

Sl.No: M19516

Course Code: MPL204T

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

**M.PHARM. DEGREE EXAMINATION – December 2018
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. Explain the ethical guidelines for biomedical research and human participants.
2. Describe the types and design in clinical trials.
3. Write note on methods and detection of Adverse drug reactions.
4. Discuss about documentation process in clinical trials.

SECTION –B

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

5. Give note on pharmacoepidemiology.
6. Brief about vaccine safety surveillance in the market.
7. Mention the responsibilities of pharmacist in pharmacovigilance.
8. Explain the roles of contract research organization and its management.
