[LP 825] OCTOBER 2019 **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. Write about the ICH guidelines in clinical trials.
2. Describe the various pharmacological and toxicological approaches to drug discovery.
3. Give an account on Abbreviated New drug Application.
4. Discuss the roles and responsibilities of sponsors and investigators in clinical research.

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

1. Regulatory environment in India.
2. Vulnerable subjects.
3. Challenges in implementation of guidelines in clinical trials.
4. Responsibilities of clinical research coordinator in clinical research.
5. Case Report form in study design.
6. Significance of Post marketing surveillance.

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