SVKM NMIMS Global University

School of PharmacyTechnology Management

Programme: Master of Pharmacy (Pharmaceutical Chemistry)/Master of Pharmacy (Pharmaceutical Quality Assurance)/Master of Pharmacy (Pharmaceutics)/Master of Pharmacy (Pharmacology)

Year: I/Semester I (Exam Year: 2025-2026)

Subject: Modern Pharmaceutical Analytical Techniques

Date: 13 Dec 2025 **Time:** 10:00 am - 01:00 pm (03:00 Hrs.)

Max Marks: 75

FINAL EXAMINATION(2025-2026)

Instructions:

1. This question paper contains 2 pages
2. All questions are compulsory
3. Figures to the right indicate full marks
4. Draw the diagrams or flow charts wherever necessary

1.	This is a sample question group (Attempt Any 5 Questions)	**10**
	1. Define fluorescence and phosphorescence	**2**
	2. Write applications of UV Visible Spectrocopy	**2**
	3. Predict the peaks obtained for isopropyl alcohol	**2**
	4. Enlist the types of ion source in MS	**2**
	5. Enlist any four types of components that can separated by Ion exchange chromatography.	**2**
	6. Enlist types of electrophoresis	**2**
	7. Explain Bioluminiscence assay.	**2**
2.	Attempt any FOUR questions of the following(Attempt Any 4 Questions)	**20**
	1. Write a note on Thermal detectors used in IR spectroscopy. Explain construction and working of any one thermal dectector	**5**
	2. Elaborate on principle and application of ^{13}CNMR	**5**

3.	Explain the nitrogen rule in mass spectrometry and its application in determining the molecular formula of organic compounds.	**5**
4.	Write a note on Gel Chromatography	**5**
5.	Write a note on types X-ray diffraction techniques	**5**
6.	Explain the principle and applications of DTA.	**5**
3.	Attempt any THREE questions of the following(Attempt Any 3 Questions)	**45**
1.	Explain in detail about principle, instrumentation, and application Spectroflurimentry. Add a note on quenching of fluorescence	**15**
2.	Discuss in details about Principle, Instrumentation and application of 1H NMR. Add a note on Spin Spin coupling and decoupling of proton	**15**
3.	Discuss in details about principle, instrumentation and application of mass spectrometry. Add a note on types of ionisation process	**15**
4.	Discuss in details about the principle, instrumentation and Application of GC. Comment on the column efficiency of GC	**15**
5.	Explain in detail about principle, instrumentation and application of UPLC. Add a note on HETP.	**15**

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School of PharmacyTechnology Management

Programme: Master of Pharmacy (Pharmaceutical Quality Assurance)

Year: I/Semester I (Exam Year: 2025-2026)

Subject: Product Development and Technology Transfer

Date: 19 Dec 2025 **Time:** 10:00 am - 01:00 pm (03:00 Hrs.)

Max Marks: 75

FINAL EXAMINATION(2025-2026)

Instructions:

1. This question paper contains 2 pages
2. All questions are compulsory
3. Figures to the right indicate full marks
4. Draw the diagrams or flow charts wherever necessary

1.	Answer the following(Attempt Any 5 Questions)	**10**
	1. What are the functions of CDSCO?	**2**
	2. What are the objectives of scale-up techniques?	**2**
	3. Enlist the nanocarriers from each class	**2**
	4. 1. Enlist the types of glass with examples of dosage forms.	**2**
	5. Enlist the composition of team members involved in technology transfer.	**2**
	6. 1. What are the various elements of the success of technology transfer?	**2**
	7. Justify the rationale for filling an ANDA.	**2**
2.	Answer the following(Attempt Any 4 Questions)	**20**
	1. 1. Elaborate on IND regulations and content requirements.	**5**
	2. Discuss in detail the pilot plant operation.	**5**

3. Discuss the Concept and operations of large-scale manufacturing techniques, considering any dosage form. **5**

4. 1. Explain the issues facing modern drug packaging. **5**

5. 1. Elaborate on Optimization and Production during technology transfer. **5**

6. Discuss any 3 quality control tests for closure and containers **5**

3. Answer the following(Attempt Any 3 Questions) **45**

1. 1. Discuss in detail the SUPAC-IR, MR, and SS guidelines with significance. **15**

2. Discuss the various physicochemical properties of the drug from preformulation perspectives. **15**

3. Discuss the large-scale manufacturing technique of fast-dissolving tablets. **15**

4. Explain the issues facing modern drug packaging and elaborate on the evaluation of plastic **15**

5. Discuss the procedure for induction to implementation, opting for the Development of technology by R&D. **15**

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School of PharmacyTechnology Management

Programme: Master of Pharmacy (Pharmaceutical Quality Assurance)

Year: I/Semester I (Exam Year: 2025-2026)

Subject: Quality Control and Quality Assurance

Date: 17 Dec 2025 **Time:** 10:00 am - 01:00 pm (03:00 Hrs.)

Max Marks: 75

FINAL EXAMINATION(2025-2026)

Instructions:

1. This question paper contains 2 pages
2. All questions are compulsory
3. Figures to the right indicate full marks
4. Draw the diagrams or flow charts wherever necessary

1.	Answer the following(Attempt Any 5 Questions)	**10**
	1. What is Quality Assurance as per WHO?	**2**
	2. Explain any two functions of HEPA filters in maintaining air quality within cleanroom areas.	**2**
	3. How will you perform the Self Sealability test according to IP on rubber closures?	**2**
	4. Differentiate between regulated and non-regulated market.	**2**
	5. What are the different methods of product disposal in pharma industry?	**2**
	6. Enlist any four specifications from ICH Q6.	**2**
	7. Explain the two purpose and two objectives of ICH.	**2**
2.	Answer the following(Attempt Any 4 Questions)	**20**
	1. Summarize the CPCSEA guidelines and their significance in animal studies.	**5**
	2. Discuss hygiene and personal record requirements as per cGMP guidelines.	**5**
	3. Explain the FPQC tests for pharmaceutical ointments as per IP.	**5**

4. Discuss the procedure of documentation and record retention in pharmaceutical industries. **5**

5. Explain the procedure for the Disintegration Test for various types of tablets as per IP. **5**

6. Justify the need for Change Control in pharmaceutical industries. **5**

3. Answer the following(Attempt Any 3 Questions) **45**

1. Describe the scope and objectives of ICH QSEM guidelines and their role in pharmaceutical regulation. **15**

2. Explain the cGMP requirements for establishing a pharmaceutical manufacturing plant as per Schedule M. **15**

3. Discuss comprehensively the various In-process Quality Control tests for Parenterals as per IP. **15**

4. Discuss the concept of Batch Manufacturing Record (BMR) with help of suitable format for the manufacturing of any one solid dosage form **15**

5. What are the possible sources of cross-contamination in a pharmaceutical plant? Illustrate preventive controls at personnel, process, and facility levels. **15**

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School of PharmacyTechnology Management

Programme: Master of Pharmacy (Pharmaceutical Quality Assurance)

Year: I/Semester I (Exam Year: 2025-2026)

Subject: Quality Management Systems

Date: 15 Dec 2025 **Time:** 10:00 am - 01:00 pm (03:00 Hrs.)

Max Marks: 75

FINAL EXAMINATION(2025-2026)

Instructions:

1. This question paper contains 2 pages
2. All questions are compulsory
3. Figures to the right indicate full marks
4. Draw the diagrams or flow charts wherever necessary

1.	Answer the following questions(Attempt Any 5 Questions)	**10**
	1. Explain the role of management commitment to quality.	**2**
	2. Explain the principles of Six Sigma.	**2**
	3. Define OOS and give one example.	**2**
	4. Explain the purpose of ICH stability testing guidelines.	**2**
	5. Why are control charts preferred for monitoring process stability?	**2**
	6. Explain the purpose of conducting benchmarking.	**2**
	7. What are the qualification requirements of the Vendor?	**2**
2.	Answer the following questions(Attempt Any 4 Questions)	**20**
	1. Elaborate on the effectiveness of handling customer complaints as a tool for continuous improvement.	**5**
	2. Evaluate the impact of CFR-21 Part 11 on electronic-records integrity.	**5**
	3. Explain the concept of self-inspection and its significance in maintaining product quality.	**5**

4. Define drug stability and explain its importance in pharmaceutical product development and list the types of stability studies as per ICH guidelines **5**

5. Explain how process capability analysis supports continuous quality improvement in manufacturing. **5**

6. Apply benchmarking to compare vendor performance on any two parameters. **5**

3. Answer the following questions(Attempt Any 3 Questions) **45**

1. Describe the different categories of cost of quality with suitable examples. **15**

2. Describe in detail about ISO 9001:2015 guidelines **15**

3. Justify how the six-system inspection model is ideal for the improvement of Quality standards with case studies **15**

4. List and explain the different types of stability studies recommended under ICH guidelines (accelerated, long-term, and intermediate), with one case study on evaluation parameters **15**

5. Analyze how benchmarking contributes to continuous quality improvement and elaborate on the types of benchmarking. **15**