[LK 825] MAY 2017 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. What are the essential documents for the conducting of clinical trials and discuss the purpose of the same?
2. Explain the functions of IRB in clinical research.
3. Define Investigator's brochure and describe about its components.
4. Elaborate on the roles and responsibilities of regulatory authority in relation to clinical trial.

II. Write notes on: **(6 x 5 = 30)**

1. Write a note on GCP.
2. Explain the importance of pharmacological information in drug discovery.
3. Preclinical testing in clinical research.
4. Informed Consent Process.
5. Safety monitoring in clinical trials.
6. Explain briefly the ICH guidelines.

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