Total No. of Questions : 4] SEAT No. :

P3996

[Total No. of Pages : 1

[5246]-224

M. Pharmacy

CLINICAL TRIALS

(2013 Pattern)

Time : 3 Hours] *[Max. Marks : 50*

Instructions to the candidates:

1) ***Question No.1 is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagram wherever necessary.***

Q1) Define clinical research. Explain the types and phases of clinical research. **[10]**

Q2) **Solve Any Three** **[15]**

a) Write the composition and responsibilities of Institutional Review Board.

b) Role and responsibilities of CRO in clinical research.

c) Explain the ethical guidelines of Declaration of Helsinki.

d) Discuss the criteria for selection of investigator in clinical research.

Q3) **Write notes on (Any three)** **[15]**

a) Investigational New drug (IND) process.

b) Inclusion and exclusion criteria.

c) Issues in Therapeutic drug monitoring.

d) Various elements in design of clinical trials.

Q4) Define informed consent. Discuss in brief the significance and contents of informed consent form. **[10]**

OR

Discuss the role of FDA in new drug development process.