**PHARMACEUTICAL JURISPRUDENCE QUESTION BANK (B-PHARM V-SEM)**

**UNIT-I**

**Drugs and Cosmetics Act, 1940 and its rules 1945 :( 10+5+2)**

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.

 **UNIT – II**

**Drugs and Cosmetics Act, 1940 and its rules 1945 :( 10+5+2)**

Long essays (10 marks):

1. Explain briefly about schedule Y.
2. Explain in detail about schedule M.
3. Discuss briefly about clinical trials as per schedule Y.
4. Write the constitution and functions of Drug Technical Advisory Board (DTAB).

Short essays (5 marks):

1. Write a note on retail sale.
2. Write a note on schedule M.
3. Write a note on Central Drug Laboratory (CDL).
4. Define and write the qualifications and duties of government analyst.
5. Write a note on general labelling requirements and give the specimen labels for schedule X drugs.
6. Describe about restricted license.
7. What are qualifications and duties of Drug Inspector?
8. Describe the general requirements of labelling under Drugs and Cosmetics Act 1940.
9. Describe schedule P, U & V under Drugs and Cosmetics Act 1940.
10. Explain in brief about wholesale and retail sale under D&C Act
11. Give the specimen label for schedule H with suitable example.
12. Explain in brief about controlling authority as per D&C Act.
13. Write a short note on schedule F.
14. Write the labelling requirements of medicines for internal use with a model labelling.

Short answers (2 marks):

1. Write any two offences and penalties for sale of drugs.
2. Enumerate two functions of PCI Inspector.
3. Give the labelling requirements and write specimen label for schedule G.
4. What is Drug Consultative Committee (DCC)?
5. Write a note on repacking license.
6. Enumerate schedule B.
7. Write the types of retail sale of drugs. Give two examples of schedule J.
8. Write a short note on Drug Control Laboratory.
9. What is schedule G & N.?
10. Write the labelling requirements for ophthalmic preparation.

**UNIT – III**

**Pharmacy Act – 1948 :( 10+5+2)**

Long essays (10 marks):

1. Write the constitution and functions of PCI.
2. Explain in detail about Education Regulation (ER) 1991.
3. Write in detail about Education Regulation of State and Joint State Pharmacy Councils.
4. Define Education Regulation. Mention the standards, regulations prescribed for Education Regulation.
5. What are subsequent registers? Mention the qualifications required for entry into first and subsequent registers.

Short essays (5 marks):

1. Write in detail on first register, subsequent register and removal of name from register as per Pharmacy Act.

Short answers (2 marks):

1. Write about preparation of first register.
2. Mention the offences and penalties in contravention of Pharmacy Act.
3. Differentiate between State and Joint State Pharmacy Council.
4. Define Education Regulation.
5. Mention the ex-officio members of PCI.

**Medicinal and Toilet Preparation Act – 1995 :( 5+2)**

Long essays (10 marks):

1. Give the design of bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations in bonded laboratory.
2. Give the design of non-bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations under non-bonded laboratory.
3. Define Drug Inspector. Mention the qualifications, degrees and powers of Drug Inspector.

Short essays (5 marks):

1. Discuss in detail about manufacture in bonded laboratory.
2. Write a short note on non-bonded laboratory.
3. Explain about ware-housing of alcoholic preparations as per M&TP Act 1995.
4. What are requirements of bonded laboratory?
5. Explain in brief about alcoholic preparations.
6. Write a note on patent and proprietary preparations.
7. Explain in brief about manufacturing of Ayurveda preparations under M&TP Act.
8. Write in brief about manufacturing in non-bonded laboratories.

Short answers (2 marks):

1. Define London proof spirit under M&TP Act.
2. Define rectified spirit as per M&TP Act.
3. Write a short note on Central Drugs Standard Control Organization (CDSCO).

**Narcotic Drugs and Psychotropic substances Act – 1985 and Rules :( 10+5+2)**

Long essays (10 marks):

1. Write the objectives of NDPS Act 1985. Discuss briefly about offences and penalties of NDPS Act 1985.
2. What are the objectives of NDPS Act 1985? Give a detailed account on cultivation, production and sale of poppy straw.

Short essays (5 marks):

1. Explain opium-poppy cultivation as per NDPS Act.
2. Define manufactured drug and controlled substances as per NDPS Act
3. Give the offences and penalties under NDPS Act.
4. Write a short note on Narcotic and Psychotropic consultative committee.
5. Describe the manufacture, sale and export of opium under NDPS Act.
6. Define manufactured drugs.
7. Write the operations controlled by central and state government under NDPS Act.
8. Write a note on manufacture of cocaine and morphine.

Short answers (2 marks):

1. What is the punishment specified for illegal cultivation of coca plant.
2. What are objectives of NDPS Act?
3. Define cannabis under NDPS Act.
4. State clandestine arrangement.

**UNIT-IV**

**Study of Salient Features of Drugs and Magic Remedies Act and its rules :( 5+2)**

Short essays (5 marks):

1. Define magic remedies. Write the classes of advertisements prohibited under D&MR Act.
2. Define drugs, advertisements and magic remedies as per D&MR Act.
3. Discuss the classes of advertisements exempted conditionally under D&MR Act.
4. Define magic remedies. Give the classes of advertisements.
5. Write the offences and penalties in contravention of D&MR Act.
6. Define advertisement and mention the objectives of D&MR Act.
7. Define magic remedies. Write a note on scrutiny of misguiding advertisements related to drugs.
8. Write about salient features of D&MR Act.

**Prevention of Cruelty to animals Act-1960 :( 5+2)**

Short essays (5 marks):

1. Give the constitution and functions of Institutional Animal Ethical Committee (IAEC).
2. Write the objectives and prevention of cruelty to animals. What are the parts of CPCSEA guidelines?
3. What are CPCSEA guidelines for breeding and stocking of animals?
4. Write about transport and acquisition of animals for experiment.
5. Write a note on power to suspend or revoke of registration as per Prevention of Cruelty to animals Act.
6. Describe the facilities to be maintained for experimentation on animals under CPCSEA guidelines.

**National Pharmaceutical Pricing Authorities :( 5+2)**

Short essays (5 marks):

1. Write a short note on National List of Essential Medicines (NLEM).
2. Explain Drugs Price Control Order (DPCO).
3. Write a note on retail price and ceiling price of scheduled formulations.
4. Write a short on DPCO.
5. Write a short on sale price of bulk drugs and retail price of formulations.
6. Who maximum allowable post manufacturing expenses (MAPE) is calculated as per DPCO.

**UNIT-V**

**Pharmaceutical Legislations :( 5+2)**

Short essays (5 marks):

1. Write the contributions of Bohre committee to the pharmacy profession.
2. Write a note on profession conduct of pharmacist.

Short answers (2 marks):

1. Give two recommendations made by Bhatia committee.
2. Give the significance of Drugs Enquiry Committee (DEC).
3. Give any three recommendations of Hathi committee.
4. Write about Mudaliar committee.
5. What is Chopra’s committee?
6. Mention the objectives of Pharmaceutical Legislations.
7. What is Hathi committee?
8. Write a note on health survey of Pharmaceutical Legislation.
9. Define Pharmaceutical Legislation.
10. Write a brief review on Pharmaceutical Legislation.

**Code of Pharmaceutical Ethics :( 5+2)**

 Short essays (5 marks):

1. Define code of ethics. Explain receiving and handling of prescription of pharmacist.
2. Discuss the code of ethics for pharmacist in relation to his trade.
3. Discuss the code of ethics for pharmacist in relation to his job.
4. Mention the role of pharmacist in relation to his medical profession.
5. Describe the role of pharmacist in relation to his profession.

Short answers (2 marks):

1. What is Apprentice Pharmacist as per the code of pharmaceutical ethics?
2. Enlist the code of pharmaceutical ethics in relation to medical profession.
3. How a pharmacist should follow fair trade practice as per code of pharmaceutical ethics.
4. Describe professional vigilance as code of pharmaceutical ethics.
5. Define Pharmaceutical Ethics.
6. Reproduce pharmacist’s oath.
7. Write a brief note on code of pharmaceutical ethics.
8. Differentiate between ethics and laws.
9. Write the role of pharmacist in health care system.

**Medical Termination of Pregnancy Act :( 5+2)**

Short answers (2 marks):

1. Write a short note on termination of pregnancy as per MTP Act.
2. Describe the places where pregnancy may be terminated as per MTP Act.
3. Write a short note on role of Chief Medical Officer (CMO).
4. Mention the objectives of MTP Act.
5. Mention the circumstances under which pregnancy can be terminated.
6. Mention the offences and penalties of MTP.

**Right to Information Act :( 2)**

Sort answers (2 marks):

1. Write a note on Central Information Commission.
2. Write a note on State Information Commission.
3. Define Right to Information.
4. What is Right to Information?
5. What are the duties of Right to Information?
6. Mention the functions of Right to Information Act.
7. Mention the responsibilities of Right to Information Act.
8. Enumerate the functions of Right to Information.

**Introduction to Intellectual Property Rights (IPR) :( 2)**

Short answers (2 marks):

1. Mention the type of patents.
2. Define copyright.
3. Write the types of patents.
4. Define patents. Mention types of patents.
5. Give the criteria for patenting of inventions.
6. Define trademark as per IPR Act