[LG 825] **APRIL 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**

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

1. Briefly write on:

   a) Double blind clinical trials
   b) Open label clinical trials
   c) Retrospective studies

2. What is mean by informed consent? Explain content and method of administration of informed consent as per regulatory authorities in clinical trials.
3. What are dosage forms? Give example. Explain different type of dosage forms.
4. Explain the protocols and method of reporting ADR under Pharmacovigilance.

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

1. How SOPs are prepared to meet the GLP standards?
2. Write the ethical consideration in the conduct of clinical trials.
3. Write a note on safety monitoring in clinical trials.
4. What are the major challenges observed in implementation of the regulatory guidelines in clinical trials?
5. Briefly write the data management in clinical trials.
6. Explain:

   a) Placebo
   b) Human Subjects
   c) Candidate drug

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