

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

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

BRANCH: PHARMACEUTICAL ANALYSIS

ADVANCED PHARMACEUTICAL ANALYSIS

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. Write in detail about the basic principles, types and applications of immune assays.
2. Describe the biological tests and assay of the following vaccines.
 - i) Rabies vaccine
 - ii) Adsorbed tetanus vaccine
 - iii) Adsorbed diphtheria vaccine
3. Explain the ICH guidelines for stability testing studies.
4. Define and classify impurities. Write in detail about quantification of impurities as per ICH guidelines.

SECTION –B

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

5. Classify the residual solvents. Describe its limits also.
6. Describe the role of P^H , temperature and dielectric constant on reaction rates with suitable examples.
7. Write in detail about ICH stability and guidelines for biological products.
8. Principle and procedure involved in non aqueous titration.