Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - MAY-2018

[Time: 3 Hours] [Max. Marks: 75]

Clinical Research

Q.P. CODE: 5140

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Explain briefly the various steps of Drug Development Process.
2. Explain the different randomization techniques used in clinical research.
3. What are the roles and responsibilities of the sponsor? Explain.
4. What are the guidelines for the preparation of case report forms? Explain.

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Explain briefly about the phases of clinical trials.
6. What is the criteria for audit process? Explain.
7. What is the difference between experimental and observational methods?
8. Write briefly in "ICH – GCP guidelines".
9. Explain the process of "Informed Consent".
10. Discuss the criteria for the inclusion and exclusion of subjects in clinical trials.
11. Discuss about the constitution and functions of ethical committee.
12. Explain the following (a) Cohort Study (b) Case control study.
13. Explain the role of data mining in clinical trial data management.
14. What are the responsibilities of stake holders in audit process?

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