

Rajiv Gandhi University of Health Sciences, Karnataka
V Year Pharm-D / II Year Pharm D Post Baccalaureate Degree Examination – 31-
May-2023

Time: Three Hours
70

Max. Marks:

CLINICAL RESEARCH (RS & RS-2)

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 the various phases of clinical trials.
2. Discuss the different pharmacological studies in drug development process.
3. Explain in detail the role of responsibilities of investigator and clinical research associate as per ICH-GCP guidelines.

SHORT ESSAYS (Answer any six)

6 x 5 = 30 Marks

4. Explain the responsibilities and compositions of IRB/IEC.
5. Explain the data management in clinical research.
6. Explain different methods of post marketing surveillance.
7. Explain CDSCO guidelines.
8. Describe the ANDA submission.
9. Explain the challenges in implementation of ethical guidelines.
10. Describe the element of an informed consent form.
11. Explain the role of regulatory authority.

SHORT ANSWERS

10 x 2 = 20 Marks

12. Define chronic toxicity.
13. Define cohort study.
14. Define subject identification code.
15. List members of ICH.
16. Define ADR and ADE.
17. Define Therapeutic index.
18. Explain Double blind studies.
19. List the different types of IND application.
20. State the goals of Good clinical practice.
21. Define case report form.
