

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

[MPHARM 0921]

**SEPTEMBER 2021
(OCTOBER 2020 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? Explain the various phases of clinical trials with examples.
2. Write the composition, member's responsibilities, functions and challenges of IRB.

II. Write notes on:

(7 x 5 = 35)

1. Briefly write on post marketing surveillance.
2. Good Clinical Practice and its principles.
3. Vulnerable subjects.
4. Roles and responsibilities of Investigator.
5. Preparation of Informed Consent Form (ICF).
6. Write a note on schedule Y.
7. What is bioequivalence study? How it is conducted?
