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

**[BPHARM0422] APRIL 2022 Sub. Code: 2081**
**(SEPTEMBER 2021 SESSION)**

**B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)**
**PCI Regulation 2017 SEMESTER VIII**
**PAPER V - PHARMACOVIGILANCE**
***Q.P. Code: 562081***

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

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

1. Explain the Working Group XII and XI objectives.
2. Explain the criteria for Drug safety evaluation in Paediatric population.
3. Methods for Causality, Severity and Seriousness Assessment of ADRs.

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

1. Various types of Drug Information Resources.
2. Explain the Post Marketing Trials.
3. Why CIOMS are important within Pharmacovigilance Work.
4. Pharmacovigilance Planning.
5. Eudravigilance.
6. Why Pharmacovigilance is needed?
7. Safety Data Management.
8. Effective communication in Pharmacovigilance.
9. Describe in details CDSCO in India.

**III. Short Answer on: Answer ALL questions (10x2=20)**

1. Classification of Adverse events following immunization.
2. Derived classification.
3. Harmonization.
4. Common technical document.
5. Elements of the Specification.
6. Types of services provided by CROs.
7. ICH Steering Committee.
8. Registries.
9. Good Pharmacovigilance Practice.
10. Genomic approaches to serious adverse drug reactions.

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

**[BPHARM 1022]** **OCTOBER 2022** **Sub. Code: 2081**
**(MARCH 2022 SESSION)**

**B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)**
**PCI Regulation 2017 - SEMESTER VIII**
**PAPER V - PHARMACOVIGILANCE**
***Q.P. Code: 562081***

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

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

1. Explain the criteria for Drug safety evaluation in Geriatrics.
2. Write the History and Scope of Pharmacovigilance.
3. Anatomical, Therapeutic and Chemical Classification of drugs.

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

1. Preventability Assessment Method.
2. Importance of Safety Monitoring.
3. Responsibility of Indian Pharmacopoeia Commission.
4. Classification of ADRs.
5. Explain the Working Group XII objectives.
6. International classification of diseases.
7. Types of services provided by CROs.
8. History of ICH.
9. Standardized MedDRA queries.

**III. Short Answer on: Answer ALL questions (10x2=20)**

1. Methods of communication.
2. Drug safety Crisis management.
3. WHO drug dictionary.
4. Periodic safety updates reports.
5. Functions of CIOMS.
6. Dechallenge.
7. Daily Defined Dose.
8. EUDRAVIGILANCE.
9. Genomic approaches to serious adverse drug reactions.
10. Derived Classification.

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

**[B.PHARM 0323] MARCH 2023 Sub. Code: 2081**
**(SEPTEMBER 2022 EXAM SESSION)**

**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. What are the objectives of Pharmacovigilance programme of India? Explain in details various methods of Monitoring, Detecting and Reporting of Adverse Drug Reactions.
2. Explain in details Spontaneous Case Reports and Case Series as Pharmacovigilance methods for vaccine safety surveillance.
3. Discuss in detail basic and specialized drug information resources in Pharmacovigilance.

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

1. Advantages and disadvantages of case control studies in vaccine safety evaluation.
2. What are the factors to be considered for the drug safety evaluation in Geriatrics?
3. Functions of central drugs standard control organization in Pharmacovigilance.
4. Write a note on Cross-sectional study.
5. Write a note on clinical trial regulations in India.
6. Drug safety evaluation in geriatric and pediatric populations
7. Explain predisposing factors of adverse drug reactions.
8. Describe Safety monitoring of medicine.
9. Write a note on Anatomical Therapeutic Chemical classification of drugs.

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

1. Importance of Pharmacogenomics.
2. Sentinel sites as active surveillance.
3. What is teratogenicity and idiosyncrasy?
4. Defined daily doses.
5. Vaccination failure.
6. Drug safety crisis management.
7. List four drugs contraindicated in pregnant and lactating women.
8. Importance of post approval expedited reporting.
9. What is Drug event monitoring?
10. Mention few primary sources of drug information.

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

**[B.PHARM 0823] AUGUST 2023 Sub. Code: 2081**
**(MARCH 2023 EXAM SESSION)**

**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.

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

**[B.PHARM 1223] DECEMBER 2023 Sub. Code: 2081**
**(SEPTEMBER 2023 EXAM SESSION)**

**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.

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

**[B.PHARM 0524]** **MAY 2024** **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 Pharmacovigilance. Discuss in detail about reporting and management of Adverse Drug Reactions along with causality assessment scales.

2. What do you meant by Vaccine Pharmacovigilance? Discuss in detail about Passive and active surveillance for vaccine safety study.

3. Discuss in detail setting up of a drug safety department in Industry.

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

1. Write a note on Good clinical practice in Pharmacovigilance studies.
2. Drug safety evaluation in geriatrics and paediatrics population.
3. Role of Pharmacist in management of Adverse Drug Reactions.
4. How will you investigate Adverse Events Following Immunization?
5. Mention the importance aspects of ICH guidelines for expedited reporting.
6. Write a note on Schedule Y.
7. Explain reasons for vaccination failure.
8. Short note on functions of contract research organization.
9. Briefly discuss the preclinical phase of safety data generation.

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

1. List out factors affecting adverse effects of vaccine.
2. What is stimulated reporting?
3. What is Genetically determined toxicities?
4. What is Safety Signals?
5. How will you calculate Daily Defined Doses?
6. Write a note on volunteers involved in clinical phases.
7. Define anaphylactic reaction.
8. Give two examples of ADR due to genetic defect in metabolism.
9. Define Targeted clinical investigations.
10. What is post marketing safety?

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

**[B.PHARM 1024] OCTOBER 2024 Sub. Code: 2081**
**(SEPTEMBER 2024 EXAM SESSION)**

**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 process of safety data generation in pharmacovigilance, including pre-clinical phase, clinical phase and post-approval phase.
2. Explain the importance of establishing a pharmacovigilance program in a hospital.
3. Describe vaccine safety surveillance and adverse events following immunization.

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

1. What is the significance of preclinical safety data generation in pharmacovigilance?
2. Why is communication important in pharmacovigilance and what are some examples of effective communication strategies?
3. What is a case-control study and how is it used in pharmacovigilance?
4. How do passive surveillance and stimulated reporting differ from active surveillance in pharmacovigilance?
5. What are some factors that can contribute to vaccination failure?
6. What are the specialized resources used for ADRs in pharmacovigilance ? with examples.
7. How does pharmacogenomics contribute to the understanding of adverse drug reactions?
8. Write a note on drug safety evaluation for Pregnancy population.
9. What are the factors considered in severity and seriousness assessment of ADR?

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

1. Why is safety monitoring of medicines important?
2. What is WHO's international drug monitoring program?
3. How are ADRs classified?
4. What is causality assessment in pharmacovigilance?
5. What is vaccine pharmacovigilance?
6. What is safety data generation in pharmacovigilance?
7. What are targeted clinical investigations in pharmacovigilance?
8. What are registries in pharmacovigilance?
9. What is stimulated reporting in pharmacovigilance?
10. What is the Pharmacovigilance Program of India (PvPI)?

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

**[B.PHARM 0925]** **SEPTEMBER 2025** **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. Write in detail about methods of drug safety evaluation in special populations.
2. Discuss the importance of communication in drug safety crisis management and regulatory agencies in Pharmacovigilance.
3. Explain the different coding systems used in pharmacovigilance with suitable examples.

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

1. What is the purpose of periodic safety update reports in pharmacovigilance?
2. What is the significance of expedited reporting in pharmacovigilance?
3. What is the Eudravigilance medicinal product dictionary and how is it used in pharmacovigilance?
4. What are common regulatory terminologies used in pharmacovigilance?
5. What is the role of the Pharmacovigilance Program of India (PvPI) in ensuring drug safety?
6. Explain the contribution of WHO International drug monitoring program in pharmacovigilance.
7. Explain the anatomical, therapeutic and chemical classification of drugs.
8. What is the CIOMS form and how is it used in pharmacovigilance?
9. Name some basic drug information resources used in pharmacovigilance.

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

1. What are the basic terminologies used in pharmacovigilance?
2. What is a case-control study in pharmacovigilance?
3. What is the purpose of pharmacovigilance?
4. What are Genetic related ADR?
5. What is the role of specialized resources for ADRs in pharmacovigilance?
6. What is the role of pharmacovigilance in post-marketing surveillance?
7. What is the purpose of drug dictionaries in pharmacovigilance?
8. What is the role of daily defined doses in pharmacovigilance?
9. What are the challenges in detecting and reporting adverse drug reactions?
10. What is the difference between a case control study and a cohort study?

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