Sl.No: M19511 **Course Code: MPA203T**

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

M.PHARM. DEGREE EXAMINATION – December 2018
Second Semester

BRANCH: PHARMACEUTICAL ANALYSIS

QUALITY CONTROL AND QUALITY ASSURANCE

Time : Three hours Maximum: 75 marks

SECTION –A

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

1. What is GLP? Discuss the principles and protocol to conduct non- clinical testing as per GLP?
2. Discuss the requirements for organization and personnel as well as construction and lay out of a pharmaceutical industry as per cGMP.
3. Explain the in process quality control tests for sterile dosage forms, ophthalmic and surgical products.
4. Discuss the steps involved in preparation, distribution and maintenance of different types of SOPs.

SECTION –B

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

5. Discuss the limits for usage of residual solvents in the manufacture of drug substance and drug products as per ICH guidelines.
6. Explain good warehousing practices to be followed in a pharmaceutical industry.
7. Write in detail the purchase specifications and store maintenance for raw materials in a pharmaceutical industry.

8. Discuss the GMP guidelines for proper sanitation in manufacturing premises and avoidance of cross contamination.

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