finishing, packing, labelling, treating or adopting any drug or cosmetic with a view to its sale or distribution but does not

include compounding or dispensing of drugs in the ordinary course or the course of retail business.

Drug Technical Advisory Board (DTAB) : Drugs Technical Advisory Board is constituted by Central Government and its work to advise the Central Government and State Government on the technical matters(Advise technical bases).

Drug Inspector : In relation to any drug or cosmetic, Drug Inspector appointed by Central Government or State Government under section 21; or

In relation to Ayurvedic, Siddha or Unani systems of Medicine, Drug Inspector appointed by Central Government or State Government

LICENSING AUTHORITY

The Central Government may appoint an authority called as "Licensing Authority" to issue licence for the import of drugs. Each State Government may appoint "Licensing Authority" to issue licence for manufacture, distribution and sale of drugs. These authorities have power to grant the license or refuse the license depending on the conditions of the applicant. These authorities may also suspend the licence if the licensee has committed any offence in the contravention of the provisions of this Act.

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CONDITIONS OF GENERAL LICENCE

While granting such licence, the licensing authority should consider the following conditions

a) The average number of such licences granted during three years immediately proceeding year.

b). The occupation, trade or business carried on by the applicant.

Where licence is granted for the wholesale (Form 20Bor 21B) and retail sale (Form 20 or of drugs in such premises should be under the control of competent person i.e. registered pharmacist and have an area of not less than 15 square meters

Dispensing and compounding of drugs

Any drug shall, if compounded or made on the licensee's premises be compounded or made under the direct and personal supervision of a registered pharmacist.

The drugs other than the sale by the way of wholesale dealing, shall be supplied only on the prescription of a Registered Medical Practitioner and shall be under personal supervision of a registered pharmacist.

The supply of any drug [other than those specified in Schedule X Narcotic & Psychotropic] on a prescription of a Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of the entry in the register shall be entered on the prescription. The following particulars shall be entered in the register:

- serial number of the entry
- the date of supply
- the name and address of the prescriber
- the name and address of the patient, or the name and address of the owner of the animal if the drug supplied is for veterinary use
- the name of drug or preparation and the quantity or in case of a medicine made up by
  the licensee, the ingredients and quantities thereof

in the case of a drug specified in Schedule C or Schedule H the name of the manufacturer of the drug, its batch number and the date of expiry of potency, if any the signature of the registered pharmacist by or under whose supervision the medicine was made up or supplied.

Supply of Schedule C drugs

The supply of Schedule C drugs by retail shall be recorded in the register. The register should include the following details.

- Serial number of entry
- Date of expiry
- Name and address of purchaser
- Name of the manufacturer, batch number and expiry date
- Sign of qualified person
- Name and quantities of drugs

Supply of other drugs

In case of drugs other than those specified in Schedule C is supplied by retail under cash or credit memo that should include the following particulars:

- Name, address and sale licence number of dealers
- Serial number of cash or credit memo
- Name and quantity of drug supplied
- Carbon copies of cash and credit memos shall be maintained by the licensee. The records shall be maintained and preserved for at least two years from the date of last entry.

Sale of Schedule H and X drugs

Schedule H and X drugs shall be sold by retail only on the prescription of Registered Medical Practitioner. The prescription should be in duplicate form one copy of this prescription should be preserved by the licensee for at least two years

- Sale of Schedule H and X drugs to Registered Medical Practitioners, hospital, dispensaries or nursing homes shall be made under the signed written prescription which shall be preserved by the licensee for at least two years.

- The premises should be under the control of registered pharmacist to supervise the sale, distribution and preservation of drugs.

- The licence shall be displaced at the prominent place open to the public.

- The purchase of drugs should be carried out from duly licensed manufacturers or dealers.

- The drugs which are specified in schedule C and C(i) should be properly stored before its sale.

- A licence in Form 20 F shall be granted to pharmacy in such area and to pharmacy which is not operating Chemists /Druggists.

- The records / registers which are maintained shall be preserved for two years from the date of last entry therein.

- If there is a change in the premises, such change should be informed to licensing authority within one month.

Dispensing of Schedule H and X drugs

- The prescription shall not be dispensed more than once unless the prescriber have stated that it may be dispensed for more than once.

- If the prescriptions contains directions, it may be dispensed for the stated number of times. It must be dispensed according to the directions.

- While dispensing Schedule H and X (Narcotic & Psychotropic) drugs, signature, names and address of the seller and date on which it is dispensed, shall be recorded

- While dispensing Schedule H and X drugs, it should not contain other preparation or any other drugs.

Storage of Schedule X (Narcotic &Psychotics) Drugs

In retail shops, Schedule X drugs shall be stored -

- Under lock and key in a cupboard or in premises recorded for the storage of these substances.
- In a part of premises solely separated from the remainder of premises and qualified person is responsible to access (sell & Store).

Records of Purchase

Records of purchase of drugs for retail sale shall be maintained by licensee and such record shall contain following particulars

- Date of purchase
- Name and address of person from whom purchased and his licence number
- Name of drug, quantity and batch number
- Name of manufacturer
- Licensee shall serially number the purchase bills including cash or credit memos and maintain it in chronological order.

Wholesale supply of drug

Drugs for wholesale supplied under cash or credit memos should include the following particulars:

- Name, address and sale licence number of licensee to whom such drugs are sold
- Serial number of cash or credit memo
- Name, quantity and batch number of drug supplied
- Name of manufacturer

Carbon copies of cash and credit memos shall be maintained by the licensee. The records shall be maintained and preserved for at least two years from the date of last entry.

Records of Purchase

Records of purchase of drugs wholesale sale shall be maintained by licensee and such record shall contain following particulars

- Date of purchase
- Name and address of person from whom purchased and his licence number
- Name of drug, quantity and batch number
- Name of manufacturer

Licensee shall serially number the purchase bills including cash or credit memos and maintain it in chronological order.

Licensee shall produce all registers and records for inspection on demand by inspector.

Description for premises

Drug store Licensee who do not require services of qualified person shall display description, **"Drug store".**

ii) Chemists and Druggists

Licensee who employ the services of qualified person shall display description, **"Chemists and Druggists"** but where drugs are not compounded against prescription.

Pharmacy +

Licensee who employ the services of qualified person shall display description, **"PHARMACY"** and where drugs are compounded against prescription.

Storage of Veterinary (Animal) medicine

- Veterinary medicines are kept in retail shops or the premises reserved for this purpose shall be labelled with direction. **"NOT FOR HUMAN USE"** for the treatment of animals only.
- The veterinary medicines shall be stored under lock and key in a cupboard or in premises reserved for this purpose.
- Part of the premises separated from the remainder of the premises and the customers will not have to access veterinary medicines.

The licensee shall not sell or stock expired drug which is registered on label, container or wrapper. He shall keep such drugs in packages or cartons aside and label the top with the words, **"Not for sale"**.

Classes of prohibited Drugs

The following classes of drugs are prohibited for its manufacture, sale, distribution, etc.

- Adulterated, spurious, misbranded drug or drug which are not of standard quality.
- Patent and proprietary medicine of which formula is not disclosed.
- Drug imported or manufactured in the contravention of the provisions of the Act.
- Drugs which may claim to cure any of the diseases specified in the Schedule J.
- Expired drugs.
- The drugs intended for its consumption by Employees State Insurance Scheme (E.S.I.S) or Government Institutions (only for govt suuply).
- Drugs intended for its distribution to the members of the medical profession as free sample and bearing on the container the words "**Physician sample, Not to be sold."**
- Drugs not intended for sale.

Sale of Cosmetics

The cosmetic which are not in the contravention of the provisions of the Act and Rules may be sold without licence. Dealer of cosmetic require a licence for the sale of cosmetic.

Conditions for grant of licence for manufacture of Cosmetics

Manufacturer of cosmetics shall satisfy the following conditions for the manufacture of cosmetics

- The manufacture of cosmetics should be conducted under the personal supervision of a competent technical staff with the following qualifications-
- Diploma in pharmacy
- Registered pharmacist

- Passed intermediate examination with Chemistry as one of the subject or any other examination approved by licensing authority.
- Manufacturing premises shall be separated from rooms for private use and shall be clean and maintain hygienic conditions during manufacturing.
- The applicant shall provide adequate space, plant and equipments for the manufacture of cosmetics.

RENEWAL OF LICENCES

The licences in Form 20, Form 21, Form 20B, Form 21B, Form 20F, Form 20G, Form 20C and Form 20D are valid for the period of five years from the date of granting them.

Before expiry of the licence's applications for the renewal of the licences in the prescribed Forms accompanied with the prescribed fees, paid through chalan, should be submitted to the Licensing Authority.

Licence for retail sale	Licence of wholesale	Application form	Licence fee (Rupees)	Additional Fee per Month (Rupees)
Form 20	Form 20-B	Form 19	1500	500
Form 21	Form 21-B	Form 19	1500	500
Form 20-F	Form 20-G	Form 19-C	500	250
Form 20-C	Form 20-D	Form 19-B	250	50

Labelling of Preparation as per Drug and cosmetic Act

1-Label of schedule 'H' Drug

<table>
<tr><td colspan="2">Cetirizine Tablets I.P</td></tr>
<tr><td>Rx. CETMAX
10 TABLETS

SCHEDULE 'H' DRUG

Warning: To be sold by retail on the prescription of registered medical Practitioner only</td><td>Label claim…
Each film coated tablet contains

Cetirizine Hydrochloride I.P ……..10mg
Excipients ……Q.S
Colour: Titanium dioxide

LIC No : 25342
Batch No : 5GL03/20
MFG Date : March 2020
EXP Date : Feb 2023
MRP (Include All taxes) : 55Rupese</td></tr>
<tr><td>0 51111 40759 2</td><td>Manufactured by: Glocal Manufacturing ltd.
Marketed By: Gloacl Marketing Business Solution, Mirzapur Distt. Saharnpur U.P 247121</td></tr>
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2- Label of Narcotic & Psychotropic schedule ‘H’ Drug

Clonazepam orally disintegrate Tablets USP	
NRx. **CLOPAM0.5** 10 TABLETS **SCHEDULE ‘H’ DRUG** **Warning:** To be sold by retail on the prescription of registered medical Practitioner only	Label claim… Each film coated tablet contains Clonazepam ……..0.5 mg Excipients ……Q.S Colour: Titanium dioxide **LIC No : 25342** **Batch No : 5GL03/20** **MFG Date : March 2020** **EXP Date : Feb 2023** **MRP (Include All taxes) : 55Rupese**
0 51111 40759 2	**Manufactured by:** Glocal Manufacturing ltd. **Marketed By:** Gloacl Marketing Business Solution, Mirzapur Distt. Saharnpur U.P 247121

3-Label of Paracetamol Syrup

PARACETAMOL, CHLORPHENIRAMINE MALEATE & PHENYLEPHRINE HCL. SYRUP	
Rx..JEMCOLD **Warning:** It is dangerous to take this preparation except under the supervision of Registered Medical Practitioner. **Caution:** Taking more than daily dose of paracetamol may cause serious lever damage or allergic reaction	**Composition** Each 100mL preparation contain Paracetamol I.P…… 250mg Chlorpheniramine Maleate I.P…. 2.0mg Phenylephrine HCL IP …5.0mg Flavour Syrup base…… q.s **LIC No : 25342** **Batch No : 5GL03/20** **MFG Date : March 2020** **EXP Date : Feb 2023** **MRP (Include All taxes) : 55Rupese**
0 51111 40759 2	**Manufactured by: Mankind Pharma** ltd. **Marketed By:** Gloacl Marketing Business Solution, Mirzapur Distt. Saharnpur U.P 247121

IMPORTANT QUESTION

1. Define Schedule C, G, H, and X.

2. Define any three out of four(a,b,c,d)

A). Adulterated Drug b). Cosmetic c).Manufacture d).Drug Inspector

3. What is the Conditions for general licence?

4. How to Storage and maintain record of Schedule X (Narcotic &Psychotics) Drugs?

5. Draw a Label of Paracetamol Syrup

(Highlight Text have important points. Take a Print of the Document or Make hand written Notes)

…… (Shmmon Ahmad)
Assistant Professor
Deptt of Pharmacy