QP Code: 824006 **Reg. No…….**

Eighth Semester B. Pharm Degree Supplementary Examinations
December 2023
Pharmaceutical Regulatory Science

(2017 Scheme)

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

- ***Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space***
- ***Answer all parts of a single question together • Leave sufficient space between answers***
- ***Draw diagrams wherever necessary***

Essays **(2x10=20)**

1. Explain the principles of Good Clinical Practices
2. Discuss the various stages of drug discovery and development process

Short Notes **(7x5=35)**

3. Describe the EU pharmaceutical legislation
4. Discuss investigational new drug approval process
5. Role of documentation in pharmaceutical regulatory approval process
6. Orange book
7. What are the objectives of New drug application
8. Explain the role of pharmacovigilance in marketing of drugs
9. Drug master file.

Answer Briefly **(10x2=20)**

10. Define drug
11. Role of code of federal regulations
12. Significance of generic drugs
13. Institutional review board
14. Define NDA and ANDA
15. Which clinical investigations are exempted from IND requirements
16. Responsibilities of ethics committee
17. Write about sponsor
18. e-CTD
19. Federal register

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