Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination - MAY-2018

[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. What is Informed Consent Form (ICF)? Discuss about structure and content of ICF for clinical study. (2+8)
2. Explain different types of study designs of clinical trials.
3. Explain in detail the assessment of severity, seriousness and preventability of adverse drug reactions (ADRs).
4. Explain about voluntary reporting of ADRs. Give reasons for under reporting of ADRs. (7+3)

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

5. Explain the different types of cost in Pharmacoeconomic study.
6. Describe the different types of error that occur in Pharmacoepidemiological study.
7. Explain about immunization safety surveillance.
8. Write the role of comparative observational studies in Pharmacovigilance.
9. Write about safety monitoring in clinical trials.
10. What is clinical study report? Write a note on its content.
11. Write the role of sponsor in clinical research.
12. Explain the ethical principles governing informed consent process.
13. Write about Argus Pharmacovigilance system.
14. Write the purpose and uses of International classification of diseases (ICD-10).

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