

GOVERNMENT OF KARNATAKA BOARD OF EXAMINING AUTHORITY
D. Pharm Part-II Examination (ER-2020) - JANUARY- 2024
PHARMACY LAW AND ETHICS

Time: 3 Hours

Max marks: 80 M

Note: i) Answer 6 questions from section A, 10 questions from section B and all questions from section C.

ii) Draw diagram wherever necessary.

iii) Answer to the point for objective type.

SECTION -A**Long Essay (Answer any six)****6X5=30 M**

1. Describe the salient features of Education Regulation- 2020
2. Describe the prescribed qualification and duties of Government Analyst
3. Describe the constitution and functions of Drugs Technical Advisory Board (DTAB)
4. Describe the criteria for a medicine to be included in the National List of Essential Medicines (NLEM)
5. State Pharmacist's Oath and describe the relationship to be maintained with the medical profession
6. Explain e-governance of license
7. Explain the salient aspects of New Drugs and Clinical Trial Rules, 2019

SECTION -B**Short Essay (Answer any ten)****10X3=30 M**

8. Describe the functions of Pharmacy Council of India
9. Explain the sampling procedure to be followed by Drug Inspector
10. What is a loan license?
11. Describe the offences and penalties under Narcotic and Psychotropic Substances Act, 1985
12. What are conditionally exempted advertisements?
13. Describe the constitution of Institutional and Animal Ethics Committee
14. Describe the salient aspects of Poisons Act, 1919
15. Give the calculation of Retail price of a formulation according to Drugs Price Control Order, 2013
16. Explain the requirements of experience / training for a registered medical practitioner to terminate a pregnancy
17. Describe the organogram of Central Drugs Standard Control Organization (CDSCO)
18. What are the different types of licenses coming under the umbrella of Pharmaceutical business?

SECTION -C**Objective type (Answer all questions)****20X1= 20M**

19. Give the colour code for biomedical waste collection bins
20. State the objective of Clinical Establishment Act
21. What is Magic remedy?
22. Define Cannabis (Hemp)
23. Define Pharmaceutical legislation
24. Explain the acronym CPCSEA
25. Give the label requirement for food products
26. Define Retail price
27. Name any two drugs included in NLEM
28. What is a Community Pharmacy?
29. Differentiate Branded drug and Generic drug
30. Enumerate the functions of blood bank
31. Rules for Drugs and Cosmetics Act were framed in the year _____
32. _____ is the National regulatory authority for Drugs and Cosmetics in India
33. Discarded medicines and cytotoxic waste should be disposed in _____
34. _____ has laid out National ethical guidelines for biomedical and health research involving human participants
35. Match the following.

A**B**

- 1) NDMA
- 2) 1948
- 3) CDSCO
- 4) Medical device

- a) Emergency use authorization
- b) Establishment of blood bank
- c) Pharmacy Act
- d) Disaster management
- e) Diagnosis, prevention and monitoring
- f) Consumer protection

2360022144040

Code No. : 2611

PHARMACY LAW AND ETHICS

[Maximum Marks : 80]

Time : 3:00 Hours]

NOTES:

- Attempt all parts.
- 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.
- Use of Pager and Mobile Phone by the students is not allowed.

Get Latest Pharma Private/ Govt. Job updates | Download B. Pharma/ D. Pharma University Exam Papers | Previous Pharmacist/ DI/ GPAT/ NIPER Papers | Pharma News Updates | D. Pharma Notes | Pharmacy College Informations | Pharma Industry Updates
Visit: <https://pharmacyindia.co.in>

PART-A (Long questions)

[6 × 5 = 30]

Answer any six questions. Each question carries equal marks.

- 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)

[10 × 3 = 30]

Answer any ten questions. Each question carries equal marks.

- 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

pharmacyindia.co.in | pharmacyindia24@gmail.com | [8171313561](tel:8171313561), [8006781759](tel:8006781759)

Download PHARMACY INDIA App from [Google Play Store](https://play.google.com/store/apps/details?id=com.pharmacyindia)

F-1547

2011

- 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 m²
b) 50 m²
c) 100 m²
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

D. PHARMA 2ND YEAR | PREVIOUS YEAR PAPER

2nd Year / Pharmacy
Subject: Pharmacy Law & Ethics

Time: 3 Hrs.

M.M.: 80

SECTION-A

Note: Multiple choice questions. All questions are compulsory (20x1=20)

Q.1 For the first time in India, a chemist shop was opened in about 1811 by

- a) Mr. Bathgate. b) Mr. Gajjar c) R.N. Chopra d) Mr. Gosh

Q.2 The Pharmacy Council reconstituted every

- a) 10 years b) 15 years c) 5 years d) 6 years

Q.3 Schedule "X" of Drug & Cosmetics Act Comprises

- a) List of i List of incurable disease b) Guideline for clinical trials.
c) List of generic drugs d) None of the above

Q.4. As per Drug & Cosmetics Act Schedule "FF" is related with

- a) Paranteral Preparation b) Ointment Formulation.
c) Skin cosmetics Preparation d) Ophthalmic Preparation

Q.5 In 1985 one of the following act was passed

- a) Drug & magic remedies b) Poisonous Act
c) Narcotic & Psychotropic Substances Act d) Drug & Cosmetics Act

Q.6 Talisman, mantra & Kanawha come under

- a) Misbranded Drugs b) Spurious Drugs
c) Magic Remedies. d) None of the above

Q.7 Animal welfare board is established by

- a) Central Government b) State Government
c) Central Council d) State council

Q.8 The latest Drug Price Control Order was passed by

- a) 2012 b) 2013 c) 2015 d) 2014

Q.9 It means a science of morals or code of moral principles

- a) Ethics. b) Morality
c) Law d) Pharmaceuticals ethics

Q.10 Indian Pharmacopoeia Commission headquarter is located at

- a) Delhi b) Mumbai
c) Hyderabad d) Ghaziabad

Q.11 CDSCO means _____

Q.12 Write the regulatory body of Australia.

Q.13 IPR mean _____

q.14 How many phases are involved in clinical trial?

Q.15 License for blood storage Centre is valid for _____

Q.16 Human anatomical wastes are categorized into which category of biomedical waste

_____.

D. PHARMA 2ND YEAR | PREVIOUS YEAR PAPER

- Q.17 the Disaster management act was made in _____
Q.18 The national Disaster management is headed by _____
Q.19 ICH means _____
Q.20 DTAB means _____

SECTION-B

Note: Short answer type questions. Attempt any ten questions out of eleven questions. (10x3=30)

- Q.21 Write the classification of medical devices with example.
Q.22 Write the names of consumer protection councils
Q.23 Explain principles of bioethics.
Q.24 Define biomedical waste, enlist the categories of biomedical waste.
Q.25 writes the objective of clinical establishment act.
Q.26 write a short note on NDA.
Q.27 Write a short note on lone license.
Q.28 write the qualification drug inspector.
Q.29 write a short note on licensing authority.
Q.30 Mention the ex-officio member of PCI.
Q.31 write a short note on clinical trial phase-IV

SECTION-C

Note: Long answer type questions. Attempt any six questions out of seven questions. (6x5=30)

- Q.32 Give the offense & penalties as per Narcotic drugs & Psychotropic substances act.
Q.33 Write the function of Animal welfare Board of India.
Q.34 what are the duties & function of FSSAI?
Q.35 Write a note on calculation of retail Price of a schedule formation.
Q.36 Write a note on Medical Termination of Pregnancy Act.
Q.37 Explain in brief the new drug development process.
Q.38 Write a note on e-governance of drug manufacture.



8106

BOARD DIPLOMA EXAMINATION, (ER-20) MAY—2023

DPH - SECOND YEAR EXAMINATION

PHARMACY LAW AND ETHICS

Time : 3 Hours]

[Total Marks : 80

PART—A

5×6=30

Instructions : (1) Answer *any six* questions.

(2) Each question carries **five** marks.

(3) Answers should be brief and straight to the point and shall not exceed five simple sentences.

1. Write about the role of pharmacist in relation to job.
2. Write the constitution and functions of PCI.
3. Define Advertisement and Magic remedies as per Drugs and Magic remedies.
4. Write a detailed account on Medical Termination which are prohibited.
5. List out various Government Pharma Regulatory bodies. Explain in detail CDSCO.
6. Give the basic requirements and functions of blood bank.
7. Write about the establishment of State Disaster Management Authority
List the powers and functions of State Authority.

PART—B

- Instructions :** (1) Answer *any ten* questions.
(2) Each question carries **three** marks.
(3) Answers should be comprehensive and criterion for valuation is the content but not the length of the answer.

8. Define the term Drug as per D&C Act.
9. What are the qualifications required for the appointment of Government analyst? What are their duties?
10. Write a short note on Educations Regulations.
11. Define poison. What are the powers of the State Govt. in regulations of the act?
12. Explain in detail Indian Pharmacopeia Commission (IPC) and its functions.
13. List out various objectives and functions of Institutional Animal Ethics Committee.
14. Define Cannabis and Coca derivatives.
15. Give the steps to be taken to disposal of unwanted pharmaceuticals.
16. Write a short note on Consumer Protection Act, 1986.
17. Write the objectives of National Pharmaceutical Pricing Authority (NPPA)
18. Describe the general requirements of labelling under D and C act.

PART—C

1×20=20

- Instructions :** (1) Answer the following questions.
(2) The question carries **one** mark.
(3) Choose the correct answer or write the **correct** answer.

19. The drugs and magic remedies act was enacted in the year
- (a) 1940
 - (b) 1948
 - (c) 1954
 - (d) 1985
20. License for retail sale of schedule-C and C1 drugs issued in which of the following forms?
- (a) 21
 - (b) 20-F
 - (c) 20-A
 - (d) 20-BB
21. The drugs which are required to be used only under medical supervision are.
- (a) schedule-M
 - (b) schedule-P
 - (c) schedule-N
 - (d) schedule-G
22. As per Poisons Act, import of poisons is regulated by
- (a) State Govt.
 - (b) Central Govt.
 - (c) Both (a) and (b)
 - (d) None of the above

| Contd...

23. Which of the following is Govt. Pharma regulatory body?
- (a) NPPA
 - (b) CDSCO
 - (c) IPC
 - (d) All of the above
24. Biomedical wastes are divided into which of the following colours?
- (a) Yellow
 - (b) Red
 - (c) Blue
 - (d) All of the above
25. The Pharmacy act was implemented in year
- (a) 1919
 - (b) 1948
 - (c) 1960
 - (d) 1986
26. Intellectual Property Rights (IPR) includes which of the following?
- (a) Patent
 - (b) Copy right
 - (c) Trade secrets
 - (d) All of the above
27. Which of the following is the objective of New Drugs and Clinical Trials Rules, 2019?
- (a) To promote clinical trials
 - (b) To maintain standards of patient safety
 - (c) To provide early assess of new drugs
 - (d) All of the above

28. Disaster management act was passed in the year
- (a) 2005
 - (b) 2010
 - (c) 2013
 - (d) 2016
29. What are the uses of Medical devices?
- (a) Diagnosing
 - (b) Monitoring
 - (c) Preventing
 - (d) All of the above
30. The interval between two blood donations should be
- (a) 6 weeks
 - (b) 8 weeks
 - (c) 10 weeks
 - (d) 12 weeks
31. Drugs enquiry committee was headed by_____.
32. Schedule X deals with_____.
33. Tenure of PCI member is_____ years.
34. FSSAI headquarters is located at_____.
35. How many hours of practical training in a hospital is required to be completed by students in the course of study?
36. NLEM stands for_____.
37. Prevention of cruelty to animals act was enacted in the year_____.
38. List of the minimum equipment required for the efficient running of the pharmacy is given in schedule_____.

★★★

pharmacyindia.co.in | pharmacyindia24@gmail.com | [8171313561](tel:8171313561), [8006781759](tel:8006781759)

Download PHARMACY INDIA App from [Google Play Store](#)