

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

[M.PHARM 1223]

**DECEMBER 2023
(OCTOBER 2023 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. Different types of detection, reporting system and management of ADR.
2. Explain the importance of establishing Pharmacovigilance Centers in hospitals. Write about Industry and National Programs related to Pharmacovigilance.

II. Write notes on:

(7 x 5 = 35)

1. Cross section studies.
2. Case Report Forms.
3. Contract Research Organisation and Management.
4. Institutional review board.
5. Active and Passive surveillance in ADR reporting.
6. Significance of Pharmacoepidemiology.
7. Good Clinical practice.
