Code No. G-13122/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) I – Semester (Main & Backlog) Examination, June 2025
Subject: Modern Pharmaceutical Analytical Techniques
(Common to All)

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

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

1. (a) Write Beer –Lambert's law and explain the deviations to it. (7 Marks)
   (b) Explain the instrumentation of FTIR. (8 Marks)

2. (a) Write principle involved in proton NMR spectroscopy. Discuss on chemical shift (7 Marks)
   (b) Explain the instrumentation of NMR with labelled schematic diagram. (8 Marks)

3. (a) Discuss about different ionization techniques of mass spectroscopy. (7 Marks)
   (b) Brief out the fragmentation patterns and rules of different organic compounds. (8 Marks)

4. (a) Write instrumentation details of HPLC with labelled schematic diagram. (10 Marks)
   (b) Differentiate between HPTLC and HPLC. (5 Marks)

5. (a) Explain about gel electrophoresis. (8 Marks)
   (b) What is X-ray crystallography? Write Brag's law. (7 Marks)

6. Write notes on
   (a) Sampling in IR spectroscopy
   (b) FT-NMR. (2 x 7.5 = 15 Marks)

7. Give informative note on
   (a) Flame emission spectroscopy
   (b) Gas chromatography (2 x 7.5 = 15 Marks)

8. (a) Explain the instrumentation of UV-Visible spectrophotometer. (10 Marks)
   (b) Write about any one X-ray crystallographic method. (5 Marks)

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Code No: G-13174/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Main & Backlog) Examination, June 2025

Subject: Quality Management System

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

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

1. (a) What is the importance of McKinsey 7s model? Explain in detail.
   (b) Define quality and write a note on quality policy.

2. (a) Write a note on classification of customers.
   (b) Write the customer perception of quality & factors on customer perception.

3. (a) Write a note on cost of quality, categories, models and preventing cost of quality.
   (b) Write the concept and principles of Six Sigma.

4. (a) Write a note on Pharmaceutical Quality Management (ICH Q10) guidelines.
   (b) Write a note on (i) CFR-21 Part 11 (ii) NABL certification and accreditation

5. (a) Write a note on quality management system in production, laboratory control and material handling.
   (b) Write a note on evaluation & handling of complaints, investigation and determination of root cause for quality systems.

6. (a) Write a note on ICH guidelines for stability testing of drug substances and drug products.
   (b) Write a note on ICH Q8 and QbD.

7. (a) Write about Quality risk management assessment, control, management of process control & quality improvement.
   (b) Write concept, importance, advantages of SQCC in measuring process control and quality improvement in manufacturing.

8. (a) Write about regulatory compliance through quality management and development of quality culture.
   (b) What is benchmarking? Write the reasons for benchmarking, types and benchmarking process.

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Code No: G-13176/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Main & Backlog) Examination, June 2025

Subject: Product Development & Technology Transfer

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

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

1. (a) Explain the detailed process for filing of NDA and ANDA.
   (b) Write a brief note on SUPAC guidelines. (10+5)

2. (a) Write the product registration guidelines for CDSCO and USFDA.
   (b) Write a note on Post marketing surveillance. (10+5)

3. Write a brief note on following properties in preformulation studies
   (i) Purity and Impurity profiles (ii) Particle size and shape
   (iii) Solubility of drugs (iv) Polymorphism

4. Write the concept and significance of pilot plant and scale up study. Write the pilot plant and scale up techniques for solid and liquid dosage forms.

5. Write the importance, different types of packaging, packaging materials used for pharmaceutical dosage forms.

6. (a) Write a detailed note on development & technology transfer from R & D to production.
   (b) Write a note on technology transfer development report and technology transfer plan and exhibit.

7. (a) Write a note on requirements of enteral packing and Aseptic packing.
   (b) Write a note on Qualitative and Quantitative technology models in technology transfer.

8. (a) Write a note on Quality control tests for (i) Containers (ii) Closures
   (b) Write a brief note on stability testing during product development.

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Code No: G-13175/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Main & Backlog) Examination, June 2025

Subject: Quality Control and Quality Assurance

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

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

1. Discuss about Quality Control and Quality Assurance. (15)

2. Discuss about
   (a) Good Laboratory Practice (8)
   (b) Protocol for control of non-clinical testing (7)

3. Explain the various CPCSEA guidelines for laboratory animal facility. (15)

4. Write about good warehousing practices. (15)

5. Write in detail about in-process quality control (IPQC) tests of tables. (15)

6. Describe the overview of ICH guidelines with Q series. (15)

7. Discuss about documentation of pharmaceutical industry. (15)

8. Write a short note on
   (a) Common Technical document (8)
   (b) Drug master file (DMF) (7)

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Code No : G-13001/PCI

FACULTY OF PHARMACY

M. Pharmacy I-Semester (PCI) (Common to All) (Backlog) Examination, December 2024

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. 9
   (b) Explain the electronic transitions in UV spectroscopy. 6

2. Explain the principle, sample handling techniques and any three 3 detectors of IR spectroscopy. 2+5+8

3. Explain the principle, working of Hallow cathode lamp, any three Interferences with remedy and Applications of Atomic Absorption Spectroscopy. 2+5+5+3

4. (a) What is the significance of chemical shift? What are the factors affecting chemical shift? 8
   (b) Write a note on spin-spin coupling, coupling constant and its Importance. 7

5. (a) Write different modes of fragmentation and fragmentation rules in Mass Spectroscopy. 9
   (b) Define Base peak, molecular ion peak and metastable ion. 6

6. (a) Write the principle and instrumentation of Capillary electrophoresis. 8
   (b) Write the principle and Instrumentation of Gel Electrophoresis. 7

7. (a) Define Braggs law and its importance. 5
   (b) Write in detail about rotating crystal technique and the applications of X-ray Diffraction. 10

8. Discuss the principle, instrumentation, working and application of 8+7
   (a) Affinity Chromatography
   (b) Gel Chromatography

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Code No. G-13024/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Quality Assurance) I - Semester (PCI) (Backlog) Examination, December 2024

Subject: Quality Management System

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

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

1. (a) Write a note on strategic planning, management and implementation.
   (b) Write a note on MCKinsey 7s Model.
   (c) Write a note on competitive analysis.

2. Write a note on (i) Classification of customers and Customers focus.
   (ii) Factors affecting customer perception (iii) Customer needs and Expectations.
   (iv) Handling of customer complaints.

3. (a) Write a note on Total Quality Management (TQM) System.
   (b) Write the principles of Six Sigma.
   (c) Write a note on ISO 9001:2015 and ISO 14001:2004.

4. (a) Write a note on (i) CFR-21 Part 11 (ii) WHO-GMP requirements.
   (b) Write a note on Pharmaceutical Quality Management (ICH Q10) guidelines.

5. (a) Write a note on Out of Specifications (OOS) and Out of Trend (OOT).
   (b) Write a note on evaluation, handling, investigation and determination of root cause for quality systems.

6. (a) Write a note on ICH guidelines for stability testing of drug substances and drug products.
   (b) Write a note on risk assessment, control, review and risk management tools.

7. (a) Write the importance of SPC in quality measurement in manufacturing of drug products.
   (b) Write the advantages of SQCC in measuring process control and quality improvement in manufacturing.

8. (a) Write about regulatory compliance through quality management and development of quality culture.
   (b) What is benchmarking? Write the reasons for benchmarking, types and benchmarking process.

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Code No: G-13025/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Backlog) Examination, December 2024

Subject: Quality Control and Quality Assurance

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

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

1. Write a short note on
   (a) Evolution of Quality Control and Quality Assurance. (8)
   (b) CPCSEA guidelines for laboratory animal facility. (7)

2. Discuss the Good Laboratory Practices for a quality control laboratory in detail. (15)

3. Explain Batch Manufacturing Records common Technical Document. (15)

4. Write a short note on
   (a) Standard Operating Procedure (8)
   (b) Batch Manufacturing Record (7)

5. Write in detail about in-process quality control (IPQC) tests of
   (a) Capsules (7)
   (b) Parenterals (8)

6. Describe sources of contamination and methods of contamination control. (15)

7. Write a short note on
   (a) Good documentation practice guidelines. (7)
   (b) Drug master file (DMF) (8)

8. Write a short note on
   (a) Handling of waste and scrap disposal. (7)
   (b) Copyright and trade mark. (8)

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Code No. G-13026/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Quality Assurance) I - Semester (PCI) (Backlog) Examination, December 2024

Subject: Product Development & Technology Transfer

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

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

1) a) Write a note on i) Investigational New Drugs Application ii) New Drug Application iii) Abbreviated New Drug Application

b) Write a brief note on SUPAC. (12+3)

2) Write the product registration guidelines for CDSCO and USFDA.

3) a) What are the objectives of preformulation studies in product development? (3+12)

b) Write a brief note on i) Purity and Impurity profiles ii) Solubility of drugs iii) Polymorphism iv) Stability testing of drugs

4) a) Write the concept, significance and layout of pilot plant scale up study. (7+8)

b) Write the large scale manufacturing techniques for solid dosage forms.

5) a) Write a note on pharmaceutical dosage form packaging requirements and packaging materials. (9+6)

b) Write a note on container closure systems for pharmaceutical dosage forms.

6) Write a note on Quality control tests for

i) Containers ii) Closures iii) Secondary Packaging materials

7) Write brief note on

i) Development of technology by R&D

ii) Technology transfer from R&D to production and Optimization

iii) Qualitative and Quantitative technology models

8) Write a note on technology transfer development report and technology transfer plan and exhibit.

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Code No: F-7239/PCI

FACULTY OF PHARMACY

M. Pharmacy I - Semester (PCI) (Common to All) (Main & Backlog) Examination, June 2024

Subject: Modern Pharmaceutical Analytical Techniques

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

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

1. (a) Explain different methods of single component and Multicomponent analysis of Pharmaceutical formulation by UV-Visible Spectroscopy. [9]
   (b) Explain the electronic transitions in UV spectroscopy. [6]

2. (a) Explain the molecular vibrations in IR. [8]
   (b) Write the sampling methods in IR spectroscopy. [7]

3. (a) Explain the principle of fluorescence. Add a note on quenching effect.
   (b) With a diagram explain the instrumentation for AAS. [8+7]

4. (a) Explain the principle and Instrumentation of NMR Spectroscopy. [8]
   (b) Write a note on spin-spin coupling and Applications of NMR [7]

5. (a) Classify the ionization techniques in MS. Explain any three methods in detail. [9]
   (b) Define Base peak, molecular ion peak and metastable ion. [6]

6. (a) Write the principle and instrumentation of flame photometry. [7]
   (b) Write notes on any two GC detectors with a neat labeled diagram. [8]

7. (a) Briefly explain the source of AA. [8]
   (b) List and explain the interferences. [7]

8. Discuss the principle, instrumentation working and application of [7+8]
   (a) Paper electrophoresis
   (b) Gel electrophoresis

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Code No: F-7264/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I-Semester (PCI) (Main & Backlog) Examination, June 2024

Subject: Quality Control and Quality Assurance

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

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

1. Differentiate GMP and cGMP. Write a detailed note on requirements and guidelines of GMP (Revised Schedule M) in pharmaceutical industry. (15)

2. Give a brief note on
   (a) CPCSEA guidelines. (7)
   (b) Q-series guidelines. (8)

3. Write in detail about in-process quality control (IPQC) tests of
   (a) Tablets (8)
   (b) Parenterals (7)

4. Explain batch manufacturing record and common technical document (CTD). (15)

5. Describe sources of contamination and methods of contamination control. (15)

6. Write a short note on
   (a) Good warehousing practices (8)
   (b) Aseptic process control (7)

7. Write brief note on following
   (a) Change control (8)
   (b) Standard operating procedures (7)

8. Write a short note on
   (a) Calculation of yields (7)
   (b) Copyright and patents (8)

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Code No. F-7265/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Quality Assurance) I - Semester (PCI) (Main & Backlog) Examination, June 2024

Subject: Product Development & Technology Transfer

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

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

1) a) Write a note on i) Investigational New Drugs Application
   ii) Abbreviated New Drug Application
   b) Write a note brief note on SUPAC and BACPAC. (8+7)
2) Write a brief note on
   i) Purity and Impurity profiles ii) Particle size and shape
   iii) Solubility of drugs iv) Techniques for the study of crystal properties
3) a) Write a note on Post marketing surveillance.
   b) Write the product registration guidelines for CDSCO and USFDA. (5+10)
4) a) Write the concept and significance of pilot plant and scale up study. (5+10)
   b) Write the pilot plant and scale up techniques for solid and liquid dosage forms.
5) a) Write a note on different packaging materials used for pharmaceutical dosage forms.
   b) Write a note on container closure systems for pharmaceutical dosage forms. (8+7)
6) a) Write a note on Quality control tests for
   i) Containers ii) Closures iii) Secondary Packaging materials
   b) Write a brief note on issues facing in modern drug packaging. (9+6)
7) Write a note on technology transfer development report and technology transfer plan and exhibit.
8) a) Write a note on Technology transfer from R&D to production and Optimization and production.
   b) Write a note on Qualitative and Quantitative technology models in technology transfer.

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Code No. F-7263/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Quality Assurance) I - Semester (PCI) (Main & Backlog) Examination, June 2024

Subject: Quality Management System

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

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

1. Write a note on
   (i) Strategy and Strategic Quality Management
   (ii) Strategic Planning & Management
   (iii) McKinsey 7s Model

2. Write a note on (i) Classification of customers and Customer focus
   (ii) Factors affecting customer perception (iii) Customer needs and Expectations
   (iv) Customer satisfaction and Customer delight.

3. (a) Write a note on Total Quality Management (TQM) System.
   (b) Write the principles of Six Sigma
   (c) Write a note on ISO 9001:2015 and ISO 14001:2004

4. (a) Write a note on Pharmaceutical Quality Management (ICH Q10) guidelines.
   (b) Write a note on (i) CFR-21 Part 11 (ii) WHO-GMP requirements.

5. (a) Write a note on Change control in quality systems.
   (b) Write a note on Out of Specifications (OOS) and Out of Trend (OOT).

6. (a) Write a note on ICH guidelines for stability testing of drug substances and drug products.
   (b) Write a note on risk assessment, control, review and risk management tools.

7. (a) Write the importance of SPC in quality measurement in manufacturing of drug products.
   (b) Write a note on Statistical Quality Control charts for measuring process control and quality improvement.

8. (a) Write about regulatory compliance through quality management and development of quality culture.
   (b) Write a note on benchmarking, reasons for benchmarking and benchmarking process.

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Code No: E-12421/PCI

FACULTY OF PHARMACY

M.Pharmacy I-Semester (PCI) (Common to all) (Backlog) Examination, November-2023

Subject: Modern Pharmaceutical Analytical Techniques

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

Note: Answer any Five Questions. All Questions carry Equal marks.

1. a) Explain the electronic transitions with suitable examples
   b) State and explain Beer- Lambert's law. Add a note on the deviations from Beer's law. (6+9)

2. a) Explain the sampling techniques in IR spectroscopy.
   b) What are the applications of IR spectroscopy (9+6)

3. a) What is the principles of flame photometrty? Explain the instrumentation.
   b) What are the factors affecting fluorescence? (9+6)

4. a) Explain chemical shift and the factors affecting chemical shift ?
   b) Draw a schematic NMR spectrum and explain splitting α signal intensity. (10+5)

5. With a neat labelled diagram, explain MS instrumentation. Draw MS spectrum for any two compounds α explain its peaks.

6. a) Classify the ionization techniques in MS. Explain any three methods in detail.
   b) Explain the fragmentation rules in MS. (9+6)

7. a) Explain HPLC instrumentation with a labelled diagram.
   b) Explain the factors affecting resolution & peak symmetry. (8+7)

8. a) Explain the principle and applications of capillary electrophoresis
   b) Classify the types of crystals and add a note on the applications of X-ray diffraction. (8+7)

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Code No: E-12447/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Product Development and Technology Transfer

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

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

1. (a) What is ANDA, what information must be provided for filing ANDA. [5]
   (b) Write a note on drug development process. [10]

2. (a) Write in detail about physico-chemical properties, solubility enhancement techniques considered during product development. [8]
   (b) Write a note on CDSCO product registration guidelines. [7]

3. (a) What are the major technical aspects to be considered during pilot plant scaleup for semi solid dosage forms. [10]
   (b) Write a note on benefits and difficulties in pilot plant scaleup. [5]

4. (a) Write a note on aseptic and medical device packing. [7]
   (b) Write in detail about Quality control tests for containers, closures, and secondary Packing materials. [8]

5. (a) Write a detailed note on development and technology transfer from R & D to Production. [8]
   (b) Write a note on documentation of technology transfer. [7]

6. (a) Write in detail about the techniques for study of crystal properties. [8]
   (b) Write in detail about stability testing during product development. [7]

7. (a) Write a note on requirements of enteral packing and aseptic packing. [8]
   (b) Write a detailed note on guidelines for post marketing surveillance. [7]

8. (a) Write a note on qualitative and quantitative technology transfer models. [8]
   (b) Write a note on SUPAC. [7]

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Code No: E-12446/PI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Quality Control and Quality Assurance

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

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

1. Differentiate Quality Control and Quality Assurance. Describe the concept and evolution of Quality Control and Quality Assurance. [15]

2. Define Good Laboratory Practice and write the protocol for conduct of non-clinical testing. [15]

3. Explain the various CPCSEA guidelines for laboratory animal facility. [15]

4. Write a short note on
   (a) Standard Operating Procedure [8]
   (b) Batch Manufacturing Record [7]

5. Write in detail about in-process quality control (IPQC) tests for
   (a) Capsules [7]
   (b) Parenterals [8]

6. (a) Describe the overview of ICH guidelines with Q series [8]
   (b) Write a short note on Calculation of yields. [7]

7. (a) Write a short note on good documentation practice guidelines. [8]
   (b) What are the different types of audits? Explain in detail audit methods and techniques involved in it. [7]

8. Write a short note on
   (a) Change Control [8]
   (b) Copyright and trade mark. [7]

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Code No: E-12445/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Quality Management Systems

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

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

1. (a) Define quality and write a note on quality policy. [8]
   (b) Write the importance of vision and mission in the quality policy. [7]

2. (a) Write in detail about perception of quality with respect to customer, how Customer complaints are handled. [8]
   (b) Write a note on cost of quality, how can we optimize costs. [7]

3. (a) Write a detailed note on principles of TQM. [8]
   (b) Write a in detail about ISO 9001: 2015. [7]

4. (a) What is OOS & OOT's? Explain in detail. [7]
   (b) Write a note on complaints and product recall. [8]

5. (a) Write in detail about IPQC and line clearance. [8]
   (b) Write a note on ICH guidelines on stability testing of pharmaceutical substances. [7]

6. (a) What is statistical process control, write in detail about statistical control charts. [8]
   (b) Write in detail about NABL accreditation and certification. [7]

7. (a) Write a note on Quality risk management. [8]
   (b) Write in detail about self-inspection. [7]

8. (a) Write a detailed note on Quality by design as per ICH. [8]
   (b) Define benchmarking, what are the reasons for bench marking. [7]

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Code No: E-12297/PCI

FACULTY OF PHARMACY

M. Pharmacy I Semester (PCI) (Common to all) (Main & Backlog) Examination, May 2023

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 labelled diagram explain UV/Visible instrumentation.
   b) What are the criteia in the solvent selection for UV spectroscopy? Give examples for solvents. What is meant by solvent effect? (9+6)

2. a) Explain the Principle, advantages and instrumentation of FTIR with a neat labelled diagram.
   b) Explain the molecular vibrations in IR spectroscopy. (10+5)

3. a) Explain the principle of fluorescence. Add a note on quenching effect
   b) With a diagram explain the instrumentation for AAS. (8+7)

4. a) Explain the principle of proton NMR spectroscopy.
   b) Explain the spin-spin coupling in NMR spectroscopy with suitable example. (7+8)

5. a) Explain the principle of mass spectroscopy.
   b) Explain any two mass analysers used in MS in detail. (7+8)

6. a) Explain GC instrumentation with a labelled diagram.
   b) Explain the applications of XRD technique. (9+6)

7. a) Explain the instrumentation & working of HPLC. (8+7)
   b) Explain the factors affecting resolution & Peak symmetry.

8. Define and classify the electrophoretic techniques. Explain the principle and applications of gel electrophoresis. (15)

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Code No: E-12321/PCI

FACULTY OF PHARMACY

M. Pharmacy (Quality Assurance) I-Semester (PCI) (Main & Backlog) Examination, May 2023

Subject: Quality Management systems

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

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

1.	(a)	What is the importance of MC Kinsey 7s model, explain in detail.	[8]
	(b)	Write a note on cost of quality.	[7]
2.	(a)	Write in detail about principles of six sigma.	[8]
	(b)	Write a note on WHO- GMP guidelines.	[7]
3.	(a)	Write a detailed note on six system inspection model.	[8]
	(b)	Write a note on quality risk management.	[7]
4.	(a)	Write in detail about statistical control charts	[7]
	(b)	Write a note on complaints, evaluation and handling of complaints.	[8]
5.	(a)	Write a note on quality management system.	[8]
	(b)	Write in detail about NABL certification and accreditation process.	[7]
6.	(a)	Write a detailed note on statistical process control	[8]
	(b)	Define benchmarking. What are the reasons for benchmarking.	[7]
7.	(a)	What is OOS and OOT's. How are they handled	[8]
	(b)	Write in detail about line clearance	[7]
8.	(a)	Write a detailed note on Quality by design as per ICH.	[8]
	(b)	Discuss about ICH Guidelines for stability testing of drug substances.	[7]

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Code No: E-12322/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I Semester (PCI) (Main & Backlog) Examination, May 2023

Subject: Quality Control and Quality Assurance

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

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. What are the advantages in cGMP over GMP. Write a detailed note on requirements and guidelines of GMP (Schedule M) in pharmaceutical industry. [15]

2. Give a brief note on
   (a) Non-Clinical testing. [5]
   (b) Controls on animal house. [5]
   (c) Distribution records [5]

3. Write in detail about in-process quality control (IPQC) tests for
   (a) Tablets [8]
   (b) Ointments [7]

4. Explain common technical document (CTD) and electronic CTD. [15]

5. Describe sources of contamination and methods of contamination control. [15]

6. Write a short note on
   (a) ICH guidelines with Q series [8]
   (b) Aseptic process control [7]

7. Write brief note on following
   (a) Handling of waste and scrap disposal [8]
   (b) Standard operating procedures [7]

8. Write a short note on
   (a) Expiry date calculation [7]
   (b) Copyright and patents [8]

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Code No: E-12323/PCI

FACULTY OF PHARMACY

M. Pharmacy (Quality Assurance) I - Semester (PCI) (Main & Backlog) Examination, May 2023

Subject: Product Development and Technology Transfer

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

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

(5 x 15 = 75 Marks)

1 (a) What is NDA, what information must be provided for NDA. [8]
(b) Write a note on product registration process as per USFDA. [7]

2. (a) Write in detail about protocols followed in pre-formulation studies and its importance. [7]
(b) Explain the solubility enhancement techniques using surfactants and co solvency technique. [8]

3. (a) What are the major technical aspects to be considered during pilot plant scaleup for solid dosage forms. [8]
(b) Write a note on SUPAC guidelines for pilot plant scaleup. [7]

4. (a) Write about the importance of pharmaceutical packing. Explain the types, and challenges in pharmaceutical packing. [5]
(b) Write a note on evaluation tests for packing material. [10]

5. (a) Write a detailed note on development & technology transfer from R & D to production. [10]
(b) Write a note on documentation of technology transfer. [5]

6. (a) What are the objectives, significance, design, and layout of plot plant scale up study for liquid dosage form. [8]
(b) Write in detail about stability testing during product development. [7]

7. (a) Write a note on qualitative and quantitative technology transfer models. [8]
(b) Write a detailed note on guidelines for post marketing surveillance. [7]

8. (a) Write a note on requirements of enteral packing and Aseptic packing. [8]
(b) Discuss about ANDA submission. [7]

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Code No. E-12084/PCI

FACULTY OF PHARMACY

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

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 labelled diagram explain UV/Visible spectrophotometer instrumentation.
(b) What are the applications of UV spectroscopy?

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

3 (a) Explain the principle of fluorescence.
(b) With a diagram explain the instrumentation for flame photometry.

4 (a) Explain the principle of proton NMR spectroscopy.
(b) Explain the following in NMR spectroscopy: Shielding and deshielding, chemical shift.

5 (a) Explain the principle of mass spectroscopy.
(b) Explain any two mass analysers used in MS in detail.

6 (a) Explain GC instrumentation with a labelled diagram. Add a note on the different types of GC columns.
(b) List and explain any 2 GC detectors.

7 (a) Explain Braggs equation and derive the equation.
(b) Explain the principle and types of Paper electrophoresis.

8 (a) Explain the principle and applications of ELISA?
(b) Explain the principle and applications of capillary electrophoresis.

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Code No: E-12108/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Backlog)
Examination, December 2022
Subject: Quality Management Systems

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

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

1. a) What is cost of quality ? Explain models of cost of quality. [8]
   b) Write a note on OSHAS guidelines. [7]

2. a) Explain the process of NABL accreditation of a chemical testing laboratory. [8]
   b) What is Out of specification (OOS)? How is OOS handled as per USFDA guidelines. [7]

3. a) What is self-inspection ? What is its importance in quality assurance and how is it executed? [8]
   b) What is market complaining? How are they evaluated? [7]

4. a) What is stress testing? Why and how is it done? [8]
   b) How risk ranking is done? Explain in brief. [7]

5. a) Enlist and explain attribute control charts. [8]
   b) Explain the indices used for process capability. [7]

6. Explain the principles of Six sigma and writes its importance in industries. [15]

7. a) Explain the customers perception of quality. [7]
   b) Explain the elements of McKinsey 7S model. [8]

8. What is HACCP? How does it help in drug manufacturing? [15]

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Code No: E-12110/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Backlog) Examination, December 2022

Subject: Product Development and Technology Transfer

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

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

1. a) Define ANDA. Explain the detailed process for filing of ANDA. [7]
   b) Define the various product registration guidelines of CDSCO. [8]

2. a) Explain the significance of co solvents and surfactants in improving solubility of poorly water soluble drugs. [8]
   b) Write about the different types of chemical stability studies conducted during product development . [7]

3. a) What is scale up process? Explain the various considerations for pilot plant scale up of semi-solid dosage forms. [10]
   b) How did the innovative processes influence the discovery and development of new era of drug products, explain the challenges incurred during development. [5]

4. a) Explain the importance of container selection and quality attributes to be considered in aseptic packaging systems. [8]
   b) Briefly describe the various issues faced during modern drug packaging systems in product development. [7]

5. a) Explain the various quality control tests conducted for checking quality of containers for enteral packaging. [10]
   b) Explain the significance of quality considerations for closures in pharmaceutical packaging. [5]

6. a) How does technology transfer occur in pharmaceutical industries? Explain the importance and requirements for technology transfer process. [8]
   b) Technology development by R&D is a dynamic process, write about the essential features of it. [7]

7. How does preformulation studies help the formulator in drug development? [15]

8. Write the significance of BACPAC and SNDA in drug registration process. [15]

Code No: E-12109/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - Semester (PCI) (Backlog) Examination, December 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 detailed note on requirements and guidelines of GMP (Schedule M) in pharmaceutical industry. [15]

2. Give a brief note on
   a) Non-Clinical testing. [5]
   b) Controls on animal house. [5]
   c) Distribution records [5]

3. Write in detail about in-process quality control (IPQC) tests of
   a) Tablets [8]
   b) Semisolids [7]

4. Explain common technical document (CTD) and electronic CTD. [15]

5. Describe sources of contamination and methods of contamination control. [15]

6. Write a short note on
   a) ICH guidelines with Q series [8]
   b) Aseptic process control [7]

7. Write brief note on following
   a) Change control [8]
   b) Standard operating procedures [7]

8. Write a short note on
   a) Expiry date calculation [7]
   b) Copyright and trade mark [8]

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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: 8312/PCI

FACULTY OF PHARMACY
M. Pharmacy (Pharm. Quality Assurance) I- Semester (PCI) Main Examination, May 2022

Subject: Product Development and Technology Transfer

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

Note: Answer any Five from the following questions. **(5 x 15 = 75 Marks)**

1. a. Define NDA. Explain the detailed process for filing of NDA.
   b. Define SUPAC guidelines. What is the main purpose of guidelines and explain their importance in filing process to USFDA.

2. a. Explain the significance of solubility in dosage form development and write in detail the various methods to improve solubility of poorly water soluble drugs.

   b. Enumerate the types of stability studies conducted during product development and explain the drug excipient compatibility studies.

3. a. What is a pilot plant? Explain the essential requirements and considerations for pilot plant scale up of solid dosage forms.
   b. Enlist the various type of novel drug delivery systems and explain the various opportunities that can be explored in formulation of NDDS.

4. What is the importance of container selection and quality attributes to be considered in medical devices packing.
5. a. Briefly explain the various quality control tests performed for establishing quality of containers for parenteral liquid dosage forms.

   b. Explain the significance of secondary packaging materials in pharmaceutical packaging.
6. a. What is technology transfer. Explain the various steps involved in technology transfer process.
   b. How are the various qualitative and quantitative technology models used in efficient technology transfer.

7. What is Preformulation. Write the main objective and the detailed protocol of preformulation.

8. Explain in detail the various documentation involved in technology transfer process from R &D to production.

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Code No: D-8310/PCI

FACULTY OF PHARMACY
M. Pharmacy (Pharm. Quality Assurance) I- Semester (PCI) Main Examination, May 2022
Subject: Quality Management Systems

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

Note: Answer any Five from the following questions. (5x15= 75 Marks)

1. a) Explain in detail the significance of Vision and mission statements in an industry. (8)
   b) Explain the concept of Pharmaceutical quality management based on ICH QI0. (7)

2. a) Explain management of risk as per ICH Q9 guidelines (8)
   b) With the help of a flow chart explain the benchmarking of a quality process.(7)

3. a) Write a note on cost optimizing strategies. (8)
   b) Write a note on NABL certification and accreditation. (7)

4. a) Explain the scope of ISO 9001: 2015. (8)
   b) What is annual product review? Why is it compiled? (7)

5. a) What are Out of specification and Out of trends? Explain. (8)
   b) What are control charts? Give their applications. (7)

6. Define Statistical Process Control (SPC). What is the importance of SPC in pharmaceutics? What are the advantageous of statistical control? (15)

7. What is cost of quality? Explain the various models of cost of quality. Write a note on six sigma. (I5)

8. a) Explain the stability testing conditions as per ICH guidelines. (8)
   b) Explain the role of HACCP in risk management. (7)

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Code No: D- 8311/PCI

FACULTY OF PHARMACY
M. Pharmacy (Pharm. Quality Assurance) I- Semester (PCI) Main Examination, May 2022

Subject: Quality Control and Quality Assurance

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

Note: Answer any Five from the following questions. (5 x 15 = 75 Marks)

1. Describe the concept and evolution of Quality Control and Quality Assurance.

2. Discuss the Good Laboratory Practices for a quality control laboratory in detail.

3. Explain the various CPCSEA guidelines for laboratory animal facility.

4. Write a short note on
   a) Standard Operating Procedure
   b) Batch Manufacturing Record
5. Write in detail about in-process quality control (IPQC) tests of
   a. Tablets
   b. Parenterals
6. a) Describe the overview of ICH guidelines with Q series
   b) Write a short note on Calculation of yields.
7. a) Write a short note on good documentation practice guidelines.
   b) What are the different types of audits? Explain in detail audit methods and techniques involved in it.
8. Write a short note on
   a) Expiry date calculation.
   b) Copyright and trade mark.

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