Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 23-Nov-2021

[Time: 3 Hours] **[Max. Marks: 75]**

CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. CODE: 5180

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary.

Answer All The Questions **10 X 7.5 = 75 Marks**

1. Write about origin and principles of International Conference on Harmonization (ICH).
2. Constitution and functions of ethical committee – institutional review board.
3. What is informed consent form? Write the structure and content of an informed consent process.
4. Mention the types and design of clinical trials. Explain about experimental studies.
5. Explain the roles and responsibilities of contract research organization and its management.
6. What is investigator brochure? Explain its content.
7. Write about clinical study report and safety monitoring in clinical trials.
8. Write the international classification of diseases. Explain different terminologies of pharmacovigilance.
9. Explain the safety pharmacology.
10. Explain in detail about assessment of predictability and preventability assessment of ADR.

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