

Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Sep 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. Explain the ethical guidelines for clinical research
2. Discuss the different Pharmacological action studies in the drug development process
3. Write a note on clinical data management in clinical trials

SHORT ESSAYS (Answer any six)

6 x 5 = 30 Marks

4. Explain CDSCO guidelines
5. Explain the phase II clinical trials
6. Write a note on drug characterization
7. Discuss about IND application
8. Role and responsibilities of auditors
9. Write a note on CRA
10. What are the different regulatory systems in USA, EUROPE and INDIA
11. Write a note on challenges in the implementation of ICH guidelines

SHORT ANSWERS

10 x 2 = 20 Marks

12. Informed consent
13. Protocol
14. Phase IV
15. Composition of IEC
16. Therapeutic index
17. Members of ICH
18. Chronic toxicity
19. Cohort studies
20. Safety monitoring
21. Investigator
