

**Rajiv Gandhi University of Health Sciences, Karnataka**  
**Sixth Semester B. Pharm Degree Examination – 30-Nov-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. Discuss in detail the principles of TQM.

**OR**

Explain the facility requirements for maintenance of sterile manufacturing area.

2. Discuss the importance of Good Laboratory Practices. Explain briefly the protocol content of non-clinical laboratory study.

**SHORT ESSAYS**

**7 x 5 = 35 Marks**

3. Explain the concept of QA and QC.

**OR**

Enlist ICH Q-series guidelines and explain any one in detail.

4. Describe the criteria for equipment selection in pharmaceutical industry.

**OR**

How is cross contamination is prevented in dispensing unit?

5. Write the reasons for disqualification of testing facilities.

6. Describe the procedure for handling of return goods.

7. Write a short note on quality audit and quality review.

8. Explain the procedure for qualification of pH meter.

9. Describe the principle of analytical method validation.

**SHORT ANSWERS**

**10 x 2 = 20 Marks**

10. Define QbD.

11. Enlist the benefits of ISO 14000.

12. Name any four Deming's principles of quality management.

13. List out the steps involved in the purchase of raw materials?

14. What are the personnel requirements as per GLP?

15. Explain the role of SOP in manufacturing unit.

16. What is Master formula record?

17. What is FIFO and LIFO?

18. Name any two parameters for qualification of UV-visible spectrophotometer.

19. Write the importance of calibration.

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