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

[LM 956] MAY 2018 **Sub. Code: 2956**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH–III – PHARMACEUTICAL ANALYSIS – MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES

Q.P. Code : 262956

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

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

1. a) Write about the toxicokinetic evaluation in preclinical studies.
   b) Importance and applications of toxicokinetic studies.

2. Write in detail about alternative methods of dissolution testing transport models.

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

1. Describe the *in vitro* assay of drug metabolites.
2. Write about the solid phase extraction techniques.
3. Explain about the effect of protein binding interactions.
4. Write about dissolution and drug releasing testing.
5. Describe the general procedures for cell culture.
6. Write about the clinical significance of bio-equivalence studies.
7. Explain about cryopreservation.

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

[LN 956] NOVEMBER 2018 **Sub. Code: 2956**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH–III – PHARMACEUTICAL ANALYSIS – MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES

Q.P. Code : 262956

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

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

1. Explain about the different Bio-analytical methods for extraction of drugs from biological matrices.

2. Write about principle and applications of :

   a) Cell viability assays b) Flow cytometry.

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

1. Describe the USFDA guidelines for bio-analytical method validation.
2. Write about the various types of cell culture.
3. Biopharmaceutical factors affecting drug bio-availability.
4. Write about microsomal approaches in metabolite identification.
5. Describe the importance and applications of toxico kinetic studies.
6. Write about the methods for assessing bio-availability.
7. Explain about cytochrome P450 based drug interactions.

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[LO 956] MAY 2019 **Sub. Code: 2956**

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(PCI New regulations 2016)
SEMESTER-II
BRANCH–III – PHARMACEUTICAL ANALYSIS – MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES

Q.P. Code : 262956

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

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

1. Write the principle and procedure involved in the extraction of drugs and metabolite from biological matrices by Protein Precipitation and Liquid-Liquid Extraction.

2. Enlist different types of Cell Culture media, various types of Cell Culture and general procedure for making a Cell Cultures.

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

1. Write the factors affecting Bioavailability of drug.
2. Write the applications of Toxicokinetic studies.
3. Enumerate the sample preparation to study Metabolites by using Rat Liver Microsome.
4. Explain about the clinical significance of Bioequivalence studies.
5. Explain about cytochrome P450 based drug interactions.
6. Explain an experimental method in detail for the determination of Permeability of drugs.
7. Discuss about the effect of Protein & Tissue-Binding Drug Interactions.

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

[LP 956] NOVEMBER 2019 **Sub. Code: 2956**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-II
BRANCH–III – PHARMACEUTICAL ANALYSIS – MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES

Q.P. Code : 262956

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

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

1. Basic consideration of Pharmacokinetics and explain about pharmacokinetic and pharmacodynamic drug interactions.

2. Explain in detail about study design and cross over study design in drug product performance.

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

1. Write about relative and absolute bioavailability.
2. Describe EMEA guidelines for bio analytical method validation.
3. What are the basic equipments used in cell culture laboratory?
4. Write about liquid-liquid extraction methods.
5. Write the experimental methods for solubility.
6. Cryopreservation.
7. Principle and application of flow cytometry.

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

[LQ 0121] JANUARY 2021 Sub. Code: 2956

(APRIL 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION

SEMESTER-II (PCI New regulations 2016)

PHARMACEUTICAL ANALYSIS – MPA

PAPER II – MODERN BIO ANALYTICAL TECHNIQUES

Q.P. Code : 262956

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

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

1. Explain in detail about Biopharmaceutical factors affecting drug Bioavailability.

2. Write about general procedure for cell culture, isolation of cells, subculture and characterisation of cells and their applications.

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

1. Write about the principle and application of MTT assay.
2. Explain the methods for assessing bioequivalence studies.
3. Explain about the effect of tissue-binding interactions.
4. Identification of metabolites using RLM microsomes.
5. Write about toxico kinetic evaluation in preclinical studies.
6. Cryopreservation.
7. Explain about generic biologics.

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

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2956
(OCTOBER 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-II (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES
Q.P. Code : 262956

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

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

1. Explain the EMEA guidelines for bio analytical method validation.

2. Protocol and sample preparation in Metabolite identification and regulatory perspectives.

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

1. Describe the *In-vivo* approaches for metabolite identification.
2. Explain the characterization of cells and their application.
3. Illustrate the importance and application of toxicokinetic studies
4. Explain *In-situ* and *In-vivo* permeability testing method.
5. Write the general principle and procedure involved in bioanalytical method.
6. Briefly explain cell subculture method
7. Illustrate the LCMS in bioactivity screening.

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

[MPHARM 0122] JANUARY 2022 Sub. Code: 2956
(APRIL 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-II (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES
Q.P. Code : 262956

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

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

1. Explain the principle, procedure involved in extraction of drugs and metabolites from biological matrices by liquid – liquid extraction.

2. Write elaborately about permeability *In-vitro, in-situ & in-vivo* Methods.

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

1. Describe the Pharmcokinetic drug interaction.
2. Explain about Microsomal assays.
3. Illustrate the sample preparation to study metabolites by using Human Liver Microsomes.
4. Explain alternative methods of dissolution testing transport model.
5. Write the general principle and procedure involved in cell viability assay.
6. Clinical significance of bioequivalence studies.
7. Explain the effect of Protein binding interactions.

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

[MPHARM 0422] APRIL 2022 Sub. Code: 2956
(OCTOBER 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-II (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES
Q.P. Code : 262956

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

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

1. Write the principle and procedure involved in the extraction of drugs and metabolite from biological matrices by solid phase extraction method.

2. Explain Bioavailability and describe alternative methods of dissolution testing transport models.

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

1. Explain about the Biopharmaceutical classification system.
2. Describe the drug interactions linked to transporters.
3. Enumerate the various types of cell culture used in bioanalytical method.
4. Describe the principle and applications of cell viability assays.
5. Explain the methods of assessing bioavailability study.
6. Briefly explain Biosimilar drug products.
7. Illustrate the LCMS in Proteomics study.

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

[M.PHARM 0922] SEPTEMBER 2022 Sub. Code: 2956
(APRIL 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES

Q.P. Code : 262956

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

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

1. a) Highlight the USFDA guidelines for bioanalytical method validation.
   b) Cytochrome P450 based drug interactions.

2. a) Enumerate the sample preparation to study metabolites by Human Liver Microsome.
   b) Discuss on Toxicokinetics evaluation in preclinical studies.

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

1. Write a note on Clinical significance of Bioequivalence studies.
2. Biosimilar products.
3. General principle and procedure involved in Protein Precipitation.
4. What is dissolution and drug release testing?
5. Describe the *in-vivo* assay of drug metabolites.
6. Effect on protein binding interactions.
7. Cell culture media and isolation of cells.

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