Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Regular/Supplementary Examinations November 2020

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 the process of Investigational New Drug Application (INDA)
2. Write the composition and responsibilities of institutional ethical committee as per Central Drugs Standard Control Organization (CDSCO)
3. Explain on safety monitoring in clinical trials

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

4. Pharmacological approaches to drug discovery
5. Nuremberg code
6. What are preclinical studies. Write the objectives of preclinical studies
7. Write the importance of International Council for Harmonization for technical requirements for pharmaceuticals for human use (ICH) E6 guideline in conducting clinical trials
8. Functions of Sponsor in Clinical trial
9. The roles of investigator during the informed consent process
10. Different types of audits in clinical trials
11. Different components of data management in clinical trials

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