SVKM NMIMS Global University

School of PharmacyTechnology Management

Programme: Master of Pharmacy (Pharmaceutics)

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

Subject: Drug Delivery System

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. Answer to each new question to be started on a fresh page.
3. Figure in right hand side indicates full marks
4. Draw the diagrams or flow charts wherever necessary.

1.	Answer the following(Attempt Any 5 Questions)	**10**
	1. Differentiate between sustained and controlled release formulations.	**2**
	2. Define rate-controlled drug delivery systems.	**2**
	3. Differentiate between feedback and modulated systems.	**2**
	4. What is meant by reservoir-type controlled release system?	**2**
	5. Differentiate between physicochemical and biological approaches in SR/CR formulations.	**2**
	6. Compare buccal and ocular systems in terms of absorption.	**2**
	7. Describe stability issues in protein formulations.	**2**
2.	Answer the following(Attempt Any 4 Questions)	**20**
	1. Describe methods for preparing controlled release formulations.	**5**
	2. Describe with an example an osmotic pump-based drug delivery.	**5**
	3. Compare matrix and reservoir-type rate-controlled drug delivery systems.	**5**

4. Explain the principle of mucoadhesion and its role in buccal drug delivery systems. **5**

5. Explain the major barriers in protein and peptide drug delivery. **5**

6. Compare advantages and disadvantages of gastro-retentive systems. **5**

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

1. Discuss various types of sustained and controlled release drug delivery systems, their design principles, and examples. **15**

2. Explain the principles, types, and activation mechanisms of Rate-Controlled Drug Delivery Systems. Also, describe feedback-regulated systems and their advantages. **15**

3. Classify Gastro-Retentive Drug Delivery Systems (GRDDS) and explain any two types in detail. **15**

4. Discuss the various conventional ocular formulations and their challenges. Write about advanced ocular formulations. Explain evaluation of ocular drug delivery system. **15**

5. Describe the design and mechanism of modern vaccine delivery systems emphasizing single-shot, mucosal, and transdermal vaccine formulations. Discuss their advantages and evaluation parameters. **15**

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**

SVKM NMIMS Global University

School of PharmacyTechnology Management

Programme: Master of Pharmacy (Pharmaceutics)

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

Subject: Modern Pharmaceutics

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. Answer to each new question to be started on a fresh page.
3. Figure in right hand side indicates full marks
4. Draw the diagrams or flow charts wherever necessary.

1.	Answer the following(Attempt Any 5 Questions)	**10**
	1. **List** two techniques for studying drug–excipient interaction.	**2**
	2. Enlist different methods for factorial designs	**2**
	3. Mention the significance of URS	**2**
	4. compare calibration and validation of equipment	**2**
	5. **Define** similarity factor (f_2).	**2**
	6. How colligative properties affect the parenteral stability?	**2**
	7. **Define** Variables in optimization	**2**
2.	Answer the following(Attempt Any 4 Questions)	**20**
	1. **Explain** the concept of Response Surface Methodology (RSM).	**5**
	2. **Explain** cleaning validation and its steps.	**5**

3. Describe production management: Production organization, materials management. **5**

4. **Explain** the stages of powder compression. **5**

5. Give the significance of Statistical design, Contour designs in **Optimization Techniques** **5**

6. Illustrate kinetics of stability in **Preformulation Concepts for New Product Development** **5**

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

1. **Define** preformulation and **explain** its objectives in **New product development** **15**

2. **Describe** the Box–Behnken design and its application. **15**

3. Define validation and explain its importance in pharmaceutical manufacturing. **15**

4. **Describe Process &** analytical method validation parameters. **15**

5. **Summarize** industrial importance of compaction and dissolution studies. **15**

SVKM NMIMS Global University

School of PharmacyTechnology Management

Programme: Master of Pharmacy (Pharmaceutics)

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

Subject: Regulatory Affair

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. Answer to each new question to be started on a fresh page.
3. Figure in right hand side indicates full marks
4. Draw the diagrams or flow charts wherever necessary.

1.	Answer the following(Attempt Any 5 Questions)	**10**
	1. **a.** Explain the main role of the Central Drugs Standard Control Organization (CDSCO) in India.	**2**
	2. Give the challenges faced by foreign pharmaceutical companies while obtaining ANDA approval for registration in the U.S.	**2**
	3. What is the purpose of ICH Q1A(R2) guideline, and why is it important in pharmaceutical development?	**2**
	4. Explain the purpose of NDA and ANDA submissions.	**2**
	5. Explain the purpose and process of informed consent in clinical trials.	**2**
	6. Describe the preparation of a drug approval dossier for international regulatory submission.	**2**
	7. Explain the role of Industry-FDA liaison in regulatory compliance.	**2**
2.	Answer the following(Attempt Any 4 Questions)	**20**
		5

1. Compare the regulatory functions of CDSCO and USFDA with respect to new drug approval and post-marketing surveillance.

2. **Analyze the key differences in regulatory approval requirements among the USFDA, EMA, MHRA, and TGA.** **5**

3. Explain the significance of the Master Formula Record (MFR) in pharmaceutical manufacturing. **5**

4. **Elaborate on the importance and essential elements of the Batch Manufacturing Record (BMR) in the pharmaceutical manufacturing process.** **5**

5. **Discuss the role and contents of the Investigational Medicinal Product Dossier (IMPD) in clinical trial submissions to the EMA.** **5**

6. Describe the concept of Pharmacovigilance and Materiovigilance, highlighting their role in post-marketing surveillance. **5**

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

1. **Critically evaluate the role of global regulatory agencies (USFDA, EMA, TGA, WHO, and CDSCO) in ensuring drug safety, efficacy, and international harmonization.** **15**

2. **Explain the regulatory pathway for approval of combination products and medical devices with reference to the USFDA and EU frameworks.** **15**

3. **Evaluate the importance and key contents of the Investigator's Brochure (IB) in ensuring ethical and safe conduct of clinical trials.** **15**

4. **Evaluate the importance of Bioavailability (BA) and Bioequivalence (BE) studies in drug product performance assessment, including their regulatory and industrial applications.** **15**

5. **Explain the importance of documentation in the pharmaceutical industry and discuss the contents and regulatory role of Master Formula Records, Batch Manufacturing Records, and Standard Operating Procedures.** **15**