Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) Degree Examination – NOV 2016

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

CLINICAL RESEARCH (RS)

Q.P. CODE: 2874

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. Describe in detail the components and process of Investigational New Drug Application (INDA).
2. Discuss in detail about CDSCO guidelines.
3. Detail the process of Phase I, Phase II and Phase III of clinical trials.

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

4. Discuss the role and responsibilities of Contract Research Coordinator (CRC).
5. Explain the design of patient informed consent form with a suitable example.
6. Discuss an overview of regulatory environment in USA, Europe and India.
7. Briefly explain the pharmacological and toxicological approach to drug discovery.
8. Explain the ethical guidelines for clinical research.
9. Define safety monitoring. Explain its role in clinical trials.
10. Discuss data management process in clinical trials.
11. Explain the challenges in the implementation of guidelines in clinical research.

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

12. Explain the criteria to involve children in conducting clinical research.
13. Functions of Drug Control General of India (DCGI).
14. Declaration of Helsinki
15. Note on CIOMS
16. Define case control studies.
17. Minimum criteria to report ADR
18. Importance of European Clinical Directive
19. Define Proof of Concept.
20. Note on Non-inferiority clinical study
21. List various criterias to classify a serious ADR.

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