

Sl.No: M21767

Course Code: MPL204T

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

**M.PHARM. DEGREE EXAMINATION – July 2019
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 about principles of International conference on Harmonization guidelines.
2. Explain about experimental study and observational study in clinical trials.
3. Write note on national programs related to pharmacovigilance.
4. Describe the roles and responsibility of clinical trial personals.

SECTION –B

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

5. Give note on safety monitoring in clinical trials.
6. Brief about establishment of pharmacovigilance centre in hospitals.
7. Mention the types and assessment of adverse drug reactions.
8. Explain the statistical methods of evaluating medication safety data.
