

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

**[M.PHARM 0524]**

**MAY 2024  
(APRIL 2024 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) Explain the Pharmacological and Toxicological approaches to Drug discovery.  
B) Describe the roles and responsibilities of Investigators and Clinical Research associates.
2. A) What is Institutional human ethical committee? Give the composition, qualification required for the members and explain the functions of the committee.  
B) Discuss the roles and responsibilities of auditors in clinical research.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Write in detail about the central drug standard control organization guidelines.
2. Explain briefly the informed consent process.
3. Explain: a) Placebo                      b) Human Subjects                      c) Candidate drug.
4. What are the major challenges observed in implementation of the regulatory guidelines in clinical trials?
5. Post marketing surveillance.
6. Source documents in clinical trial.
7. Write the significance of preclinical testing in clinical research.

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