

Sl.No: M21162

Course Code: MPL204T

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

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

**BRANCH: PHARMACOLOGY**

**CLINICAL RESEARCH AND PHARMACOVIGILANCE**

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 recent methods of Pharmacovigilance and its significance.
2. Give an account of International Conference on Harmonization – Good Clinical Practice (ICH-CGP) Guidelines.
3. What is Pharmacoepidemiology? Mention its applications. Discuss various epidemiological research methods with merits and demerits.
4. Write an extensive note on adverse drug reactions with suitable examples.

**SECTION –B**

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

5. Summarize the roles and responsibilities of Clinical Trial Investigator and Study Coordinator.
6. Discuss the Guidelines for ADR reporting.
7. Describe the roles of Institutional Review Board and ICMR in detail.
8. Write notes on Clinical Trail Monitoring and Safety Monitoring.

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