Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 27-Jul-2022

[Max. Marks: 75]

[Time: 3 Hours]

CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. CODE: 5180

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

10 X 7.5 = 75 Marks

Answer All The Questions

1. Explain the ethical guidelines for bio medical research and human participant according to ICMR.
2. Discuss in detail about international classification of diseases and international non-proprietary names of drugs.
3. What is ADR? Discuss about severity and seriousness assessment in ADR.
4. What is clinical trial? Write the different types and design of clinical trial and explain in detail about Non-Randomized Controlled Trials.
5. What is informed consent process? Explain ethical principles governing informed consent process.
6. Write the different terminologies of ADR. Add a note on pharmacovigilance.
7. Discuss in brief about cohort study and case control studies.
8. Write in brief about evaluation of medication safety and Pharmacoeconomics.
9. Define pharmacovigilance. Write a note on history and progress in pharmacovigilance.
10. Explain in detail WHO international drug monitoring programme.

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