QP Code: 824006 **Reg. No……**

Eighth Semester B. Pharm Degree Regular/Supplementary Examinations March 2025
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. Describe the drug development process
2. Explain Independent Ethics committee formation and working procedures

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

3. Stages of drug discovery
4. Explain clinical trial protocol
5. Approval process and timelines involved in Investigational New Drug
6. Explain an overview of Regulatory authorities of United states
7. Explain Common Technical Document
8. Describe Pharmacovigilance-safety monitoring in clinical trials
9. Orange book

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

10. What is Federal Register
11. What is ASEAN Common Technical Document
12. Define Abbreviated New Drug Application (ANDA)
13. Informed consent.
14. What is exclusivity
15. What is investigator's brochure
16. What is a DMF
17. Sponsor's role in clinical trials
18. Define GMP and GCP
19. Code of Federal Regulations.

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