[PHARMD 0321] **MARCH 2021** **Sub. Code: 3825**

(OCTOBER 2020 EXAM SESSION)

PHARM. 'D' (POST BACCALAUREATE)

DEGREE EXAMINATION

FIFTH YEAR (2009-2010 Regulation)

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. Define Investigator's brochure and describe about its components.
3. What are dosage forms? Give example. Explain different type of dosage forms.
4. Explain Bias and discuss in detail about various sources of bias and methods to avoid Bias.

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

1. How SOPs are prepared to meet the Good Laboratory Practices standards?
2. Write the ethical consideration in the conduct of Clinical trials.
3. Write the safety issues on the investigational new drugs.
4. What are the major challenges observed in implementation of the regulatory guidelines in clinical trials?
5. Write a note on schedule Y.
6. What is Randomization? Brief about static and adaptive designs.

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