

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 1223]

**DECEMBER 2023
(OCTOBER 2023 EXAM SESSION)**

Sub. Code: 2974

**M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH**

Q.P. Code: 262974

Time: Three hours

Answer ALL Questions

Maximum: 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. A) What is clinical trial? Explain the various phases of clinical trials.
B) In a clinical trial, one of study subjects named Mr. X is hospitalized for the complaints of sudden collapse. In this situation what will be the procedure and responsibilities of investigator, study coordinator, sponsor and contract research organizations.
2. Explain the various clinical trial start up activities in the order of undertaking.

II. Write notes on:

(7 x 5 = 35)

1. Describe the investigational new drug application submission.
2. What is study close-out visit? Discuss the documents and procedures involved in the close-out visit.
3. What is clinical trial audit? Discuss the types of process of audits.
4. Quality control and quality assurance in clinical data management.
5. ICH – GCP guidelines in the conduct of clinical trials.
6. What all are the essential documents for clinical trial?
7. Discuss with example the case report form.
