Code: 17S09104

M.Pharm I Semester Regular Examinations February 2018

CLINICAL RESEARCH

(Pharmacy Practice)

(For students admitted in 2017 only)

Time: 3 hours Max. Marks: 60

Answer all the questions

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1 (a) Why new drugs are required to be developed? Explain the process of new drug development.

(b) Write a note on ICMR guidelines in conduct of clinical trials.

OR

2 What are the ethical issues in biomedical research? Explain the role of ethical committee in protecting the rights of patients participating in clinical trials.

3 Explain the roles and responsibilities of investigator.

OR

4 What is contract research organization? Explain the roles and responsibilities of CROs.

5 Write a detailed description about investigators brochure.

OR

6 Explain about clinical trials start up activities.

7 What is clinical trial monitoring? Explain about preparation and conduct of clinical trial monitoring.

OR

8 Explain about safety reporting, product reconciliation and destruction.

9 What is clinical trial audit? Explain the role and responsibilities of stake holders in clinical trial audit process.

OR

10 What is data management plan? Explain about data cleaning, mining and warehousing.

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