

Rajiv Gandhi University of Health Sciences, Karnataka
Sixth Semester B. Pharm Degree Examination – 08-Nov-2024

Time: Three Hours

Max. Marks: 75

PHARMACEUTICAL QUALITY ASSURANCE

Q.P. CODE: 5028

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 the requirements for environmental control and maintenance of sterile manufacturing area

OR

Discuss the key elements, principles and importance of Total Quality Management approach

2. Discuss personnel, building and equipment requirement for GLP

SHORT ESSAYS

7 x 5 = 35 Marks

3. Write a note on ISO 9000 and ISO 14000

OR

Define QbD and write a note on QbD tools

4. Describe the criteria for equipment selection and maintenance in pharmaceutical industry

OR

How is the cross contamination prevented in dispensing and production areas

5. Discuss the quality control tests for secondary packing materials

6. Discuss the benefits and requirements of SOP

7. Write a note on complaints and evaluation of complaints

8. Elaborate on calibration procedure of pH meter

9. Explain the process validation with a suitable example

SHORT ANSWERS

10 x 2 = 20 Marks

10. Define Accuracy and precision
11. Write the significance of NABL
12. Define ICH guidelines
13. Write the difference between GMP and cGMP
14. Name any four Deming's principles of quality management
15. What are the materials used for primary packaging?
16. Define BFR and MFR
17. What is quality audit and quality review?
18. What are the different types of qualifications?
19. List out the importance of good warehousing practice
