Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination - JUNE-2019

[Time: 3 Hours] [Max. Marks: 75]

Clinical Research & Pharmacovigilance -II

Q.P. CODE: 5180

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

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Define clinical trials. Write the requirements to conduct clinical trials as per schedule Y. (2+8)
2. Explain the monitoring visits in initiation, conduction and closing of clinical trials.
3. Explain in detail the role and responsibilities of clinical research coordinator and sponsor. (5+5)
4. Explain the different techniques of medication safety assessment.

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Explain the principles of safety pharmacology.
6. Describe the steps involved in formulation a study decision in Pharmacoepidemiology.
7. Define Surveillance. Explain different types of surveillance.
8. Write the steps involved in establishment of Pharmacovigilance centres in hospitals.
9. Write a note on statistical methods for evaluating medication safety data.
10. What is Investigator Brochure? Explain its content.
11. Explain about different types of observational studies.
12. Explain the ethical guidelines for clinical research.
13. Define contract research organization. Write about its management.
14. Write a note on different versions of International classification of diseases.

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