# B. PHARMACY

# 5 SEM IMPORTANT QUESTIONS

PHARMACEUTICAL JURISPRUDENCE

#### UNIT-I

#### Drugs and Cosmetics Act, 1940 and its rules 1945:

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.

# 10 MARKS

1. Aims & objectives of drug & cosmetic act . What are the condition for granting license for drug manufacture

## 5 MARKS

- 1. What is loan & repackaging license
- 2. Explain manufacture of drug , prohibition of manufacture and rules of certain drugs

### 2 MARKS

1. Schedule - A-Y

#### **10 Hours**

### UNIT-II

#### Drugs and Cosmetics Act, 1940 and its rules 1945.

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

# 10 MARKS

1. Brief note on administration of act & rule

## 5 MARKS

- 1. Explain schedule M/X/P
- 2. Explain labelling & packaging of drug
- 3. Duties and qualification of drug inspector
- 4. Explain DTAB

## 2 MARKS

1. Offences & penalties in sale of drug

### UNIT-III

### **10 Hours**

- Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties
- Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

# 10 MARKS

- 1. Brief note on pharmacy act
- 2. Narcotic drug & psychotropic substance

- 1. Differentiate between state & joint pharmacy
- 2. Short note on registration of pharmacist
- 3. Difference between inbond & outside bond
- 4. Short note on medicinal & toilet preparation act
- 5. Preparation of ayurvedica patent, homeopathic & propieratory preprarations

- 1. What is drug abuse?
- 2. Explain export of alcoholic preparation

- Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

# 10 MARKS

- 1. What are CPC SEA guidance & also explain institutional animal ethics committee?
- 2. What are the salient features of drug & magic remedies act

- 1. Explain DPCO
- 2. Salient feature of drug & remedies
- 3. CPC SEA guidelines

- 1. What is NLEM
- 2. What is revoke registration

#### **07 Hours**

- Pharmaceutical Legislations A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- Medical Termination of Pregnancy Act
- Right to Information Act
- Introduction to Intellectual Property Rights (IPR)

# 10 MARKS

1. Give a brief note on pharmaceutical legalization

- 1. What are the role of health, survey & development committee
- 2. Significance of pharmacists oath & what is it?
- 3. What is MTP?
- 4. What is RTI
- 5. What is code of pharmaceutical ethics
- 6. Hathi committee

- 1. What is IPR
- 2. Hathi committee
- 3. Mudaliar committee
- 4. What is DEC?