Code No. D-8261/PCI

FACULTY OF PHARMACY

M. Pharmacy I - Semester (Common to All) (PCI) (Main & Backlog) Examination, May 2022

Subject: Modern Pharmaceutical Analytical Techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 (a) State and explain Beer-Lambert's Law. Add a note on the deviations from Beer's law.
(b) Explain the concept of chromophore, auxochrome and bathochromic shift with suitable examples.

2 (a) Explain the instrumentation of FTIR with a neat labelled diagram. Add a note on the advantages of FTIR.
(b) Explain the mplecular vibrations in IR.

3 (a) What is the principle AAS? Explain the instrumentation.
(b) List the differences between AAS and flame photometry.

4 What is the significance of chemical shift? What are the factors affecting chemical shift? Name the internal standard and justify its selection as internal standard in NMR spectroscopy.

5 What is the principle of Mass Spectrometry? With a neat labelled diagram briefly explain the components of MS instrumentation.

6 (a) Classify the ionization techniques in MS. Explain any three methods in detail.
(b) Define Base peak, molecular ion peak and metastable ion.

7 (a) Explain the principle of X-ray diffraction.
(b) Explain HPLC instrumentation with a labelled diagram.

8 (a) Explain the experimental set up required for gel electrophoresis.
(b) Describe the principle and applications of RIA.

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Code No. D-8276/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination, May 2022

Subject: Food Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 Define carbohydrates? Explain various methods for determination of carbohydrates.

2 (a) List out the quality control tests for fats and oils. Explain the principle, procedure and significance of saponification value.
(b) Explain any two methods for determination of vitamin A.

3 Write about the following.
(a) Analysis of preservatives.
(b) Analysis of different flavors and flavor enhancers.

4 (a) Explain the Gerber method for analysis of fat in milk.
(b) Explain Kjedahl method for determination of protein in ice creams.

5 Explain various methods for determination of organophosphorus and organochlorine pesticides in fruits and vegetables.

6 (a) Give any two methods for determination of Vitamin B_{12}.
(b) Explain 2, 6 dichlro phenol indophenol method for determination of Vitamin C.

7 Write about the following
(a) BIS and AGMARK
(b) Determination of salt content in butter by Volhard's method.

8 (a) Explain the Karl fischer method for determination of moisture in proteins.
(b) Explain the determination of Ethyl alcohol content in Beer.

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Code No. D-8275/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination, May 2022

Subject: Pharmaceutical Validation

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 (a) Define qualification and validation. Write about design qualification and performance qualification phases of analytical equipment.
(b) Explain the calibration procedure of glassware used in analytical work.

2 (a) How do you qualify UV spectrophotometers? Explain.
(b) Write short note on re-validation process.

3 Write short notes on
(a) Cleaning validation
(b) Pharmaceutical water system validation

4 Describe method validation parameters as per ICH guidelines for validation of new analytical procedures.

5 (a) Describe qualification procedure of HPLC instrument.
(b) Explain the criteria of patentability of an invention and steps in patent application.

6 (a) Explain the procedure involved in qualification and calibration of FTIR.
(b) Write about factory acceptance test and site acceptance test.

7 (a) Explain the steps involved in preparation of Validation Master Plan (VMP)
(b) Write short note on Digital significance of 21 CFR part II.

8 (a) What is an intellectual property right? Explain about different types of IPR.
(b) Discuss the rights and responsibilities of patentee.

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Code No. D-8274/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination, May 2022

Subject: Advanced Pharmaceutical Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 Explain the guidelines for reporting and control of degradation products in new drug products. Give the classification of residual solvents and their limits in drug substances and drug products.

2 Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents. Write a short note on qualification of degradation products.

3 Write about
(a) Control of elemental impurities
(b) Potential sources of elemental impurities.

4 Write about different analytical techniques used in characterization of degradants. What is impurity profiling and give its importance in testing of pharmaceutical products.

5 Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals. What are accelerated stability studies and how do you calculate shelf life of drug products.

6 Write the principle, procedure and applications of radioimmunoassay. Write short note on optical Immunoassay.

7 Discuss the biological assay of diphtheria vaccine. Write the principle and procedure involved in bioassay of Human anti haemophilic vaccine.

8 Discuss the different polymerase chain reaction studies for gene expression. Explain the different steps involved in production of antibodies.

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Code No. D8001/PCI

FACULTY OF PHARMACY

M. Pharmacy I Semester (PCI) (Suppl) Examination, December 2021 (COMMON TO ALL)

Subject: Modern Pharmaceutical Analytical Techniques

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.
(3 x 25 = 75 Marks)

1 (a) State and explain Beer-Lambert's law. Add a note on the deviations from Beer's law.
(b) Explain the electronic transitions in UV spectroscopy.

2 (a) Explain the principle and instrumentation of FTIR with a neat labelled diagram.
(b) Explain the named advantages of FTIR.
(c) What are the major differences between Dispersive instruments and FTIR?

3 (a) What is the principle of Fluorescence? Explain the radiative and non radiative pathways of relaxation.
(b) Add a note on the factors affecting fluorescence.

4 (a) Explain NMR instrumentation with a diagram.
(b) Briefly explain shielding and deshielding with suitable example.

5 (a) What is the principle of MS? With a neat labelled diagram briefly explain the components of MS instrumentation.

6 (a) Classify the ionization techniques in MS. Explain any three methods in detail.
(b) Define Base Peak, molecular ion peak and metastable ion.

7 (a) Explain GC instrumentation with a labelled diagram.
(b) What are the applications of HPLC?

8 (a) Explain the experimental set up required for capillary electrophoresis.
(b) Describe the principle and application of ELISA.

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Code No. D8015/PCI

FACULTY OF PHARMACY

M.Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Suppl) Examination, December 2021

Subject: Pharmaceutical Validation

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.

(3 x 25 = 75 Marks)

1 a) Define qualification and explain the different phases of qualification process of analytical equipment.
b) Write short notes on re-validation process.

2 Write about the following:
a) Validation master plan
b) Factory acceptance test and site acceptance test.
c) Calibration of analytical balance.

3 a) Describe validation procedure for HVAC system.
b) Write about cleaning-in-place (CIP).

4 Describe the method validation parameters for a new analytical method as per ICH Guidelines.

5 a) What is an intellectual property right? Explain about different types of IPR.
b) Discuss the rights and responsibilities of patentee.

6 a) What is a Patent? Explain the procedure for filing an application for patent in India.
b) What is patent infringement and its scope?

7 a) Explain the procedure involved in qualification and calibration of HPLC.
b) Write short note on Digital significance of 21 CFR part II?

8 a) Describe in detail about cleaning validation process.
b) Write the role of intellectual property in pharmaceutical industry?

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Code No. D8014/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I - Semester (PCI)(Suppl.)

Examination, December 2021

Subject: Advanced Pharmaceutical Analysis

Time: 2 Hours **Max. Marks: 75**

Answer any three questions. All questions carry equal marks.

(3 x 25 = 75 Marks)

1 a) Define Impurity and give the classification of impurities in new drug substances
b) Explain the guidelines for reporting and control of degradation products in new drug products.

2 a) Classify elemental impurities and write about control of elemental impurities.
b) Explain about potential sources of elemental impurities in pharmaceutical products.

3 a) How do you perform stability studies for drug products as per ICH guidelines? Explain.
b) How do you perform photo stability of formulations?

4 a) Describe different analytical techniques used in characterization of degradants.
b) Write about ICH stability guidelines for biological products.

5 a) Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals.
b) What are accelerated stability studies and how do you calculate shelf life of drug products.

6 Write about the following
a) Enzyme immunoassay
b) Optical Immunoassay

7 a) Discuss the biological assay of diphtheria vaccine
b) What are antitoxins? Give biological assay of Tetanus antitoxin.

8. Write the principle, procedure and applications of PCR studies.

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Code No. D 8016/PCl

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCl) (Suppl.)

Examination, December 2021

Subject: Food Analysis

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.

(3 x 25 = 75 Marks)

1 a) Explain determination of Ash and mineral constituents in food materials.
b) Define and classify proteins. Explain Kjeldahl method for determination of overall protein concentration in food Samples.

2 a) Discuss the principle, procedure and significance of acid value.
b) Explain any two methods for determination of Vitamin B_1

3 Write about the following
a) Analysis of thickening and jelling agents
b) Method of detection of permitted and non permitted dyes.

4 Explain the following methods for determination of fat in milk.
a) Gerber method
b) Rose-Gottlieb method

5 a) Explain the multi residue gas chromatographic method for determination Of synthetic pyrethroid in fruits and vegetables.
b) Write a note on BIS and AGMARK.

6 Write about the following
a) Determination of titrable acidity in dried milk
b) Analysis of preservatives

7 Explain different methods for determination of Vitamin B_{12}.

8 Explain the determination of ethanol and methanol in wine samples.

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Code No. 12115/PCI

FACULTY OF PHARMACY
M.Pharmacy I Semester (PCI) (Main & Backlog) Examination, July 2021
(COMMON TO ALL)

Subject: Modern Pharmaceutical Analytical Techniques

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three from the following questions. **(3 x 25 = 75 Marks)**

1 (a) With a neat labelled diagram explain UV/Visible instrumentation.
(b) Briefly explain the electronic transitions with examples.

2 (a) Explain the molecular vibrations in IR.
(b) Write the sampling methods in IR spectroscopy.

3 (a) Explain the principle of flame photometry.
(b) With a diagram explain the instrumentation for flame photometry.
(c) List some metals that can be analysed by flame photometry.

4 (a) Explain the principle of proton NMR spectroscopy.
(b) What is the significance of chemical shift? What are the factors affecting chemical shift?
(c) What is the internal standard used in NMR spectroscopy? Why it is selected as internal standard?

5 (a) List and explain the steps in MS.
(b) What are the mass analysers used in MS? Explain any two in detail.

6 (a) Explain HPLC instrumentation with a labelled diagram.
(b) List and explain any 2 GC detectors.

7 (a) Explain Bragg's equation and derive the equation.
(b) Explain the principle and the materials required for Paper electrophoresis.

8 (a) Explain the principle and types of RIA?
(b) Briefly explain Zone electrophoresis and Moving boundary electrophoresis.

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Code No. 12145/PCI

FACULTY OF PHARMACY
M.Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Main & Backlog) Examination, July 2021

Subject: Pharmaceutical Validation

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three from the following questions. **(3 x 25 = 75 Marks)**

1 a) Define qualification and validation. Write about design qualification and performance qualification phases of analytical equipment.
b) Explain the calibration procedure of glassware used in analytical work.

2 a) How do you qualify UV spectrophotometers? Explain.
b) Write short note on re-validation process.

3 Write short notes on
a) Cleaning validation
b) Pharmaceutical water system validation.

4 Describe method validation parameters as per ICH guidelines for validation of new analytical procedures.

5 a) What is an intellectual property right? Explain about different types of IPR?
b) Explain the criteria of patentability of an invention and steps in patent application.

6 a) Explain the procedure involved in qualification and calibration of FTIR.
b) Write about factory acceptance test and site acceptance test?

7 a) Explain the steps involved in preparation of validation master plan (VMP).
b) Write short note on digital significance of 21 CFR part II?

8 a) Write about international patenting requirement procedure?
b) Write about PCT and WIPO.

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Code No. 12144/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI)(Main & Backlog)

Examination, July 2021

Subject : Advanced Pharmaceutical Analysis

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three Questions. **(3 x 25 = 75 Marks)**

1 a) Explain the guidelines for reporting and control of elemental impurities in new drug products.
   b) Give the classification of residual solvents and their limits in drug substances and drug products.

2 a) Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents.
   b) Write short note on qualification of degradation products.

3 a) Explain the factors affecting stability of drug substance and drug products.
   b) How do you perform photo stability of formulations?

4 a) Describe different analytical techniques used in characterization of degradants.
   b) What is impurity profiling and give its importance in testing of pharmaceutical products.

5 a) Write about HPLC as finger printing tool in stability testing of Phytopharmaceuticals.
   b) What are accelerated stability studies and how do you calculate shelf life of drug products.

6 Write about the following
   a) Radio immunoassay
   b) Fluro Immunoassay

7 a) Describe the principle and procedure involved in the biological assay of oxytocin
   b) Write the principle and procedure involved in bioassay of Human anti haemophilic vaccine

8 a) Discuss different polymerase chain reaction studies for gene expression.
   b) Explain the different steps involved in production of antibodies.

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Code No. 12146/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog)

Examination, August2021

Subject : Food Analysis

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three Questions. **(3 x 25 = 75 Marks)**

1 Define carbohydrates? Explain various methods for determination of carbohydrates.

2 a) List out the quality control tests for fats and oils. Explain the principle, procedure and significance of acid value
b) Explain any two methods for determination of vitamin C

3 Write about the following
a) Analysis of preservatives
b) Analysis of different flavors and flavor enhancers.

4 a) Explain the Gerber method for analysis of fat in milk.
b) Explain Kjeldahl method for determination of protein in ice creams.

5 Explain various methods for determination of organophosphorus and organochlorine pesticides in fruits and vegetables.

6 a) Give any two methods for determination of Vitamin B_{12}.
b) Explain any one method for determination of Vitamin A.

7 Write about the following
a) BIS and AGMARK
b) Determination of salt content in butter by Volhard's method.

8 a) Explain the Karl fischer method for determination of moisture in proteins.
b) Explain the determination of Ethyl alcohol content in Beer.

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Code No. 6360/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Suppl.) Examination, November 2020

Subject: Food Analysis

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three questions. **(3 x25=75 Marks)**

1 Explain briefly the various qualitative and quantitative methods used for analyzing food carbohydrates.

2 (a) Write the different means used for classifying amino acids with appropriate examples.

(b) Explain the procedure, principle and significance for determining peroxide value and unsaponifiable matter in fats and oils.

3 (a) Define the following chemically with one structural example
i) Carbohydrate ii) Proteins iii) Amino acids
iv) Lipids v) fats/oils

(b) What are the vitamins? Explain the principle and significance for the microbiological methods used for the determination of spoilage and / or adulterants in fats and oils.

4 List out the spoilage products adulterants of fats and oils. Explain any five methods used for the determination of spoilage and/or adulterants in fats and oils.

5 Enlist any five food additives along with their uses and limits. Write the procedure and principle of any one method

6 Explain the various analytical methods employed for assuring the quality of ice creams.

7 (a) Explain the various methods used for the determination of pesticide residues in fruits and vegetables.
(b) Write briefly about USFDA regulation of food products.

8 (a) Describe the various test used to analyze the purity of wines.
(b) Explain the test which is conducted to analyze non-permitted dyes in food products.

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Code No: 6359/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Suppl.)

Examination, November 2020

Subject : Pharmaceutical Validation

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three questions. **(3 x 25 = 75 Marks)**

1. Explain the following
   a) Types of patent applications
   b) Objectives and advantages of validation

2 Explain the procedure for following
   a) Calibration of Volumetric glassware
   b) Sampling methods for cleaning validation

3. List out and explain the analytical method validation parameters.

4. Explain the various types of trademarks and don'ts in trademarks with suitable examples

5. Write note on the following.
   a) Define and explain the types of process validation
   b) Different steps involved in the calibration of HPLC

6. What are the different phases of water system validation?

7. What are the different parameters in HVAC to be examined?

8. Write note on the following
   a) Clean in place
   b) Validation master plan.

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CODE NO: 6102/PCI

FACULTY OF PHARMACY

M. Pharmacy I – Semester (Main & Backlog) Examination, January 2020 (Common Paper for all Except Pharmacy Practice)

Subject : Modern Pharmaceutical Analytical Techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. (a) State and explain Beer- Lambert's law. Add a note on the deviations from Beer's law. 8
   (b) Explain solvents and the selection criteria for UV/Visible spectroscopy. 4
   (c) What is solvent shift? 3

2. (a) Explain the principle and instrumentation of FTIR with a neat labelled diagram. 8
   (b) Explain about the sampling techniques and applications of FR spectroscopy 7

3. (a) What is the principle of Fluorescence? Explain the radiative and non radiative pathways of relaxation. 7
   (b) Add a note on the factors affecting fluorescence and quenchers in fluorescence. 6
   (c) What are the criteria for a molecule to exhibit the phenomena of fluorescence 2

4. (a) Explain the principle of proton NMR spectroscopy. 5
   (b) What is the significance of chemical shift. What are the factors affecting chemical shift ? 6
   (c) Explain about spin-spin crippling and it's importance in NMR 4

5. (a) Classify the ionization techniques in MS. Explain any three methods in detail. 12
   (b) Differentiate between Base peak and molecular ion peak. 3

6. (a) Explain HPLC instrumentation. 10
   (b) What are the applications of HPLC? 5

7. (a) Explain Braggs equation and derive the equation. 8
   (b) What is the principle involved in rotating crystal technique? 7

8. Explain the principle, working and applications of
   (a) Capillary electrophoresis $7\frac{1}{2}$
   (b) Gel electrophoresis $7\frac{1}{2}$

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Code No: 6131/PCI

FACULTY OF PHARMACY

M. Pharmacy (Phar. Analysis) I-Semester (PCI) (Main & Backlog) Examination,

February 2019

Subject: Advanced Pharmaceutical analysis

Time: 3 hours **Max. Marks: 75**

Note: Answer any five Questions. All Questions carry Equal Marks

1 a) Explain the guidelines for reporting and control of degradation products in new drug products. 10
b) Explain the classifications of residual solvents and their limits in substances and drug products. 5

2 a) Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents. 10
b) Write short note on qualification of degradation products. 5

3 Write about :
a) Control of elemental impurities 8
b) Potential sources of elemental impurities. 7

4 a) Write about different analytical techniques used in characterization of degradants. 10
b) What is impurity profiling and give its importance in testing of pharmaceutical products. 5

5 a) Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals. 10
b) What are accelerated stability studies and how do you calculate shelf life of drug products. 5

6 a) Write the principle and procedure and applications of radioimmunoassay. 10
b) Write short note on optical Immunoassay. 5

7 a) Discuss the biological assay of diphtheria vaccine. 7
b) Write the principle and procedure involved in bioassay of Human anti haemophilic vaccine. 8

8 a) Discuss the different polymerase chain reaction studies for gene expression. 8
b) Explain the different steps involved in production of antibodies. 7

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Code No: 6133/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma Analysis) I-Semester (PCI) (Main & Backlog) Examination, January 2020

Subject : Food Analysis

Time: 3Hours **Max. Marks: 75**

Note: Answer Any Five Questions. All Questions Carry Equal marks

1. Classify proteins with examples. Describe the process of digestion. Absorption and metabolism of proteins and amino acids. 5+10

2 a) What are dietary fibers and crude fibers? Write their application and methods employed for analyzing them 2+8
b) What are vitamins? Classify them with suitable examples 1+4

3. a) Explain the process of digestion and absorption of carbohydrates and proteins/amino acids. 5+5
b) Explain the various process used for refining of fats and oils. 5

4. What are fats and oils chemically? Explain the various methods used for the analysis of fats and oils 1+14

5. a) Explain about occurrence and characteristic properties of natural pigments. 5
b) Explain the various methods used for the detection of natural dyes. 10

6. Explain the various analytical methods employed for assuring the quality of butter. 15

7. a) Explain any three legislation regulations of food products. 12
b) What are the effects of pest and insects on food. 3

8. a) Describe the various tests used to analyze the purity of beer. 10
b) Explain the test which is conducted to analyze the presence of pesticides in milk products. 5

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Code No.6132/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination, January 2020

Subject: Pharmaceutical Validation

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 Explain the following terms. 5+5+5
(a) User requirement specification
(b) Factory acceptance test
(c) Site acceptance test

2 Write note on the following
(a) Calibration of FTIR. (7)
(b) Cleaning in place (8)

3 Define IPR. Explain the criteria of patentability of an invention and describe the steps involved in patent application. (1+7+7)

4 Explain the difference between qualification, calibration, validation and explain about instrument qualification. (5+10)

5 Write note on the following.
(a) What are the different types of water used in pharmaceutical industry?
(b) Different steps involved in the calibration of HPLC instrument. (7+8)

6 (a) Discuss about pharmaceutical water system validation.
(b) Explain the procedure to calibrate wavelength of UV instrument. (10+5)

7 (a) Describe the Method Validation parameters for new Analytical method.
(b) What is meant by revalidation and when to revalidate? (12+3)

8 Write note on the following
(a) Types of process validation.
(b) Validation master plan. (8+7)

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Code No. 13303/PCI

FACULTY OF PHARMACY

M. Pharmacy (Common paper for all Specialization) I-Semester (PCI)
(Suppl.) Examination, August 2019

Subject : Modern Pharmaceutical Analytical Techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 a) Write Beer-Lambert's law and derive the expression 5

b) Mention the different methods of quantitative analysis by uv-visible spectroscopy. Explain any one method in detail. 10

2. a) Explain the interpretation procedure of IR spectra of different organic compounds in detail. With examples of schematic IR spectra.

b) What is fluorescence? Write the factors affecting fluorescence. 5

3. a) What is chemical shift? Write the factors influencing chemical shift? 8

b) Write a note on FT-NMR 7

4. a) Explain the instrumentations and working of mass spectrometer with schematic diagram. 8

b) Write the fragmentation patterns of different organic compounds observed in mass spectroscopy. With the help of schematic mass spectra of a few compounds 7

5. Describe the components and working procedure of HPLC with a neat labeled block diagram. 15

6. a) Write the principle, instrumentation and working of zone electrophoresis. 8

b) Write the principle and theory of X-ray diffraction study using Brag's law 7

7. a) Write the principle and instrumentation of flame photometry 7

b) Write notes on any two GC detectors 8

8. Explain the principle, equipment, procedure, advantages and applications of IR Spectrophotometer 15

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Code No: 13318/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I – Semester(PCI) (Supple.) Examination, August 2019

Subject: Food Analysis

Time: 3hrs **Max Marks: 75**

Note: Answer any five questions, all questions carry equal marks

1. Enlist the general methods for analyzing proteins and amino acids. Explain any three of them with suitable examples.

2. a) Enlist the factors responsible of fats and oils. Explain any three methods used for measuring the spoilage of fats and oils.
   b) Classify lipids with structural examples.

3. a) Explain the general methods of identifying and estimating natural and artificial stabilizers.
   b) Describe any two methods used for detecting natural dyes as coloring agents in food stuffs along with suitable examples.

4. a) Describe the various tests to analyze the purity of wines.
   b) Explain the test which is conducted to analyze the presence of bacteria in ice creams.

5. Give examples of organophosphorous and organochlorine pesticides. Explain the methods employed for analyzing them in mangoes.

6. a) Explain the process of digestion, absorption and metabolism of proteins.
   b) Define chemically fats and oils along with structural examples. Describe the various methods employed for refining fats and oils.

7. a) Describe the role of various legislations available for regulating food products.
   b) What is vinegar chemically? Describe the variable methods employed for analyzing the purity of vinegar.

8. (a) Explain the role of TLC and HPLC in the analysis of carbohydrates along with an appropriate example.
   (b) Distinguish between intense sweeteners and bulk sweeteners with examples. Describe any two tests used for the detection of saccharin in foods and beverages.

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Code No. 13317 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I – Semester (PCI) (Suppl.) Examination,

August 2019

Subject: Pharmaceutical Validation

Time: 3 Hours **Max.Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 Explain the following terms:
   a) User requirement specification 5
   b) Factory acceptance test 5
   c) Site acceptance test. 5

2 Write note on the following:
   a) Calibration of volumetric glassware 7
   b) Cleaning in place 8

3 Define IPR. Explain the criteria of patentability of an invention and describe the steps involved in patent application. 1+7+7

4 Explain the difference between qualification, calibration, validation and explain about instrument qualification. 5+10

5 Write note on the following:
   a) Different types of waters used in pharmaceutical industry. 7
   b) Different steps involved in the calibration of HPLC instrument. 8

6 a) Discuss about pharmaceutical water system validation. 10
   b) Explain the procedure to calibrate wavelength of UV instrument. 5

7 a) Describe the method validation parameters for new analytical method. 12
   b) What is meant by revalidation and when to revalidate? 3

8 Write note on the following:
   a) Types of process validation 8
   b) Validation master plan. 7

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CODE NO: 13147/PCI

FACULTY OF PHARMACY

M. Pharmacy (Common Paper for all Specialization) I – Semester (Main & Backlog) Examination, January 2019 Subject : Modern Pharmaceutical Analytical Techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1) a) With a neat labeled diagram explain UV/Visible instrumentation. **8**

b) Briefly explain the electronic transitions with examples **8**

2) a) Explain the factors affecting vibrational frequencies in IR. **8**

(b) Write the sampling methods in IR spectroscopy. **7**

3 (a) Briefly explain the source of AAS. **8**

(b) List and explain the interferences. 5

(c) List some metals that can be analysed by AAS. 2

4 (a) Explain NMR instrumentation.

(b) Briefly explain spin-spin coupling with a suitable example. 7

5 (a) What is the principle of MS. With a neat labelled diagram briefly explain the components of MS instrumentation. 8

(b)Explain Quadrupole and time of flight analysers in detail. 7

6. (a) What are the column efficiency parameters? 7

(b) List and explain any 2 GC detectors. 8

7. Explain the principle and application of capillary electophoresis. Give a labelled diagram to indicate the components of the instrument.

8 (a) Discuss the principle, instrumentation working and application of

a. Paper electrophoresis

b. Gel electrophoresis 7+8

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Code No: 13162/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I – Semester (PCI) (Main & Backlog) Examination, February 2019

Subject: Food Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. a) Enlist the various methods available for quantitatively analyzing food carbohydrates. Write the procedure, principle and advantages/disadvantages of any three of them. 1+9
   b) Describe briefly the various pathways involved in protein metabolism. 5

2 a) Explain the various methods employed for the determination of adulterants in fats and oils. 10
   b) Describe briefly about hydrogenation of vegetable oils. 5

3. a) Why methyl paraben is used in food stuffs. Explain the various qualitative and quantitative methods employed for identifying methyl paraben in food stuffs. 1+9
   b) Give example of permitted and non permitted synthetic dyes that can be used as coloring agents in food stuffs. Explain any one method used to detect non-permissible dyes in foods? 5

4. a) List down the various adulterantand contaminantsmilk. Explain how freezing point depression (along with the procedure) determination is useful for identification of milk adulterants). 2+6
   b) Write the procedure, principle and significance of Gerber test and Babcock test with respect to analysis of milk. 7

G them with suitable examples. 10

   b) Explain briefly aboutBIS and AGMARK. 5
6. a) Describe the methods employed for the detection and estimation of antioxidants in fat/oils and food products. 10
   b) Describe the principle involved in the microbiological assay of vitamin B series. 5

7. Classifyfood carbohydrates with examples. Explain the process of digestion, absorption and metabolism of food carbohydrates. 3+12

8. a) Write down the composition of cheese. Describe the test carried out for the analysis of cheese. 2+10
   b) What are lipids? Write the qualitative tests used for the identification of lipids. 1+2

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Code No. 13161 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog)

Examination, February 2019

Subject: Pharmaceutical Validation

Time: 3 Hours **Max.Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 Explain the following:
a) Define and explain various Intellectual Property Rights. 5
b) Write about procedure of obtaining an International Patent. 10

2 Explain the procedure for following:
a) Calibration of FTIR 5

b) Sampling methods for cleaning validation. 10

3 List out and explain the analytical method validation parameters. 15

4 Explain the various types of trademarks and don'ts in trademarks with suitable examples. 10+5

5 Write note on the following:
a) Define and explain the types of process validation 8
b) Different steps involved in the calibration of analytical balance. 7

6 a) What are the different phases of water system validation? 10
b) Explain the procedure to calibrate wavelength of UV instrument. 5

7 a) What are the different parameters in HVAC to be examined? 12

b) What is meant by revalidation and when to revalidate? 3

8 Write note on the following:
a) Electronic records 5
b) Validation master plan. 10

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Code No. 13160 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Phar.Analysi.) I – Semester (PCI) (Main & Backlog)

Examination, January 2019

Subject: Advanced Pharmaceutical Analysis

Time: 3 Hours **Max.Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 a) Define Impurity and give the classification of impurities in new drug substances. 5

b) Explain the guidelines for reporting and control of elemental impurities in new drug products. 10

2 a) Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents. 10

b) Write short note on qualification of degradation products. 5

3 a) Explain the factors affecting stability of drug substance and drug products. 10

b) How do you perform photo stability of formulations? 5

b)

4 a) Write about different analytical techniques used in characterization of degradants. 10

products. 5

5 a) Write about HPTLC as finger printingtool in stability testing of phytopharma

ceuticals. Reddy Hyderabad

b) What are accelerated stability studies and how do you calculate shelf life of drug 10

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6 Write about the following

a) Enzyme immunoassay 8

b) Optical Immunoassay 7

7 a) Describe the principle and procedure involved in the biological assay of oxytocin. 8

b) What are antitoxins? Give biological assay of Tetanus antitoxin. 7

8 a) Discuss the different polymerase chain reaction studies for gene expression. 8

b) Explain the different steps involved in production of antibodies. 7

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Code No. 1289/PCI

FACULTY OF PHARMACY

M. Pharmacy (Common to All) I-Semester (PCI) (Suppl.) Examination,

August 2018

Subject: Modern Pharmaceutical Analytical Techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Discuss the instrumentation of double beam UV visible spectrophotometer with a neat labeled diagram. (10)

(b) What is Isobestic point? Explain with a labeled UV spectrum giving tow examples. (5)

2 (a) Compare the instrumentation and working a dispersive and foruier transform IR spectrometers. Write the advantages and disadvantages of the two techniques. (10)

(b) Draw a schematic IR spectrum for any one compound and indicate the absorption wave number regions for any four functional groups in the compound. (5)

3 (a) Explain

(i) Chemical shift and factors influencing chemical shift.

(ii) Spin-spin coupling and coupling constant. (6)

(b) Draw a schematic HNMR spectrum for any onecompound and explain the

(i) Chemical shift values (ii) Nature of protons (iii) Number of protons (3)

4 (a) Discuss the theory and principle of mass spectroscopy and explain the instrumentation and working of mass spectrometer with a neat labeled diagram. (10)

(b) What is fragmentation? Explain the following by taking a simple example

(i) Fragmentation peaks (ii) Molecular ion peak (iii) Base peak (5)

5 (a) Discuss the theory of HPLC. Describe the instrumentation and working of HPLC with a neat labelled diagram. (10)

(b) Draw a schematic HPLC chromatomgram and explain

(i) Retention time (ii) Resolution (iii) Peak Asymmetry (5)

6 (a) Discuss the theory and principle of electrophoresis. Explain the method of capillary electrophoresis and its applications with examples. (12)

(b) What is isoelectric focusing? (3)

7 (a) Discuss the theory and principle of Gas chromatography. Explain the instrumentation and working of Gas chromatography and explain various stationary and mobile phases used in GC. (11)

(b) How non voralile compounds can be analysed by GC. Explain the technique with few examples? (4)

8 Write a note on :

(a) Flame emission spectroscopy (6)

(b) Instrumentation and application of Florescence spectroscopy (9)

Code No. 1302/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Supple.) Examination, August 2018

Subject: Advanced Pharmaceutical Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Define impurity and write classification of impurities in drug substances with examples. (5)
(b) Describe analytical procedures for quantification of impurities in drug products As per ICH guidelines and mention their threshold limits. (10)

2 (a) Classify and write the potential sources of elemental impurities. (5)
(b) Describe instrumentation and analytical procedures for analysis of carbon, hydrogen, nitrogen and sulphur impurities. (10)

3 (a) Write the systematic approach to stability evaluation of drug substances. (8)
(b) Explain the influence of temperature, pH buffering species ionic strength and dielectric constant on drug stability. (7)

4 Write an account on WHO and ICH guidelines for stability testing. (15)

5 (a) Explain the role of analytical instruments (HPTLC & HPLC) in interaction and complexity studies of phytopharmaceuticals. (10)
(b) Write a note on stability testing protocols for herbal drugs. (5)

6 (a) Define bioassay. Describe the principle and method involved in bioassay of any one biological product. (8)
(b) What are antitoxins? Give biological assay of tetanus antitoxin. (7)

7 (a) Describe basic principles of radio immune assay. Enumerate its applications and limitations. (10)
(b) Describe the production of antibodies. (5)

8 (a) Write an account on Impurity profiling and degradation product characterization studies for gene regulation. (10)
(b) Classify residual solvents by risk assessment and describe their limits. (5)

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Code No. 1303/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Supp.) Examination, August 2018

Subject: Pharmaceutical Validation

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Define qualification and explain the different phases of qualification process of analytical equipments.
(b) Write short notes on re-validation process. 5

2 Write about the following 3x5=15
(a) Validation master plan.
(b) Factory acceptance test and site acceptance test.
(c) Calibration of analytical balance.

3 (a) Describe validation procedure for HVAC system. 10
(b) Write about cleaning-in-place (CIP). 5

guidelines. Library 15

4 Describe the method validation parameters for a new of analytical method as per ICH

5 (a) What is an intellectual property right? Explain about different types of IPR.
India. Hyderabad 9 8
(b) Discuss the rights and responsibilities of patentee. 7

6 (a) What is a Patent? Explain the procedure for filing an application for patent in

(b) What is patent infringement and its scope. 6

7 (a) Explain the procedure involved in qualification and calibration of HPLC 10
(b) Write short note on Digital significance of 21 CFR part II. 5

8 (a) Describe in detail about cleaning validation process. 10
(b) Write about preventive maintenance. 5

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Code No. 1304/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Supple.) Examination, August 2018 Subject: Food Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Explain determination of Ash and mineral constituents in food materials. (8)
(b) Define and classify proteins. Explain Kjeldahl method for determination of overall protein concentration in food Samples. (7)

2 (a) Discuss the principle, procedure and significance of acid value. (7)
(b) Explain any two methods for determination of Vitamin B_1 (8)

3 Write about the following
(a)Analysis of thickening and jelling agents. (7)
(b) Method of detection of permitted and non permitted dyes. (8)

4 Explain the following methods for determination of fat inmilk. (15)
(a) Gerber method
(b) Rose- Gottlieb method

synthetic pyrethroid in fruits and vegetables. 8)

5 (a) Explain the multi residue gas chromatographic method for determination of (7)
(b) Write a note on BIS and AGMARK.
(a) Determination of titrable acidityCollegein dried milk. (8)

6 Write about the following.

(b) Analysis of preservatives (7)

7 Explain different methods for etermination of Vitamin B_{12} (15)

8 Explain the determination ethanol and methanol in wine samples. (15)

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Code No. 1152/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Main) Examination, February 2018 Subject: Pharmaceutical Validation

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Define qualification and validation. Write about design qualification and performance qualification phases of analytical equipment. 10
(b) Explain the calibration procedure of glassware used in analytical work. 5

2 (a) How do you qualify UV spectrophotometers? Explain. 10
(b) Write short note on re-validation process. 5

3 Write short notes on
(a) Cleaning validation 8
(b) Pharmaceutical water system validation 7

4 Explain the ICH guidelines for validation of new analytical procedures. 15

5 (a) What is an intellectual property right? Explain about different types of IPR. 8

6 (a) Write about international patenting requirement procedure. 8
(b) Write about the role of Intellectual Property in Pharmaceutical Industry. Give few recent examples. 7

7 (a) Explain the procedure involved in qualification and calibration of FTIR. 10
(b) Write about factory acceptancetest and site acceptance test. 5

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8 (a) Explain the steps involved in preparation of validation Master Plan (VMP). 10
(b) Write short note on Digital significance of 21 CFR part II. 5

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Code No. 1151/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Main) Examination, February 2018 Subject: Advanced Pharmaceutical Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Explain in-detail about impurity profiling of new drug product. (10)
(b) Write classification and identification of elemental impurities. (5)

2 (a) Explain briefly protocol adopted for stability testing of drugs. (8)
(b) Describe briefly accelerated stability studies and determination of shelf-life. (7)

3 (a) Explain various principles and testing procedures involved in degradant characterization. (8)
(b) Describe ICH stability guidelines for biological products. (7)

4 (a) Write an account on requirements for stability testing of phytopharmaceuticals. (7)
(b) Describe the principle and methods involved in HPLC finger printing with suitable examples. (8)

5 (a) Mention different types of tetanus vaccine. Explain bioassay of adsorbed tetanus vaccine. (8)
(b) Describe the principle and procedure involved in bioassay of any one biological product. (7)

6 (a) Describe the principle, instrumentation and applications of radio immune assay. (8)
(b) Describe procedures for separation of bound and unbound drug during immunoassay. (7)

7 (a) Write an account on elemental impurities and their determination. (10)
(b) Explain basic principle and applications of PCR studies. (5)

8 (a) Write classification, potential sources, control and identification of residual solvent impurities. (10)
(b) Describe the production of antibodies. (5)

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Code No. 1153/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Main) Examination, February 2018 Subject: Food Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 Define carbohydrates? Explain various methods for determination of carbohydrates. (15)

2 (a) List out the quality control tests for fats and oils. Explain the principle, procedure and significance of saponification value. (7)
(b) Explain any two methods for determination of vitamin A. (8)

3 Write about the following.
(a) Analysis of preservatives. (8)
(b) Analysis of different flavors and flavor enhancers. (7)

4 (a) Explain the Gerber method for analysis of fat in milk. (7)
(b) Explain Kjeldahl method for determination of protein in ice creams. (8)

5 Explain various methods for determination of organophosphorus and organochlorine pesticides in fruits and vegetables. (15)

6 (a) Give any two methods for determination of Vitamin B_{12}. (10)
(b) Explain 2, 6 dichlro phenol indophenol method for determination of Vitamin C. (5)

7 Write about the following
(a) BIS and AGMARK. (8)
(b) Determination of salt content in butter by Volhard's method. (7)

8 (a) Explain the Karl fischer method for determination of moisture in proteins. (7)
(b) Explain the determination of Ethyl alcohol content in Beer. (8)

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