Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D / II Year Pharm-D (Post Baccalaureate) Degree Examination – NOVEMBER 2015

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 pharmacological and toxicological approaches to the drug discovery.
2. Explain in detail the various phases of clinical trials.
3. Describe the role and responsibilities of sponsor and investigator as per ICH-GCP guidelines.

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

4. Describe the drug characterization in drug discovery.
5. Explain the safety monitoring in clinical trial.
6. Write a note on ANDA submission.
7. What are the elements of informed consent process?
8. Explain various regulatory systems in USA and India.
9. Write a note on challenges in implementation of ICH guidelines.
10. Write a note on IND application.
11. Designing of CRF.

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

12. Phase 0
13. Preclinical studies.
14. Therapeutic index.
15. Quality assurance and quality control.
16. Subject identification code.
17. Members of ICH.
18. Clinical trial protocol.
19. Define ADR and ADE.
20. Explain confidentiality.
21. Composition of IEC.

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