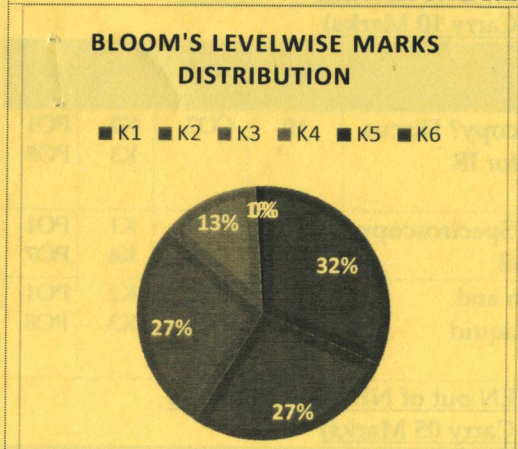
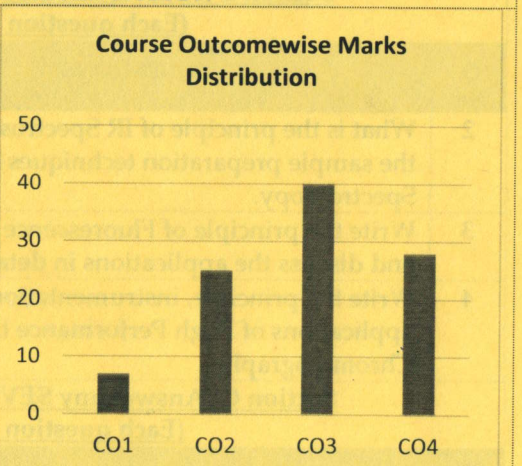
9	Discuss the principle and application of RIA.	5	CO3, CO4	K1 K3	PO1 PO7
10	Write short notes on column packaging techniques in column chromatography.	5	CO3	K1 K2	PO1
11	Discuss the practical requirements for Thin Layer Chromatography.	5	CO3	K1 K3	PO1 PO7
12	Discuss the applications of UV-Visible Spectroscopy.	5	CO1	K3 K4	PO9
13	Discuss the detectors used in IR Spectroscopy.	5	CO3	K1 K2	PO1

CO- Course Outcomes, **KL**- Knowledge Level, **PO** – Program Outcome

Course Outcomes	CO1	Analyze the the presence of Chemicals and Excipients used in the formulation.
	CO2	The analysis of various drugs in single and combination dosage forms
	CO3	Understand the theoretical and practical principles of the instruments
	CO4	Apply the advanced analytical instrumental techniques in characterization of the drugs and excipients in the formulation

GRAPHICAL REPRESENTATION





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[16-01-2026]
END SEM EXAMINATION
School of Pharmacy

Program	**Master of Pharmacy**		
Subject Name	**Modern Pharmaceutical Analytical Techniques**	**Session**	**Odd, 2025-26**
Semester	**I**	**Year**	**Jan, 2026**
Time: 3 Hour Max. Marks : 75	• Start writing from 2nd page onwards; **don't Write on the 1st Page Backside** • **Answer all Questions of Section A (Compulsory)** • **Answer Any *Two* out of *Three* of Section B** • **Answer Any *Seven* out of *Nine* of Section C** • **Possession of Mobile Phones** or any kind of **Written Material, Arguments with the Invigilator or Discussing with Co-Student** will comes under **Unfair Means** and will **Result** in the **Cancellation of the Papers.**		
Knowledge Level (KL)	**K1** : Remembering	**K3** : Applying	**K5** : Evaluating
	K2 : Understanding	**K4** : Analysing	**K6** : Creating

Section A (Each question Carry 01 Mark from Q1-i to xx) – 20 Marks

Q. N 1	QUESTIONS	Marks	COs	KL	PO
i	Which radiation source is used in UV-Visible Spectroscopy? a. Tungsten lamp b. Xenon arc lamp c. Deuterium Lamp d. All of these	1	CO3	K1	PO1
ii	When absorption intensity of compound is increased, it is called_____. a. Bathochromic shift b. Hypsochromic shift c. Hyperchromic shift d. Hypochromic shift	1	CO4	K2, K3	PO2
iii	Chromatography is an analytical technique and it is used for a. Identification of chemical species b. Separation of chemical species c. Quantification of chemical species d. All of the above	1	CO4	K4, K5	PO1
iv	What is the relation between wavelength and wavenumber? a. Directly proportional b. Inversely proportional c. Not related d. Both a and b	1	CO3	K1, K3	PO9

v	Which radiation has vibrational transitions a. Microwave b. Infrared c. X-ray d. Y-ray	1	CO3	K1	PO1
vi	The grating in UV spectrophotometer is made up of a. Glass b. Polystyrene c. KBr d. Quartz	1	CO3	K2	PO10
vii	For linear molecules, the vibrational degrees of freedom will be a. 3n-4 b. 3n-5 c. 3n-6 d. 3n-7	1	CO1	K3, K4, K5	PO8
viii	More the shielding effect a. Lower the chemical shift b. Higher the chemical shift c. No change in the chemical shift d. All of the above	1	CO3	K3, K4	PO2
ix	The most commonly employed reference compound in NMR is a. Nujol b. NaCl c. TMS d. KBr	1	CO3	K1, K2	PO1
x	Number of signals provided by Acetone in NMR spectroscopy. a. Zero b. One c. Two d. Three	1	CO3	K3 K4	PO9
xi	The intensity for base peak is taken as a. 90 b. 100 c. 110 d. 200	1	CO3	K1 K2	PO1
xii	What is the delta value for TMS in NMR? a. 0 b. 5 c. 10 d. 25	1	CO3	K1 K2	PO1
xiii	In Iodine chamber, which colour spots are seen a. Red Colour b. Blue Colour c. Yellow Colour d. Brown Colour	1	CO1	K3 K4	PO8
xiv	Which detector is not used in Fluorimetry? a. Phototube b. Photovoltaic cell c. Bolometer d. PMT	1	CO3	K1 K3	PO1, PO2
xv	Collisional quenching occurs due to: a. Presence of halides b. Presence of heavy metals c. Increased temperature d. All of these	1	CO1	K1 K3	PO1, PO2
xvi	In post column derivatization can be done by a. Adjusting pH to alkaline b. Adjusting pH to acidic c. Using an acid or alkaline buffer d: All of the above	1	CO1	K3 K4	PO8
xvii	What is detected in indirect ELISA? a. Enzyme only b. Antigen only c. Antibody only d. None of these	1	CO4	K4	PO7
xvii i	Compared to ELISA, RIA is a. Less sensitive b. Equally safe c. More sensitive but hazardous d. Cheap	1	CO4	K1 K2	PO2 PO6
xix	In gradient elution HPLC, what happens to the composition of the mobile phase during the run? a. It changes gradually over time b. It remains constant c. It fluctuates randomly d. It is replaced by the stationary phase	1	CO3	K3 K4	PO7 PO8
xx	Which type of elements is used to analyze by Flame Photometry? a. Group IV elements b. Group IA elements c. Group IIA elements d. Both b and c	1	CO1, CO2	K3 K4	PO10

Section B (Answer any TWO out of THREE) – 20 Marks
(Each question Carry 10 Marks)

Q. No.	QUESTIONS	Marks	COs	KL	PO
2	What is the principle of IR Spectroscopy? Discus the sample preparation techniques for IR Spectroscopy.	10	CO2	K2 K3	PO1 PO8
3	Write the principle of Fluorescence Spectroscopy and discuss the applications in detail.	10	CO4, CO2	K1 K4	PO1 PO7
4	Write the principle, instrumentation and applications of High Performance Liquid Chromatography.	10	CO2, CO3, CO4	K2 K3	PO1 PO8

Section C (Answer any SEVEN out of NINE) – 35 Marks
(Each question Carry 05 Marks)

Q. No.	QUESTIONS	Marks	COs	KL	PO
5	Write different types of vibrations in IR Spectroscopy.	5	CO3	K1 K2	PO1
6	What is chemical shift and discuss any two factors affecting chemical shift?	5	CO4	K1 K2	PO9
7	Write short notes on MALDI.	5	CO2	K1	PO1
8	Write short notes on auxochrome and chromophore.	5	CO3	K1 K3	PO1 PO7

3	Mention your understanding between Conventional dosage and Sustained Release (SR) dosage form with suitable examples. Discuss briefly the parameters need to be taken care during designing of a Sustained Release (SR) or Controlled Release (CR) solid dosage form over Conventional dosage form.	10	CO 1 CO 2	K1, K2	PO2
4	What are the barriers to protein delivery, what are the challenges of protein delivery and what factors affect protein absorption?	10	CO 3	K4	PO6

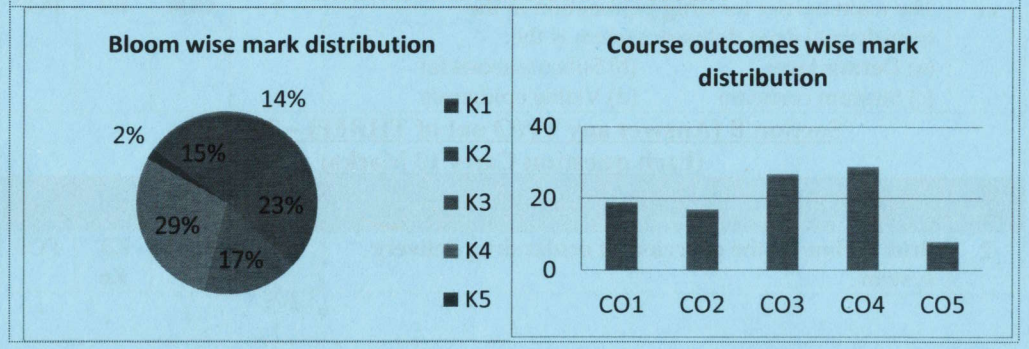
Section C (Answer any SEVEN out of NINE) – 35 Marks
(Each question Carry 05 Marks)

Q. No.	QUESTIONS	Marks	COs	KL	PO
5	Discuss penetration enhancers in trans transdermal drug delivery systems	5	CO3	K4	PO7
6	Write a short note on dose dumping	5	CO5	K2	PO5
7	Write a short note on the importance of 3D printing in pharmaceuticals	5	CO4	K4, K6	PO9
8	Write note on various Physiochemical and Biological factors approaches for SR or CR formulations.	5	CO2	K2	PO8
9	Write a note on Telepharmacy from a Pharmacist's Perspective	5	CO4	K4	PO9
10	Write a note on single shot vaccine	5	CO4	K3	PO8
11	What do you understand regarding pH activated drug delivery system	5	CO3	K2	PO5
12	Write the principle of controlled drug delivery Ssystem	5	CO1	K4	PO6
13	What are the underlying principles of mucoadhesion	5	CO3	K3	PO5

CO- Course Outcomes, **KL**- Knowledge Level, **PO** – Program Outcome

Course Outcomes	CO1	Understand the various approaches for development of novel drug delivery systems
	CO2	Analyse the criteria for selection of drugs and polymers for the development of delivering system
	CO3	Create and evaluate different formulations of Novel drug delivery systems
	CO4	Understand about novel technologies for drug targeting and delivery
	CO5	Evaluation of drug bioavailability and factors influencing bioavailability

GRAPHICAL REPRESENTATION



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[19-01-2026]
END SEM EXAMINATION
School of Pharmacy

Program	Master of Pharmacy		
Subject Name	Drug Delivery System	Session	Odd, 2025-26
Semester	I	Year	Jan, 2026

Time: 3 Hour
Max. Marks : 75

- Start writing from 2nd page onwards; **don't Write on the 1st Page Backside**
- **Answer all Questions of Section A (Compulsory)**
- **Answer Any *Two* out of *Three* of Section B**
- **Answer Any *Seven* out of *Nine* of Section C**
- **Possession of Mobile Phones** or any kind of **Written Material, Arguments with the Invigilator or Discussing with Co-Student** will comes under **Unfair Means** and will **Result** in the **Cancellation of the Papers**.

Knowledge Level (KL)			
	K1 : Remembering	**K3 :** Applying	**K5 :** Evaluating
	K2 : Understanding	**K4 :** Analysing	**K6 :** Creating

Section A (Each question Carry 01 Mark from Q1-i to xx) – 20 Marks

Q. N 1	QUESTIONS	Marks	COs	KL	PO
i	The technology utilized to present the drug to the desired body site for drug release and absorption is _____ (a) Metabolism (b) Drug absorption (c) Drug Elimination (d) None of above	1	CO5	K1	PO1
ii	Which of the following is a natural polymer commonly used in ocular drug delivery? (a) PLGA (b) Chitosan (c) Polyacrylamide (d) Povidone	1	CO2	K1	PO1
iii	Any of the dosage form that maintains the therapeutic blood or tissue levels of drug by continuous release of medication for a prolonged period of time, after administration of a single dose is_____ (a) Controlled release dosage form (b) Timed release dosage form (c) Sustained release dosage form (d) None of the above	1	CO1	K2	PO1
iv	Which route of drug administration is most likely to lead to the first-pass effect (a) Parenteral (b) Dermal (c) Rectal (d) Oral	1	CO1	K1	PO2
v	The spherical vesicles having an aqueous core enclosed by one or more phospholipid bilayers are called_____	1	CO3	K3	PO3

	(a) Liposome (b) Niosome (c) TDDS (d) MEDDS				
vi	Aqueous eyedrops are prone to microorganism hence required suitable concentration of preservative phenylmercuric nitrate (a) 0.0002% (b) 0.002% (c) 0.02% (d) 0.2%	1	CO4	K4	PO3
vii	The percentage of solids in the frozen plug in the ophthalmic preparation should be between approximately (a) 4 and 50% (b) 2 and 25% (c) 1 and 12% (d) None of above	1	CO4	K5	PO5
viii	Which ocular drug delivery systems form following have maximum contact time? (a) Ointment (b) Eye drop (c) Ocusert (d) Eye lotion	1	CO3	K3	PO3
ix	The eye drops are limited to (a) rapid tear turnover (b) blurred vision (c) Quick absorption (d) All	1	CO4	K4	PO4
x	How do viscosity-enhancing agents like HPMC or PVA improve the bioavailability of ocular drugs? (a) By increasing drug solubility (b) By reducing the pH of tears (c) By actively transporting the drug across the cornea (d) By increasing precorneal residence time	1	CO5	K5	PO6
xi	The primary disadvantage of sustained release formulations is: (a) Improved patient compliance (b) Dose dumping potential (c) Reduced frequency of dosing (d) Maintenance of steady drug levels	1	CO1	K1, K2	PO9
xii	Which factor is considered a biological factor influencing controlled release drug delivery systems? (a) Drug solubility (b) Partition coefficient (c) Biological half-life of the drug (d) pKa of the drug	1	CO2	K1	PO1
xiii	An elementary osmotic pump generally consists of a core tablet containing the drug and an osmogen, surrounded by a: (a) Permeable coating (b) Soluble membrane (c) Semi-permeable membrane with a delivery orifice (d) Non-erodible matrix	1	CO3	K3	PO5
xiv	In targeted drug delivery, the term "passive targeting" primarily refers to: (a) The use of monoclonal antibodies to target a specific receptor (b) Guiding drugs to the target site using an external magnetic field (c) Accumulation of the drug carrier in specific tissues due to enhanced permeability and retention (EPR) effect (d) Immediate drug release into systemic circulation	1	CO4	K3	PO4
xv	A drug candidate suitable for a Gastro-Retentive Drug Delivery System (GRDDS)typically has: (a) A very short half-life (b) Primary absorption in the stomach or upper intestine (c) Degradation in acidic gastric fluid (d) A local effect in the colon	1	CO5	K4	PO8
xvi	The drug contained in a core, which is surrounded by a polymer membrane, and it is released by diffusion through this rate controlling membrane is _____ (a) Matrix diffusion system (b) Reservoir diffusion system, (c) ORO delivery system (d) None of above	1	CO1	K3	PO7
xvii	Which model describes drug release from a planar matrix system where the release rate is proportional to the inverse square root of time? (a) First-order kinetics (b) Zero-order kinetics (c) Higuchi model (d) Korsmeyer-Peppas model	1	CO1	K4	PO8
xviii	Polymers used in controlled drug delivery systems are classified based on their: (a) Origin, biodegradability, and charge (b) Colour, shape, and flammability (c) Taste and odour (d) Cost of production	1	CO2	K3	PO8
xix	The "Ocusert" system for ocular drug delivery is a classic example of which type of system? (a) Bio-erodible insert (b) Non-erodible insert (c) Soluble ocular film (d) Suspension formulation	1	CO4	K2	PO5
xx	The main barrier for drug permeation in the transdermal drug delivery system is the: (a) Dermis layer (b) Subcutaneous fat (c) Stratum corneum (d) Viable epidermis	1	CO4	K3	PO7

Section B (Answer any TWO out of THREE) – 20 Marks
(Each question Carry 10 Marks)

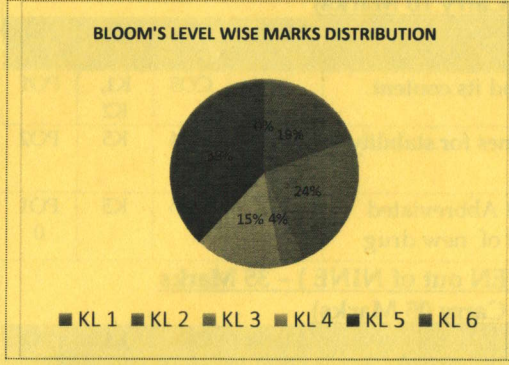
Q. No.	QUESTIONS	Marks	COs	KL	PO
2	Brief outline on the overview of ocular drug delivery system	10	CO4	K3, K6	PO5

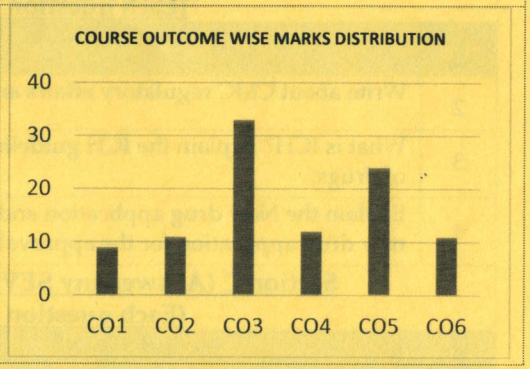
8	What is Dossier and explain the steps required for the preparation of dossier?	5	CO3	K4	PO2
9	Explain Post marketing surveillance.	5	CO5	K5	PO2
10	Explain the documentation required in Pharmaceutical Industries.	5	CO3	K4	PO4
11	Write down the importance of contact research organization.	5	CO3	K2	PO7
12	Shortly write about the primary goal and content of HIPPA.	5	CO6	K5	PO2
13	Shortly write about Investigators Brochure and its purpose.	5	CO3	K5	PO2

CO- Course Outcomes, **KL**- Knowledge Level, **PO** – Program Outcome

Course Outcomes	CO1	Understand the concepts of innovator and generic drugs, drug development process.
	CO2	Understand and remember the regulatory guidance's and guidelines for filing and approval process.
	CO3	Understand and apply the preparation of Dossiers and their submission to regulatory agencies in different countries.
	CO4	Analyze the post approval regulatory requirements for actives and drug products.
	CO5	Understand and apply regarding the submission of global documents in CTD/ eCTD formats.
	CO6	Understand and apply the Clinical trials requirements for approvals for conducting clinical trials. Understand and apply the Pharmacovigilence and process.

GRAPHICAL REPRESENTATION





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[27-01-2026]
END SEM EXAMINATION
School of Pharmacy

Program	**Master of Pharmacy**		
Subject Name	**Regulatory Affairs**	**Session**	**Odd, 2025-26**
Semester	**I**	**Year**	**Jan, 2026**
Time: 3 Hour Max. Marks : **75**	• Start writing from 2nd page onwards; **don't Write on the 1st Page Backside** • **Answer all Questions of Section A (Compulsory)** • **Answer Any *Two* out of *Three* of Section B** • **Answer Any *Seven* out of *Nine* of Section C** • **Possession of Mobile Phones** or any kind of **Written Material, Arguments with the Invigilator or Discussing with Co-Student** will comes under **Unfair Means** and will **Result** in the **Cancellation of the Papers**.		
Knowledge Level (KL)	**K1** : Remembering	**K3** : Applying	**K5** : Evaluating
	K2 : Understanding	**K4** : Analysing	**K6** : Creating

Section A (Each question Carry 01 Mark from Q1-i to xx) – 20 Marks

Q. N 1	QUESTIONS	Marks	COs	KL	PO
i	Batch Manufacturing Record is prepared by a) Research & Development Team b) Production unit c) QA d) QC	1	CO1	K2, K1	PO9
ii	In Pharma companies Regulatory Affairs Personnel is responsible for a) Analysis of the content of the active ingredient in the formulation b) Approval for drug federal, state and local governing agencies c) Undertaking stability studies of the drug products d) Supervision of the production of the formulation	1	CO2	K5	PO1
iii	ANDA approval process comes under which section a) Section505(j) b) Section505(b)2 c) Section505(b)1 d) None of the above	1	CO2	K1 K3	PO2
iv	ANDA is tailored by the study in comparison to NDA being involved to study bioavailability, animal studies and clinical studies is a) Bioavailability b) Bioequivalence c) Clinical studies d) None of the above	1	CO2	K5	PO2

v	The drug product performance is important because a) Drug product shows in turn the bioavailability of drug substance b) Bioavailability in turn is related to pharmacodynamics response c) Both a & b d) None of the above	1	CO4	K4	PO1
vi	Under SUPAC, Level-3 changes require a) Stability data b) Dissolution data c) Bioequivalence d) All of the above	1	CO3	K3	PO2
vii	Post marketing surveillance helps in a) Verification of risk analysis b) Performance in different user population c) Access to more patients and sustainability d) All of these	1	CO6	K5	PO1
viii	DMF deals with drug substance, drug substance Intermediate and drug product is a) Type-I b) Type-II c) Type-III d) Type-IV	1	CO1	K1, K2	PO1
ix	Therapeutics goods administration is the regulatory body of a) Australia b) United Kingdom c) China d) India	1	CO2	K2, K3	PO10
x	CTD is designed to a) Provide a harmonized structure and format for new product application b) Provide clinical efficacy in module-5 c) Both a & b d) None of the above	1	CO5	K5	PO1
xi	What does "IND" stand for in the context of drug development? a) International Drug Notice b) Investigational New Drug c) Initial New Drug Application d) Indian National Drug	1	CO3	K1, K2	PO2
xii	CMC section is made up of- a) Synthetic/fermentation chemistry b) Analytical chemistry c) Formulation chemistry d) All	1	CO5	K1, K2	PO1
xiii	What is placebo? a) The subjects do not know which study treatment they receive b) Patients injected with placebo and active doses c) Fake treatment d) Signed document of the recruited patient for the clinical trial procedures	1	CO1	K4	PO2
xiv	The guidelines for good manufacturing practice in India is a) 21 CFR Part 4 b) Schedule M c) 21 CFR Part 211 d) Eudralex Volume 4	1	CO1	K1, K2	PO1
xv	QSEM of ICH guidelines include- a) Quality/safety/efficacy/multidisciplinary b) Quantity/ source/ efficacy/ multidisciplinary c) Quality/safety/efficacy/multidrug d) All	1	CO5	K3	PO2
xvi	The detection, assessment and the prevention of adverse effect of the drug is known as- a) Pharmacogenomics b) Pharmacovigilance c) Pharmacoeconomics d) None	1	CO6	K2, K3	PO2
xvii	MHRA was set up in a)April 2003 b) April 2004 c) April 2006 d) April 2000	1	CO2	K1, K2	PO2
xvii i	Post approval regulatory affairs of FDA include- a) Drug- drug interaction b) Pharmacoeconomics c) Expanded Efficiency d) All	1	CO4	K5	PO2
xix	MHRA is an executive agency of- a) Canada b) United Kingdom c) China d) India	1	CO2	K1, K2	PO1
xx	Phase III clinical trials primarily focus on: a) Initial safety in a small group b) Dosage optimization c) Confirming efficacy & monitoring side effects in large populations d) Post-marketing surveillance	1	CO6	K4, K5	PO1

Section B (Answer any TWO out of THREE) – 20 Marks
(Each question Carry 10 Marks)

Q. No.	QUESTIONS	Marks	COs	KL	PO
2	Write about CMC regulatory affairs and its content.	10	CO5	K1, K2	PO1
3	What is ICH? Explain the ICH guidelines for stability of drugs.	10	CO4	K5	PO2
4	Explain the New drug application and Abbreviated new drug application for the approval of new drug	10	CO3	K5	PO10

Section C (Answer any SEVEN out of NINE) – 35 Marks
(Each question Carry 05 Marks)

Q. No.	QUESTIONS	Marks	COs	KL	PO
5	What do you mean by CTD? Mention the benefits of CTD.	5	CO5	K4	PO1
6	Explain Hatch- Waxman act and amendments.	5	CO1	K1, K2	PO2
7	What regulatory requirements are required for the approval of APIs?	5	CO2	K5	PO1

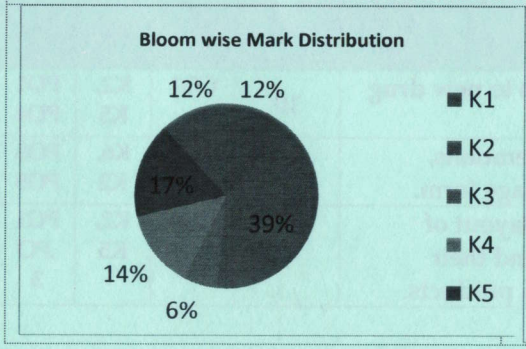
Section C Short Notes (Answer any SEVEN out of NINE) – 35 Marks
(Each question Carry 05 Marks)

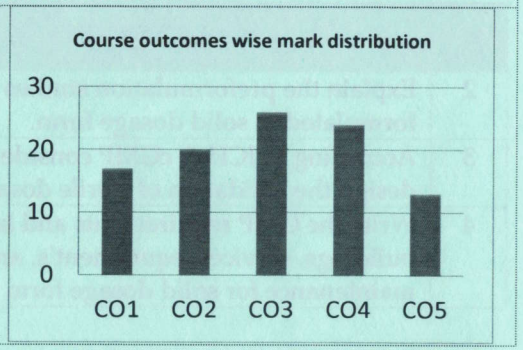
Q. No.	QUESTIONS	Marks	COs	KL	PO
5	Explain the stages of Equipment validation	5	CO2, CO3	K1, K2	PO2
6	Differentiate between validation and calibration.	5	CO2 CO3	K1, K2	PO3
7	What could be done to minimize defects in tablet manufacturing? Explain briefly in c context with tablets defects with respect to tablet compression.	5	CO4	K4, K5, K6	PO7
8	Write a short note on Accelerated stability studies	5	CO5	K1, K2	PO5
9	How to plot the drug release data using Higuchi and Peppas model.	5	CO3	K4	PO8
10	Shortly write about different drug excipient interaction.	5	CO1	K2, K4	PO3
11	How is pyrogen tests performed on parenteral preparations?	5	CO5	K3	PO5
12	Explain the role of friction during the tablet compression cycle	5	CO4	K2, K3	PO4
13	Explain the important considerations required during the formulation of a pharmaceutical suspension	5	CO3	K2	PO9

CO- Course Outcomes, KL- Knowledge Level, PO – Program Outcome

Course Outcomes	CO1	Analyze the elements of preformulation studies
	CO2	Understand the Active Pharmaceutical Ingredients and Generic drug Product development
	CO3	Understand and apply the Industrial Management and GMP Considerations
	CO4	Create and apply the optimization Techniques & Pilot Plant Scale Up Techniques
	CO5	Understand apply and evaluate the Stability Testing, sterilization process & packaging of dosage forms

GRAPHICAL REPRESENTATION





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[21-01-2026]
END SEM EXAMINATION
School of Pharmacy

Program	Master of Pharmacy		
Subject Name	Modern Pharmaceutics	Session	Odd, 2025-26
Semester	I	Year	Jan, 2025
Time: 3 Hour Max. Marks : 75	• Start writing from 2nd page onwards; **don't Write on the 1st Page Backside** • **Answer all Questions of Section A (Compulsory)** • **Answer Any TWO out of THREE of Section B LONG ANSWER** • **Answer Any SEVEN out of NINE of Section C SHORT NOTES** • **Possession of Mobile Phones** or any kind of **Written Material, Arguments with the Invigilator or Discussing with Co-Student** will comes under **Unfair Means** and will **Result** in the **Cancellation of the Papers**.		
Knowledge Level (KL)	**K1** : Remembering	**K3** : Applying	**K5** : Evaluating
	K2 : Understanding	**K4** : Analysing	**K6** : Creating

Section A (Each question Carry 01 Mark from Q1-i to Q1-xx) –20 Marks

Q. N 1	QUESTIONS	Marks	COs	KL	PO
i	SEDDS produce _____ after administration a) Emulsions b) Flocculated Suspension c) Deflocculated Suspension d) None of these	1	CO1	K1	PO1
ii	Which property of a drug is most likely to be influenced by polymorphism? a) Water solubility b) Optical rotation c) Partition coefficient d) Half life	1	CO1	K4, K5	PO3
iii	Which instrument is commonly used to determine polymorphism? a) UV-Vis spectrophotometer b) IR spectrophotometer c) Powder X-ray diffractometer d) Colorimeter	1	CO1	K2, K4	PO4
iv	The crystalline form of a drug usually shows: a) Higher solubility b) Lower melting point c) Better stability d) More rapid absorption	1	CO2	K1, K2	PO2
v	In the layout of pharmaceutical buildings, what is the main purpose of segregating production areas? a) To reduce energy costs b) To prevent contamination and ensure	1	CO4	K1, K2	PO2

	product safety c) To increase storage space d) To facilitate employee commuting				
vi	What is the primary objective of current Good Manufacturing Practices (cGMP)? a) To maximize profits for pharmaceutical companies b) To ensure products are consistently produced and controlled according to quality standards c) To reduce the number of employees in production d) To focus solely on marketing strategies	1	CO3	K3	PO3
vii	What is a key effect of high friction during tablet ejection? a) Improved tablet hardness b) Increased risk of capping or sticking c) Enhanced solubility of the drug d) Uniform force distribution	1	CO3	K2	PO6
viii	Prospective validation is the validation ____ production. a) During b) Before c) After d) All the above	1	CO3	K3	PO5
ix	Glidants are used in the manufacturing of tablets to a) Increase the flow properties of granules b) Reduce the die sticking c) Improve the elegance of tablet d) Both a) & b)	1	CO4	K4	PO5
x	In the context of government regulations, which agency primarily oversees pharmaceutical validation in the US? a) WHO b) FDA c) EMA d) ICH	1	CO3	K4	PO6
xi	Following are the defects on tablet compression except a) Lamination b) Picking & Sticking c) Capping d) Orange peel effect	1	CO5	K3	PO5
xii	Which type of validation is specifically applied to tablet dosage forms to ensure uniformity and dissolution? a) Process validation b) Analytical method validation c) Equipment validation d) Cleaning validation	1	CO3	K4	PO5
xiii	Which factor in compression physics can alter the distribution of forces? a) Die wall lubrication b) Tablet color c) Solvent type for solubility testing d) Ambient humidity	1	CO4	K6	PO5
xiv	What items should be examined for process evaluation? a) Mixing Speed b) Mixing area c) Drying temp. d) All of the above	1	CO5	K6	PO9
xv	For high barrier packaging in collapsible tubes ___ tubes are used a) Metal tubes b) Plastic tubes c) Rubber tubes d) All	1	CO5	K6	PO9
xvi	In ICH guidelines, accelerated stability testing typically uses conditions like: a) 25 °C / 60 % RH b) 40 °C / 75 % RH c) 30 °C / 80 % RH d) 5 °C / 60 % RH	1	CO6	K3	PO6
xvii	The advantage of blister pack over strip pack is a) More mechanical protection b) More child resistance c) More air space d) All	1	CO4	K5	PO8
xvii i	The crystalline form of a drug usually shows: a) Higher solubility b) Lower melting point c) Better stability d) More rapid absorption	1	CO3	K5	PO7
xix	The key elements of TQM a) Ethics b) Teamwork c) Training d) All	1	CO4	K4	PO4
xx	The stability factors in sterile dosage forms are a) Temperature b) Light c) Oxygen d) All	1	CO5	K4	PO6

Section B Long Answer (Answer any TWO out of THREE) – 20 Marks
(Each question Carry 10 Marks)

Q. No.	QUESTIONS	Marks	Cos	KL	PO
2	Explain the preformulation studies to new drug formulated in solid dosage form.	10	CO1	K2, K5	PO1 PO4
3	According to ICH & cGMP considerations, design the validation of sterile dosage form.	10	CO2, CO3	K6, K2	PO3 PO5
4	Write the GMP requirements and layout of buildings, services, equipment's, and their maintenance for solid dosage form products.	10	CO4	K2, K5	PO1 ,PO 3