

Rajiv Gandhi University of Health Sciences, Karnataka
Sixth Semester B. Pharm Degree Examination – 14-May-2025

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 in detail the principle concepts of Total Quality Management

OR

Describe in detail about personnel responsibilities, training and hygiene in pharmaceutical industry.

2. Discuss the objectives and significance of Good Laboratory Practices. Explain briefly the protocol for conduct of non-clinical laboratory study.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Explain the various steps involved in the purchase of equipments

OR

Define cross-contamination. How it is prevented in production facilities

4. What is QbD? Explain the elements of QbD program

OR

Write a note on ISO 9000 with merits and demerits

5. What is closure? Enlist different types of closures. Outline their quality control test
6. Write the elaborative note on batch formula record
7. Write a detail description on material Management
8. Enlist the reasons for a product recall. Explain different types of recalls
9. How analytical equipments can be validated?

SHORT ANSWERS

10 x 2 = 20 Marks

10. Outline the benefits of ISO 14000
11. Define quality assurance and quality control
12. Define NABL accreditation
13. What is CAPA? Write its significance
14. What is Master formula record?
15. Write the significance of FIFO and LIFO
16. Write the significance of calibration
17. What are the materials used for secondary packaging?
18. Name any four factors that affect selection of equipments
19. Write the significance of HEPA filter usage
