

Sl.No: M2054

Course Code: MPL204T

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

**M.PHARM. DEGREE EXAMINATION – JANUARY 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. Demonstrate the types and design of clinical trial. Write briefly on the documentations of clinical trials.
2. Write briefly on the types, detection, reporting system and management of Adverse Drug reactions.
3. Describe the roles and responsibilities of the personnel involved in clinical Trials.
4. a. Discuss the history, scope and significance of Pharmacovigilance.  
b. Write elaborately on roles and responsibilities of Contract Research Organization.

**SECTION –B**

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

5. Summarize the randomized and non - randomized clinical trial.
6. Write notes on the Bias in Pharmacoepidemiology.
7. Write elaborately on Vaccine Safety Surveillance.
8. Explain Cohort and Case Control Observational Studies.

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