

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

**B.PHARM. DEGREE EXAMINATION – JULY 2019
Sixth Semester**

QUALITY ASSURANCE

Time : Three hours

Maximum: 75 marks

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

1. a) Explain the concept of quality control, quality assurance. (5)
b) Write philosophic involved in TQM. (5)
2. a) Write short note on finished product stability testing. (5)
b) Write note on importance of NABL accreditation. (5)
3. a) Write the calibration of UV- visible spectrophotometer. (5)
b) Compare and contrast batch and master formula records. (5)

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

4. Brief the types of validation.
5. Write the significance of plant layout design.
6. Write the note on QBD tools.
7. Define validation and write the procedure involved in the process of validation.
8. Write brief note on product recall.
9. Analytical method validation.
10. Write the purpose of test and control articles.
11. Write the stages involved in NABL accreditation.
12. Personnel responsibilities.

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

13. Elements of TQM.
14. Types of quality control test for containers.
15. Define SOP.
16. Define distribution records.
17. Define accuracy.
18. Disqualification of testing facilities.
19. Define purchase specifications.
20. Types of audits.
21. Define ISO and name the class as per 9001:2015.
22. Leakage test.