Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 09-Nov-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 about the documentation involved in the clinical trial.
2. Provide elaborative discussion on different phases of clinical trials.
3. Explain in detail about Pharmacoepidemiology.
4. Discuss about the pharmacological and toxicological approaches to drug discovery.
5. Write a note on Institutional Review Board and Ethical committee.
6. Write a note on Safety Pharmacology and Pharmacoeconomics.
7. Write a note on roles and responsibilities in Pharmacovigilance.
8. Write a note on regulatory considerations of pharmacovigilance.
9. Explain confidentiality, Impartial witness, Inclusion and Exclusion criteria.
10. What is ADR? Discuss the severity and seriousness assessment in ADR.

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