

Q.P. Code: 501326

Reg. no.:

Fifth Year Pharm D Degree Supplementary Examinations January 2026

Clinical Research

Time: 3 Hours

Total Marks: 70

- *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 table/diagrams/flow charts wherever necessary*

Essay:

(3x10=30)

1. Define Clinical Trials. Explain various phases of a clinical trial
2. Discuss in detail about Investigational New Drug Application
3. Explain the principles of Good Clinical Practice

Short notes:

(8x5=40)

4. Give an overview of drug regulatory environment in USA and India
5. Discuss briefly on pharmacological and toxicological studies in drug development
6. Discuss the composition, roles and responsibilities of Institutional Ethical Committee
7. Explain the methods of post marketing surveillance
8. Explain about auditing in clinical research
9. What are the different types of pharmaceutical dosage forms? Mention their advantages and disadvantages
10. Briefly explain Data Management in Clinical Research
11. Discuss about informed consent process
