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

[M.PHARM 0922] **SEPTEMBER 2022** **Sub. Code: 2988**
(APRIL 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New regulations 2016)
PHARMACOLOGY - MPL
PAPER IV – CLINICAL RESEARCH AND PHARMACOVIGILIANCE

Q.P. Code : 262988

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

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

1. Define and discuss about different types of ADR. Write briefly about methods, assessment and management of ADR.

2. Discuss briefly about Clinical Trials, types, designs, RCT and Non RCT. Mention the role sponsor, coordinator, CRO and management.

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

1. Define active and passive surveillance.
2. International classification of diseases.
3. Pharmacoepidemiology.
4. Cross Sectional studies.
5. Interpretation and Computation in clinical trials.
6. Role and responsibility of Pharmacovigilance.
7. Cost effective in Pharmacoeconomic studies.

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

[M.PHARM 0423] **APRIL 2023** **Sub. Code: 2988**
(OCTOBER 2022 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. Define ADR. Mention its types, Detection and reporting methods.

2. Briefly discuss about Clinical Trials, types, designs, RCT and Non RCT. Mention the role sponsor, coordinator, CRO and management.

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

1. Informed consent.
2. Evaluation of Medical safety.
3. Role and responsibility of Pharmacovigilance.
4. Cost and effectiveness in Pharmacoeconomic.
5. Schedule Y.
6. Pharmacoepidemiology.
7. ARIS G and Vigiflow.

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

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 2988**
(APRIL 2023 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. Give an account of ethical guidelines for biomedical research and human participant.

2. a) Contract research organization and its management.
   b) Role and responsibilities of clinical trial personnel.

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

1. Role and responsibilities of pharmacovigilance.
2. Bias in Pharmacoepidemiology.
3. Guidelines for ADR reporting.
4. Pharmacoeconomics.
5. Targeted clinical investigation in ADR.
6. Aris G pharmacovigilance.
7. ICMR.

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

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 2988
(OCTOBER 2023 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. Different types of detection, reporting system and management of ADR.

2. Explain the importance of establishing Pharmacovigilance Centers in hospitals. Write about Industry and National Programs related to Pharmacovigilance.

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

1. Cross section studies.
2. Case Report Forms.
3. Contract Research Organisation and Management.
4. Institutional review board.
5. Active and Passive surveillance in ADR reporting.
6. Significance of Pharmacoepidemiology.
7. Good Clinical practice.

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

[M.PHARM 0524] MAY 2024 Sub. Code: 2988
(APRIL 2024 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. Detail explanation about ICH-GCP guidelines.

2. Describe case control, cohort observational studies (Data and designing of studies) of clinical trials.

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

1. Institutional review board (IRB).
2. Investigator Brochure.
3. Sponsors.
4. Significance of safety monitoring.
5. Regulatory terminologies of ADR.
6. Current methods of Pharmacovigilance and its significance.
7. WHO international drug monitoring programme.

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

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 2988**

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. The key players in the conduct of a clinical trial and their responsibilities.

2. Importance of adverse reactions, their types based on Pharmacology and their detection and reporting methods.

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

1. WHO principles of Good Clinical Practice.
2. Information brochure.
3. Pharmacovigilance programme of India.
4. Clinical trial monitoring.
5. Softwares used in Pharmacovigilance.
6. Ethical principles guiding Informed consent.
7. Bias and methods of minimizing it in clinical trials.

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

[M.PHARM 1025] **OCTOBER 2025** **Sub. Code: 2988**

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. The clinical trial documents: Investigator's brochure and case report form.

2. a) Pharmacoeconomics, the factors affecting it and its applications.
   b) The methods of Pharmacoeconomic evaluation of drugs.

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

1. Types of Clinical trials.
2. Information to be submitted while reporting an ADR.
3. Responsibilities of a Pharmacovigilance centre.
4. Responsibilities of Principle investigator.
5. International classification of diseases (ICD).
6. Informed consent form.
7. Vigiflow.

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