

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

**M.PHARM. DEGREE EXAMINATION – July 2019  
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. Discuss the protocol for stability testing of new drug substances and products as well as new dosage forms as per ICH guidelines.
2. Discuss in detail the CPCSEA guidelines for laboratory animal facility.
3. Explain the process quality control procedures for the solid dosage forms according to Indian Pharmacopoeia.
4. Describe the operations and aseptic process control in the manufacturing of sterile products.

**SECTION –B**

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

5. Explain the role of quality assurance in non-clinical testing.
6. Enumerate in detail various quality control tests for containers, closures and packing materials.
7. Discuss the details of master formula and batch formula records.
8. Discuss the processing of intermediates and bulk products as per GMP guidelines.