Code No. D-8303/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Supply) Examination, May 2022

Subject: Quality Control and Quality Assurance

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

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

1 Write a short note on the following:
(a) Quality control
(b) Quality Assurance
(c) Non clinical testing.

2 Explain the various CPSCEA guidelines for laboratory animal facility.

3 Define IPQC. Explain in detail about various IPQC tests for
(a) Capsules
(b) Parenterals.

4 Give a brief note on:
(a) Quality audit plan
(b) Protocols and reports
(c) Distribution records.

5 Discuss the Good laboratory practices for a quality control laboratory in detail.

6 (a) Explain the various documents to be maintained by the quality control department.
(b) Explain Master formula and Batch formula records.

7 Explain various CGMP guidelines according to schedule M.

8 Write a note on:
(a) Sanitation of manufacturing premises.
(b) Drug product inspection.
(c) Production record review.

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Code No. D-8302/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Supply) Examination, May 2022

Subject: Modern Bio Analytical Techniques

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

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

1 (a) Write the general principle and procedure involved in protein precipitation method.
(b) Explain the Bioanalytical method validation as per USFDA guidelines.

2 (a) Describe the compendial methods of dissolution testing.
(b) Write about different experimental methods for solubility determination.

3 (a) Discuss about Cytochrome P450 based drug interactions.
(b) Write about clinical significance of Bioequivalence studies.

4 (a) Write about cryopreservation and storage of cells.
(b) Describe different techniques for characterization of cells along with their applications.

5 (a) Discuss in detail about Bioequivalence protocol.
(b) Write about clinical significance of Bioequivalence studies.

6 (a) Write about equipment used in cell culture lab.
(b) Discuss about Biopharmaceutical factors affecting drug bioavailability.

7 (a) Discuss about different approaches for quantification of metabolites.
(b) Write about different cell culture media.

8 (a) Write about in-vivo and in-vitro methods for checking cellular permeability of new drug products.
(b) Write in brief about drug interactions linked to transporters.

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Code No. D8069/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Main & Backlog) Examination, December 2021

Subject: Quality Control and Quality Assurance

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

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

1 Describe the concept, components of Quality control and Quality assurance.

2 Explain the various CPSCEA guidelines for laboratory animal facility.

3 Define IPQC explain in detail various IPQC tests for
(a) Tablets.
(b) Ointments.

4 Write a brief note on:
(a) Quality audit plan.
(b) Batch formula record.

5 Write a note on:
(a) Sanitation of manufacturing premises.
(b) Drug product inspection.
(c) Production record review.

6 Describe sources of contamination and methods of contamination control.

7 Write in detail about
(a) SOP
(b) Protocols and reports.

8 Discuss the Good laboratory practices for a quality control laboratory in detail.

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Code No. D8068/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Main & Backlog) Examination, November 2021

Subject: Modern Bio Analytical Techniques

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

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

1 (a) Explain about different sample preparation approaches involved in bio-analytical methods.
(b) Explain the following validation parameters in bio-analytical method validation as per
USFDA guidelines.
Linearity
Specificity

2 (a) What is BIoavaialbility? Give the Biopharmaceutical Factors affecting drug Bioavailability.
(b) Write the Biopharmaceutics classification system defined by FDA.

3 (a) What is enzyme inhibition? Discuss about drug interactions due to enzyme inhibition with examples.
(b) Discuss about drug-protein binding interactions with examples.

4 (a) Write about principles, instrumentation and applications of flow cytometry.
(b) Write about basic equipments used in cell culture lab.

5 (a) Explain different study designs in bioequivalence studies.
(b) Differentiate absolute and relative bioavailability with illustrative examples and equations.

6 (a) Write about cryopreservation and storage of cells.
(b) Discuss the importance and applications of Toxicokinetic studies.

7 (a) Discuss about different approaches for identification of metabolites,
(b) Write short note on clinical significance of bioequivalence studies.

8 (a) Describe the compendial methods of dissolution testing.
(b) Write about *in-vivo* and *in-vitro* methods for checking cellular permeability of new drug products.

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Code No. D8067/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Main & Backlog) Examination, December 2021

Subject: Advanced Instrumental Analysis

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

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

1 (a) Explain about method development and trouble shooting in HPLC.
(b) Write about Chiral analysis of Pharmaceuticals using HPLC.

2 (a) Discuss about Ion-Pair chromatography.
(b) Explain about head space sampling and columns used in Gas chromatography.

3 (a) Write the principle and applications of Super critical fluid chromatography.
(b) Explain about principles and methods of capillary electrophoresis.

4 Explain about the following ionization techniques in mass spectrometry.
(a) FAB (b) Electron impact (c) MALD (d) ESI.

5 (a) Write about spin-spin coupling and coupling constant.
(b) Write in detail about COSY.

6 (a) Write about Nano Liquid Chromatography.
(b) Discuss the principle and detectors use din Gas chromatography.

7 (a) Explain about various parameters used in HPLC.
(b) Discuss about 2D NMR.

8 (a) Explain about Quadrpole and Time of flight in MS analysis.
(b) Write about LC-NMR.

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Code No. D8070/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Main & Backlog) Examination, December 2021

Subject: Herbal and Cosmetic Analysis

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

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

1 (a) Write a notes on efficacy of herbal medicines products.
(b) Discuss the validation of herbal therapies.

2 (a) How can we determine microbial contamination in herbal formulations?
(b) How foreign matter is determined in herbal drugs?

3 (a) Explain the adulterant screening of herbal drugs and their products using modern analytical techniques.
(b) Write notes on WHO guidelines on quality assessment of herbal drugs.

4 (a) Explain WHO guidelines for safety monitoring of natural medicine.
(b) Write notes on bio drug-food interactions with suitable examples.

5 (a) Explain the Indian standard specification laid down for sampling and testing of dental products.
(b) Write a note on analysis of skin creams as per BIS.

6 Write notes on
(a) Global marketing management.
(b) Determination of ester value of cosmetic products.
(c) Analysis of personal hygiene preparations.

7 Write about Indian patent law applicable for herbal drugs and natural products.

8 (a) Write notes on pharmacokinetic issues related to herbal remedies.
(b) Discuss on an herbal monograph.

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Code No: 12148/PCI

FACULTY OF PHARMACY

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

July 2021

Subject: Modern Bio analytical techniques

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

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

1. a. Write about Liquid-Liquid extraction as sample preparation technique.
   b. Explain the Bioanalytical method validation as per USFDA guidelines.

2. a. Describe the compendial methods of dissolution testing.
   b. Write about different experimental methods for solubility determination.

3. a. Explain about different pharmacokinetic drug interactions.
   b. Write the importance and applications of Toxicokinetic studies.

4. a. Write about cryopreservation and storage of cells.
   b. Describe different techniques for characterization of cells along with their applications.

5. a. Explain different study designs in bioequivalence studies.
   b. Differentiate absolute and relative bioavailability with illustrative examples and equations.

6. a. Write about basic equipments used in cell culture lab.
   b. Write about principles, instrumentation and applications of flow cytometry.

7. a. Discuss about different approaches for identification of metabolites.
   b. Write short note on clinical significance of bioequivalence studies.

8. a. Describe the principles and applications of Cell viability assays.
   b. Write about Rat liver microsomes and Human Liver microsomes.

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Code No. 12147/PCI

FACULTY OF PHARMACY

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

Examination, August 2021

Subject: Advanced Instrumental Analysis

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

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

1. a) Explain the following.
   i) Capacity factor ii) Plate heigent iii) Resolution
   b) Explain briefly about
   i) UPLC ii) Chiral analysis in HPLC

2. a) Explain the following
   i) Ion pair chromatography ii) Affinity chromatography
   b) Explain principle and derivitization techniques involved in gas chromatography?

3. a) Explain the principle and instrumentation of super critical fluid chromatography
   b) Explain characteristics, Principles, methods and modes of capillary electrophoresis

4. a) Explain the instrumentation and fragmentation rules of mass spectrometry
   b) Explain the following ionization techniques
   i) Electron impact ii) Field lionization

5. Explain the following
   i) Chemical shift ii) Spin – spin coupling iii) Double resonance

6. Explain instrumentation, Solvents and various trouble shooting methods in HPLC

7. Explain about isotopic peaks, metastable ions and various mass analysers used in mass spectrometry

8. Explain the following techniques?
   i) FT-NMR ii) 13CNMR iii) Cosy

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Code No: 12149/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) II-Semester (PCI) (Suppl.)

Examination, July 2021

Subject: Quality control and Quality assurance

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

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

1) Write a detailed note on requirements and guidelines of GMP (schedule M) in Pharma industries?

2) Write a short note on the following
   a) Quality control.
   b) Quality assurance.
   c) Non clinical testing.

3) Define IPQC. Explain in detail about various IPQC tests for
   a) Tablets
   b) Ophthalmics

4) Explain
   a) Batch formula Record
   b) Master formula Record

5) Write the detail notes on the following
   a) Expiry date calculation.
   b) Limitations of production.
   c) Calculation of yields.

6) Explain the various CPSCEA guidelines for laboratory animal facility.

7) Describe the quality control test for containers, closures and secondary packing materials?

8) Write a note on
   a) Sanitation of manufacturing premises.
   b) Drug product inspection.
   c) Production record review.

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Code No: 12150/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmceutical. Analysis) II-Sem. (PCI) (Suppl.)

Examination, July 2021

Subject: Herbal & Cosmetic Analysis

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

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

1. a) How can we differentiate herbal drugs from conventional drugs?
   b) Explain the validation protocol for herbal therapies.

2. a) What is adulteration and deterioration? Write the causes and measures of it.
   b) Explain the DNA finger printing technique in identification of drugs of natural origin.

3. a) Give brief explanation on adulterant screening using modern analytical instruments.
   b) Write the protocol for stability testing of herbal drugs.

4. a) Explain the bio-drug and bio-food interactions with suitable examples.
   b) Write a note on challenges in monitoring the safety of herbal medicines.

5. Explain the general methods of analysis of raw materials used in cosmetic manufacture as per BIS.

6. Write the analysis of baby care products and dental products as per BIS.15

7. Write notes on:
   a) Efficacy of herbal medicine products
   b) Global marketing management of herbal drugs
   c) Determination of acid value of cosmetic products.

8. Compare the monographs of herbal drugs of different pharmacopoeias.

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Code No: 6362/PCI

FACULTY OF PHARMACY

M. Pharmacy (Phar. Analysis) II – Semester. (PCI) (Main & Backlog)

Examination, October 2020
Subject : Modern Bio-Analytical Techniques

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

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

1. a) Explain about different sample preparation approaches in bioanalytical methods.
   b) Explain the following validation parameters in bioanalytical method validation as per USFDA guidelines.
      i) Linearity ii) Precision

2. a) Discuss about Biopharmaceutical factors affecting drug bioavailability.
   b) Write the Biopharmaceutics classification system defined by FDA.

3. a) Explain different types of PK-PD drug interactions with suitable example.
   b) Discuss the role of LC-MS in bioactivity screening and proteomics.

4. a) Write about basic equipments used in cell culture lab.
   b) Write about principles, instrumentation and applications of flow cytometry.

5. a) Explain different methods for assessment of bioavailability of new drug product.
   b) Write the clinical significance of bioequivalence studies.

6. a) Discuss the importance and applications of Toxicokinetic studie.
   b) Write about different cell culture media.

7. a) Write about *in-vivo* and *in- vitro* methods for checking cellular permeability of new drug products.
   b) Write in brief about drug interactions linked to transporters.

8. a) Describe the principles and applications of Cell viability assays.
   b) Write about Rat liver microsomes and Human Liver microsomes.

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Code No: 6361/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) II-Semester (PCI) (Suppl.) Examination,

October 2020

Subject : Advance Instrumental Analysis

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

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

1. Explain Various parameters to be varied in HPLC method development

2. Explain the following
   a. Chiral chromatography
   b. Preparative HPLC

3. a) Explain the stationary phases and principles involved in size exclusion chromatography.
   b) Explain about instrumentation and detectors used in gas chromatography.

4. Explain the principle, instrumentation and applications of super critical fruid chromatography.

5. a) Explain about Mc – lafferty rearrangement?
   b) Explain the following imization techniques a. FAB b. MALDI c. EII

6. a) What is chemical shift and explain about factors inflaming chemical shift
   b) Explain the following
      a. Coupling constant
      b. 2D – NMR

7. a) Write in detail about capillary electrophori's
   b) Explain the following
      a. HPTLC
      b. Ion-pair chromatography

8. Explain the following
   a) Polysaceharide CSP's b. LC-MS
   b) Qudrapole mass analyser

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Code No: 6363/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) II-Semester (PCI) (Main & Backlog)

Examination, October 2020

Subject: Quality Control and Quality Assurance

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

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

1) Write a detailed note on requirements and guidelines of GMP (schedule M) in Pharma industries?

2) Write a short note on the following
   a) Quality control.
   b) Quality assurance.
   c) Non clinical testing.

3) Define IPQC. Explain in detail about various IPQC tests for
   a) Tablets
   b) Ophthalmics

4) Explain
   a) Batch formula Record
   b) Master formula Record

5) Write the detail notes on the following
   a) Expiry date calculation.
   b) Limitations of production.
   c) Calculation of yields.

6) Explain the various CPSCEA guidelines for laboratory animal facility.

7) Describe the quality control test for containers, closures and secondary packing materials?

8) Write a note on
   a) Sanitation of manufacturing premises.
   b) Drug product inspection.
   c) Production record review.

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Code No: 6364/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Analysis) II-Sem. (PCI) (Main & Backlog)

Examination, October 2020

Subject: Herbal & Cosmetic Analysis

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

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

1. (a) Write the WHO guidelines for herbal drug standardization.
   (b) Compare the herbal drugs with conventional drugs.

2. (a) Explain the different types adulteration of herbal drugs with suitable examples
   (b) How foreign matter is determined in herbal drugs?

3. Explain the adulterant screening of herbal drugs and their products using modern analytical techniques.

4. (a) Write the WHO guidelines for safety monitoring of natural medicine.
   (b) Explain bio-drug interactions with suitable examples.

5. Write notes on determination of
   (a) Saponification value
   (b) Moisture content.
   (c) Heavy metals

6. Write notes on
   (a) DNA finger printing technique.
   (b) Effect of herbal medicine on clinical laboratory testing
   (c) Analysis of personal hygiene preparations.

7. Write about Indian patent law applicable for herbal drugs and natural products.

8. (a) Write the spontaneous reporting schemes for bio-adverse reactions.
   (b) Write the general methods of analysis of raw materials used in cosmetic manufacture as per BIS.

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Code No: 6136/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma Analysis) II-Semester (PCI) (Suppl.) Examination, January 2020

Subject: Quality Control and Quality Assurance

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

Note: Answer Any Five Questions. ALL Questions carry Equal Marks.

1	a) Explain about Quality Control and Quality Assurance.	8
	b) Write in detail about Total Quality Management.	7
2	a) Explain the control on environmental pollution.	8
	b) Explain the maintenance of sterile areas.	7
3	Write in detail about inprocess Quality Control (IPQC) testing of Tablets and parenterals.	15
4	a) Explain the various documents to be maintained by the quality control department.	7
	b) Explain Master formula and Batch formula records.	8
5	Discuss about	
	a) Mix-up's and cross contamination.	8
	b) Aseptic process control	7
6	Discuss the Good laboratory practices for a quality control laboratory in detail.	15
7	Explain the following	
	a) Non-clinical testing.	5
	b) Controls on animal house	5
	c) Report Preparation.	5
8	Explain various quality control tests for Glass as a packaging material.	15

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Code No. 6134/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) II-Semester (PCI) (Suppl.) Examination, January 2020

Subject : Advance Instrumental Analysis

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

Note: Answer Any Five Questions. All Questions Carry Equal Marks**.**

1. a) Explain about various parameters like peak shape. Capacity factor, plate number plate height and resolutions to be considered in HPLC chromatogram 10
   b) Write about HPLC importance in chiral analysis of pharmaceuticals? 5

2. a) Discuss about ion pair chromatography 5
   b) Explain the instrumentation and pharmaceutical applications of HPTLC 10

3 a) Write the principle and instrumentation of SFC? 7
   b) Explain about CE-MS Hyphenation? 8

4. a) Elaborate with neat sketch diagram different types of ionization techniques and analyzers in mass spectrometry? 15

5. a) What do you mean by chemical shift? Explain the various factors influencing it? 10
   b) Write about correlative spectroscopy? (COSY) 5

6. a) Write about various columns used in GLC? 8
   b) Discuss the principle and applications of size exclusion chromatography? 7

7. a) Explain about HILIC approach in HPLC? 7
   b) Discuss about C^{13} NMR 8

8. a) Explain about Q-TOF hyphenation (MS.MS) 7
   b) Write the principle and stationary phases used in affinity chromatography? 8

Code No. 6137/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) II-Semester (PCI) (Suppl.) Examination, January 2020

Subject: Herbal & Cosmetic Analysis

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

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

1 Explain the following: (15)
(a) Iodine value
(b) Peroxide value
(c) Ester value

2 Explain the following in the evaluation of cosmetic products. (15)
(a) Moisture content
(b) Viscosity
(c) Heavy metals

3 What are the different sampling and testing procedures of the following cosmetics products. (15)
(a) Baby care products
(b) Dental products
(c) Skin care products

4 Explain briefly the DNA finger printing techniques in identification of drugs. (15)

5 Briefly explain the WHO and AYUSH guidelines for safety monitoring of natural products. (15)

6 (a) Explain briefly the adulteration screening using modern analytical instruments. (8)
(b) Briefly explain the protocols for stability testing of natural products. (7)

7 (a) Describe different measures used in monitoring the safety of herbal products. (7)
(b) Explain with suitable examples about: (8)
(i) bio drug –drug interactions (ii) bio drug-food interactions

8 Explain the protocols of Indian and International patent laws applicable in herbal drugs and natural products. (15)

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Code No: 6135/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma Analysis) II- Semester (PCI) (Suppl.) Examination, January 2020

Subject: Modern Bio Analytical Techniques

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

Note: Answer Any Five Questions. ALL Questions carry Equal Marks.

1. a) What is the importance of extraction of drugs and metabolites from biological matrices? 5

   b) Describe the bioanalytical method procedure for liquid and solid phase extraction? 10

2. a) Mention the different alternative methods of dissolution testing. 11

   b) Define solubility & permeability based on biopharmaceutics classification system. 4

3. Describe various drug (pk-pd) interactions)? 15

4. Discuss the principles and applications of flow cytometry. 15

5. Write the different methods for the assessment of bioavailability and bioequivalence? 15

6. a) Explain the drug permeability by in-vivo method? 8

   b) Write notes on cross over design. 7

7. Write notes on the following

   a) Drug interaction linked to transporters. 8

   b) Cryopreservation techniques. 7

8. Discuss about the design and evaluation of bioequivalence studies. 15

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Code. No: 13335/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Analysis) II-Semester (PCI) (Main) Examination, August 2019

Subject : Advanced Instrumental Analysis

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

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

1. (a) Explain the following chromatographic parameter (i) Capacity factor (ii) Selectivity (iii) Resolution 9
   (b) Explain the principle involved in UPLC and compare it with HPLC in terms of different parameters? 7

2. (a) Explain the Principle involved in size exclusion chromatography and write about commercially available columns and their properties. 7
   (b) Explain in detail about derivatisation in Gas chromatography 8

3. (a) Explain the principle and applications of super critical fluid chromatography? 7
   (b) What is capillary electrophoreses? Explain its principle, methods and modes of CE? 8

4. (a) What is the theory involved in mass spectrometry and explain the following ionization techniques (i) Electron impact (ii) field ionization (iii) MALDI ionization 10
   (b) Explain Mc. Lafferty arrangement with example. 5

5. (a) Define chemical shift? Explain the factors influencing chemical shift. 7
   (b) Draw a schematic NMR spectra and explain the interpretation for the following compounds (i) Diethylether (ii) Ethoxyacetic acid (iii) n- propyl formate

6. (a) Explain the following techniques
   1. NOESY 2. COSY 8
   (b) Explain the following mass analyzers in detail
   1. Quadruple 2. Time of flight

7. (a) What is enantiomeric separations? Explain role of HPLC in chiral analysis? 7
   (b) Write the principle, head space sampling and columns used in gas chromatography

8. (a) Explain the principle involved in the following hyphenated techniques
   (i) LC-MS (ii) LC-NMR (iii) CE-MS 7
   (b) Write the applications of
   (i) LC-MS (ii) LC-NMR (III) CE-MS 8

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Code No. 13338/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) II-Semester (PCI) (Main) Examination, August 2019

Subject: Herbal & Cosmetic Analysis

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

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

1 (a) Write a note on efficacy of herbal medicine products. (5)
(b) Explain the pharmacodynamic and pharmacokinetic issues of herbal medicines. (10)

2 (a) Write about sampling procedures of drugs of natural origin. (7)
(b) How foreign matter is determined in herbal drugs? (8)

3 (a) Explain the adulterant screening of herbal drugs and their products using modern analytical techniques. (10)
(b) Write a note on effect of herbal medicine on clinical laboratory testing. (5)

4 (a) Write the spontaneous reporting schemes for bio drug adverse reactions and bio drug –drug interactions. (10)
(b) Give the challenges in monitoring the safety of herbal medicine. (5)

5 (a) Explain the Indian standard specification laid down for sampling and testing of baby care products. (10)
(b) Write a note on analysis of skin creams as per BIS. (5)

6 Write notes on : (3x5)
(a) Global marketing management
(b) Determination of ash value of cosmetic products
(c) Analysis of personal hygiene preparations

7 Write about Indian patent law applicable for herbal drugs and natural products. (15)

8 (a) Write about DNA finger printing techniques in identification of natural drugs. (7)
(b) Discuss the stability testing of natural products. (8)

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Code No: 13337/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma Analysis) II- Semester (PCI) (Main) Examination, Aug. 2019

Subject: Quality Control and Quality Assurance

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

Note: Answer Any Five Questions. ALL Questions carry Equal Marks.

1. Write a detailed note on requirements and guidelines of GMP(schedule M) in Pharma industries? 15
2. Write brief notes on
   a) Good warehousing practice 7
   b) Pharmaceutical inspection convention 8
3. Describe the quality control test for containers, closures and secondary packing materials? 15
4. a) Write a short note on good documentation practice guidelines. 6
   b) What are the different types of audits? Explain in detail audit methods and techniques involved in it. 9
5. Describe the guidelines of CPCSEA 15
6. a) Explain the quality control test for ointments according to IP 8
   b) Release of finished product. 7
7. Write brief notes on following
   a) Change control 7
   b) SOP 8
8. Describe sources of contamination and methods of contamination control? 15

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Code No: 13336/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma Analysis) II- Semester (PCI) (Main) Examination, Aug. 2019

Subject: Modern Bio Analytical Techniques

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

Note: Answer Any Five Questions. ALL Questions carry Equal Marks.

1. a) What is the importance of extraction of drugs and metabolites from biological matrices?

   b) Describe the bioanalytical method procedure for liquid and solid phase extraction? 15

2. a) Mention the different alternative methods of dissolution testing transport models 11

   b) Define solubility & permeability based on biopharmaceutics classification system. 4

3. Describe various drug interaction (pk-pd) interactions)? 15

4. Discuss the principles and applications of flow cytometry. 15

5. Write the different methods for the assessment of bioavailability and bioequivalence? 15

6. a) Explain the drug permeability by in-vivo method? 8

   b) Write notes on cross over design. 7

7. Write notes on the following

   a) Drug interaction linked to transporters. 8

   b) Cryopreservation techniques. 7

8. Discuss about the design and evaluation of bioequivalence studies. 15

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Code No. 13182/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Analysis) II-Semester (PCI) (Suppl.) Examination, February 2019

Subject: Herbal & Cosmetic Analysis

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

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

1 Write a short note on the following: (15)
   a) Herbal and Conventional drugs
   b) Adulteration and Deterioration
   c) Types of adulteration

2. Write a short note on the following: (15)
   a) WHO guidelines
   b) AYUSH guidelines

3. Explain briefly about: (15)
   a) acid value
   b) saponification value
   c) rancidity

4. Explain briefly the evaluation of the following cosmetic products according to Bureau of Indian Standards. (15)
   a) Hair products
   b) Skin creams
   c) Lip sticks

5. Write a note on effect of herbal medicine on clinical lab testing? (15)

6. Explain briefly the stability testing of natural products? (15)

7. Explain briefly about bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples? (15)

8. Explain briefly the WHO guidelines in quality assessment of herbal drugs? (15)

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Code No. 13181/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II-Semester (PCI) (Suppl.) Examination, February 2019

Subject: Quality Controls and Quality Assurance

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

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

1 Write a short note on the following
   a) Quality control. (5)
   b) Quality assurance. (5)
   c) Non clinical testing. (5)

2 Explain the various CPSCEA guidelines for laboratory animal facility. (15)

3 Define IPQC. Explain in detail about various IPQC tests for
   a) Capsules. (8)
   b) Parenterals. (7)

4 Give a brief note on
   a) Quality audit plan. (5)
   b) Protocols and reports. (5)
   c) Distribution records. (5)

5 Discuss the Good laboratory practices for a quality control laboratory in detail. (15)

6 a) Explain the various documents to be maintained by the quality control department. (7)
   b) Explain Master formula and Batch formula records. (8)

7 Explain various cGMP guidelines according to schedule M.

8 Write a note on
   a) Sanitation of manufacturing premises (5)
   b) Drug product inspection. (5)
   c) Production record review. (5)

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Code No. 13179/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II-Semester (PCI) (Suppl.) Examination, February 2019

Subject: Advance Instrumental Analysis

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

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

1 Write the principle involved in HPLC and explain the following.
(a) Peak shapes (b) Plate number (c) Plate height (10)
(d) Explain various pumps used in HPLC. (5)

2 Explain the principle and stationary phases of the following: (2x7½)
(a) Ion Exchange chromatography (b) Affinity chromatography

3 Write in detail about Instrumentation, columns and detectors used in Gas chromatography. (15)

4 (a) Explain the instrumentation and applications of super critical fluid chromatography. (7)
(b) Explain characteristics and pharmaceutical analysis of capillary electrophoresis. (8)

5 (a) Explain the following ionization techniques
(a) chemical ionization (b) FAB (c) ESI (9)
(b) Explain fragmentation pattern of
(a) Alcohols (b) Aldehydes (c) aliphatic acids (6)

6 Explain the following: (3x5)
(a) Spin-spin coupling
(b) Coupling constant
(c) Nuclear magnetic double resonance

7 Write about the principles instrumentation and applications of : (2x7½)
(a) TLC
(b) Size exclusion chromatography

8 (a) Explain in detail about chiral stationary phases (CSP's). (6)
(a) Explain principle and applications of HPTLC. (9)

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Code No. 13180/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Analysis) II-Semester (PCI) (Suppl.) Examination, February 2019

Subject: Modern Bio Analytical Techniques

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

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

1	Write about the following sample preparation techniques. (a) Solid phase extraction (b) Liquid Liquid extraction (c) Explain the Bioanalytical method validation as per USFDA guidelines.	6 9
2	(a) Discuss about Biopharmaceutical factors affecting drug bioavailability. (b) Write the Biopharmaceutics classification system defined by FDA.	10 5
3	(a) What is enzyme inhibition? Discuss about drug interactions due to enzymeinhibition with examples. (b) Discuss about drug-protein binding interactions with examples.	7 8
4	(a) Write about principles, instrumentation and applications of flow cytometry. (b) Write about cryopreservation and storage of cells.	9 6
5	(a) Explain different study designs in bioequivalence studies. (b) Differentiate absolute and relative bioavailability with illustrative examples and equations. **Dr. .Adish**	10 5
6	(a) Discuss the importance and applications of Toxicokinetic studies. (b) Write about basic equipments used in cell culture lab.	8 7
7	(a) Discuss about different approaches for identification of metabolites. (b) Write short note on clinical significance of bioequivalence studies.	10 5
8	(a) Describe the compendia methods of dissolution testing. (b) Write about *in-vivo* and *in- vitro* methods for checking cellular permeabilityof new drug products.	7 8

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Code No. 1205/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Analysis) II-Semester (PCI) (Main) Examination,

August 2018

Subject: Advance Instrumental Analysis

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

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

1 a. Explain about various types of columns and column problems in HPLC. (9)
b. Write the principle and advantages of Ultra and Nano liquid chromatography? (6)

2 a. Discuss about ion exchange chromatography and write in detail about its applications? (7)
b. Explain the various components of HPTLC and write its advantages over column chromatography? (8)

3 a. Write about various detectors used in GLC? (10)
b. Explain the principle and basic configuration of capillary electrophoresis? (5)

4 Elaborate with neat sketch, the instrumentation of mass spectrometry? (15)

5 a. What do you mean by chemical shift? Explain the various factors influencing it? (10)
b. Explain about nuclear double resonance and its applications? (5)

6 a. Mention various tandem MS/MS systems and explain any one briefly with neat sketch? (9)
b. Discuss the principle and applications of size exclusion chromatography? (6)

7 a. Explain about preparative HPLC? (7)
b. Discuss about FT NMR with reference to C^{13} NMR (8)

8 a. Explain about LC-NMR hyphenation. (9)
b. Write about fragmentation ruleS in MS? (6)

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Code No. 1206/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Analysis) II-Semester (PCI) (Main) Examination, August 2018

Subject: Modern Bio Analytical Techniques

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

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

1 Write notes on bio analytical method validation as per FDA Guidelines? (15)

2 Explain the factors effecting for enhancement of bioavailability of drugs? (15)

3 Describe the Cytochrome P450-based drug interactions ? (15)

4 Write brief notes on
a) Various types of cell culture (8)
b) LC-MS in bioactivity screening and proteomics (7)

5 Describe the principles and applications of cell viability assays of MTT assays?(15)

6 Write the alternate methods for dissolution testing? (15)

7 a) Define and explain bioavalability, bioequivalence and biosimilar. (6)
b) Write about various design to conduct bioavailability studies. (9)

8 a) Discuss about the bioanalytical methods such as protein precipitation. (7)
b) Describe the various solubility techniques. (8)

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Code No. 1208/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm.Analysis) II-Semester (PCI) (Main) Examination, August 2018

Subject: Herbal & Cosmetic Analysis

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

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

1 (a) Write note Herbal medicines Vs Conventional drugs. 5
(b) Explain the standardization of herbal drugs according to WHO guidelines. 10

2 What is adulteration and deterioration? Explain types, causes and measure of adulteration. 15

3 (a) Describe the stability testing of natural products with suitable examples. 8
(b) Write a note on effect of herbal medicine on clinical laboratory testing. 7

4 (a) Write the spontaneous reporting schemes for bio drug adverse reactions and bio drug-food interactions. 10
(b) Write about AYUSH guideline on safety monitoring of natural medicine. 5

5 Explain the general methods of analysis of raw materials used in cosmetic manufacture as per BIS. 15

6 Write the analysis of lipsticks and hair products as per BIS. 15

7 Write notes on 3x5=15
(a) Determination of pesticide residues in herbal formulations.
(b) Challenges in monitoring the safety of herbal medicines.
(c) Determination of iodine value of cosmetic products.

8 Write about Indian patent law applicable for herbal drugs and natural products. 15

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Code No. 1207/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm.Analysis) II-Semester (PCI) (Main) Examination, August 2018

Subject: Quality Controls and Quality Assurance

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

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

1 Describe concept, components of Quality Assurance and Quality control. (15)

2 What are the requirements of an organization and personnel as per USFDA? (15)

3 Describe the in process quality control and finished products quality control of tablet according to Indian pharmacopeia. (15)

4 Write a brief notes on a) Quality audit plan (8)
b) Batch formula record (7)

5 Write the detail notes on the following
(a) Expiry date calculation (5)
(b) Limitations of production (5)
(c) Calculation of yields (5)

6 a) Describe the overview of ICH Guidelines with Q series (8)
b) Write notes on SOP. (7)

7 a) Write note on the aseptic process control. (8)
b) Write about the organization and personnel responsibilities as per WHO. (7)

8. a) Describe the onsite sanitation of manufacturing premises (8)
b) Write note on finished product (7)

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Code No. 1205/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Analysis) II-Semester (PCI) (Main) Examination,

August 2018

Subject: Advance Instrumental Analysis

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

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

1 a. Explain about various types of columns and column problems in HPLC. (9)
b. Write the principle and advantages of Ultra and Nano liquid chromatography? (6)

2 a. Discuss about ion exchange chromatography and write in detail about its applications? (7)
b. Explain the various components of HPTLC and write its advantages over column chromatography? (8)

3 a. Write about various detectors used in GLC? (10)
b. Explain the principle and basic configuration of capillary electrophoresis? (5)

4 Elaborate with neat sketch, the instrumentation of mass spectrometry? (15)

5 a. What do you mean by chemical shift? Explain the various factors influencing it? (10)
b. Explain about nuclear double resonance and its applications? (5)

6 a. Mention various tandem MS/MS systems and explain any one briefly with neat sketch? (9)
b. Discuss the principle and applications of size exclusion chromatography? (6)

7 a. Explain about preparative HPLC? (7)
b. Discuss about FT NMR with reference to C^{13} NMR (8)

8 a. Explain about LC-NMR hyphenation. (9)
b. Write about fragmentation ruleS in MS? (6)

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