

6600124

GOVERNMENT OF KARNATAKA BOARD OF EXAMINING AUTHORITY
<https://pharmacyindia.co.in/> 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.

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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

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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?

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SECTION -C

Objective type (Answer all questions)

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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.

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

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

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