

Rajiv Gandhi University of Health Sciences, Karnataka
VIII Semester B. Pharm Degree Examination – 23-Nov-2021

Time: Three Hours

Max. Marks: 75 Marks

PHARMACOVIGILANCES

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

OR

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

2. Define Adverse drug reactions. Discuss in detail causality, severity and seriousness assessment of ADRs.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Write a note on communicating vaccine safety with regulatory agencies.

OR

Briefly explain severity assessment of ADRs.

4. Explain Pre- marketing and Post marketing clinical trials.

OR

Role of Pharmacist in management of ADRs.

5. Write a note on clinical trial regulations in India.
6. Discuss in detail drug safety evaluation in pregnant and lactating women.
7. What are the requirements of individual case safety reports?
8. Discuss in detail WHO drug dictionary and coding in pharmacovigilance.
9. Explain periodic safety update reports (PSURs).

SHORT ANSWERS

10 x 2 = 20 Marks

10. Importance of vaccine safety.
11. What is preclinical phase?
12. Vaccination failure.
13. Give examples of ADRs due to genetic defect in distribution.
14. What are the factors to be considered while evaluating drug safety in Geriatrics?
15. Eudravigilance.
16. ICH guidelines for pharmacovigilance planning.
17. What is primary purpose of ICH?
18. List few drugs causing teratogenicity?
19. What is CIOMS form?
