[Total No. of Questions - 22] [Total No. of Printed Pages - 2]

DEC-23-0097

BP-804 ET (Pharmaceutical Regulatory Science)

B.Pharm-8th (PCI)

Time : 3 Hours **Max. Marks : 75**

Note: The questions paper contains three section I, II, III. Attempt any two questions from section I and attempt any seven questions from section II. Section III is compulsory, attempt all questions in this Section.

SECTION-I (2×10=20)

Long Answer (Any Two)

1. Explain in detail the stages of Drug discovery and drug development process.
2. Write an exhaustive note on the regulatory approval process for the ANDA.
3. What is CTD? Discuss the process involved in its submission.

SECTION-II (7×5=35)

Short Note Answer (Any Seven)

4. Write a note on 21 CFR in clinical trials.
5. What is the purpose of Purple book?
6. Discuss the composition of the Institutional Ethics committee.
7. Explain the procedure for the export of pharmaceutical products.
8. Give an overview of the drug regulatory authority of United States of America.
9. Write a note on the Generic drug product development.

10. Explain the importance of safety monitoring in clinical trials.
11. Mention GCP obligations of the Monitors.
12. Write a note on common Technical Document.

SECTION-III (10×2=20)

Short Answer (Compulsory)

13. What are non clinical studies?
14. Give functions of CDSCO.
15. Explain the term Innovator.
16. When impartial witness is required in informed consent process?
17. What is orange book?
18. Give various types of DMF.
19. TGA is abbreviation for .....
20. Define adverse event.
21. What is Clinical Trial Protocol?
22. Explain Subsequent New Drug.