Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – DEC-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 briefly about ANDA submission.
2. Explain the ethical guidelines in clinical research. What are the challenges in implementation of guidelines?
3. Write about data management and briefly explain its components.

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

4. Discuss about CDSCO guidelines.
5. Responsibilities of auditor and clinical research associate.
6. Discuss the regulatory environment in USA.
7. Discuss the various dosage forms used during drug discovery process.
8. Principles of ICH-GCP
9. Write a note on phase II trials.
10. Roles and responsibilities of sponsor and investigator as per ICH-GCP
11. Composition and responsibilities of IRB

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

12. Types of IND
13. Cross-over design
14. Case report form (CRF)
15. Toxicological approaches
16. Declaration of Helsinki
17. Safety monitoring
18. Multicentre trials
19. ADR reporting
20. Methods of post marketing surveillance
21. Inclusion of pregnant women and nursing mothers in clinical trials

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