Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 06-Jun-2023

[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. Explain Good Clinical Practice (ICH-GCP) guidelines.
2. Guidelines for biomedical research and human participant as per ICMR.
3. Mention the types and design of clinical trials. Explain observational study.
4. Explain the role and responsibilities of clinical research sponsor.
5. Write in detail about case report form and management of adverse drug reactions.
6. Define pharmacovigilance. Explain establishing pharmacovigilance centers in hospitals.
7. Explain the statistical methods for evaluating medication safety data.
8. Explain guidelines for the reporting of ADR by Argus and Aris G Pharmacovigilance.
9. Explain Pharmacoeconomics.
10. Guidelines for preparation of clinical trial protocol.

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