

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

[LQ 0121]

JANUARY 2021

Sub. Code: 2974

(APRIL 2020 EXAM SESSION)

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 ethical committee? Explain its constitution, function and challenges in the implementation of ethical guidelines.
2. What are clinical trial documents? Explain the various documents with its guidelines to prepare.

II. Write notes on:

(7 x 5 = 35)

1. What is drug discovery? Explain the various approaches to drug discovery.
2. After study enrollment, a subject met with an accident and admitted in the hospital. In this situation - what will be the responsibility of study coordinator and investigator?
3. Describe the different sampling methods in clinical research.
4. If you are a clinical trial auditor and during the audit if you find some of the misconduct in study site, what will be your audit report and follow-up?
5. Procurement and storage of investigation product.
6. ICMR guideline in conduct of clinical trials.
7. Describe the electronic data capturing system.
