Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – NOV 2017

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874 / 2890

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 Abbreviated New Drug Application (ANDA) submission.
2. Explain spontaneous reporting of ADR with suitable examples. What are the merits and demerits of spontaneous reporting?
3. Discuss the principles of ICH-GCP guidelines.

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

4. Enumerate designing of case report form (CRF) with a suitable example.
5. Discuss electronic data processing.
6. Explain the role of Business Process Outsourcing (BPOs) in conducting clinical research in India.
7. Explain the objectives of various phases of clinical trial.
8. Discuss in detail about CDSCO guidelines.
9. Explain the role of clinical trial personnel in premature termination or suspension of a study.
10. Discuss conflict of interest in clinical trials.
11. Write a note on Fast track and Priority review.

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

12. What are LD50 and ED50?
13. Name the critical pharmacokinetic parameter in drug development
14. Define double blinded method.
15. Role of Uppsala monitoring centre (UMC) in safety monitoring.
16. Components of documentation form.
17. Explain Waiver of consent.
18. Note on 21CFR Part 312.
19. Write a note on cohort studies.
20. Responsibilities of contract research organization
21. Use of placebo in clinical trials

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