

QP Code: 824006

Reg. No.....

**Eighth Semester B. Pharm Degree Regular/Supplementary
Examinations March 2026
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 different modules of Common Technical Document
2. Discuss the registration of Indian drug product in overseas market. Write a note on procedure for export of pharmaceutical product

Short Notes

(7x5=35)

3. Explain the composition and functions of IRB
4. Discuss on 21 CFR
5. Discuss preclinical study in the drug development process
6. Write the objective of Hatch Waxman Act
7. Discuss generic product drug development
8. Discuss the role of pharmacovigilance and the process of monitoring in clinical trials
9. Write a note on purple book

Answer Briefly

(10x2=20)

10. Define Clinical Trial Protocol
11. Federal Register
12. NDA
13. ANDA
14. Phase III clinical trial
15. Orange book
16. CDSCO
17. USFDA
18. GCP obligations of investigators
19. Drug master file
