

QP Code: 824006

Reg. No.....

**Eighth Semester B. Pharm Degree Supplementary Examinations
October 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. Explain about Drug Development Process. Add a note on stages of drug discovery
2. What is CTD. Explain CTD modules with granularity

Short Notes

(7x5=35)

3. Explain in brief about New Drug Application
4. Discuss organization structure and function of TGA
5. Write in brief about ASEAN Common Technical Document (ACTD)
6. What is informed consent in clinical trials. Describe the informed consent procedure in clinical trials
7. Discuss the formation and working procedure for Institutional Review Board (IRB)
8. Describe about Purple book and its regulatory importance
9. What is Code of Federal Regulations. Add a note on their regulatory importance

Answer Briefly

(10x2=20)

10. Innovator drug
11. GCP
12. Safety monitoring in clinical trials
13. Concept of generics
14. DMF
15. Electronic common technical document
16. Phase II clinical trials
17. Post marketing Surveillance
18. IND
19. CRO

CORRECTION / NO-CORRECTION FILE
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QPCODE: 824006

Dated: 21-10-2025

Question No.19

Modified as "Clinical Research Organisations."

Corrections/Modifications/Replacement of Questions if any shall be made available to all students. Take the print out of the Correction File in such cases and distribute to all students.

(Sd/-)

CONTROLLER OF EXAMINATIONS