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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