

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

[B.PHARM 0823]

**AUGUST 2023
(MARCH 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. Define Adverse Drug Reactions. Discuss in detail causality, severity and seriousness assessment of Adverse Drug Reactions.
2. Discuss in detail of Cohort and case control study.
3. Explain the establishing Pharmacovigilance program in the hospital.

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

1. Explain immunization safety surveillance system.
2. Discuss in detail drug safety evaluation in pregnant and lactating women.
3. Write a note on Post Approval Phase.
4. Discuss the importance of effective communication in Pharmacovigilance.
5. What is periodic Safety Update Reports?
6. Write a note on Pharmacovigilance of India.
7. Write a note on risk benefit assessment of vaccine.
8. Organization and functions of International Council on Harmonization.
9. Explain individual case study reports.

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

1. Prescription event monitoring.
2. Importance of vaccine safety.
3. What is teratogenicity? Give examples.
4. Genetic polymorphism.
5. Give the application of Defined daily dose in Pharmacovigilance.
6. What is preclinical phase?
7. Genetic related Adverse Drug Reactions with examples.
8. Define safety surveillance.
9. Stimulated reporting.
10. Factors affecting immunization safety.
