

Sl.No: M2049

Course Code: MPA203T

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

**M.PHARM. DEGREE EXAMINATION – JANUARY 2021
Second Semester**

BRANCH: PHARMACEUTICAL ANALYSIS

QUALITY CONTROL AND QUALITY ASSURANCE

Time : Three hours

Maximum: 75 marks

**(Draw neat labeled diagrams wherever necessary
your answer should be specific to the questions asked)**

SECTION –A

I. Answer any **THREE** questions: **(3 x 15 = 45)**

1. Explain the concept of quality control and quality assurance. Explain ICH. Explain the ICH guidelines with special emphasis on Q-series guidelines.
2. Explain about CGMP guidelines according to schedule M, USFDA and EMEA coverings.
3. Explain about documentation in pharmaceutical industry.
4. What is GLP? Explain the scope of GLP and explain about the protocol for the conduct of non – clinical testing.

SECTION –B

II. Answer any **THREE** questions: **(3 x 10 = 30)**

5. Aseptic process control.
6. Master formula record.
7. Quality control test for containers.
8. Quality control of surgical products.
