

Sl.No: M21136

Course Code: MPA103T

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

**M.PHARM. DEGREE EXAMINATION – September 2021  
First Semester**

**BRANCH: PHARMACEUTICAL ANALYSIS**

**PHARMACEUTICAL VALIDATION**

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. Define qualification and validation. Write about design qualification and performance qualification phases of analytical equipment.
2. Describe various phases in drug development and drug approval.
3. Validation of HVAC system.
4. Explain qualification of Gas Chromatography.

**SECTION –B**

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

5. Explain Intellectual Property Protection.
6. Write in detail about cleaning validation process.
7. Write short notes on 21 CFR part 11 and GAMP 5.
8. Procedures involved in qualification and calibration of volumetric flask and beaker.

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