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

[LP 988] NOVEMBER 2019 **Sub. Code: 2988**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH-VI – PHARMACOLOGY – MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. Code : 262988

Time : Three hours **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Define clinical trials, type and design, experimental study - RTC and Non RTC. Explain about cohort, case control, cross sectional studies.

2. Evaluation of medication safety and establishing pharmacovigilance center in hospitals, industry for national programs related to pharmacovigilance. Role and responsibilities in pharmacovigilance.

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

1. Pharmacoepidemiology.
2. Vaccine safety surveillance.
3. ICMR.
4. Ethical guidelines for biomedical research and human participant - schedule Y.
5. ADR detection and reporting methods.
6. Aris G pharmacovigilance and vigiflow.
7. Clinical trial monitoring - safety monitoring in CT.

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