2874_2014_1_S181.doc

Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Jan 2014

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 toxicological approach to drug development process
2. Explain in detail the informed consent process
3. Discuss data management and it's components

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

4. Write a note on case control studies
5. Explain parenteral dosage forms in drug development process
6. What are the different regulatory systems in USA, EUROPE and INDIA
7. Write a note on GCP guidelines
8. Write a note on Abbreviated New Drug Application
9. Methods of Post marketing surveillance
10. Explain the inclusion and exclusion criteria for clinical research
11. Explain the responsibilities of IRB

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

12. Drug control general of India
13. European clinical directive
14. Phase III
15. Single blind method
16. Contract research coordinators
17. Investigator selection
18. Chronic toxicity
19. Case report form
20. Role of auditor
21. Mutagenicity and carcinogenicity.

*****