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

[LL 952] NOVEMBER 2017 **Sub. Code: 2952**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICAL ANALYSIS – MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS

Q.P. Code : 262952

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

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

1. Write the principle and procedures involved in the biological assays of:
   a) Adsorbed Diphtheria vaccine b) Rabies Vaccine c) Heparin sodium

2. Define and classify Impurities. Describe and draw a flow chart showing schematic representation of quantification techniques for impurity profiling of drugs. Enumerate the degradation products content of batches and their list.

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

1. Describe the ICH stability guidelines for biological products.
2. Write the general analytical procedures for identification of elemental impurities.
3. Classify elemental impurities and how do you control in Pharmaceutical products.
4. Write in detail about the regulatory requirements for Phyto-pharmaceuticals.
5. Explain about the separation techniques in Immunoassays.
6. Enlighten the principles of Enzyme Immunoassay.
7. Describe the application of HPLC/HPTLC finger printing in Phyto-pharmaceuticals.

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

[LM 952] MAY 2018 **Sub. Code: 2952**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICAL ANALYSIS – MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS

Q.P. Code : 262952

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

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

1. Write the principle and procedures involved in the biological assays of:
   a) Adsorbed Tetanus vaccine b) Antivenom c) Oxytocin

2. Describe in detail about stability testing of Phyto-pharmaceuticals with special emphasis on protocols, finger printing and interactions by means of appropriate examples.

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

1. Classify residual solvents and write the analytical procedure for any one residual solvent.
2. Describe about quantification of impurities as per ICH guidelines.
3. Describe the methods of C, H, N and S analysis with principle.
4. Write in detail about sources of elemental impurities and their identification tests.
5. Explain about the production of antibodies as well as flow chart.
6. Enlighten the principles of Radioimmunoassay.
7. Describe the ICH stability guidelines for biological products.

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

[LN 952] NOVEMBER 2018 **Sub. Code: 2952**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICAL ANALYSIS – MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS

Q.P. Code : 262952

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

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

1. Write in detail about the regulatory requirements for HPTLC/TLC finger printing in stability testing of Phytopharmaceuticals.

2. Write note on stability studies and concepts of validation accelerated stability testing and shelf life prediction.

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

1. What is Heparin sodium I.P? Explain the tests and Assay.
2. Describe the Optical Immuno Assay.
3. Write note on ICH stability guidelines for biological products.
4. Write note on buffering species ionic strength and dielectric constant.
5. Write the analytical procedures for Carbon and Hydrogen Elemental Impurities.
6. Write the general principles and classification of Residual solvents.
7. Write note on WHO and ICH stability testing guidelines.

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

[LO 952] MAY 2019 **Sub. Code: 2952**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICAL ANALYSIS – MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS

Q.P. Code : 262952

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

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

1. Classify Elemental impurities and how these are controlled in pharmaceutical products. Write the general Analytical procedures for identification of elemental impurities.

2. Write the principle, method development, stability studies and concepts of Validation.

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

1. Describe the principles of Radio Immuno Assay.
2. Write the biological tests and assay of Tetanus Anti toxin.
3. Write note on PCR studies for gene regulation.
4. Describe the photosensitivity testing guidelines.
5. How do you describe the production steps of Antibodies?
6. What are the Regulatory requirements for the stability testing of Phyto pharmaceuticals?
7. Write note on listing of degradation products in specifications.

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

[LP 952] NOVEMBER 2019 **Sub. Code: 2952**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH III – PHARMACEUTICAL ANALYSIS – MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS

Q.P. Code : 262952

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

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

1. Write the special emphasis on basics of impurity profiling and degradent characterization. Describe the methods for the quantification of impurities as per ICH guidelines.

2. Write the basic principles involved in the Immunoassays. Give a flow chart showing production of antibodies. Discuss in detail about quantification and applications of immunoassays.

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

1. Enlighten the Procedure for the biological assay of Tetanus antiserum.
2. Write the procedures for C, H, N and S analysis.
3. Describe about potential sources of elemental impurities.
4. Write in detail about the stability testing protocols for Phyto-pharmaceuticals.
5. Write short notes on Bioassay of Antivenom.
6. Explain about the stability testing protocols with important parameters.
7. Describe the HPLC/HPTLC finger printing with interactions for Phyto-pharmaceuticals.

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

[LQ 0121] JANUARY 2021 Sub. Code: 2952

(APRIL 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION

SEMESTER-I (PCI New regulations 2016)

PHARMACEUTICAL ANALYSIS – MPA

PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS

Q.P. Code : 262952

Time : Three hours Answer ALL Questions Maximum : 75 Marks

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

1. Write the principle and procedures involved in the biological assays of :
   a) Tetanus antitoxin b) Antivenom c) Oxytocin

2. Write the basics of impurity profiling and degradation products including characterization. Explain the methods for the quantification of impurities as per ICH guidelines.

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

1. Write the analytical procedures for H, N and S analysis.
2. Write the basic principles involved in the immunoassays.
3. How do you control Elemental impurities in Pharmaceutical products?
4. Write in detail about the regulatory requirements for Phytopharmaceuticals.
5. Describe the ICH stability guidelines for biological products with suitable example.
6. Explain the finger printing techniques in Phytopharmaceuticals by HPLC/HPTLC.
7. Describe about the principles and applications of Radioimmunoassay.

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

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2952
(OCTOBER 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS
Q.P. Code : 262952

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

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

1. Elaborate the classification, analytical procedure and limits of residual solvent impurities in drug products.

2. Describe the ICH guidelines for accelerated stability testing and the shelf life calculation.

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

1. Describe the decision tree for identification and qualification of degradation in new drug product.
2. Enumerate the factors influencing stability testing studies in drug products.
3. Explain HPTLC finger print techniques in stability testing of Phytopharmaceuticals.
4. Summarize the principle and applications of PCR studies.
5. Write the principle and procedure involved in the biological assay of Adsorbed Diphtheria vaccine.
6. Classify and write sources of elemental impurities.
7. Compare and contrast between Enzyme and Fluoro Immuno Assays.

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

[MPHARM 0122] JANUARY 2022 Sub. Code: 2952
(APRIL 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS
Q.P. Code : 262952

Time : Three hours Answer ALL Questions Maximum : 75 Marks

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

1. Elaborate the characterization and Method development for degradation in Pharmaceuticals.

2. Explain the principle, procedure, applications and demerits of the following
   a) Radio immuno assay b) Enzyme immuno assay.

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

1. Classify and write reporting level of residual solvent impurities.
2. Outline PCR studies for gene regulation.
3. Discuss rationale for the reporting and control of degradation products in new drug products.
4. Write the principle and procedure involved in the biological assay of Adsorbed Tetanus Vaccine.
5. Summarize the regulatory requirements for stability testing of Phytopharmaceuticals.
6. Discuss Source and control of elemental impurities.
7. Recall the biological test and assay of Heparin sodium.

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

[MPHARM 0422] APRIL 2022 Sub. Code: 2952
(OCTOBER 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS
Q.P. Code : 262952

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

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

1. Elaborate, Accelerated stability testing and photo stability testing with emphasis of ICH.

2. Classify impurities in drug substance and explain in details about organic & solvent impurities.

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

1. Discuss qualification of degradation products in new drug products.
2. Explain the principle and instrumentation used for quantification of Carbon, Hydrogen, Nitrogen and Sulphur.
3. Explain any two strategies used for method development techniques for estimation of impurities.
4. Write the principle and procedure involved in the biological assay of oxytocin.
5. Explain HPLC finger print techniques in stability testing for Phytopharmaceuticals.
6. Outline principle, Procedure and applications of luminescence immuno assay techniques.
7. Enumerate Principle, Procedure and applications of PCR.

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

[M.PHARM 0922] SEPTEMBER 2022 Sub. Code: 2952
(APRIL 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS

Q.P. Code : 262952

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

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

1. a) Explain the listing of degradation products in specifications, qualification of degradation Products.

   b) Explain the concepts of accelerated stability testing and shelf life calculation.

2. a) Write the principle and procedure and applications of Enzyme immunoassay.
   b) Principle and procedure involved in the biological assays of Rabies vaccine and Heparin sodium.

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

1. Classify the elemental impurities and explain the Identification of Potential Elemental Impurities.
2. Explain the regulatory requirements for herbal drugs.
3. Write a note on luminescence immunoassay.
4. Explain the WHO and ICH stability testing guidelines.
5. Write the principle and instrumentation of C, H, N and S analysis.
6. Quantification of impurities as per ICH guidelines.
7. Write a note on Active Pharmaceutical Ingredient impurities.

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