Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 12-Nov-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. What is Informed Consent Form (ICF)? Discuss about structure and content of ICF for clinical study.
2. Explain about voluntary reporting of ADRs. Give reasons for under reporting of ADRs.
3. Explain in detail various phases of clinical trials.
4. Explain the different techniques of medication safety assessment.
5. Write the composition and responsibilities of Institutional Review Board.
6. Explain the different methods of Pharmacoeconomic evaluation.
7. Describe the steps involved in formulating a study decision in Pharmacoepidemiology.
8. Write a note on different versions of International classification of diseases.
9. Write the role of study coordinator/investigator in clinical research.
10. What is Pharmacovigilence? Write about establishment of pharmacovigilance centres in hospital.

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