

Q.P. Code: 201340

Reg. no.:

**Second Pharm D Post Baccalaureate Degree Regular/Supplementary
Examinations July 2022**

Paper I – 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. Discuss the composition, responsibilities and procedures of Institutional Ethics Committee.
2. Define investigational new drug application and its procedure for submission.
3. ICH guidelines on good clinical practice.

Short notes:

(8x5=40)

4. Explain the pharmacological and toxicological approaches to drug discovery
5. Roles and responsibilities of investigators and clinical research associates
6. Phase III and phase IV clinical trials
7. Ethical guidelines in clinical research
8. Challenges in the implementation of good clinical practice guidelines.
9. Safety monitoring in clinical research
10. Designing of a clinical study protocol
11. Data management in clinical research
