

Rajiv Gandhi University of Health Sciences, Karnataka

Sixth Semester B. Pharm Degree Examination – 27-Jun-2022

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. Explain scope and objectives of GLP.

OR

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

2. Write in detail about NABL accreditation, principles and procedures.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Write in brief on processing of pharmaceutical complaints.

OR

Explain the elements of TQM.

4. What are the steps involved in validation?

OR

Differentiate between GLP and GMP.

5. Describe the quality control tests for containers.
6. Write in brief about preparation of new SOP.
7. Write brief note on QbD tools.
8. Write the process for maintenance of stores for raw materials.
9. **Describe the steps involve in qualification of UV visible spectrophotometer**

SHORT ANSWERS

10 x 2 = 20 Marks

10. What is batch formula record?
11. Define calibration.
12. Give the importance of Quality control.
13. What is ISO 14000?
14. Define ICH guidelines.
15. What is secondary packing materials? Give two examples.
16. What is Quality review?
17. What is 'Recall' in pharmaceutical industry?
18. What are types of qualifications?
19. Define Validation.
