

Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 06-Nov-2024

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. What is Vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance

OR

Define pharmacovigilance. Add a note on detection, reporting and management of ADRs in hospital

2. Discuss in detail basic and specialized drug information resources in pharmacovigilance

SHORT ESSAYS

7 x 5 = 35 Marks

3. Write about contract research organization

OR

Role of CDSCO in pharmacovigilance

4. What are the prerequisite for setting up of pharmacovigilance center in hospital?

OR

Write a note on ATC classification of drugs

5. Write a note on pre-marketing and post-marketing clinical trials
6. Write a note on Periodic safety update reports
7. Write about different methods of causality assessment of ADRs
8. Explain in detail WHO drug dictionary and coding in pharmacovigilance
9. Write a note on targeted clinical investigations

SHORT ANSWERS

10 x 2 = 20 Marks

10. Vaccination failure
11. List few drugs causing teratogenicity
12. Give examples of pharmacokinetic ADRs
13. Explain daily define dose
14. What are the minimum criteria required for the valid report?
15. What are the three minimum principles of GCP?
16. Write a note on volunteers involved in clinical trials
17. Define AEFI
18. Importance of using standard dictionary
19. What do you mean by dechallenge and rechallenge?
