

VINAYAKA MISSION'S RESEARCH FOUNDATIONS, SALEM
(Deemed to be University)

Pharm.D DEGREE EXAMINATION - July 2019
Fifth Year

CLINICAL RESEARCH

Time: Three hours

Maximum: 70 marks

I. Write essays on any **TWO** questions: (2 x 15 = 30)

1. Discuss pharmacological and toxicological approaches followed in drug discovery.
2. Explain the different phases of clinical trial with its importance.
3. Outline the role and responsibilities of clinical trial person as per international conference on Harmonization – Good clinical practice guidelines.

II. Write short answers on any **SIX** questions: (6 x 5 = 30)

4. Steps involved in investigational new drug application.
5. Mention any two methods involved in post marketing surveillance.
6. State the central drug standard control organization guidelines.
7. Describe the composition of institutional review board.
8. List out the important ethical guidelines in clinical research.
9. Explain the drug regulatory requirements in Europe.
10. Write the importance of informed consent process.
11. What are the components in data management?

III. Write short notes on any **FIVE** question: (5 x 2 = 10)

12. Differentiate abbreviated new drug applications and investigational new drug application.
13. Mention few challenges in the implementation of clinical practice guidelines.
14. Mention the role of IEC in research.
15. Importance of case report form.
16. What is meant by safety monitoring in clinical trial.
17. State the importance of clinical trial.
