Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations
November 2022

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. Explain in detail various phases of clinical trials
2. Explain in detail the formulation development process during drug discovery and lead optimization
3. Write about data management and briefly explain its components

Short notes: **(8x5=40)**

4. Discuss about CDSCO guidelines
5. Responsibilities of auditor and clinical research associate
6. Principles of ICH-GCP guidelines
7. Discuss the regulatory environment in USA
8. Explain Institutional Review Board (IRB)
9. Enumerate designing of case report form (CRF) with a suitable example
10. Explain the ethical guidelines in clinical research
11. Explain in detail the informed consent process

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