

VINAYAKA MISSION'S RESEARCH FOUNDATION
(Deemed to be University), SALEM

B.PHARM. DEGREE EXAMINATION – October 2021
Sixth Semester

QUALITY ASSURANCE

Time : Three hours

Maximum: 75 marks

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

1. Write essay on plant layout and construction of pharma industry. (5+5)
2. Write in detail about the concepts and philosophy of GMP. (5+5)
3. Give the definition, principles, importance and scope of validation. (2 1/2+2 1/2+2 1/2+2 1/2)

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

4. Explain the content of master formula record.
5. Quality control test procedure for containers and closures. (2 1/2 +2 1/2)
6. Brief about the elements of TQM.
7. Define quality audit and classify with example. (2+3)
8. How to handle the return goods?
9. Write a note on Reports and Documents in pharma industry. (2 1/2 +2 1/2)
10. Disqualification of testing facilities.
11. Test and control articles.
12. Principles of Analytical method Validation.

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

13. Define complaints.
14. Note on SOP.
15. Define accuracy.
16. Elements in Qbd.
17. Benefits of ISO 9000.
18. Draw pharma plant layout.
19. Distribution records.
20. Aim of GLP.
21. Contents of Quality documentation.
22. Packing materials.
