Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Aug / Sep 2011

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 a clinical trial protocol as per ICH-GCP guidelines
2. Briefly explain the pharmacological and toxicological approaches to drug discovery
3. Describe briefly the various phases of clinical trials. Add a note on methods of post – marketing surveillance

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

4. Discuss safety monitoring in clinical trials
5. Write a note on ANDA submission
6. Give an overview of the regulatory environment in India
7. Discuss the drug characterization techniques
8. Discuss the challenges in the implementation of ethical guidelines
9. Describe the roles and responsibilities of the investigator as per ICH-GCP guidelines
10. Explain the design of a patient informed consent form with a suitable example
11. Discuss CDSCO guidelines

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

12. Who sponsors clinical trials
13. Give the importance of orange book and drug master file
14. What are the goals of good clinical practice
15. Name the different types of clinical trials
16. Explain Biopharmaceutical classification system
17. Write a short note on informed consent process
18. What are the different IND types
19. Write a short note on Cohort studies
20. Name the critical PK parameters in drug development
21. Define randomization and unblindings

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