Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D / II Year Pharm-D (Post Baccalaureate) Degree Examination – MAY 2016

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874

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

LONG ESSAYS (Answer any two) **2 x 10 = 20 Marks**

1. Discuss about various approaches to drug discovery in drug development process.
2. Describe briefly about roles and responsibilities of clinical research associate in clinical trial.
3. Discuss about designing of protocol for clinical study.

SHORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

4. Write a short note on IND.
5. Explain the responsibilities of IEC.
6. Write about the CDSCO guidelines for Good Clinical Practice (GCP).
7. Write the challenges in implementation of guidelines in the clinical trials.
8. Role and responsibilities of clinical research co-ordinator in clinical research.
9. Define serious adverse event in clinical trial and responsibilities of investigators in reporting.
10. Elaborate the steps involved in process to get NDA approval by US FDA.
11. Explain the process of CRF designing in detail.

SHORT ANSWERS **10 x 2 = 20 Marks**

12. Cohort studies.
13. Responsibilities of regulatory authority.
14. Objectives of Phase I clinical trial.
15. Define commercial and non commercial clinical trials.
16. Goal of preclinical studies.
17. Informed consent for children
18. What is "data clarification form"?
19. Safety monitoring.
20. What do you mean by "clinical data coding".
21. Differentiate between audit and inspection.

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