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

[LM 988] MAY 2018 **Sub. Code: 2988**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH-VI – PHARMACOLOGY – MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. Code : 262988

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

I. Elaborate on: **(2 x 20 = 40)**

1. Types, design and documentation of clinical trials.
2. Current methods of Pharmacovigilance and its significance.

II. Write notes on: **(7 x 5 = 35)**

1. Contract research organization and its management.
2. Roles and responsibilities of Pharmacovigilance.
3. Bias in Pharmacoepidemiology.
4. Guidelines for ADR reporting.
5. Sponsors.
6. Schedule Y.
7. Informed consent process.

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

[LN 988] NOVEMBER 2018 **Sub. Code: 2988**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH-VI – PHARMACOLOGY – MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. Code : 262988

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

I. Elaborate on: **(2 x 20 = 40)**

1. Give an account of International Conference on Harmonization-Good Clinical Practice (ICH-CGP) Guidelines.

2. Types, detection, reporting system and management of Adverse Drug Reactions (ADR).

II. Write notes on: **(7 x 5 = 35)**

1. Clinical Trial Protocol and its amendments.
2. Statistical methods for evaluating medication safety data.
3. Pharmacoeconomics.
4. Institutional review board (IRB).
5. Spontaneous reporting system.
6. Regulatory terminologies of ADR.
7. Passive and active Surveillance in ADR reporting.

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

[LO 988] MAY 2019 **Sub. Code: 2988**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH-VI – PHARMACOLOGY – MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. Code : 262988

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

I. Elaborate on: **(2 x 20 = 40)**

1. What is Pharmacoepidemiology and what are its applications?
   Discuss the various epidemiological research methods along with their advantages and disadvantages.

2. Describe the roles and responsibilities of the personnel involved in clinical trials.

II. Write notes on: **(7 x 5 = 35)**

1. Types of 'costs' in pharmacoeconomic studies.
2. Types of clinical trials.
3. GCP guidelines.
4. Investigator's Brochure.
5. Basic features of WHO's International classification of diseases.
6. Vigiflow.
7. National Pharmacovigilance programme of India.

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

[LP 988] NOVEMBER 2019 **Sub. Code: 2988**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH-VI – PHARMACOLOGY – MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. Code : 262988

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

I. Elaborate on: **(2 x 20 = 40)**

1. Define clinical trials, type and design, experimental study - RTC and Non RTC. Explain about cohort, case control, cross sectional studies.

2. Evaluation of medication safety and establishing pharmacovigilance center in hospitals, industry for national programs related to pharmacovigilance. Role and responsibilities in pharmacovigilance.

II. Write notes on: **(7 x 5 = 35)**

1. Pharmacoepidemiology.
2. Vaccine safety surveillance.
3. ICMR.
4. Ethical guidelines for biomedical research and human participant - schedule Y.
5. ADR detection and reporting methods.
6. Aris G pharmacovigilance and vigiflow.
7. Clinical trial monitoring - safety monitoring in CT.

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

[LQ 0121] JANUARY 2021 Sub. Code: 2988

(APRIL 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION

SEMESTER-II (PCI New regulations 2016)

PHARMACOLOGY – MPL

PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. Code : 262988

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Guidelines to the preparation of documents, protocol, investigation brochure, case report forms, clinical trial monitoring.

2. Clinical investigations and vaccine safety surveillance, spontaneous reporting system and regulatory authorities guidelines for ADR reporting.

II. Write notes on: **(7 x 5 = 35)**

1. Terminologies for ADR.
2. Safety pharmacology.
3. ICH.
4. Cohort study.
5. WHO-International drug monitoring programme.
6. GCP.
7. Argus.

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

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2988
(OCTOBER 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-II (PCI New regulations 2016)
PHARMACOLOGY - MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE
Q.P. Code : 262988

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Describe the methods and guidelines for ADR reporting and monitoring.
2. Roles and responsibilities of clinical trial personnel: Investigator, study coordinator, sponsor, contract research organization.

II. Write notes on: **(7 x 5 = 35)**

1. Principles of ICH-GCP in clinical trials.
2. Describe the functioning of VigiFlow.
3. Applications of Pharmacoeconomics.
4. International classification of diseases
5. Write a note on observational research methods. Differentiate cohort and case-control Studies.
6. Discuss the various elements of consent form and add a note on the basic principles of informed consent.
7. Pharmacoepidemiology.

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

[MPHARM 0122] JANUARY 2022 Sub. Code: 2988
(APRIL 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-II (PCI New regulations 2016)
PHARMACOLOGY - MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILANCE
Q.P. Code : 262988

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Explain the Indian and International aspects of pharmacovigilance. Add a note on WHO International drug monitoring programme.

2. Describe the composition and functions of ethical committee as per ICMR guidelines.

II. Write notes on: **(7 x 5 = 35)**

1. Role and responsibilities of investigator in clinical trial.
2. Spontaneous reporting of ADR with suitable examples.
3. Cross-sectional study.
4. Contract Research Organization.
5. Role of pharmacoepidemiology in pharmacovigilance.
6. Phases of clinical trials and their objectives.
7. Evaluation of medication safety.

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