Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree Examination – 04-Jan-2020

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 the different post marketing surveillance methods and explain them.
2. Explain the ethical guidelines for clinical research.
3. Describe the various drug characterization techniques during drug development process.

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

4. Explain the toxicological approach in drug discovery.
5. Describe the role of clinical research associate.
6. Explain the components of data management.
7. Describe pre-clinical trials.
8. Explain about elements of informed consent process.
9. Explain about composition and responsibilities of institutional review board.
10. Explain the role of sponsor.
11. Describe about the regulatory system in Europe.

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

12. List the critical pharmacokinetic parameters in drug development.
13. Define human equivalent dose.
14. Define confidentiality.
15. Define case control studies.
16. List the different types of blinding.
17. Methods to take informed consent in research involving children.
18. Write any two challenges in the implementation of guidelines.
19. Define regulatory authority.
20. Define abbreviated new drug application.
21. Explain the importance of drug master file.

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