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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