Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – DEC-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. What do you mean by expedited reporting in clinical trial? Discuss in detail the safety reporting as per schedule Y.
2. Explain in detail the process of designing study protocol in clinical trials. Add a note on importance of CRF.
3. Discuss in detail the IND application.

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

4. Write a note on lead selection and optimization in drug development process.
5. Write the application of computers in clinical data management.
6. Write a note on fast track and priority review of drug/vaccine approval.
7. Explain the toxicological approach to drug development process.
8. Write a note on Meta analysis.
9. Ethical issues in involving pregnant women as research participant.
10. Explain the essential documents in conducting clinical trials.
11. What are different regulator system in USA, Europe and India?

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

12. Importance of performing mutagenecity and carcinogenicity studies.
13. Role of PVPI in ADR management
14. Regulations for orphan drugs
15. Advantages of randomized controlled clinical trial.
16. What is 'The Orange Book'?
17. What is subject identification code?
18. Significance of Non-Therapeutic Study.
19. Coding of investigational products.
20. Uses of Clinical Trial Document (CTD).
21. Role of auditor in clinical data management.

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