[LM 825] MAY 2018 **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. Define Bias. Discuss in detail about various sources of bias and methods to avoid Bias.

2. Describe in detail about regulatory setup that governs the clinical research process in India.

3. Explain the components of clinical research protocol and the process of protocol preparation.

4. Discuss in detail about various methods used in post marketing safety monitoring process.

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

1. Write a note on general parameters involved in inclusion and exclusion criteria.
2. Write the responsibilities of sponsor's in clinical trial.
3. Write the functions of data and safety monitoring board.
4. Define IND application and write contents of IND application.
5. Write a short note on drug discovery process.
6. Write the safety issues on the investigational new drugs.

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