

Rajiv Gandhi University of Health Sciences, Karnataka
Sixth Semester B. Pharm Degree Examination – 17-Nov-2023

Time: Three Hours

Max. Marks: 75 Marks

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. List and explain Q series guidelines of ICH.

OR

Describe the requirements of organization and personal responsibilities as per schedule M.

2. Explain in detail the quality control test for packaging materials.

SHORT ESSAYS

7 x 5 = 35 Marks

1. Explain the principles are of TQM.

OR

Explain the scope and features of NABL accreditation.

4. Discuss the steps involved in the purchase specification.

OR

Write a note on maintenance of stores for raw materials.

5. Give reasons for disqualification of testing facilities in GLP.
6. Explain briefly the protocol for conducting Non-clinical lab studies.
7. What are complaints and how they are evaluated documents maintenance in pharmaceutical industry?
8. How do you handle disposal of waste products in pharmaceutical unit?
9. Discuss the parameters for qualification of UV-visible spectrophotometer.

SHORT ANSWERS

10 x 2 = 20 Marks

10. Write the difference between QA and QC.
11. What are the benefits of QbD?
12. Write a note on personal hygiene in pharmaceutical unit.
13. Name different types of containers used in pharmaceutical industries.
14. What is DMF and give its importance.
15. What is quality audit and quality review.
16. Write the difference between qualification and validation.
17. Explain the concept of FIFO.
18. Write the difference between prospective and retrospective validation.
19. Write the objective of ISO14000.
