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ER20-PH–26T

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BOARD DIPLOMA EXAMINATION, (ER-20)

JULY/AUGUST—2024

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 comprehensive and criterion for valuation is the content but not the length of the answer.

1. Describe the procedure for registration of Pharmacists. 5

2. Explain Loan License and Repacking License. 2½+2½=5

3. Elaborate the duties of Drug Inspectors. 5

4. Explain the prohibition of manufacture and sale of certain drugs. 2½+2½=5

5. Explain the prohibition of certain advertisements. 5

6. Explain the code of ethics for pharmacist in relation to his trade. 5

7. Explain the New Drug Application (NDA). 5

PART—B

3×10=30

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

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

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

8. List the classes of drugs prohibited from import. 3

9. Explain the Constitution and functions of DCC. 1½+1½=3

10. Mention the qualification required for Government Analyst. 3

11. State the objectives of Poisons Act-1919. 3

12. Outline the composition and functions of FSSAI. 1½+1½=3

13. Mention the objectives of Pharmaceutical Policy 2002. 3

14. State the objectives of Medical Termination of Pregnancy Act and Rules. 3

15. Mention the types of licenses in Good Regulatory Practices. 3

16. Explain the functions of Blood Bank. 3

17. Mention the basic aspects of Biomedical Waste Management Rules, 2016. 3

18. Mention the standards of Medical Devices. 3

PART—B

1×20=20

Instructions : (1) Answer **all** questions.

(2) The question carries **one** mark.

(3) Choose the ***correct*** answer or write the ***correct*** answer.

19. Indian Journal of Pharmacy was started in

(a) 1939

(b) 1940

(c) 1955

(d) 1965

20. The Education Regulation (ER) is published in official gazette by

(a) The Ministry of Education

(b) The Central Government

(c) Drug Controller

(d) The President of PCI

21. As per D & C Act, Schedule-N is related to

(a) list of equipments for running pharmacy

(b) place for opening retail pharmacy

(c) list of equipment required for manufacturing of drug

(d) standards for cosmetics

22. For license granted to sell by Retail Drugs specified in Schedule C & C1 drugs form no. required is

(a) form 20

(b) form 20B

(c) form 21

(d) form 21B

23. According to Schedule P, Insulin Injection should be stored

(a) at 2 °C to 8 °C

(b) at ≤ 5 °C

(c) at 20 °C

(d) at room temperature

24. Talisman, Mantras and Kavacha come under

(a) misbranded drug

(b) magic remedies

(c) spurious drug

(d) adulterated drug

25. The cruelty of animal includes

(a) not giving food

(b) causing pain

(c) keeping in a small cage

(d) All of the above

26. Find out the List-B poison.

(a) Aconite

(b) Chloroform

(c) Belladona

(d) Potassium cyanide

27. What are the common bioethical issues?

(a) Eugenics

(b) Euthanasia

(c) Organ Donation

(d) All of the above

28. Hawking of drugs is a part of ethics related to

(a) pharmacist in relation to his job

(b) pharmacist in relation to his trade

(c) pharmacist in relation to his own profession

(d) pharmacist in relation to his medical profession

29. What period of pregnancy is MTP safe?

(a) First trimester

(b) Second trimester

(c) Third trimester

(d) All of the above

30. The Headquarters of CDSCO is located at

(a) Mumbai

(b) Chennai

(c) Delhi

(d) Kolkata

31. Animal studies, Clinical trials, bioavailability studies are part of which application process?

(a) IND

(b) NDA

(c) ANDA

(d) None of the above

32. First pass metabolism occurs in

(a) liver

(b) kidney

(c) pancreas

(d) intestine

33. NLEM stands for _____.

34. Labeling conditions for Schedule H drug is _____.

35. _____ is the developer of Blood Bank.

36. Bioethics means _____.

37. National Disaster Act was passed in the year _____.

38. A person who purchases Goods and Services is called _____.

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BOARD DIPLOMA EXAMINATION, (ER-20)

JUNE—2024

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 comprehensive and criterion for valuation is the content but not the length of the answer.

1. Explain the Constitution and functions of Pharmacy Council of India. 2½+2½

2. Explain the conditions to be fulfilled to obtain licence for manufacture of drugs for test, examination and analysis.

3. Explain the Constitution and functions of DTAB. 3+2

4. Elaborate the duties of Drug Inspectors.

5. Explain the Prohibition of certain advertisements.

6. Explain the code of ethics for Pharmacist in relation to his Job.

7. Explain New Drug Application (NDA).

PART—B

3×10=30

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

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

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

8. Explain the duties of Government Analyst.

9. Mention the scheduled C and Cl drugs with examples. 2+1

10. Explain Drugs prohibited for sale in India.

11. Describe the composition of Institutional animal ethics committee.

12. Outline the composition of FSSAI.

13. Explain the Calculation for Retail price of formulations.

14. List out the places approved for termination of Pregnancy as per MPT Act.

15. Explain the documents need to be maintained in the hospital pharmacy as per GRP.

16. Outline the requirements of blood bank.

17. Outline the biomedical waste management at the hospitals.

18. Explain the standards for Medical Devices

PART—C

1×20=20

Instructions : (1) Answer **all** questions.

(2) The question carries **one** mark.

(3) Answer should be single word or single sentence.

19. Government appointed a drug enquiry committee under the Chairmanship of _____ in 1931.

(a) Acharya Prafulla Chandra Ray

(b) Lt. Col. R. N. Chopra

(c) Prof. T. K. Gajjar

(d) Dr. Ghosh

20. The main objective of the Pharmacy Act, 1948 is to

(a) control the advertisement of drugs

(b) regulate the profession of Pharmacy

(c) prevents suffering of Animals

(d) regulate the sale of narcotic drugs

21. As per D and C act "schedule FF" is related with

(a) parenteral preparation

(b) ointment formulation

(c) skin cosmetic preparation

(d) ophthalmic preparation

22. Which of the following is prohibited to be imported?

(a) Toilet preparations

(b) Ayurvedic drugs

(c) Scheduled G drugs

(d) Misbranded drugs

23. Aspirin sodium comes under

(a) Schedule G

(b) Schedule H

(c) Schedule J

(d) Schedule W

24. A drug that is imported under a name which belongs to another drug is

(a) misbranded

(b) psychotropic drug

(c) adulterated drug

(d) spurious drug

25. Advertisement of drug claiming to cure a disease mentioned in Schedule J is

(a) permitted

(b) exempted

(c) prohibited

(d) None of the above

26. The main objective of Poisons Act was

(a) to achieve adequate supply

(b) to achieve equal distribution

(c) to import poisons

(d) to regulate and control of Import, Possession and sale of Poisons

27. A registered medical practitioner may terminate pregnancy if it is

(a) not less than 20 weeks

(b) not more than 20 weeks

(c) not more than 12 weeks

(d) None of the above

28. How many human volunteers are selected for Phase I Clinical trial?

(a) 1-10

(b) 300-3000

(c) 20-300

(d) 20-100

29. On what does Phase 3 clinical testing is done?

(a) Large-scale tests in people with the target disease

(b) Healthy human volunteers

(c) Widespread differentiated population

(d) People with the target disease and condition

30. Licence for blood storage centre valid for

(a) 3 years

(b) 2 years

(c) 5 years

(d) 1 year

31. The Clinical Establishment Act has been forced by

(a) State Government

(b) Central Government

(c) PCI

(d) None of the above

32. Kennedy Institute of Ethics was created in which year?

(a) 1970

(b) 1973

(c) 1917

(d) 1971

33. Consumer Protection Act is significant to

(a) all goods and services

(b) immovable goods

(c) movable goods

(d) selected all goods and services

34. The National Disaster Management Authority is headed by the

(a) Prime Minister

(b) President of India

(c) Governor of States

(d) Chief Minister of States

35. PCI is constituted every _____ years.

36. Full form of CDSCO is _____.

37. The science of morals or code of moral principle is defined as _____.

38. Full form of NLEM_____.

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BOARD DIPLOMA EXAMINATION, (ER-20)

MARCH/APRIL—2024

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 comprehensive and criterion for valuation is the content but not the length of the answer.

1. Write the differences between State Pharmacy Council and Joint State Pharmacy Council. 5

2. Describe the prohibited drugs for manufacture and sale under the Drugs and Cosmetics Act 1940. 5

3. What are the qualification and duties of Government Analyst? 2+3

4. Explain the retail price and ceiling price of scheduled formulations. 2·5+2·5

5. What is the oath promise of Pharmacist? 5

6. Describe the import of medical devices. 5

7. Explain the steps involved in the new drug development process. 5

PART—B

3×10=30

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

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

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

8. List out any six acts related to drugs and pharmacy profession. 3

9. Define the following terms : 1+1+1

(a) Adulterated drugs

(b) Misbranded drugs

(c) Spurious drugs

10. What are schedule C and C_1 drugs? Give two examples. 2+1

11. Explain illicit traffic. 3

12. What are the duties of food authority as per FSSAI? 3

13. What are the functions of the Institutional Animal Ethics Committee? 3

14. Write the functions of blood bank. 3

15. Define biomedical waste and write the categories of biomdeical waste. 1+2

16. Define patent and Intellectual Property Rigth. 1·5+1·5

17. Write the objectives of Consumer Protection Act. 3

18. Write the classification of medical devices. 3

PART—C

1×20=20

Instructions : (1) Answer **all** questions.

(2) Each question carries **one** mark.

(3) Answer should be single word or single sentence.

19. The Poisons Act was passed in

(a) 1919

(b) 1926

(c) 1948

(d) 1939

20. Central register is maintained by

(a) MCI

(b) AICTE

(c) Central council

(d) State council

21. The Pharmacy Council is reconstituted every

(a) 15 years

(b) 10 years

(c) 5 years

(d) 6 years

22. As per D&C Act, Schedule FF includes

(a) biological and special products

(b) other special products

(c) standards for ophthalmic prep

(d) standards for surgical dressings

23. License shall be issued for drugs specified in Schedule C and C1 for wholesale drugs is

(a) 20B

(b) 21B

(c) 20G

(d) 21A

24. Medicinal cannabis means

(a) injection of cannabis

(b) spirit of cannabis

(c) extract of cannabis

(d) ganja

25. Any announcement made orally or by means of producing or transmitting light, sound or smoke, is known as

(a) order

(b) commitment

(c) resolution

(d) advertisement

26. CPSCEA head office is situated in

(a) Mumbai

(b) New Delhi

(c) Chennai

(d) Kolkata

27. Full form of IAEC is

(a) Institutional Animal Ethics Corporation

(b) Institutional Animal Ethics Committee

(c) Institutional Animal Entitled Committee

(d) None of the above

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

(a) Food Safety Officer

(b) designated officer

(c) Assistant Commissioner

(d) Commissioner

29. What is the meaning of ED in calculation of retail price of drug?

(a) Extreme demand

(b) Extra duty

(c) Excise duty

(d) Emergency duty

30. Pharmacist in relation to his profession is

(a) pharmacist- vigilance

(b) law-abiding citizen

(c) decoram and property

(d) All of the above

31. If the pregnancy of woman is beyond 12 weeks and up to 20 weeks, then for medical termination of pregnancy

(a) permission from civil court is necessary

(b) opinion of one doctor is necessary

(c) opinion of two doctors are necessary

(d) opinion of medical board is necessary

32. The drug regulatory authority in India is _____

(a) USFDA

(b) CDSCO

(c) MHRA

(d) TGA

33. According to Biopharmaceutics Classification System, Class II drugs have

(a) high solubility/ high permeability

(b) low solubility/ high permeability

(c) high solubility/ low permeability

(d) low solubility / low permeability

34. Consumer Protection Act is significant to

(a) movable goods

(b) immovable goods

(c) particular goods and services

(d) All of the above

35. High-risk devices belong to which class of medical devices?

(a) Class B

(b) Class A

(c) Class C

(d) Class D

36. Schedule P_1 contains _____.

37. The ex-officio member of the Pharmacy Council of India _____.

38. In New Drug Development, ANDA is _____.

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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

3×10=30

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. 3

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. 3

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

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_____.

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