**[LD 825]** **OCTOBER 2013** **Sub. Code: 3825**

**PHARM. D / POST BACCALAUREATE DEGREE EXAMS**

**FIFTH YEAR**

**PAPER I – CLINICAL RESEARCH**

***Q.P. Code : 383825***

**Time : 3 hours** **Maximum : 70 marks**

**I. Elaborate on :** **(2x20=40)**

1. What is ANDA? What are the drugs come under ANDA? What is meant by generic drugs? Write a note on post marketing surveillance.

2. What is Institutional human ethical committee? Give the composition, qualification required for the members. Explain the functions of the committee.

**II. Write notes on :** **(10x3=30)**

1. Explain the importance of Pharmacological information in drug discovery.
2. Name various chemical characteristics of the drug.
3. Write a not on GCP.
4. What are the challenges faced by the investigator in clinical trials.
5. Write a not on schedule Y.
6. Explain the responsibility of the auditors in clinical trials.
7. Explain the protocol involved in data management in clinical research.
8. Differentiate Phase II & Phase III clinical trials.
9. Why randomization is important in clinical research?
10. Write the significance of preclinical testing in clinical research.

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