

Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – MAY-2018

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 in detail the various phases of clinical trial.
2. Explain clinical trial protocol as per ICH-GCP guidelines.
3. Discuss in detail the IND application.

SHORT ESSAYS (Answer any six)

6 x 5 = 30 Marks

4. Explain pre-clinical trials
5. Explain the importance of dosage form design in pre-clinical and clinical stages.
6. Write short note on clinical trial design.
7. Write a note on Abbreviated New Drug Application (ANDA)
8. Write a note on regulations for OFF-Label drug use.
9. Explain in detail the informed consent process
10. Explain composition and responsibilities of IRB.
11. Write a note on Quality Assurance (QA) and Quality Control (QC) in clinical data management.

SHORT ANSWERS

10 x 2 = 20 Marks

12. What is Human Equivalent Dose (HED)? How to convert animal dose to HED?
13. Functions of EMEA.
14. Note on Non-inferiority clinical study.
15. Methods of sample size calculations in clinical trials.
16. Define false positive result with an example.
17. Define bias.
18. Note on CIOMS.
19. Importance of confidentiality statement in investigator brochure.
20. Functions of DCGI
21. Phases of Vaccine Trials
