

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

[B.PHARM 1223]

**DECEMBER 2023
(SEPTEMBER 2023 EXAM SESSION)**

Sub. Code: 2081

**B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER XI - PHARMACOVIGILANCE**

Q.P. Code: 562081

Time: Three hours

Maximum: 75 Marks

I. Elaborate on: Answer any Two questions (2x10=20)

1. Discuss the Pharmacovigilance Programme in the Hospitals.
2. Discuss the Risk Factors for Vaccine Failure.
3. Write a note on Expedited reporting.

II. Short Notes on: Answer any Seven questions (7x5=35)

1. Applications of Pharmacovigilance.
2. Responsibilities of the Ethics Committee as per Schedule Y.
3. Importance of safety monitoring.
4. Basic purpose of National Pharmacovigilance Programme.
5. Daily Defined Doses.
6. Basic drug information resources.
7. Detection and Reporting Program of ADR.
8. Standardized Med DRA queries.
9. Classification of ADRs on etiological basis.

III. Short Answer on: Answer ALL questions (10 x 2=20)

1. Harmonization.
2. Partners in Pharmacovigilance.
3. Various Pharmacovigilance methods.
4. Role of Eudravigilance of PV in Europe.
5. COSTART and INNM.
6. Examples of Active surveillance system.
7. Contract Research Organization.
8. What are the ADR detection and reporting programmes?
9. Pharmacogenomics.
10. Functions of CIOMS.
