

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

[MPHARM 0122]

**JANUARY 2022
(APRIL 2021 EXAM SESSION)**

Sub. Code: 2988

**M.PHARMACY DEGREE EXAMINATION
SEMESTER-II (PCI New regulations 2016)
PHARMACOLOGY - MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE
*Q.P. Code : 262988***

Time : Three hours

Answer ALL Questions

Maximum : 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Explain the Indian and International aspects of pharmacovigilance. Add a note on WHO International drug monitoring programme.
2. Describe the composition and functions of ethical committee as per ICMR guidelines.

II. Write notes on:

(7 x 5 = 35)

1. Role and responsibilities of investigator in clinical trial.
2. Spontaneous reporting of ADR with suitable examples.
3. Cross-sectional study.
4. Contract Research Organization.
5. Role of pharmacoepidemiology in pharmacovigilance.
6. Phases of clinical trials and their objectives.
7. Evaluation of medication safety.
