Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 12-Nov-2021

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. Discuss about different methods of post marketing surveillance.
2. Explain the monitoring visits in initiation, conduction and closing of clinical trials.
3. Explain briefly about ANDA submission.

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

4. Role of Eudravigilance in safety monitoring.
5. Role and responsibilities of sponsor in clinical trials.
6. Give an overview of regulatory environment in India.
7. Mention the criteria required for selection and recruitment of study subjects.
8. Write a note on clinical data archive.
9. Explain the role of investigators in clinical trials.
10. Write a note on methods of randomization.
11. Write a note on statistical design in clinical trials.

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

12. Define maximum tolerated dose.
13. Objectives of ICH E6.
14. Define unexpected ADR.
15. Submission of Periodic Safety Update Report (PSUR) in India.
16. Selection and withdrawal of subjects in clinical trials.
17. Role of Clinical Research Coordinator (CRC).
18. Note on centralized and decentralized marketing in EU.
19. Consent for Vulnerable subject.
20. Criteria for unblinding the investigational drug.
21. Regulations for Counterfeit drugs

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