STATE BOARD OF TECHNICAL EDUCATION
TELANGANA
DIPLOMA EXAMINATION (ER-2020)
ER2020-APR-2023
II Year , PHARMACY END EXAM

ER20-26T
PHARMACY LAW & ETHICS

PCODE
10206

Session: FN

Exam Date: 01-05-2023
Duration: 3 Hours [10:00 AM To 01:00 PM]

[Total Marks: 80]

PART-A

20 X 1 = 20

Instructions: 1. Answer the following questions.
2. Each question carries **ONE** mark.

1. Nominated or elected member of PCI shall hold office for a term of _____
2. What is the main objective of Drugs and Cosmetic Act 1940?
3. What is the role of Custom Collector?
4. Drugs and magic remedies act was passed in _____
5. FSSAI has issued an advisory banning the use of which material for wrapping and packaging of food items.
6. How many human volunteers are selected for Phase I Clinical Trials?
7. Pharmaceutical legislation covers both _____ and _____ aspects of the society.
8. To Manufacture drugs for the purpose of examination , test or anlysis has to obtain license in _____ form and the application to issue a license in _____ form.
9. What does DTAB stands for?
10. _____ includes notices, circulars, labels, wrapper or announcement made orally or by producing/transmitting light, sound or smoke.
11. Phooka or doom dev includes process of _____
12. Expand ANDA.
13. Define Registered Pharmacist.
14. What is the minimum area specification required for Wholesale of drugs premises?
15. Bioethics was improved from four fronts namely _____
16. Define Code of Pharmaceutical Ethics.

17. Which application form to be submitted for retail sale of drugs other than schedule-x drugs?

18. When application for a renewal of license to be made under FSSAI , 2006?

19. Digitalis and Ergot Preparations are covered under _____ Schedule.

20. Human anatomical wastes are categorized under biomedical waste management as

a. Blue

b. Yellow

c. Red

d. White

PART-B

Instructions: 1. Answer any **TEN** questions. 10 X 3 = 30
2. Each question carries **THREE** marks.

21. Define Medical Practitioner.

22. What is Schedule FF, Schedule J, Schedule V as per Drugs and Cosmetics Act1940?

23. What are the functions of Drugs Consultative Committee?

24. What are the offences and penalties under Medical termination of Pregnancy act?

25. Write the objectives of Institutional Animals Ethics Committee.

26. As per BCS system of classification how the drugs are classified?

27. Write about recommendations of Drug Enquiry Committee.

28. How do State Government regulate possession for sale and sale of any poison?

29. Write a note on E-Governance required in import of drugs and medical devices.

30. Mention the Government Pharma Regulator Bodies?Write the role of these bodies.

31. What is the role of National Executive Committee under Disaster Management act?

PART-C

Instructions: 1. Answer any **SIX** questions. 6 X 5 = 30
2. Each question carries **FIVE** marks.

32. Explain the procedure of preparation of first register.

33. What are the conditions required for grant of a Loan Licence?

34. Discuss the penalities for manufacturing and sale of drugs in contravention of D&C Act, 1940.

35. Write about a) the constitution and functions of Narcotic and Psychotropic consultative Committee.

b) Functions of Officers of Central Government.

36. Briefly describe any two general steps involved in biomedical waste managaement.

37. Explain E-governance in hospital pharmacy and pharma manufacturing.

38. Enlist the functions of Blood bank. Explain any three functions.