

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

**[M.PHARM 0922]**

**SEPTEMBER 2022  
(APRIL 2022 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. What is clinical trial audit? Explain the audit process, follow up documentation and fraud and misconduct management.
2. Explain ICH GCP and ICMR guidelines in conduct of clinical trials.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Randomization techniques.
2. Various phases of clinical trials
3. Roles and responsibilities of Monitor.
4. Health outcome measures.
5. Bioequivalence Studies.
6. Study close-out visit preparation and report.
7. Data mining and warehousing.

\*\*\*\*\*