

Rajiv Gandhi University of Health Sciences, Karnataka
Sixth Semester B. Pharm Degree Examination – 29-Nov-2021

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. Discuss the important principles of Total Quality Management.

OR

Describe the requirements for environmental control and layout of sterile manufacturing area.

2. Explain the objectives and scope of GLP.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Write a note on ISO 9000 and ISO 14000.

OR

Explain briefly about ICH stability testing.

4. Discuss the maintenance of raw material stores.

OR

Describe the SOP for purchase specification.

5. Explain the procedure for qualification of UV visible spectrophotometer.

6. Write a note on material Management.

7. Discuss the QC tests for secondary packing materials.

8. Explain briefly CTD and its modules.

9. Explain the handling of market complaints.

SHORT ANSWERS

10 x 2 = 20 Marks

10. Define TQM.
11. What are the materials used for secondary packaging?
12. Differentiate calibration and qualification.
13. Define MFR.
14. What are the objectives of validation?
15. Write about quality documentation.
16. What are the personal responsibilities in plant layout?
17. Enlist Q series of ICH guidelines.
18. Define NABL accreditation.
19. Name different types of validation.
