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

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2988
(OCTOBER 2020 EXAM SESSION)

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. Describe the methods and guidelines for ADR reporting and monitoring.
2. Roles and responsibilities of clinical trial personnel: Investigator, study coordinator, sponsor, contract research organization.

II. Write notes on: **(7 x 5 = 35)**

1. Principles of ICH-GCP in clinical trials.
2. Describe the functioning of VigiFlow.
3. Applications of Pharmacoeconomics.
4. International classification of diseases
5. Write a note on observational research methods. Differentiate cohort and case-control Studies.
6. Discuss the various elements of consent form and add a note on the basic principles of informed consent.
7. Pharmacoepidemiology.

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