[LI 825] APRIL 2016 **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. Explain the Pharmacological and Toxicological approaches to Drug discovery.
2. Describe the roles and responsibilities of Investigators and Clinical Research associates.
3. Discuss the challenges in the implementation of Good Clinical Practice guidelines.
4. Describe the guidelines of Central drug standard control organization.

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

1. Abbreviated New Drug Application.
2. Various types of post marketing surveillance.
3. Ethical principles in Clinical research.
4. Explain the contents in Investigational new drug application.
5. Safety monitoring in Clinical research.
6. Responsibilities of Institutional review board.

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