

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

[LQ 0121]

JANUARY 2021

Sub. Code: 2988

(APRIL 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. Guidelines to the preparation of documents, protocol, investigation brochure, case report forms, clinical trial monitoring.
2. Clinical investigations and vaccine safety surveillance, spontaneous reporting system and regulatory authorities guidelines for ADR reporting.

II. Write notes on:

(7 x 5 = 35)

1. Terminologies for ADR.
2. Safety pharmacology.
3. ICH.
4. Cohort study.
5. WHO-International drug monitoring programme.
6. GCP.
7. Argus.
