Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 11-Nov-2023

Time: Three Hours **Max. Marks: 75 Marks**

PHARMACOVIGILANCE
Q.P. CODE: 5037

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary
All the Questions are compulsory

LONG ESSAYS **2 x 10 = 20 Marks**

1. Define Adverse Drug Reactions. Classify ADRs with suitable examples. Explain the mechanism of Type-B adverse drug reactions.

   OR

   Explain in detail the comparative observational researches as tools in pharmacovigilance.

2. Discuss in detail the establishment and operation of drug safety department in pharmaceutical industry.

HORT ESSAYS **7 x 5 = 35 Marks**

3. Explain briefly Schedule Y of D and C Act.

   OR

   Write a note on Expedited reporting and post approval expedited reporting.

4. Discuss various methods used to detect and monitor ADRs with its merits and demerits.

   OR

   How will you communicate vaccine safety issues with healthcare facilities and Media?

5. Write a note on Med DRA.
6. Discuss in detail post approval phase of drug safety data generation.
7. What are the basic drug information resources for ADRs?
8. Organization and objectives of ICH.
9. Write a short note on contract research organisation.

SHORT ANSWERS **10 x 2 = 20 Marks**

0. Factors affecting AEFI surveillance.
11. What is CIOMS working groups?
12. Define Eudravigilance.
13. Give two examples of ADRs due to genetic defect in metabolism.
14. **VAERS.**
15. Safety Signals.
16. What is phase III of clinical trials?
17. How will you calculate DDD?
18. Objectives of CDSCO (India).
19. Stimulated reporting.

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