[KX 825] **SEPTEMBER 2010** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

(Regulations 2008-2009)

(Candidates admitted from 2008-2009 onwards)

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 70 marks**

Answer ALL questions

I. Elaborate on: **(2 x 20 = 40)**

1. Define Clinical Trials?
   Discuss in detail five various phases involved in drug development process.

2. Discuss the composition, responsibilities and procedures of IRB/IEC.

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

1. Significance of post marketing surveillance.
2. Roles and responsibilities of Investigations.
3. Study designs in a clinical trail.
4. Informed consent process.
5. ICH guidelines in clinical trials.
6. Purposes of an audit in a clinical trial.

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