[LF 825] **OCTOBER 2014** **Sub. Code: 3825**

DOCTOR OF PHARMACY (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**

Answer All questions

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

1. Define investigational new drug application and describes the component and categories of investigational new drug application.
2. Discuss in detail the overview of regulatory environment in Europe.
3. Explain in detail the roles and responsibilities of regulatory authority and contract research coordinators.
4. Describe in detail the various approaches to drug discovery.

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

1. Write short note on various phases of clinical trials.
2. Describe briefly the ethical guidelines in clinical research.
3. Write a note on data management and its components.
4. Explain briefly the ICH guidelines.
5. Write note on informed consent process.
6. Post marketing surveillance.

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