

Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 25-Nov-2022

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. Discuss in details vaccine safety surveillance.

OR

Define Pharmacovigilance. Discuss the role of Pharmacist in detection, reporting and management of ADRs in hospital.

2. Explain in detail Med DRA and WHO-ART.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Explain predisposing factors of Adverse drug reactions.

OR

Write a note on ATC classification of drugs.

4. How will you investigate AEFI?

OR

Role of CDSCO in pharmacovigilance.

5. Write a note on post approval expedited reporting.

6. Write a note on ICH-GCP guidelines.

7. Write a note on targeted clinical investigations.

8. What are the factors to be considered for the drug safety evaluation in Geriatrics?

9. Write a note on Cross-sectional study.

SHORT ANSWERS

10 x 2 = 20 Marks

10. What do you mean by Dechallenge and rechallenge?
11. List out types of products in WHO-drug dictionary.
12. Write any two objectives of preclinical phase in drug safety.
13. Explain daily defined doses.
14. What are the limitations of pre clinical phases?
15. What are the objectives of ICH?
16. What is post marketing safety?
17. How will you calculate defined daily dose?
18. Define CIOMS and MedDRA.
19. What is pharmacogenomics?
