[PHARMD 0122] **JANUARY 2022** **Sub. Code: 3825**

(OCTOBER 2021 EXAM SESSION)

PHARM 'D' AND PHARM. 'D' (POST BACCALAUREATE) DEGREE EXAMINATION

FIFTH YEAR (2009-2010 Regulation)

PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Answer ALL Questions** **Maximum : 70 Marks**

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

1. Discuss in detail about the overview of regulatory environment in Europe and USA.
2. Define Drug Discovery and development. Explain the various stages of drug development process.
3. Explain in detail the roles and responsibilities of regulatory authority and contract research coordinators.
4. Discuss the importance of safety monitoring in Clinical trials.

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

1. Investigational New Drug Application.
2. Responsibilities of institutional Review Boar
3. Informed consent process.
4. Purposes of an audit in a Clinical trial.
5. Good clinical practice and its principles.
6. Study designs in a Clinical trial.

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