Code No: H-8082/PCI

FACULTY OF PHARMACY

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

Subject: Quality Management System

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

Note: Answer any five Questions. All Questions carry equal marks. **(5x15=75 Marks)**

1. (a) Explain in detail the significance of Vision and mission statements in an industry.
   (b) Explain the elements of McKinsey 7S model.

2. (a) Write a note on classification of customers and customer focus & their perception on quality.
   (b) Write a note on Customer needs, Expectations and handling of customer complaints.

3. (a) Write a note on Total Quality Management (TQM) System in quality management.
   (b) Write the principles of Six Sigma concept in quality management.

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

5. Write a note on
   (i) Out of specifications (OOS) and Out of Trend (OOT).
   (ii) Corrective and Preventive actions

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

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) Define benchmarking. Write the reasons, types and process of benchmarking.

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Code No: H-8083/PCI

FACULTY OF PHARMACY

M. Pharmacy (Ph. Quality Assurance) I-Semester (PCI) (Backlog) Examination, December 2025

Subject: Quality control and Quality assurance

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

Note: Answer any Five questions **(5 x 15 = 75 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 in process 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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Quality Assurance

Code No: H-8084/PCI

FACULTY OF PHARMACY

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

Subject: Product Development and Technology Transfer

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

Note: Answer any Five 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. Write the product registration guidelines for CDSCO and USFDA.

3. (a) Write the concept and objectives of preformulation studies in product development. Write a brief note on Solubility studies, crystal properties and polymorphism.
   (b) Write a note on stability testing during product development.

4. Write the concept, significance and layout of pilot plant scale up study. Write the largescale manufacturing techniques for solid dosage forms.

5. Discuss pharmaceutical dosage form packaging requirements and packaging materials with examples.

6. Write a note on quality control tests for i) Containers ii) Closures iii) Secondary Packaging materials.

7. What is technology transfer? Explain the various steps and documentation involved in technology transfer process.

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

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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-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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