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

[LM 986] MAY 2018 **Sub. Code: 2986**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH–VI – PHARMACOLOGY – MPL
PAPER II – PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code : 262986

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

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

1. Describe in detail the reproductive toxicity studies as specified in the ICH guidelines.

2. a) What is IND and what is its importance?
   b) What are the documents to be submitted to the regulatory authorities as per Schedule Y before carrying out the clinical trial of a new drug in India?

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

1. Core battery CNS tests.
2. Repeated dose oral toxicity studies.
3. Good laboratory practices.
4. *In vitro* methods for assessing renal toxicity.
5. GI toxicity studies.
6. OECD-dermal toxicity studies.
7. Alternative methods to animal toxicity studies.

****

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

[LN 986] NOVEMBER 2018 **Sub. Code: 2986**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH–VI – PHARMACOLOGY – MPL
PAPER II – PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code : 262986

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

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

1. Describe the endocrine alterations in female reproductive system, maternal and development toxicity.

2. a) Explain various studies for carcinogenicity testing.

   b) Give an over view of point mutations.

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

1. Spermatogenesis.
2. Write about OECP guidelines for toxicity studies.
3. Adverse event reporting in clinical trials.
4. Write on acute toxicity studies of novel drugs and its significance.
5. Ocular toxicity testing.
6. Discuss the steps involved in the conduct of a IND.
7. Alternative methods to animal toxicity testing.

****

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

[LO 986] MAY 2019 **Sub. Code: 2986**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH–VI – PHARMACOLOGY – MPL
PAPER II – PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code : 262986

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

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

1. Describe in detail the OECD principles of Good Laboratory Practice (GLP).
2. Describe various methods of evaluation of toxicokinetics in preclinical studies.

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

1. Concept and importance of drug development.
2. What is IND and write its importance?
3. Toxicity studies specified in EPA guidelines.
4. OECD inhalational toxicity studies.
5. *Invivo* carcinogenicity studies.
6. *Invivo* methods of genotoxicity.
7. *Invivo* methods of assessing male reproductive toxicity studies.

****

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

[LP 986] NOVEMBER 2019 **Sub. Code: 2986**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH–VI – PHARMACOLOGY – MPL
PAPER II – PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code : 262986

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

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

1. a) Explain the new drug safety assessment as per ICH guidelines.
   b) What is the regulatory toxicology?

2. a) Describe the experimental considerations for toxicity assessment on humans.
   b) Give an account of dermal toxicity.

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

1. Write about the clinical signs toxicity.
2. Write a note on reproductive toxicology.
3. Allergenicity testing.
4. Good Laboratory Practice (GLP).
5. Xenobiotics.
6. Immunotoxicity.
7. Toxicokinetics.

****

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

[LQ 0121] JANUARY 2021 Sub. Code: 2986

(APRIL 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION

SEMESTER-II (PCI New regulations 2016)

PHARMACOLOGY – MPL

PAPER II – PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code : 262986

Time : Three hours Answer ALL Questions Maximum : 75 Marks

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

1. Describe regulatory guidelines for conducting toxicity studies as per schedule – Y.
2. Describe detail concepts and importance of safety pharmacology.

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

1. Alternative methods to animal toxicity studies.
2. Principles of toxicokinetics.
3. Write briefly ICH guidelines toxicity studies.
4. Acute eye irritation toxicity studies.
5. *Invivo* methods of genotoxicity studies.
6. Assessing renal toxicity studies.
7. *Invivo* methods of assessing female reproductive toxicity studies.

****

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

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2986
(OCTOBER 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-II (PCI New regulations 2016)
PHARMACOLOGY - MPL
PAPER II – PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - II
Q.P. Code : 262986

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

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

1. Explain the regulatory aspects for conducting toxicity studies.as per OECD guidelines.

2. a) What is IND and its importance.
   b) What are the doucment to be submitted to the regultory authorites as per schedule Y before carring out the clinical trials of a new drug in India.

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

1. Toxicity studies specified in EPA guidelines.
2. Good laboratory practices.
3. Invivo methods of Carcino genicity.
4. Write about invivo methods of assessing male reproductive toxicity studies.
5. Toxicokinetics.
6. Explain about Anti Anxiety test.
7. Alternative methods involved in toxicity studies.

****

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

[MPHARM 0122] JANUARY 2022 Sub. Code: 2986
(APRIL 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-II (PCI New regulations 2016)
PHARMACOLOGY - MPL
PAPER II – PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - II
Q.P. Code : 262986

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

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

1. Elaborate details on Alternates for Animal toxicity models.
2. Explain in detail the reproductive toxic studies as per specified in ICH guidelines.

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

1. Alternative methods to evaluate genotoxicity.
2. Write a note on reproductive toxicology.
3. Adverse event reporting in clinical trials.
4. ICH Guidelines.
5. Toxicity studies specified in **EPA** guidelines.
6. Explain about in-vivo carcinogenicity studies.
7. Give the concept and importance of drug development.

****

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

[M.PHARM 0922] SEPTEMBER 2022 Sub. Code: 2986
(APRIL 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New regulations 2016)
PHARMACOLOGY - MPL
PAPER II - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code : 262986

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

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

1. Explain the OECD principles of Good Laboratory Practice.

2. Describe the CNS safety pharmacology studies.

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

1. Write notes on mechanistic and regulatory toxicology.
2. Discuss the regulatory guidelines of Schedule Y.
3. Explain the test item characterization in regulatory toxicology studies.
4. Write notes on saturation kinetics.
5. Eye irritation studies employing OECD guideline 405.
6. Explain female reproductive toxicity studies.
7. Discuss on the renal safety pharmacology studies.

****

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

[M.PHARM 0423] APRIL 2023 Sub. Code: 2986
(OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New regulations 2016)
PHARMACOLOGY - MPL
PAPER II - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code: 262986

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

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

1. Discuss in detail the regulatory guidelines for conducting toxicity studies.

2. Explain the importance and industrial perspectives of IND studies.

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

1. Explain the female reproductive toxicity studies.
2. Write a note on dermal irritation employing OECD guideline.
3. Detail the importance of safety pharmacology studies.
4. Add notes on Ames test.
5. Discuss the importance of toxicokinetics.
6. HERG assay.
7. Explain chronic oral toxicity studies.

****

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

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 2986**
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACOLOGY - MPL
PAPER II - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code: 262986

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

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

1. Explain the OECD guidelines for the conduct of acute, subacute and chronic toxicity studies.

2. Importance and various methods in regulatory toxicity studies.

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

1. Importance and application of toxicokinetics.
2. Teratogenicity studies.
3. Assessing G.I. toxicity studies.
4. OECD skin sensitization toxicity studies.
5. Ames Test.
6. List of study needed for IND submission.
7. Dermal irritation toxicity studies.

****

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

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 2986
(OCTOBER 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACOLOGY - MPL
PAPER II - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code: 262986

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

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

1. Explain the OECD regulatory guidelines for conducting toxicity studies.

2. Describe the acute skin sensitization toxicity studies according to OECD guideline 406.

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

1. Write notes on segment III of female reproductive toxicity studies.
2. List of studies needed for IND submission.
3. Alternative methods to animal toxicity testing.
4. Chromosomal aberration test.
5. Write the applications of toxicokinetic studies.
6. Explain core battery CNS studies.
7. Acute inhalational toxicity studies.

****

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

[M.PHARM 0524] MAY 2024 Sub. Code: 2986
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACOLOGY - MPL
PAPER II - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code: 262986

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

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

1. Explain IND application submission.

2. What are regulatory toxicity studies? Explain the toxicity studies to be performed as per regulatory toxicity protocol to market a product.

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

1. Male reproductive toxicity.
2. OECD guidelines for sub acute toxicity studies.
3. Post marketing surveillance for safety assessment.
4. How ex vivo method is used in animal toxicity testing.
5. What is toxicokinetics? How it is evaluated in preclinical testing?
6. How renal safety is assessed for the new chemical molecule?
7. Dermal toxicity studies.

****

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

[M.PHARM 1124] **NOVEMBER 2024** **Sub. Code: 2986**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACOLOGY - MPL
PAPER II - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code: 262986

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

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

1. Explain various stages of drug development as per traditional methods.

2. How genotoxicity and teratogenicity of the new chemical entities are determined? Explain.

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

1. In vivo carcinogenicity studies.
2. GLP in animal testing.
3. Skin irritation studies as per OECD guidelines.
4. Restructured 3D tissue as alternative methods of toxicity testing.
5. Toxic metabolites formation and drug discovery importance explain.
6. Schedule Y.
7. Chromosomal aberration studies.

****

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

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 2986**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACOLOGY - MPL
PAPER II - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code: 262986

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

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

1. Explain in details the OECD guidelines for the conduct of acute, subacute and chronic toxicity studies.

2. Explain the CNS, Respiratory system safety pharmacology studies.

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

1. ICH Guidelines.
2. Write notes on alternative methods to animal toxicity studies.
3. Explain the list of studies need for IND submission.
4. Write about Invivo methods of assessing female reproductive toxicity studies.
5. Explain eye irritation studies as per OECD guidelines.
6. Explain the Ames genotoxicity studies.
7. Importance and applications of toxicokinetic studies.

****

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

[M.PHARM 1025] **OCTOBER 2025** **Sub. Code: 2986**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACOLOGY - MPL
PAPER II - PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Q.P. Code: 262986

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

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

1. What are OECD guidelines? Explain the OECD guidelines of toxicity performance for drugs used in human for prolonged period.

2. Name different alternative methods of animal toxicity studies. What are the advantage and limitations of this method? Explain the conduction of Toxicity studies as per ICH guidelines.

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

1. Female reproductive toxicity studies.
2. CNS safety pharmacology studies.
3. Eye irritation studies.
4. Inhalation toxicity studies.
5. State the application of toxicokinetic in drug discovery.
6. HERG assay.
7. Define IND and write the importance of IND.

****