**QP Code: 824006** **Reg. No……**

## Eighth Semester B. Pharm Degree Supplementary Examinations
## November 2024
## 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 various types of drug master files
2. Discuss the classification of drugs in New drug application

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

3. Challenges in drug regulatory affairs
4. Types of INDs
5. What is exclusivity
6. Explain the differences in submission of documents to NDA and ANDA
7. Explain on preclinical studies in drug discovery process
8. Describe the investigator's brochure
9. Generic drugs

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

10. Define clinical trial
11. Describe common technical document
12. New chemical entity
13. What is bioequivalence
14. What is a Dossier
15. Role of monitor in clinical trials
16. Define GMP and GCP
17. What is informed consent
18. Composition of Institutional ethics committee
19. Orange book

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