Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 15-Jun-2022

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

CLINICAL RESEARCH (RS & RS2)

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 Investigational New Drug (IND) application.
2. Explain in detail the roles and responsibilities of the following as per ICH-GCP guideline a) Investigator b) Clinical research associate c) Regulatory authority
3. Discuss about the different methods of post marketing surveillance.

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

4. With schematic representation, discuss integrated drug development process.
5. Explain inclusion and exclusion criteria in selection of clinical trial subjects.
6. Briefly, explain phase 1 and phase 2 clinical trials.
7. Write about safety monitoring in clinical trials.
8. Explain in detail the process of clinical trials for vaccines.
9. Discuss the regulatory environment in USA, Europe and India.
10. Discuss in detail about Institutional Review Board.
11. Write the application of computer in clinical data management.

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

12. Define therapeutic index.
13. Clinical trials for fixed dose combinations.
14. Define clinical trial.
15. Differentiate Adverse Drug Reaction (ADR) and Adverse Drug Effect (ADE).
16. Define Ethics.
17. List members of ICH.
18. Define protocol.
19. List global ADR reporting Forms.
20. Explain ANOVA.
21. Expand the following terminologies: IND, DCGI, PvPI, BPO

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