

Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 12-Jun-2024

Supply

Time: Three Hours

Max. Marks: 75

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

What do you mean by Vaccine Pharmacovigilance? Discuss in detail Passive and active surveillance for vaccine safety study

2. Discuss in detail the requirements for setting up of a drug safety department in a hospital

SHORT ESSAYS

7 x 5 = 35 Marks

3. Discuss in details clinical trials for drug safety data generation

OR

Write a note on Good clinical practice in pharmacovigilance studies

4. Write a note on Schedule Y

OR

Write a note on targeted clinical investigations

5. Write a note on Cross-sectional study
6. Explain Individual case study reports(ICSR)
7. Write a note on International classification of diseases
8. Discuss in detail the various drug information resources in Pharmacovigilance
9. Describe the drug safety evaluation in Geriatrics

SHORT ANSWERS

10 x 2 = 20 Marks

10. Define PvPI
11. List any four drugs that cause teratogenicity
12. What is PSUR and DSUR?
13. What do you mean by Dechallenge and rechallenge?
14. Define Vigiflow, WHO-ADR, ADE?
15. What are the three minimum GCP principles?
16. How will you calculate DDD?
17. Write a note on Probable, Predictable in causality assessment of ADR
18. Write a note on Eudravigilance
19. What is phase IV of clinical trials?
