Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Mar 2013

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. Explain the different stages of drug development process.
2. Describe the composition & responsibility of IRB.
3. Discuss the different methods used in post marketing surveillance.

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

4. Explain the role of investigators in clinical trial.
5. Write the ethical principles of clinical research.
6. Elaborate on patient consent process.
7. Write a note on pre clinical studies.
8. What are the regulatory systems in USA?
9. Explain CRF.
10. What is IND? Enlist the different criteria for IND application.
11. Explain the data management in clinical research.

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

12. Randomization
13. Informed consent
14. Essential documents for clinical trials
15. Cross sectional study
16. Safety monitoring
17. Biopharmaceutical classification system
18. Phase II clinical trial
19. ANDA
20. Clinical research coordinator
21. Investigational product

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