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 Hrs **Max Marks: 75**

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

1	a)	Explain abt Quality Control and Quality Assurance.	8
	b)	Write in detail abt 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 abt inprocess Quality Control (IPQC) testing of Tablets and parenterals.	15
4	a)	Explain the varis documents to be maintained by the quality control department.	7
	b)	Explain Master formula and Batch formula records.	8
5		Discuss abt	
	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 varis 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 Hrs **Max. Marks: 75**

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

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

2. a) Discuss abt 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 abt 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 y mean by chemical shift? Explain the varis factors influencing it? 10
   b) Write abt correlative spectroscopy? (COSY) 5

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

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

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

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Code No. 6137/PCI

FACULTY OF PHARMACY

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

Subject: Herbal & Cosmetic Analysis

Time: 3 Hrs **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 abt: (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 Hrs **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 varis 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 abt 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 Hrs **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 abt commercially available columns and their properties. 7
   (b) Explain in detail abt 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 compnds (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 Hrs **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 abt 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 spontanes repor ting 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 abt Indian patent law applicable for herbal drugs and natural products. (15)

8 (a) Write abt 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 Hrs **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 warehsing 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 srces 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 Hrs **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 varis 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 abt 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 Hrs **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 abt: (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 abt 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 Hrs **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 varis CPSCEA guidelines for laboratory animal facility. (15)

3 Define IPQC. Explain in detail abt varis 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 varis documents to be maintained by the quality control department. (7)
   b) Explain Master formula and Batch formula records. (8)

7 Explain varis 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 Hrs **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 varis 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 abt 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 cpling
(b) Cpling constant
(c) Nuclear magnetic dble resonance

7 Write abt the principles ins trumentation and applications of : (2x7½)
(a) TLC
(b) Size exclusion chromatography

8 (a) Explain in detail abt chiral stationary phases (CSP's). (6)
(b) 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 Hrs **Max. Marks: 75**

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

1	Write abt the following sample prepar ation techniques. (a) Solid phase extraction (b) Liquid Liquid extraction (c) Explain the Bioanalytical method validation as per USFDA guidelines.	6 9
2	(a) Discuss abt Biopharmaceutical factors affecting drug bioavailability. (b) Write the Biopharmaceutics classification system defined by FDA.	10 5
3	(a) What is enzyme inhibition? Discuss abt drug interactions due to enzyme inhibition with examples. (b) Discuss abt drug -protein binding interactions with examples.	7 8
4	(a) Write abt principles, instrumentation and applications of flow cytometry. (b) Write abt 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.	10 5
6	(a) Discuss the importance and applications of Toxicokinetic studies. (b) Write abt basic equipments used in cell culture lab.	8 7
7	(a) Discuss abt 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 abt *in-vivo* and *in- vitro* methods for checking cellular permeability of new drug products.	7 8

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FACULTY OF PHARMACY

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

August 2018

Subject: Advance Instrumental Analysis

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

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

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

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

3 a. Write abt varis 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 y mean by chemical shift? Explain the varis factors influencing it? (10)
b. Explain abt nuclear dble resonance and its applications? (5)

6 a. Mention varis 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 abt preparative HPLC? (7)
b. Discuss abt FT NMR with reference to C^{13} NMR (8)

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

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FACULTY OF PHARMACY

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

Subject: Modern Bio Analytical Techniques

Time: 3 Hrs **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) Varis 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 abt varis design to conduct bioavailability studies. (9)

8 a) Discuss abt the bioanalytical methods such as protein precipitation . (7)
b) Describe the varis 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 Hrs **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 spontanes reporting schemes for bio drug adverse reactions and bio drug-food interactions. 10
(b) Write abt 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 abt 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 Hrs **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 abt 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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FACULTY OF PHARMACY

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

August 2018

Subject: Advance Instrumental Analysis

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

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

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

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

3 a. Write abt varis 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 y mean by chemical shift? Explain the varis factors influencing it? (10)
b. Explain abt nuclear dble resonance and its applications? (5)

6 a. Mention varis 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 abt preparative HPLC? (7)
b. Discuss abt FT NMR with reference to C^{13} NMR (8)

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

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