Code No. : 2611

PHARMACY LAW AND ETHICS

Time : 3:00 Hours] **[Maximum Marks : 80**

NOTES :

i) Attempt **all** parts.

ii) Students are advised to specially check the Numerical Data of question paper in both versions. If there is any difference in Hindi Translation of any question, the students should answer the question according to the English version.

iii) Use of Pager and Mobile Phone by the students is not allowed.

PART - A

(Long questions)

Answer any six questions. Each question carries equal marks. **[6 × 5 = 30]**

Q1) Write a note on registration of pharmacists.

Q2) Give the constitution and functions of Pharmacy Council of India.

Q3) Discuss various powers of drug inspector as per Drugs and Cosmetics Act 1940.

Q4) Give the offences and penalties under Narcotic Drugs and Psychotropic Substances Act. 1985.

Q5) What is Food Safety Officers? Write the powers of food safety officer.

Q6) Describe the ethics for Pharmacist in relation to his job during his service.

Q7) What is hospital waste? Give the methods of disposal of hospital waste.

PART - B

(Short questions)

Answer any ten questions. Each question carries equal marks. **[10 × 3 = 30]**

Q1) Give the recommendations of Drug enquiry committee.

Q2) What are the duties of the PCI inspectors?

Q3) Define the term as per Drugs and Cosmetics Act 1940:

a) Drug

b) Cosmetic

c) Qualified person

Q4) Write a note on schedule N.

Q5) Write a note on loan licence.

Q6) Give the classes of advertisements which are prohibited under the drugs and magic remedies. (Objectionable advertisement) Act. 1954

Q7) Write the functions of Institutional Animal Ethics Committee.

Q8) Write the main features of the Drugs price control order-2013.

Q9) What are the provisions under which the RMP may terminate the pregnancy of a woman as per the MTP Act, 1971.

Q10) Give the role of central drugs standards control organization.

Q11) Write the functions of blood bank.

PART - C

(Objective type questions) [20 × 1

Answer all questions. Each question carries equal marks.

Q1) The Pharmacy act was came into force on 4th March _____.

a) 1947 b) 1948

c) 1949 d) none

Q2) The first PCI was constituted in the year_____.

a) 1947 b) 1948

c) 1949 d) none

Q3) The Drugs which are imported under the names of other drugs are called as _____.

a) Adulterated drug b) Misbranded drug

c) Spurions drug d) None

Q4) The schedule of standards for cosmetics is _____.

a) Schedule C b) Schedule M

c) Schedule R d) Schedule S

Q5) Diacetylmorphine is also known as _____.

a) Ecgonine b) Cocaine

c) Heroin d) none

Q6) The prevention of cruelty to animal act was passed in the year_____.

a) 1960 b) 1961

c) 1962 d) 1965

Q7) Food safety and standards authority of India has been established under Food Safety and Standards Act,_____.

a) 2004 b) 2005

c) 2006 d) 2007

Q8) Food and adulteration act, was passed in _____

a) 1953 b) 1954

c) 1955 d) 1956

Q9) The price fixed by the government for a new drug under paragraph 5; is known as _____.

a) Retail price
b) Maximum retail price
c) Both (a) and (b)
d) None

Q10) The first national list of essential medicines of India was prepared and released in _____.

a) 1994
b) 1995
c) 1996
d) 1998

Q11) _____ means scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another

a) Pharmacoeconomic
b) Pharmacodynamic
c) Pharmacokinetics
d) Pharmacovigilance

Q12) The rules of human conduct binding to all persons in state or nation is called _____. (Ethics/Law)

Q13) If the pharmacist is making an attempt to capture the business of fellow pharmacist is said to be _____. (Cut-throat competition/ clandestine arrangement)

Q14) A 12 weeks pregnancy can be terminated with the consent of _____. (2RMPs/3RMPs)

Q15) _____ is any distinctive word, phrase, logo, symbol, design, picture, styling or a combination of one or more of these elements.

a) Patents
b) Trademark
c) Copyright
d) None

Q16) Ministry of health and family welfare has notified the "New Drugs and Clinical Trials" Rule, 2019 on _____.

a) 23rd March 2019
b) 24th March 2019
c) 25th March 2019
d) 26th March 2019

Q17) The blood bank unit shall have a minimum requirement floor area of _____.

a) 10 m^2
b) 50 m^2
c) 100 m^2
d) None

Q18) _____ is a state of the art technology for safe disposal of medical waste.

a) Plasma Pyrolysis
b) Inertization
c) Incineration
d) Microwave irradiation

Q19) The disaster management act was passed in _____.

a) 2003
b) 2005
c) 2008
d) 2009

Q20) The medical devices involving low risk levels are categorized under _____.

a) Class A
b) Class B
c) Class C
d) Class D

Code No. : 2611

PHARMACY LAW AND ETHICS

Time : 3.00 Hours] **[Maximum Marks : 80**

NOTES:

i) Attempt all parts.

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iii) Use of Pager and Mobile Phone by the students is not allowed.

PART - A

[6 × 5 = 30]

Answer any six questions. Each question carries equal marks.

Q1) Define and classify sale of drugs as per Drugs and Cosmetics Act 1940. Write about retail sale of drugs.

Q2) What are the objectives of Patent Act 1970? Write in short about procedure to get the patent.

Q3) Write a short note on any one of the following :

a) Education Regulations

b) Brand Vs Generic medicines

Q4) Give the bonafied reasons for termination of pregnancy under medical termination of pregnancy Act 1970.

Q5) What do you understand by code of Pharmaceutical ethics ? Write in brief about ethics for pharmacist in relation to his job.

Q6) Write the objectives of Drugs Price control Order 2013. How will you calculate the ceiling price of scheduled formulation?

Q7) Write the constitution of pharmacy council of India.

PART - B

[10 × 3 = 30]

Answer any ten questions. Each question carries equal marks.

Q1) Explain the role of Central Drugs Standards Control Organization (CDSCO).

Q2) Define the "advertisement" or "magic remedies" as per objectionable advertisement Act 1954.

Q3) Write the functions of drugs inspector

Q4) Define "Adulterated Drugs" as per Drugs and Cosmetics Act 1940.

Q5) Write short note on Poison Act 1919.

Q6) Write in brief about schedule C and C_1.

Q7) Write short note on clinical trials.

Q8) What is repacking license?

Q9) Give qualifications required for Government Analyst.

Q10) What are the objectives of consumer protection Act 2019 ?

Q11) What are the salient features of clinical establishment Act 2010?

PART - C

[20 × 1 = 20]

Answer all questions. Each question carries equal marks.

Multiple Choice Questions/Fill in the blanks/One word/One sentence questions.

Q1) Metformin drug comes under which of the following schedules?

a) Schedule C and C_1

b) Schedule G

c) Schedule H

d) Schedule K

Q2) Recommended temperature for storing the product at one place is

a) 0°C - 8°C

b) 8°C - 15°C

c) 15°C - 25°C

d) Above 25°C

Q3) Schedule M describes which of the following?

a) Standards for surgical dressings

b) Good Manufacturing Practices

c) Life Period of drugs

d) None of the above

Q4) Which of the following is the full form of FSSAI?

a) Food safety & sample Authority of India

b) Fire Safety & Standards Authority of India

c) Fire safety & sanitisation Authority of India

d) Food safety & standards Authority of India

Q5) The optimum dose of therapy is determined in which of the following phases of clinical trials?

a) Phase I

b) Phase II

c) Phase III

d) Phase IV

Q6) Which of the following is the drug regulatory body in India?
a) Central Drugs Standard Control Organisation
b) Food Safety & Standards Authority of India.
c) Pharmacy council of India
d) Food and Drug Administration.

Q7) Among the elected members of PCI six members are elected by which of the following?
a) UGC
b) MCI
c) AICTE
d) None of these

Q8) Central Drug Laboratory is situated at _____.

Q9) A person which is dependent on narcotic drug or psychotropic drug is known as _____.

Q10) What is schedule G?

Q11) Form No. _____ is used to apply for the license of retail sale of schedule C and C_1 drugs.

Q12) Advertisement of drug claiming cure of cancer is _____.

Q13) Pharmacy Act was implemented in the year _____.

Q14) Write the functions of blood bank.

Q15) Disaster Management Act was passed in the year _____.

Q16) Write the full form of CPCSEA.

Q17) Methods used for the treatment of biomedical waste are _____ and _____.

Q18) The minimum qualification for the registration of pharmacist is _ _____.

Q19) What is bioethics?

Q20) Write the full form of DTAB.

(हिन्दी अनुवाद)

नोट : सभी खण्डों को हल कीजिए ।

खण्ड – (अ)

किन्हीं छः प्रश्नों के उत्तर दीजिए । प्रत्येक प्रश्न के अंक समान हैं। [6 × 5 = 30]

प्र.1) ड्रग्स एवं कास्मेटिक्स अधिनियम 1940 के अनुसार औषधियों की परिभाषा एवं वर्गीकरण कीजिए । औषधियों की खुदरा बिक्री के बारे में लिखिए ।

प्र.2) पेटेंट अधिनियम 1970 के उद्देश्य क्या हैं? पेटेंट प्राप्त करने की प्रक्रिया के बारे में संक्षेप में लिखिए ।

प्र.3) निम्नलिखित में से किसी एक पर संक्षिप्त टिप्पणी लिखिए :
अ) शिक्षा विनियमन
ब) ब्रांड बनाम जेनरिक दवाएं

प्र.4) गर्भ का चिकित्सीय समापन अधिनियम 1970 के अन्तर्गत गर्भावस्था को समाप्त करने के वास्तविक कारण बताइए ।

प्र.5) फार्मास्यूटिकल एथिक्स के कोड से आप क्या समझते हैं? फार्मेसिस्ट के लिए उसकी नौकरी के संबंध में नैतिकता (एथिक्स) के बारे में संक्षेप में लिखिए ।

प्र.6) औषधी मूल्य नियंत्रण आदेश अधिनियम 2013 के उद्देश्य लिखिए । आप शेड्यूल्ड फार्मूलेशन के अधिकतम मूल्य की गणना कैसे करेंगे?

प्र.7) भारतीय फार्मेसी काउन्सिल का संगठन लिखिए ।

खण्ड – (ब)

किन्हीं दस प्रश्नों के उत्तर दीजिए । प्रत्येक प्रश्न के अंक समान हैं। [10 × 3 = 30]

प्र.1) केन्द्रीय औषधि मानक नियंत्रण संगठन (CDSCO) की भूमिका की व्याख्या कीजिए ।

प्र.2) आपत्तिजनक विज्ञापन अधिनियम 1954 के अनुसार "विज्ञापन" अथवा "जादुई इलाज" की परिभाषा दीजिए ।

प्र.3) औषधि निरीक्षक के कार्य लिखिए ।

प्र.4) ड्रग्स एवं कास्मेटिक्स अधिनियम 1940 के अनुसार "मिलावटी दवाओं" की परिभाषा दीजिए ।

प्र.5) विष अधिनियम 1919 पर संक्षेप में टिप्पणी लिखिए ।

प्र.6) अनुसूची C एवं C_1 के बारे में संक्षेप में लिखिए ।

प्र.7) चिकित्सीय परीक्षण पर संक्षेप में टिप्पणी लिखिए ।

प्र.8) रीपैकिंग लाइसेंस क्या है?

प्र.9) सरकारी विश्लेषक के लिए वांछित योग्यताएं दीजिए ।

प्र.10) उपभोक्ता संरक्षण अधिनियम 2019 के उद्देश्य क्या हैं?

प्र.11) क्लीनिकल प्रतिष्ठान अधिनियम 2010 की मुख्य विशेषताएं क्या हैं?

खण्ड - (ब)

[20 × 1 = 20]

सभी प्रश्नों के उत्तर दीजिए। प्रत्येक प्रश्न के अंक समान हैं।

बहुविकल्पीय प्रश्न/रिक्त स्थानों की पूर्ति/एक शब्द / एक वाक्य प्रश्न :

प्र.1) मेटफार्मिन औषधि निम्नलिखित अनुसूचियों में से किसके अन्तर्गत आती है?

अ) अनुसूची C और C_1 ब) अनुसूची G

स) अनुसूची H द) अनुसूची K

प्र.2) उत्पाद को ठंडे स्थान पर रखने के लिए अनुशंसित तापमान है :

अ) 0°C-8°C ब) 8°C - 15°C

स) 15°C-25°C द) 25°C से अधिक

प्र.3) अनुसूची M निम्नलिखित में से किसे बताता है?

अ) सर्जिकल ड्रेसिंग के लिए मानक ब) अच्छा उत्पादन अभ्यास

स) औषधियों की जीवन अवधि द) उपरोक्त में कोई नहीं।

प्र.4) निम्नलिखित में से FSSAI का पूर्ण रूप क्या है?

अ) फूड सेफ्टी एण्ड सैम्पल एथारिटी ऑफ इण्डिया । ब) फायर सेफ्टी एण्ड स्टेण्डर्ड एथारिटी ऑफ इण्डिया ।

स) फायर सेफ्टी एण्ड सैनेटाइजेशन एथारिटी ऑफ इण्डिया । द) फूड सेफ्टी एण्ड स्टेण्डर्ड एथारिटी ऑफ इण्डिया ।

प्र.5) क्लीनिकल परीक्षण के निम्नलिखित किस चरण में चिकित्सा की इष्टतम (आप्टीमम) खुराक निर्धारित की जाती है?

अ) चरण I ब) चरण II

स) चरण III द) चरण IV

प्र.6) भारत में औषधि नियामक संस्था निम्नलिखित में कौन है?

अ) केन्द्रीय औषधि मानक नियंत्रण संगठन ब) भारतीय खाद्य सुरक्षा एवं मानक प्राधिकरण

स) भारतीय फार्मेसी काउन्सिल द) खाद्य एवं औषधि प्रशासन

प्र.7) पी सी आई के निर्वाचित सदस्यों में से छः सदस्य निम्नलिखित में मे किसके द्वारा निर्वाचित होते हैं?

अ) यू जी सी ब) एम सी आई

स) ए आई सी टी इ द) उपरोक्त में कोई नही

प्र.8) केन्द्रीय औषधि प्रयोगशाला ..... में स्थित है।

प्र.9) एक व्यक्ति जो नशीली औषधि अथवा मनः प्रभावी औषधि पर निर्भर है, ... कहलाता है।

प्र.10) अनुसूची G क्या है?

प्र.11) फार्म संख्या ..... का उपयोग अनुसूची C एवं C_1 की औषधियों की खुदरा बिक्री के लाइसेंस के लिए आवेदन के लिए किया जाता है।

प्र.12) कैंसर के इलाज का दावा करने वाली औषधि का विज्ञापन ..... है।

प्र.13) फार्मेसी अधिनियम वर्ष ..... में लागू किया गया था।

प्र.14) ब्लड बैंक के कार्यों को लिखिए ।

प्र.15) आपदा प्रबन्धन अधिनियम वर्ष ..... में पारित हुआ था।

प्र.16) CPCSEA का पूर्ण रूप लिखिए ।

प्र.17) जैव चिकित्सा अपशिष्ट के उपचार के लिए उपयोग की जाने वाली विधियां ..... और ..... हैं।

प्र.18) फार्मेसिस्ट के पंजीकरण के लिए न्यूनतम योग्यता ..... है।

प्र.19) बायोएथिक्स क्या है?

प्र.20) DTAB का पूर्ण रूप लिखिए।

PHARMACY LAW AND ETHICS

Time Allowed : 3:00 Hours

Maximum Marks : 80

Notes: (i) Attempt **all** questions.

(ii) Students are advised to specially check the numerical data of question paper in both versions. If there is any difference in Hindi translation of any question, the students should answer the question according to the English version.

(iii) Use of Pager and Mobile phone by the students is not allowed.

PART-A

(Long Answer Type Questions)

[6x5=30]

Note : Answer **any six** questions. Each question carries equal marks.

Q.1. Discuss the constitution and functions of pharmacy council of India.

Q.2. Define Narcotics and Psychotropic substances. Give the prohibitions under Narcotic Drugs and Psychotropic substance Act 1985.

Q.3. Discuss the distribution of drugs to in-patients in a hospital.

Q.4. Give the salient feature and amendments of Medical Termination of Pregnancy Act.

Q.5. Define code of Pharmaceutical Ethics. Write down the ethical principles.

Q.6. Write note on penalties under the Poison Act 1919.

Q.7. What are the objective of Drugs Price Control Order (DPCO)?

PART-B

(Short Answer Type Questions)

[10x3=30]

Note : Answer **any ten** questions. Each question carries **equal** marks.

Q.1. Write a note on History of Pharmacy Profession in India.

Q.2. What are Misbranded drugs?

Q.3. Write a note on DTAB.

Q.4. Describe Hathi Committee.

Q.5. Elaborate a note Indian Pharmacopoeia Commission (IPC).

Q.6. Elaborate the basic requirement for Blood Bank.

Q.7 Write the qualification and duties of drugs Inspector.

Q.8. Elaborate the following schdules as per Drugs and Cosmetics Act 1948 :

(a) Schedule G (b) Schedule H

Q.9. Write tho disposal methods for Biomedical Wastes?

Q.10. What are Medical Devices?

Q.11. Write a note on loan licence.

PART-C

(Objective Type Questions)

[20x1=2

Note : Answer all questions. Each question carries equal marks.

Q.1. PCI is reconstituted as every _____.

(a) 1 year (b) 2 years (c) 4 years (d) 5 years

Q.2. The drug samples taken by the drug inspector of analysis are sent to _____.

(a) Government Analyst (b) Drug controller of India

(c) Testing laboratories (d) Chemical analyst

Q.3. The members of DTAB hold the office for a period of _____.

(a) 3 years (b) 5 years (c) 7 years (d) 8 years

Q.4. _____ are examples of Norcotic Drugs.

(a) Opium (b) Coca (c) Hemp (d) All of the above

Q.5. Display signboard or notices by a registered medical practitioner on his premises fall under ___

(a) Regular advertisement (b) Permitted advertisement

(c) Exempted advertisement (d) Prohibited advertisement

Q.6. Any announcement made orally or by means of producing or transmitting light, sound or sm is known as _____.

(a) Order (b) Commitment (c) Resolution (d) Advertisement

Q.7. _____ may regulate the possession and sale of any specified poison.

(a) Central government (b) Poisons control authority

(c) State government (d) Poision rehabilittion bureau.

Q.8. The code of ethics of pharmacy is developed by _____.

(a) PCI (b) SPC (c) MCI (d) DCGI

Q.9. A consent of _____ is required for termination of pregnancy of 20 weeks.

(a) Doctor holding MBBS degree (b) Gynaecologist

(c) Doctor holding MD degree (d) Two Registered Medical Practitioners

Q.10. The head quarter of CDSCO is located in _____.

(a) Mumbai (b) Kokata (c) Chennai (d) New Delhi

11. The interval between two blood donations should be _____ (6 weeks / 12 weeks).

12. _____ is not guaranteed under Consumer Protection Act, 2019.

(a) Right to choose (b) Right to exploitation

(c) Right to be heard (d) Right to seek redressal

13. _____ are the uses of medical devices.

(a) Diagnosing (b) Monitoring (c) Preventing (d) All of the above

14. The high risk medical devices are classified under _____ (class B/class D).

15. Jurisprudence is the study of _____.

(a) Public health (b) Fundamental legal principles

(c) Materanity health (d) Health Education

16. Drug inspector is appointed under _____ section of the Act.

(a) 42 of IPC (b) 36 of IPC (c) 21 of IPC (d) 41 of IPC

17. List of minimum equipment required for the efficient running of pharmacy is given in _____.

(a) Schedule F (b) Schedule M (c) Schedule J (d) Schedule N

18. Papaver Somniferum yields _____.

19. The Poison Act came into existence in the year _____.

20. According to FSSAI, _____ shall be responsible for inspection of food business, drawing samples and sending them to food analyst for analysis.

---x---