

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

[LO 988]

MAY 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. What is Pharmacoepidemiology and what are its applications?
Discuss the various epidemiological research methods along with their advantages and disadvantages.
2. Describe the roles and responsibilities of the personnel involved in clinical trials.

II. Write notes on:

(7 x 5 = 35)

1. Types of 'costs' in pharmaco-economic studies.
2. Types of clinical trials.
3. GCP guidelines.
4. Investigator's Brochure.
5. Basic features of WHO's International classification of diseases.
6. Vigiflow.
7. National Pharmacovigilance programme of India.
