Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Feb / Mar 2012

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 the various drug characterization techniques during drug development process
2. Discuss the principles of ICH-GCP guidelines
3 Describe in detail investigational new drug application

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

4. Give an overview of the regulatory environment in India
5. Write a short note on clinical trial design
6. Explain the design of a Case Report Form with a suitable example
7. Discuss the pharmacological approaches to drug discovery
8. Explain responsibilities and compositions of Institutional Review Board (IRB)
9. Describe pre-clinical trials
10. What are the elements of an informed consent
11. Write a short note on Abbreviated New Drug Application

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

12. Define Human Equivalent Dose (HED). How to convert an animal dose to HED
13. Classify drugs according to Biopharmaceutical Classification System
14. What are the in vitro assay methods for predicting PK in drug discovery
15. Explain randomized clinical trial
16. Define ADR and ADE
17. What is the role of a Contract Research Organization
18. Selection and withdrawal of subjects in clinical trails
19. Write a short note on toxicological studies
20. Explain the role of auditors
21. What are the objectives of phase II study

*****