

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

B.PHARM. DEGREE EXAMINATION – August 2018
Third Year

PHARMACEUTICAL QUALITY ASSURANCE

Time : Three hours

Maximum: 70 marks

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

1. How is the philosophy of TQM applicable to pharmaceutical industry in achieving “Zero defect concept” through TQM?
2. Write in detail about location design, plant layout and construction of a pharmaceutical manufacturing facility?
3. What is ICH? Explain on the functioning and methodology of drafting a guideline in ICH?

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

4. What are the different types of waste? Explain the method adopted for waste disposal of pharmaceutical.
5. What is MFR? Brief on the content of master formula record.
6. Explain on the good laboratory practice procedure adopted in pharmaceutical industry
7. Name and describe on the various parameters performed in analytical method validation?
8. Explain the method adopted in selection, purchase and maintenance of equipment.
9. Define audit. Explain the audit process performed in pharmaceutical laboratories?
10. Describe on the “six sigma concept” .
11. Write on the specimen protocols maintained for clinical and non clinical testing

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

12. Define calibration and validation
13. What does CFR part – 211 represent.
14. Which is the regulatory body of India for pharmaceutical?
15. Brief on distribution record.
16. Expand US – FDA
17. Distinguish b/w Qc and QA
