Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination - JAN-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. Explain the process of designing study protocol in clinical trials. Write the importance of informed consent process.
2. Give a detailed account of ICH-GCP guidelines.
3. Explain the international classification of diseases.
4. Describe the data reporting form, banned drug regulatory considerations in Pharmacovigilance.

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

5. Role of regulatory authority in clinical trials.
6. Write about Nuremberg code 1946.
7. Write a note on Informed Consent Process.
8. Write short note on Schedule Y.
9. Define, types and management of ADR.
10. Write about passive and active surveillance.
11. Write a note on vaccine safety surveillance.
12. Write short notes on Cohort study.
13. Objectives of good clinical practice (GCP).
14. Explain the history and progress of PV.

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