

**VINAYAKA MISSION'S RESEARCH FOUNDATION  
(DEEMED TO BE UNIVERSITY), SALEM**

**B.PHARM. DEGREE EXAMINATION – July 2021  
Sixth Semester**

**QUALITY ASSURANCE**

Time : Three hours

Maximum: 75 marks

I. Write essays on any **TWO** questions: (2 x 10 = 20)

1. Explain the scope and limitations of good laboratory practice.
2. Detailed note about the overview of ICH guidelines for QSEM.
3. Define SOP and detail about SOP of different manufacturing process.

II. Write short answers on any **SEVEN** questions: (7 x 5 = 35)

4. Good warehousing practice.
5. Protocol for conduct of non - clinical laboratory study.
6. Batch formula record.
7. Calibration of pH meter.
8. Quality control test for closures.
9. Note on sanitation in pharma industry.
10. Quality audit.
11. Control of contamination.
12. Principles and procedures of NABL accreditation.

III. Write short notes on : (10 x 2 = 20)

13. Define records.
14. Elements of QbD program.
15. Note on personal records in pharma industry.
16. Types of validation.
17. Contents in master formula record.
18. Define calibration.
19. Waste disposal.
20. Elements in ISO9000.
21. Define complaints.
22. Define Quality control.

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