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

[LO 956] MAY 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. 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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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 2956**

(APRIL 2023 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) Discuss about the bioequivalence studies.
   b) Principles and application of flow cytometry.

2. Write the principle involved in the extraction of drugs and metabolite from biological matrices by protein precipitation of solid and liquid phase extraction.

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

1. Write about dissolution and drug releasing testing.
2. Write the purpose of Bio availability studies.
3. Write about relative and absolute bioavailability.
4. What are the regulatory aspects followed for metabolite identification?
5. Human Liver Microsomes (HLM).
6. PK-PD drug interactions.
7. LC-MS in bioactivity screening and proteomics.

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

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 2956
(OCTOBER 2023 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 about bioavailability, purpose of bio availability studies, relative and absolute bioavailability and methods for assessing bioavailability.

2. Explain in detail about various type of drug interactions:
   a) The effect of protein-binding interactions.
   b) Cytochrome P-450 based drug interaction.
   c) Drug interactions linked to transporters.

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

1. Characterisation of cells and their applications.
2. Describe the USFDA guidelines for bio-analytical method validation.
3. In-vitro assay of drug metabolites.
4. Write about isolation of cells.
5. Write about other novel sample preparation methods for extraction of drugs from biological matrices.
6. Explain about LC-MS in proteomics.
7. Explain about microsomal assays.

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

[M.PHARM 0524] MAY 2024 Sub. Code: 2956
(APRIL 2024 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) Effect of tissue binding interactions and interactions linked to transporters.
   b) General principle and procedure involved in Protein Precipitation.

2. a) Write the alternative methods of dissolution testing transport models.
   b) Discuss about cytochrome P450 drug interactions.

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

1. Protein Binding interactions.
2. Highlight the EMEA guidelines for bioanalytical method validation.
3. Cross over study designs - Explain.
4. Experimental methods for determining solubility.
5. General procedure for cell cultures.
6. LC-MS in bioactivity screening and proteomics.
7. Relative and Absolute Availability.

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

[M.PHARM 1124] **NOVEMBER 2024** **Sub. Code: 2956**

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. What are the basic consideration of pharmacokinetics and explain about Pharmacokinetics and pharmacodynamics drug interactions.

2. Assign the different types of cell culture media, various types of cell culture and general procedure for making cell cultures.

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

1. Explain about cytochrome P450 based drug interaction.
2. Write the importance and application of toxicokinetic studies.
3. Write about principle and application of MTT assay.
4. Discuss the experimental method in detail for the determination of permeability of drugs.
5. Describe USFDA guidelines for bioanalytical method validation.
6. Write about dissolution and drug releasing testing.
7. Note on LCMS in bio activity screening.

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

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 2956**

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 sample preparation procedures emphasizing novel sample preparation techniques for extraction of drugs and metabolite from biological matrices.

2. Write designing, evaluation and conducting Bioequivalent study for drugs. Mention the guidelines for Bioequivalent study.

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

1. Microsomal approaches for Invitro metabolites study.
2. Toxicokinetic evaluation in preclinical study.
3. Concisely mention Invitro & Invivo methods for permeability testing of drugs.
4. Differentiate USFDA and EMEA guidelines for bioanalytical method validation.
5. Denote basic equipments for cell culture lab.
6. Cryopreservation and its importance.
7. Mention physio chemical factors controlling bioavailability of drugs.

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

[M.PHARM 1025] **OCTOBER 2025** **Sub. Code: 2956**

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 on invitro dissolution testing, its alternative methods and rug release study for various dosage forms.

2. a) Elaborate on microsomal assays and their importance.
   b) Briefly write on cell viability assays.

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

1. Cross over study design in Bioequivalence drug testing.
2. Write Solid and liquid phase extraction of drugs.
3. Effect of protein binding on drug efficiency.
4. Biopharmaceutical classification system and effect of solubility ion drug absorption.
5. Role of bioanalytical methods for estimation of drugs from biomatrix.
6. Enumerate drug transport models.
7. Discuss principle and application of flow cytometry.

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