Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Aug 2013

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 in detail the role and responsibilities of
   a) investigator and b) clinical research associate as per ICH-GCP
2. Write about the different methods of post marketing surveillance. Briefly explain Phase I and II clinical trials.
3. Discuss in detail about CDSCO guidelines.

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

4. Note on drug characterization in drug development process.
5. Write about safety monitoring in clinical trials.
6. Explain the role and responsibilities of sponsor as per ICH-GCP.
7. Comment on challenges in the implementation of ethical guidelines.
8. Write a note on IND.
9. Discuss the informed consent process.
10. Draw drug discovery process flow chart.
11. Designing of CRF

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

12. Examples of Dosage forms used deuring drug development process
13. Explain biopharmaceutical classification system.
14. Explain (a) confidentiality (b) impartial witness.
15. Inclusion and exclusion criteria
16. Importance of drug master file (DMF)
17. NDA and ANDA
18. Role of auditor in clinical data
19. Importance of preclinical data
20. Name the different types of clinical trials.
21. Subject identification code

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