

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

B.PHARM. DEGREE EXAMINATION – February 2020
Third Year

PHARMACEUTICAL QUALITY ASSURANCE

Time : Three hours

Maximum: 70 marks

I. Write essays on any **TWO** questions: **(2 x 15 = 30)**

1. Explain various document maintenance in pharmaceutical industry.
2. What is calibration and validation? Explain the calibration and validation of any one analytical equipment.
3. Write a detailed note on ISO 14000 family.

II. Write short essays on any **SIX** questions: **(6 x 5 = 30)**

4. List the Q1 to Q11 technical documents of ICH.
5. Describe the recalling procedure.
6. Write a note on material management.
7. Brief about GMP.
8. Write about control of contamination in sterile area.
9. Explain the QC test for secondary packaging materials.
10. Write about various regulatory aspects of US- FDA.
11. Write a note on GATT policy.

III. Write short notes on any **FIVE** questions: **(5 x 2 = 10)**

12. Define accuracy and precision.
13. List the types of glass containers.
14. Define TQM.
15. Explain GLP, NABL, ICH and SOP.
16. What is the role of regulatory authorities in India?
17. What is patent and intellectual property rights?
