Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – June-2019

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 clinical trials and monitoring. Discuss different types of monitoring visits in detail.
2. Write a note on accelerated approval, fast track and priority review in approval of drugs/vaccine.
3. Explain in detail the process of designing study protocol in clinical trials. Add a note on importance of CRF.

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

4. Write a note on active surveillance in ADR reporting.
5. Discuss observational studies.
6. Explain the regulatory aspects of clinical trials for surgical procedures/ medical devices.
7. Write a note on Quality Assurance (QA) and Quality Control (QC) in clinical data management.
8. Discuss in detail about institutional review board.
9. Explain the basic methodologies and study designs of BA/BE studies.
10. Write about safety monitoring in clinical trials.
11. Discuss in detail about CDSCO guidelines.

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

12. Significance of sub acute toxicity
13. Note on Nuremberg trials
14. Explain confidentiality and impartial witness in clinical trials.
15. List the guidelines and acts that govern the conduct of clinical trials in India.
16. Advantages of multicentre trails.
17. Drug labeling requirement in clinical studies.
18. Clinical trial insurance for trial subjects.
19. What is subject identification code?
20. Regulatory requirement for research involving children.
21. Biopharmaceutical classification of drugs

*****