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Booklet No. 50465

QUESTION BOOKLET

Booklet Series A

DRUG & COSMETICS ACT, 1940 AND RULES, 1945; NDPS ACT; PHARMACY ACT; DRUG PRICE CONTROL ORDER; POISONS ACT, 1919; DMR, 1954; OTHER ALLIED ACTS

SAMPLE DIRE-2013

Subject Code : 05

Time Allowed : 2 Hours | Maximum Marks : 100

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3. Candidate must fill in the necessary information in the space provided on the supplied OMR (Optical Mark Recognition) Answer Sheet before commencement of the Examination. *See directions on the backside of the OMR Answer Sheet.*
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1. The First Schedule to the Drugs and Cosmetics Act, 1940 prescribes

   (A) standards for cosmetics

   (B) standards for medical devices

   (C) authoritative books of Ayurvedic, Sidhha and Unani Tibb system

   (D) standards of the drugs to be complied with by imported drugs

2. Which of the following is *not* a 'drug' as per the law?

   (A) Empty gelatin capsule

   (B) Mosquito repellent cream

   (C) Substances for diagnosis of disease

   (D) None of the above

3. Who among the following is the Chairman of Drug Technical Advisory Board?

   (A) The Drugs Controller of India

   (B) The President of Pharmacy Council of India

   (C) The President of Medical Council of India

   (D) The Director General of Health Services

4. The Central Drugs Laboratory is situated in

   (A) Mumbai

   (B) Kolkata

   (C) Delhi

   (D) Lucknow

5. A drug not labelled in the prescribed manner shall be treated as

   (A) adulterated drug

   (B) spurious drug

   (C) misbranded drug

   (D) mischievous drug

6. Powers of the Inspectors appointed under the Drugs and Cosmetics Act, 1940 are mentioned under which of the following Sections of the Act?

   (A) 20

   (B) 21

   (C) 22

   (D) 23

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7. Minimum penalty for selling any adulterated or spurious drug causing death or grievous harm to any person in India is

(A) imprisonment of ten years and fine of ten lakh rupees

(B) imprisonment of five years and fine of ten thousand rupees

(C) imprisonment of ten years and fine of ten thousand rupees

(D) imprisonment of five years and fine of ten lakh rupees

8. A licence to import drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945 shall be issued in

(A) Form 8

(B) Form 8A

(C) Form 10

(D) Form 10A

9. If any person willfully obstructs a Drugs Inspector in the exercise of his powers, then this is a

(A) noncognizable and non-bailable offence

(B) noncognizable and bailable offence

(C) cognizable and nonbailable offence

(D) cognizable and bailable offence

10. Establishments licensed for sale of drugs shall be inspected at least

(A) not less than once in a month

(B) not less than once in a year

(C) not less than once in every two years

(D) not less than once in every three years

11. An application for grant of a licence to sell drugs other than those specified in Schedule X shall be made in

(A) Form 18

(B) Form 19

(C) Form 20

(D) Form 21

12. An original licence to sell drugs, unless sooner suspended or cancelled, shall be valid for

(A) two years

(B) three years

(C) four years

(D) five years

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13. Minimum area of the shop to obtain a wholesale licence to sell and stock drugs shall be

(A) five square metres

(B) ten square metres

(C) fifteen square metres

(D) twenty square metres

14. A licensee shall maintain an Inspection Book in which of the following 'Forms' under the Drugs and Cosmetics Act, 1940?

(A) Form 35

(B) Form 36

(C) Form 37

(D) Form 38

15. A competent technical staff for the manufacture of drugs must be

(A) a graduate in pharmacy with at least 18 months' practical experience in the manufacture of drugs

(B) a diploma in pharmacy with at least 24 months' practical experience in the manufacture of drugs

(C) Either (A) or (B)

(D) None of the above

16. The warning, 'To be sold by retail on the prescription of a Registered Medical Practitioner only', shall appear on the label of

(A) Schedule H drug

(B) Schedule X drug

(C) Schedule H drug and Schedule X drug

(D) Schedule G drug

17. Which of the following diseases (which a drug may not purport to prevent or cure) is not covered under Schedule J to the Drugs and Cosmetics Rules, 1945?

(A) Diabetes

(B) Obesity

(C) Hypertension

(D) Parkinsonism

18. No colour is permitted to be used in drugs except mentioned in the Drugs and Cosmetics Rules, 1945 under

(A) Rule 126

(B) Rule 127

(C) Rule 128

(D) Rule 129

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19. Requirements of factory premises for the manufacture of cosmetics are mentioned in the Drugs and Cosmetics Rules, 1945 under

(A) Schedule M

(B) Schedule MI

(C) Schedule MII

(D) Schedule MIII

20. Fluoride content in toothpaste shall not be more than

(A) 100 p.p.m.

(B) 500 p.p.m.

(C) 1000 p.p.m.

(D) 1500 p.p.m.

21. Schedule F to the Drugs and Cosmetics Rules, 1945 prescribes the

(A) requirements for the functioning and operation of a blood bank

(B) standards for surgical dressings

(C) list of drugs to be prescribed

(D) standards for disinfectant fluids

22. Every drug manufacturer shall maintain manufacturing and analytical records to the Drugs and Cosmetics Rules, 1945 as per

(A) Schedule M

(B) Schedule U

(C) Schedule V

(D) Schedule T

23. Under Schedule Y to the Drugs and Cosmetics Rules, 1945, responsibility of a sponsor includes

(A) review of trial protocol to ensure rights and safety of the trial subjects

(B) conduct of the trial according to the GCP guidelines

(C) provision of adequate medical care to the participant for any adverse events

(D) submission of status reports on the clinical trial to the licensing authority

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24. Study conditions for long-term stability testing of new drugs is

(A) 30 °C ± 2 °C/ 65% RH ± 5% RH

(B) 30 °C ± 2 °C/ 75% RH ± 5% RH

(C) 40 °C ± 2 °C/ 65% RH ± 5% RH

(D) 40 °C ± 2 °C/ 75% RH ± 5% RH

25. Schedule FF to the Drugs and Cosmetics Rules, 1945 contains the list of

(A) drugs which can be marked under generic names only

(B) drugs which are habit-forming

(C) standards for ophthalmic preparation

(D) drugs which are exempted from certain provisions applicable to manufacturing

26. Schedule S to the Drugs and Cosmetics Rules, 1945 contains the list of

(A) standards for patent or proprietary medicines

(B) standards for cosmetics

(C) life periods of drugs

(D) pack sizes of drugs

27. Chlorpropamide and Dexamphetamine drugs belong to

(A) Schedule G and Schedule X respectively

(B) Schedule X and Schedule H respectively

(C) Schedule H and Schedule Q respectively

(D) Schedule Q and Schedule M respectively

28. The Drugs Consultative Committee shall be constituted by

(A) the Parliament

(B) the State Government

(C) the Central Government

(D) Any of the above

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29. Example of Schedule C drug is

(A) fish liver oil

(B) insulin

(C) ergot

(D) barbital

30. Which of the following drugs are prohibited to be imported?

(A) Spurious drugs

(B) Toilet preparations

(C) Schedule H drugs

(D) All of the above

31. The person in charge of State Drugs Laboratory is

(A) Assistant Drugs Controller

(B) Drugs Controller

(C) Government Analyst

(D) Drugs Inspector

32. Premises licensed for sale of drugs having services of a Registered Pharmacist but where drugs are not compounded against prescriptions is called as

(A) Pharmacy

(B) Chemist and Druggist

(C) Drug Store

(D) All of the above

33. Analysis and test of samples of vaccines are carried out at

(A) Central Indian Pharmacopoeia Laboratory, Ghaziabad

(B) Pasteur Institute of India, Coonoor

(C) Central Drugs Testing Laboratory, Thane

(D) Central Research Institute, Kasauli

34. Digitalis belongs to

(A) Schedule C

(B) Schedule C(1)

(C) Schedule G

(D) Schedule X

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35. The samples of drugs taken by the Drugs Inspector are sent for analysis to

(A) the Drugs Controller

(B) any testing Laboratory

(C) the Government Analyst

(D) any of the above

36. Drugs Inspector shall be deemed to be public servant under Section

(A) 12 of IPC

(B) 21 of IPC

(C) 42 of IPC

(D) 48 of IPC

37. Application for the issue of a permit to import small quantities of drugs for personal use shall be made in

(A) Form 12

(B) Form 12A

(C) Form 12AA

(D) Form 12B

38. Drug sample shall be sent to the Government Analyst for test or analysis by a Drugs Inspector

(A) through registered post

(B) in a sealed packet

(C) together with a memorandum in Form 1

(D) All of the above

39. Licensed manufacturer shall maintain the reference samples of drugs [other than those specified in Schedule C, C(1) and X] till

(A) three months after the date of expiry of the drugs

(B) six months after the date of expiry of the drugs

(C) nine months after the date of expiry of the drugs

(D) twelve months after the date of expiry of the drugs

40. A drug which is manufactured under a name which belongs to another drug is called as

(A) adulterated drug

(B) spurious drug

(C) misbranded drug

(D) All of the above

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41. The main object of the Pharmacy Act, 1948 is to

(A) control the advertisement of drugs

(B) regulate the profession of pharmacy

(C) prevent the infliction of unnecessary pain or suffering on animals

(D) All of the above

42. A person is called as 'Registered Pharmacist', if he is

(A) holding diploma in pharmacy

(B) having sufficient experience in pharmacy profession

(C) having his name entered in the State Register of Pharmacists

(D) holding degree in pharmacy

43. Who among the following is not a member of the Pharmacy Council of India?

(A) The Director General, Health Services

(B) The Drugs Controller of India

(C) The Director, Central Drugs Laboratory

(D) The Director, Central Research Institute

44. Joint State Pharmacy Councils are constituted for

(A) 5 years

(B) 7 years

(C) 10 years

(D) the period specified under the interstate agreements

45. The Vice President of the Pharmacy Council of India (PCI) is

(A) appointed by the President of PCI

(B) elected by its members

(C) nominated by the Central Government

(D) selected by the UGC

46. Minimum age of a person to be registered as a Pharmacist is

(A) 21 years

(B) 16 years

(C) 18 years

(D) No age limit

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47. The name of a Registered Pharmacist can be removed from the register, if

(A) his name was entered by error in the register

(B) his name was entered due to misrepresentation of a material fact

(C) he was convicted of any offence

(D) Any of the above

48. The number of persons elected for the Pharmacy Council of India from the teaching profession is

(A) five

(B) six

(C) seven

(D) eight

49. A person who falsely claims himself as a Registered Pharmacist shall be punishable with a

(A) fine of five hundred rupees on first conviction and imprisonment of six months on any subsequent conviction

(B) fine of five thousand rupees on first conviction and imprisonment of six months on any subsequent conviction

(C) fine of five hundred rupees on first conviction and imprisonment of three months on any subsequent conviction

(D) fine of five thousand rupees on first conviction and imprisonment of three months on any subsequent conviction

50. Regulations that prescribe minimum standard of education required for qualification as a Pharmacist is called as

(A) pharmacy regulation

(B) teaching regulation

(C) education regulation

(D) central pharmaceutical regulation

51. The Narcotic Drugs and Psychotropic Substances Act was passed in the year

(A) 1940

(B) 1955

(C) 1985

(D) 2000

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52. Coca, hemp and opium are defined under

(A) The Pharmacy Act

(B) The Drugs and Cosmetics Act

(C) The Narcotic Drugs and Psychotropic Susbtances Act

(D) The Poisons Act

53. Plant of the species of Papaver, from which opium or any phenanthrene alkaloid can be extracted, is called

(A) opium poppy

(B) opium derivative

(C) heroin

(D) All of the above

54. Cannabis means

(A) hemp

(B) charas

(C) ganja

(D) All of the above

55. Opium does not include any preparation containing not more than

(A) 0·2% morphine

(B) 0·02% morphine

(C) 0·1% morphine

(D) 0·01% morphine

56. Poppy straw means all parts, except

(A) flower

(B) stem

(C) root

(D) seed

57. Prepared opium

(A) is an extract suitable for smoking

(B) is any medicine containing opium

(C) is also called as hemp

(D) has undergone the processes to adapt it for medicinal use

58. Ganja means which of the following parts of the plant?

(A) Only seeds

(B) Only leave

(C) Only flowering or fruiting tops

(D) All parts of the plant

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59. Opium shall be manufactured only by the

(A) authorized persons

(B) Central Government opium factories

(C) licence holders

(D) cultivators

60. Punishment for consumption of any narcotic drug or psychotropic substance is

(A) imprisonment up to six months or fine up to twenty thousand rupees or both

(B) rigorous imprisonment up to six months or fine up to ten thousand rupees or both

(C) imprisonment up to two years or fine up to twenty thousand rupees or both

(D) rigorous imprisonment up to one year or fine up to twenty thousand rupees or both

61. The Drugs (Prices Control) Order, currently in force, was passed in the year

(A) 1987

(B) 1995

(C) 2005

(D) 2010

62. Who has the power to fix the ceiling price of scheduled formulations?

(A) State Government

(B) Central Government

(C) Lok Sabha

(D) Rajya Sabha

63. Which of the following drugs is a scheduled bulk drug?

(A) Alprazolam

(B) Codeine

(C) Salbutamol

(D) Amikacin

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64. Contravention of any provisions of the Drugs (Prices Control) Order shall be punishable with the provision of the

(A) Drugs and Cosmetics Act, 1940

(B) Narcotic Drugs and Psychotropic Substances Act, 1985

(C) Essential Commodities Act, 1955

(D) Industries (Development and Regulation) Act, 1952

65. As per DPCO, every manufacturer shall submit yearly information on turnover and allocation of sales and expenses in

(A) Form II

(B) Form IV

(C) Form V

(D) Form VI

66. The Drugs (Prices Control) Order is applicable to

(A) Ayurvedic medicines

(B) Homoeopathic medicines

(C) Unani medicines

(D) None of the above

67. Under DPCO, an application to revise the ceiling price for a scheduled formulation shall be submitted by the manufacturer in

(A) Form VI

(B) Form V

(C) Form III

(D) Form II

68. The Poisons Act was passed in the year

(A) 1904

(B) 1910

(C) 1914

(D) 1919

69. Who has the power to regulate possession for sale and sale of any poison?

(A) State Government

(B) Central Government

(C) Drugs Controller

(D) Parliament

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70. As per the Poisons Act, in India any poison

(A) can be imported freely

(B) cannot be imported at all

(C) can be imported only under a valid licence

(D) can be imported with permission of the State Governor

71. Unlawful sale of any poison in India is punishable with

(A) imprisonment up to three months or fine of five hundred rupees or both

(B) imprisonment up to three years or fine of five thousand rupees or both

(C) imprisonment up to three months or fine of five thousand rupees or both

(D) imprisonment up to three years or fine of five hundred rupees or both

72. The Medicinal and Toilet Preparations (Excise Duties) Act came into force in

(A) 1940

(B) 1945

(C) 1950

(D) 1955

73. Under the Medicinal and Toilet Preparations (Excise Duties) Act, manufacture of any dutiable goods without a valid licence is punishable with

(A) imprisonment up to six years or fine of twenty thousand rupees or both

(B) imprisonment up to six months or fine of two thousand rupees or both

(C) imprisonment up to six months or fine of twenty thousand rupees or both

(D) imprisonment up to six years or fine of two thousand rupees or both

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74. A nonbonded manufactory shall be inspected by the officer at least

(A) once every month

(B) once every two months

(C) once every six months

(D) once every year

75. Application for licence to manufacture goods liable to duty of excise, under the Medicinal and Toilet Preparations (Excise Duties) Act shall be made in

(A) Form A.L.1

(B) Form A.L.2

(C) Form A.L.3

(D) Form A.L.4

76. The Drugs and Magic Remedies (Objectionable Advertisements) Rules came into force in the year

(A) 1954

(B) 1955

(C) 1956

(D) 1957

77. Publication of the advertisement is prohibited that refers to the use of any drug for the treatment of

(A) cancer

(B) plague

(C) tuberculosis

(D) All of the above

78. Person contravening any provision of the Drugs and Magic Remedies (Objectionable Advertisements) Act is punishable with

(A) imprisonment up to three months or fine or both

(B) imprisonment up to four months or fine or both

(C) imprisonment up to five months or fine or both

(D) imprisonment up to six months or fine or both

79. Which of the following is a 'Magic Remedy'?

(A) Talisman

(B) Mantra

(C) Kavacha

(D) All of the above

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80. Which of the following is violation of the Drugs and Magic Remedies (Objectionable Advertisements) Act?

(A) Display of signboard by a registered medical practitioner offering treatment for any disease

(B) Publication of a book only for scientific purpose, suggesting the use of a drug in the treatment of any disease

(C) Advertisement relating to any drug sent confidentially to a registered medical practitioner

(D) None of the above

81. The Prevention of Cruelty to Animals Act was enacted in the year

(A) 1940 (B) 1950

(C) 1960 (D) 1970

82. Which of the following does not come under the cruelty to animals?

(A) Experiments on animals for new discovery useful for saving human life

(B) Willfully and unreasonably administering any injurious drug to animal

(C) Treating any animal so as to subject it to unnecessary pain or suffering

(D) Failure to provide sufficient food, drink or shelter to the animal by its owner

83. Experiments on animals for the discovery of new drugs is allowed under which of the following Sections of the Prevention of Cruelty to Animals Act?

(A) Section 4

(B) Section 14

(C) Section 24

(D) Section 34

84. Who among the following has the responsibility to establish Society for Prevention of Cruelty to Animals (SPCA)?

(A) Central Government

(B) State Government

(C) Animal Welfare Board

(D) Institutes carrying out animal experiments

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85. Animal Welfare Board of India constituted under the Prevention of Cruelty to Animals Act is situated in

(A) New Delhi

(B) Mumbai

(C) Chennai

(D) Kolkata

86. The Drugs Cosultative Committee is constituted under which of the following Sections of the Drugs and Cosmetics Act?

(A) Section 3

(B) Section 5

(C) Section 7

(D) Section 9

87. Function of the Drugs Consultative Committee is to

(A) make rules to implement the Drugs and Cosmetics Act

(B) give consultation to pharmaceutical companies

(C) advise the government in issues related to the Drugs and Cosmetics Act

(D) All of the above

88. Standards of quality for drugs are prescribed in

(A) the First Schedule to the Drugs and Cosmetics Act, 1940

(B) the Second Schedule to the Drugs and Cosmetics Act, 1940

(C) the Schedule D to the Drugs and Cosmetics Rules, 1945

(D) the Schedule J to the Drugs and Cosmetics Rules, 1945

89. Cosmetic means any article intended to

(A) affect the structure of the human body

(B) destruct vermin or insects

(C) alter the appearance of the human body

(D) All of the above

90. Manufacture in relation to any drug does not include the process of

(A) ornamenting

(B) labelling

(C) packing

(D) compounding

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91. Which of the following does not come under the prohibition of manufacture of drugs?

(A) Manufacture for sale of any drug which is not of standard quality

(B) Manufacture for sale of any drug without a valid licence

(C) Manufacture for sale of any misbranded drug

(D) Manufacture of drugs for the purpose of examination, test or analysis

92. The application for grant of licence to manufacture drugs other than those specified in Schedule C, C(1) and X shall be made in and corresponding licence shall be issued in

(A) Forms 27B and 28B respectively

(B) Forms 27 and 28 respectively

(C) Forms 24F and 25F respectively

(D) Forms 24 and 25 respectively

93. The applicable fees for taking licence to manufacture drugs other than those specified in Schedule C, C(1) and X are

(A) licence fee of ₹ 6,000 and inspection fee of ₹ 1,000

(B) licence fee of ₹ 5,000 and inspection fee of ₹ 1,500

(C) licence fee of ₹ 6,000 and inspection fee of ₹ 1,500

(D) licence fee of ₹ 5,000 and inspection fee of ₹ 1,000

94. Application for permission to import or manufacture new drugs to undertake clinical trials should be made in

(A) Form 21

(B) Form 44

(C) Form 11

(D) Form 12A

95. The latest amendment in the Drugs and Cosmetics Act was made in the year

(A) 1999

(B) 2005

(C) 2008

(D) 2010

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96. Specific requirements for manufacture of sterile products and parental preparations are prescribed in which of the following parts of the Schedule M?

(A) Part IA

(B) Part IB

(C) Part IC

(D) Part ID

97. The Pharmacy Council of India 'Education Regulations' for the Diploma Course in Pharmacy, that is currently in force, was passed in the year

(A) 1981

(B) 1985

(C) 1991

(D) 1995

98. Name of a person is entered in the central register under the Pharmacy Act after

(A) he submits an application for registration to Central Council in the prescribed manner

(B) he submits an application for registration to the State Council in the prescribed manner

(C) receipt of the report of registration of a person in the register for a State

(D) Both (B) and (C)

99. Who among the following shall not be a member of State Council under the Pharmacy Act, 1948?

(A) A Registered Pharmacist elected from the State

(B) A registered pharmacist nominated by the State Government

(C) The Government Analyst

(D) The Director of Central Drugs Laboratory

100. Which of the following is *not* a psychotropic substance under the Narcotic Drugs and Psychotropic Susbtances Act?

(A) Barbital

(B) Estazolam

(C) Albendazole

(D) Mazindol

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