

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

**B.PHARM. DEGREE EXAMINATION – JANUARY 2020
Sixth Semester**

QUALITY ASSURANCE

Time : Three hours

Maximum: 75 marks

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

1. a) Define and write the elements of QBD. (5)
b) Write the procedure involved in the sterile area maintenance. (5)
2. a) TQM. (5)
b) Write the principle and procedure for NABL accreditation. (5)
3. a) Write the importance and scope of validation. (5)
b) Write note on GLP testing facilities. (5)

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

4. GMP guidelines.
5. Brief the content in master formula record.
6. ICH stability study guidelines.
7. Enumerate the contents in SOP.
8. Requirements for GLP.
9. Define quality audit and classify with examples.
10. Write the difference between clinical and non clinical testing facilities.
11. Good ware housing practice.
12. Handling of return goods.

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

13. Define precision.
14. Quality control test for glass containers.
15. Tools involved in QBD.
16. Contents in batch formula record.
17. Element in TQM.
18. Draw an ideal plant layout for pharmaceutical production.
19. Write the name of philosophies in TQM.
20. Define primary and secondary packing materials.
21. Define complaints.
22. Calibration of pH meter.