Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 17-Nov-2022

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

CLINICAL RESEARCH (RS & RS2)

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 in detail the process of designing study protocol in clinical trials. Add a note on the importance of CRF.
2. Explain about the clinical data management in clinical trials.
3. Describe the different stages of drug development process.

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

4. Explain about IND and enlist different criteria for investigational new drug application.
5. Explain about safety monitoring in clinical research.
6. Explain the role and responsibilities of investigators.
7. Explain the regulatory system in India.
8. Explain the inclusion and exclusion criteria for clinical trial.
9. Explain the role of contact research coordinators.
10. Describe about Good clinical practice.
11. Explain ethical guidelines in clinical research.

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

12. Define orange book and drug master file.
13. Define cross sectional study.
14. Define randomization.
15. Write any two roles of auditors.
16. Define Phase II.
17. Define Informed consent form.
18. Different dosage forms used in during drug discovery process.
19. Define biopharmaceutical classification system.
20. Define quality assurance and quality control.
21. Explain waiver of consent.

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