Date- 22/11/2021 morning

Roll Number ---------- **(Total Number of Questions 13)** **(Total number of Printed Pages 01)**

Programme	B. Pharmacy
Semester	5th
Subject	Pharmaceutical Jurisprudence
Subject Code	BP505T
Paper ID	76790
Time	3Hours
Maximum Marks	75

Instructions to Candidates: *No supplementary/continuation sheet will be issued to the candidates. Answer the questions precisely.*
Section A consists of Ten parts of 2 marks each (Objective Type); Attempt **ALL.*
***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*
**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section A (10 X2 = 20)

1. Give very short answers to the followings (2 marks each):

i.	Schedule M
ii.	Medicinal Hemp and Poppy Straw
iii.	Patent
iv.	List of Permitted colors
v.	Central drug Laboratory
vi.	National list of essential medicines
vii.	Drug Consultive committee
viii	Loan License
ix.	Hathi Committee
x.	Schedule G

Section B (2 X 10 = 20)

2.	What are the qualifications prescribed for appointment, power and duties of drug inspectors?
3.	State objectives of Pharmacy act. Write constitution and functions of State Pharmacy Council.
4.	Write about the official procedure of cultivation, Production of opium and sale & distribution of opium products.

Section C (7 X 5 = 35)

5.	Give constitution and function of DTAB
6.	Discuss Drug Price Control Order in brief.
7.	What is manufacturing in bond? Describe the layout and requirements of bonded and non bonded laboratory.
8.	Define the term Magic Remedies. Discuss the classes of advertisement prohibited.
9.	Write a note on prevention of cruelty to animals act.
10.	Write a brief note on Medical termination of pregnancy act.
11.	Discuss the origin scope and development of Pharmaceutical legislation of India.
12.	Give general procedure and conditions for obtaining a license for sale of drugs and cosmetics act in 1940.
13.	Write a note on Intellectual Property Rights.

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**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section A (10 X2 = 20)

1. Give very short answers to the followings (2 marks each):

i.	What is Loan Licence?
ii.	Define RMP and its role.
iii.	What is Patent or Proprietary medicine?
iv.	Explain Schedule M.
v.	Define Cosmetics.
vi.	Write about Cannabis.
vii.	Explain Drugs Enquiry Committee.
viii.	What is Trademark?
ix.	Define an Advertisement.
x.	Write full form of MAPE.

Section B (2 X 10 = 20)

2.	Write note on constitution of PCI. What are education regulations and how are they implemented by PCI?
3.	What are CPCSEA guidelines for breeding and stocking of animals? Write about transport and acquisition of animals for experiment.
4.	Give design of bonded laboratory. Discuss in detail about manufacturing of alcoholic preparations in bonded laboratory.

Section C (7 X 5 = 35)

5.	Write brief note on Mudaliar committee.
6.	Define Drug Inspector. Mention qualifications, degrees and powers of drug inspector.
7.	Explain opium poppy cultivation as per NDPS Act.
8.	Write a short note on National List of Essential Medicine.
9.	What are precedents and subsequent conditions for grant of license to manufacture of drugs and cosmetics specified in schedule C, C_1 and X.
10.	What is Right To Information? Mention the functions of Right To Information Act.
11.	Write a brief note on code of pharmaceutical ethics.
12.	Write a note on DTAB.
13.	What are subsequent registers? Mention qualifications required for entry in First and Subsequent register.

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Programme	B. Pharmacy
Semester	5th
Subject	Pharmaceutical Jurisprudence
Subject Code	BP505T
Paper ID	76760
Time	3Hours
Maximum Marks	75

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Section A consists of Ten parts of 2 marks each (Objective Type); Attempt **ALL.*

***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*

**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A **(10X2=20)**

1.	Give very short answers to the followings
i.	What is Drug Consultative Committee (DCC)?
ii.	Define trademark as per IPR Act
iii.	Define Pharmaceutical Legislation.
iv.	Write a short note on termination of pregnancy as per MTP Act.
v.	Write a note on Central Information Commission.
vi.	Define copyright.
vii.	Differentiate between ethics and laws.
viii.	What is the punishment specified for illegal cultivation of coca plant?
ix.	Write a brief note on code of pharmaceutical ethics.
x.	Define London proof spirit under M&TP Act.

Section- B **(2X10=20)**

2.	Write the constitution and functions of Drug Technical Advisory Board (DTAB).
3.	What are the objectives of NDPS Act 1985? Give a detailed account on cultivation, production and sale of poppy straw.
4.	Define Drug Inspector. Mention the qualifications, degrees and powers of Drug Inspector.

Section- C **(7X5=35)**

5.	Explain about ware-housing of alcoholic preparations as per M&TP Act 1995.
6.	Define manufactured drug and controlled substances as per NDPS Act.
7.	Define magic remedies. Write a note on scrutiny of misguiding advertisements related to drugs.
8.	What are CPCSEA guidelines for breeding and stocking of animals?
9.	Describe the role of pharmacist in relation to his profession.
10.	Write a brief note on National List of Essential Medicines (NLEM)?
11.	Write in detail on first register, subsequent register and removal of name from register as per Pharmacy Act.
12.	Describe the general requirements of labelling under Drugs and Cosmetics Act 1940.
13.	Explain in detail about prohibition of manufacture and sale of certain drugs under Drugs and Cosmetics Act 1940.

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15 JUN 2023

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****Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A (10 X2 = 20)

1.	Give very short answers to the followings
i.	Define Schedule H.
ii.	Full form of NLEM and DPCO.
iii.	What is RTI act?
iv.	What is Code of ethics?
v.	What is MAPE with its formula?
vi.	What is drug consultive committee?
vii.	Define advertisement.
viii.	What is registered pharmacist?
ix.	Differentiate between adulterated and spurious drugs.
x.	Define cosmetics.

Section- B (2 X 10 = 20)

2.	What are the qualifications for appointment of a drug inspector? Explain their duties and procedures.
3.	Describe the condition imposed on import, export and shipment of Narcotic substances according to Narcotics drugs and Psychotropic substances act.
4.	Write a note of Drug and magic remedies in detail.

Section- C (7 X 5 = 35)

5.	Write a note on Intellectual property rights.
6.	Give constitution and function of DTAB.
7.	Write a note on Hathi committee.
8.	What is the purpose of code of Ethics? How it help the profession.
9.	What conditions are required for grant of license to manufacture of drugs and cosmetics specified in schedule C, C_1 and X.
10.	Write a note on Mudaliar Committee.
11.	Write the functions of Right to Information Act.
12.	Describe the constitution of PCI. What are education regulations and how are they implemented according to PCI.
13.	Describe the prevention of animal cruelty.

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(Evening)

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****Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section A **(10 X2 = 20)**

1.	Give very short answers to the following:
i.	What are Psychotropic Substances?
ii.	What is DPCO? Mention the objective of DPCO.
iii.	Write about drugs related to schedule X and Y.
iv.	Differentiate between Inbond and Outbond manufacturing?
v.	What is the main requirement for a loan license?
vi.	Write down the role of the Drug Enquiry Committee.
vii.	What are the Offences and Penalties for objectionable advertisements?
viii.	Define DTAB and DCC.
ix.	Name the places from where are drugs imported into India.
x.	Difference between State and Joint State Pharmacy Council.

Section B **(2 X 10 = 20)**

2.	What are the conditions for the grant of License and license for the manufacture of drugs?
3.	Explain the procedure for export of the alcoholic preparation in laboratories?
4.	Describe in detail the Narcotic Drugs and Psychotropic Substances Act 1985 and Rules.

Section C **(7 X 5 = 35)**

5.	Give the composition and functions of the Pharmacy Council of India.
6.	Give Offences and Penalties related to the import of Drugs?
7.	Write a note on the Drug Technical Advisory Board?
8.	What are Magic Remedies? Mention the objectionable and exempted advertisements related to drugs.
9.	Write a brief note on the Medical Termination of Pregnancy Act.
10.	What are CPCSEA guidelines for the Breeding and Stocking of Animals?
11.	What are the qualifications and responsibilities of Drug Inspectors?
12.	Give General labelling requirements for the drugs.
13.	Write a brief note on the National List of Essential Medicines (NLEM).

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14/6/24 (Morning)

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**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A **(10 X2 = 20)**

1.	Give a very short answers to the followings:
i.	How does schedule M function and what does it regulate?
ii.	What are the uses and regulations concerning medicinal hemp and poppy straw?
iii.	How can one obtain a patent for a pharmaceutical product?
iv.	Which colors are permitted for use in pharmaceuticals according to regulatory standards?
v.	What are the functions of the central drug laboratory?
vi.	How the national list of essential medicines determined is and what does it include?
vii.	What role does the Drug Consultative Committee play?
viii	How does a loan license operate in the pharmaceutical industry?
ix.	What were the main recommendations provided by the hathi committee?
x.	What aspects does Schedule G cover and what are its requirements?

Section- B **(2 X 10 = 20)**

2.	What are the qualifications prescribed for appointment, power and duties of drug inspectors?
3.	State objectives of Pharmacy act. Write constitution and functions of state pharmacy council.
4.	Write about the official procedure of cultivation, production of opium and sale and distribution of opium products.

Section- C **(7 X 5 = 35)**

5.	Give constitution and function of the drug technical advisory board (DTAB).
6.	Discuss drug price control order in brief.
7.	What is manufacturing in bond? Describe the layout and requirements of bonded and non bonded laboratory.
8.	Define the term magic remedies. Discuss the classes of advertisement prohibited.
9.	Write a note on prevention of cruelty to animals act.
10.	Write a brief note on medical termination of pregnancy act.
11.	Discuss the origin scope and development of pharmaceutical legislation of India.
12.	Give general procedure and conditions for obtaining a license for sale of drugs and cosmetics act in 1940.
13.	Write a note on Intellectual property rights.

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28 11 24
(Evening)

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**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A **(10 X2 = 20)**

1.	Give very short answers to the followings:
i.	Explain Schedule X.
ii.	What is the purpose of CCSEA (CPCSEA)?
iii.	What is pharma Intellectual Property Right (IPR)?
iv.	Define approved drug colors.
v.	Role of Central Drug Laboratory (CDL)
vi.	What does the National List of Essential Medicines (NLEM) include, and why is it important?
vii.	What is the purpose of the drug advisory committee?
viii.	Meaning of loan license?
ix.	National fund for controlling drug abuse.
x.	What is the RTI Act in pharma?

Section- B **(2 X 10 = 20)**

2.	What is manufacturing in bond? Describe the layout and requirements of bonded and non bonded laboratory.
3.	What are the qualifications prescribed for appointment, power and duties of drug inspectors?
4.	State objectives of pharmacy act. Write constitution and functions of state pharmacy council.

Section- C **(7 X 5 = 35)**

5.	Define ceiling price and retail price. Write formulae to calculate retail price.
6.	Mention the drug price control order, 1995.
7.	Give a note on warehousing of alcoholic preparation.
8.	Explain prescription and non prescription products.
9.	Mention the purpose of medicinal and toilet preparation act-1955.
10.	Discuss the origin scope and development of pharmaceutical legislation of India.
11.	Define the term magic remedies. Discuss the classes of advertisement prohibited.
12.	Write a note on prevention of cruelty to animals act.
13.	Write a brief note on medical termination of pregnancy act.

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****Section -C consists of Nine questions carrying 5 marks each (Short Answer); attempt any SEVEN.*

Section- A **(10X2=20)**

1.	Give very short answers to the followings:
i.	State the role of the Hathi committee.
ii.	Mention two functions of the central drug laboratory.
iii.	What is the purpose of the national list of essential medicines?
iv.	Write a short note on regulation of medicinal hemp and poppy straw.
v.	State key features of schedule G drugs.
vi.	What is meant by a loan license?
vii.	State the function of the drug consultative committee.
viii	Why is schedule M important in GMP?
ix.	What is the use of the list of permitted colours?
x.	State the meaning of patent in pharmaceuticals.

Section -B **(2 X 10 = 20)**

2.	Outline the official procedure for cultivation, production, sale, and distribution of opium and its products.
3.	Describe the qualifications required for appointment of drug inspectors and summarize their powers and duties.
4.	State the main objectives of the pharmacy act and explain the constitution and functions of the state pharmacy council.

Section C **(7 X 5 = 35)**

5.	Trace the evolution, scope, and growth of pharmaceutical legislation in India.
6.	Summarize the main provisions and purpose of the drug price control order (DPCO).
7.	Write a concise note on intellectual property rights (IPR) relevant to pharmaceuticals.
8.	Provide a short note on the prevention of cruelty to animals act and its major safeguards.
9.	Outline the structure and key roles of the drugs technical advisory board (DTAB).
10.	Explain the term magic remedies. Mention the categories of advertisements prohibited under the act.
11.	Write a brief overview of the medical termination of pregnancy (MTP) act and its key provisions.
12.	Define manufacture in bond. Describe layout and requirements of bonded vs. non-bonded labs.
13.	State the procedure and conditions for obtaining a drug sale license under the D&C Act, 1940.

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