[LH 825] **OCTOBER 2015** **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**

Answer ALL questions

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

1. Define Clinical Trials. Discuss in detail five various phases involved in drug development process.
2. What are the essential documents for the conducting of clinical trials and its purpose?
3. What is Institutional human ethical committee? Give the composition, qualification required for the members and explain the functions of the committee.
4. Discuss the roles and responsibilities of auditors in clinical research.

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

1. Write in detail the central drug standard control organization guidelines.
2. Explain briefly the informed consent process.
3. Write a note on data management.
4. Describe briefly the ethical guidelines in clinical research.
5. Write briefly the Source documents in clinical trial.
6. What are the responsibilities of clinical data manager?

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