Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 06-Jun-2024

[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 in detail about ICH-GCP guidelines for clinical trials.
2. Write briefly about case report form and investigator brochure in clinical trial documentation.
3. Discuss the roles and responsibilities of contrast research organization (CRO) and its management.
4. Explain the work flow of different reporting software's in ADR.
5. Define institutional review board. Who needs to obtain IRB review and approval?
6. Discuss about Cohort study in clinical trials. Explain clinical trial safety monitoring.
7. Explain randomized clinical trial (RCT) and non-randomized clinical trial.
8. What is pharmacovigilance? Describe the importance of establishing pharmacovigilance centres in hospitals.
9. What is safety pharmacology? Write about regulatory guidelines of safety pharmacology.
10. Explain in detail about WHO international drug monitoring programme.

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