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

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 70 marks**

Answer All questions

I. Elaborate on: **(2 x 20 = 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: **(10 x 3 = 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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