

Rajiv Gandhi University of Health Sciences, Karnataka

Sixth Semester B. Pharm Degree Examination – 16-Dec-2020

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.

LONG ESSAYS (Answer any Two)

2 x 10 = 20 Marks

1. Explain ICH Q1 guidelines for stability testing of drug and drug product.
2. Discuss briefly cGMP guidelines for construction, maintenance and sanitation of pharmaceutical unit.
3. Explain the objectives and scope of GLP.

SHORT ESSAYS (Answer any Seven)

7 x 5 = 35 Marks

4. Write the elements of ISO 9000.
5. Write the procedure for NABL accreditation.
6. How is the cross contamination prevented in dispensing and production areas.
7. How do you audit vendor for ensuring purchase specification?
8. Explain the QC test for secondary packaging material.
9. Discuss the procedure for conducting non clinical laboratory studies.
10. Discuss the SOP for disposal of waste in pharmaceutical unit.
11. Elaborate on master formula record.
12. Write the procedure for qualification of UV- Visible spectrophotometer.

SHORT ANSWERS (Answer All)

10 x 2 = 20 Marks

13. Write any four elements of TQM.
14. Define QA and QC.
15. What is cross contamination and mix up contamination?
16. Name any four types of closures.
17. What is DMF? Give its importance?
18. What is quality audit and quality review?
19. Define calibration, qualification and validation.
20. Write briefly the scope of validation.
21. Name the parameters used for analytical method validation.
22. What is the difference between QMS and EMS?
