HINDU COLLEGE OF PHARMACY (AUTONOMOUS)

Amaravathi Road – GUNTUR -522002. A.P.

Regd. No: …… **MPH -101T**

Total No. of Questions: 14 **Total No. of Pages: 2**

I/II M. Pharmacy Regular Degree 1st Semester end Theory Examinations April, 2026 - (Admitted in 2025-2026 Autonomous Batch)

Pharmaceutics

Subject Code & Name: MPH -101T Modern Pharmaceutical Analytical Techniques.

Time Duration: 3.00 Hrs. **Max. Marks: 75 Marks.**

CO1	The analysis of various drugs in single and combination dosage forms
CO2	To Determine the Compounds by Spectroscopy Techniques.
CO3	To Determine the compounds by Chromatography Techniques.
CO4	To Determine the Compounds by Electrochemical and thermal methods.
CO5	To Interpret the Compounds by various analytical Techniques.

Bloom's Taxonomy Levels-(BL) (L1-Remembering, L2-Understanding, L3–Applying, L4-Analysing, L5–Evaluating, L6-Creating)

SECTION – A

ANSWER ANY FIVE QUESTIONS **(5 X 10M = 50 Marks)**

Q. No.	Questions	Marks	CO	BL
1	Explain the construction and working of the UV-Visible spectrophotometer with a neat diagram. Discuss pharmaceutical applications and solvent effects.	10	CO1	L3
2	Describe the NMR spectroscopy principle. Explain chemical shift, spin-spin coupling, and coupling constant with examples and pharmaceutical applications.	10	CO2	L3
3	Discuss ionization techniques in mass spectroscopy (EI, ESI, MALDI). Explain quadrupole and TOF analyzers with diagrams.	10	CO2	L4
4	Define chromatographic parameters affecting resolution. Explain the HPLC principle, instrumentation, and applications with a flow diagram.	10	CO3	L4
5	Describe capillary electrophoresis and isoelectric focusing with labelled diagrams. Discuss separation factors.	10	CO3	L4
6	Explain the principle and instrumentation of Gas Chromatography. Analyze the influence of carrier gas and stationary phase on separation efficiency.	10	CO4	L3
7	a) Compare Flame Emission Spectroscopy and Atomic Absorption Spectroscopy. b) Explain in detail about Radio Immuno Assay with applications	10	CO5	L4

SECTION – B

ANSWER ANY FIVE QUESTIONS **(5 X 5M = 25 Marks)**

Q. No.	Questions	Marks	CO	BL
8	Write a note on the FTIR spectrometer and vibrational frequency factors.	5	CO1	L3
9	Explain the role of solvents in NMR and the nuclear Overhauser effect (NOE).	5	CO2	L3
10	Describe mass fragmentation rules and metastable ions.	5	CO2	L4
11	Differentiate TLC and HPTLC with applications.	5	CO3	L3
12	State Bragg's law. Explain the X-ray powder diffraction technique.	5	CO3	L3
13	Explain the principle and mechanism of Affinity chromatography	5	CO4	L3
14	What is quenching? Enlist spectrofluorimetric quenchers.	5	CO5	L4

****All the Best ****

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Regd. No: …… **MPH-102T**

Total No. of Questions: 14 **Total No. of Pages: 02**

I/II M. Pharmacy Regular Degree 1st Semester end Theory Examinations
April, 2026 - (Admitted in 2025-2026 Autonomous Batch)
Pharmaceutics Specialization

Subject Code & Name:MPH-102T Drug Delivery System.

Time Duration: 3.00 Hrs. **Max. Marks: 75 Marks.**

CO1	The various approaches for development of novel drug delivery systems.
CO2	The criteria for selection of drugs and polymers for the development of delivering system.
CO3	The formulation and evaluation of Novel drug delivery systems.
CO4	Able to understand the importance of Personalized medicine and 3D printing of Pharmaceuticals

Bloom's Taxonomy Levels-(BL) (L1-Remembering, L2-Understanding, L3–Applying, L4-Analysing, L5–Evaluating, L6-Creating)

SECTION – A

ANSWER ANY FIVE QUESTIONS **(5 X 10M = 50 Marks)**

Q. No.	Questions	Marks	CO	BL
1	Explain the basic concepts, advantages and disadvantages of sustained release and controlled release formulations. Discuss the physicochemical and biological factors influencing SR/CR drug delivery systems	10	CO1	L2
2	Discuss the classification, properties and applications of polymers used in controlled drug delivery systems.	10	CO2	L2
3	Explain the principle, advantages and limitations of gastro-retentive drug delivery systems (GRDDS). Describe various approaches used to prolong gastric residence time.	10	CO3	L3
4	Describe the principle of mucoadhesion in buccal drug delivery systems and explain different methods of formulation and evaluation of buccal drug delivery systems.	10	CO3	L3
5	Explain the structure of skin and barriers to transdermal drug delivery. Discuss the role of penetration enhancers in transdermal drug delivery systems.	10	CO2	L2
6	Discuss the barriers for protein and peptide drug delivery and explain different strategies used to improve their delivery.	10	CO3	L3
7	Explain the concept of personalized medicine and discuss the role of pharmacogenetics and 3D printing in pharmaceutical dosage forms.	10	CO4	L4

SECTION – B

ANSWER ANY FIVE QUESTIONS **(5 X 5M = 25 Marks)**

Q. No.	Questions	Marks	CO	BL
8	Write short notes on rate-controlled drug delivery systems.	5	CO1	L1
9	Explain mechanically activated drug delivery systems with suitable examples.	5	CO1	L2
10	Discuss feedback regulated drug delivery systems.	5	CO1	L2
11	Write short notes on ocular drug delivery barriers and methods to overcome them.	5	CO2	L2
12	Explain the mechanism of drug permeation through buccal mucosa.	5	CO3	L2
13	Discuss transdermal drug delivery evaluation methods.	5	CO3	L3
14	Write a note on vaccine delivery systems and mucosal vaccine delivery.	5	CO4	L2

****All the Best ****

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Regd. No: …… **MPH-103T**

Total No. of Questions: 14 **Total No. of Pages: 2**

I/II M. Pharmacy Regular Degree 1st Semester end Theory Examinations April, 2026 - (Admitted in 2025-2026 Autonomous Batch) Pharmaceutics Specialization

Subject Code & Name: MPH-103T Modern Pharmaceutics.

Time Duration: 3.00 Hrs. **Max. Marks: 75 Marks.**

CO1	**Define optimization.** Explain the **concept and parameters of optimization** in pharmaceutical formulation with suitable examples.
CO2	**Discuss ICH and WHO guide lines for calibration and validation of equipments**
CO2	**Explain the** merits and objectives of validation**.**
CO2	**Write a short note on the** scope of pharmaceutical validation
CO4	**Explain the** process of compression and compaction **in tablet manufacture.**
CO4	**Write a short note on** physics of tablet compression

Bloom's Taxonomy Levels-(BL) (L1-Remembering, L2-Understanding, L3–Applying, L4-Analysing, L5–Evaluating, L6-Creating)

SECTION – A

ANSWER ANY FIVE QUESTIONS **(5 X 10M = 50 Marks)**

Q. No.	Questions	Marks	CO	BL
1	Discuss in detail about the role of materials management in pharma production	10 M	04	02
2	How will you determine the solid state stability profile of a new compound	10M	01	05
3	Write about the following A) Higuchi and Peppas Plots B) Area under the curve and standard error of mean	 05M 05M	 06 06	 01 01
4	Explain the terms ‘performance qualification’ and ‘design qualification’ in detail with examples	10M	03	02
5	Write the various approaches used for the enhancing solubility of the drug in the oral liquid formation development	10M	06	01
6	A) Write the In-vitro method used for the determination of pyrogens in parenteral preparations B) What is validation and write its objectives	05M 05M	01 03	01 01
7	A) Explain how sales forecast deserves for many business decisions	05M	04	02
	B) Differentiate between compression and consolidation. Explain the term compressibility index	05M	05	04

SECTION – B

ANSWER ANY FIVE QUESTIONS **(5 X 5M = 25 Marks)**

Q. No.	Questions	Marks	CO	BL
8	Explain in detail the concept of total quality management	05M	04	02
9	Write about tooling of the tablet compression machine	05M	05	01
10	Explain the Ficks laws of diffusion and write their importance	05M	05	02
11	Differentiate between f 1 and f 2 factors	05M	06	01
12	Write about the Chi square test	05M	06	01
13	What do you understand by the term 'preventive maintenance' and write its importance in the production	05M	04	01
14	Compare the formulation additives of small volume Parenterals and large volume parenterals with respect to stability and therapeutic efficacy	05M	02	03

****All the Best ****

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I/II M. Pharmacy Regular Degree 1st Semester end Theory Examinations
April, 2026 - (Admitted in 2025-2026 Autonomous Batch)
Pharmaceutics Specialization

Subject Code & Name: MPH-104T Regulatory Affairs.

Time Duration: 3.00 Hrs. **Max. Marks: 75 Marks.**

CO1	To understand the concepts of innovator and generic drugs and drug development process.
CO2	The regulatory guidance's and guidelines for filling and approval process.
CO3	Preparation of Dossiers and their submission to regulatory agencies in different countries.
CO4	Post approval regulatory requirements for actives and drug products
CO5	Submission of global documents in CTD/eCTD formats
CO6	Clinical trails requirements for approval for conducting clinical trials

Bloom's Taxonomy Levels-(BL) (L1-Remembering, L2-Understanding, L3–Applying, L4-Analysing, L5–Evaluating, L6-Creating)

SECTION – A

ANSWER ANY FIVE QUESTIONS **(5 X 10M = 50 Marks)**

Q. No.	Questions	Marks	CO	BL
1	What is the Hatch–Waxman Act and why is it important in the development and approval of generic drugs?	10	1	1
2	Compare the regulatory requirements and guidelines for pharmaceutical product approval in the European Union, MHRA and TGA.	10	2	2
3	Develop a structured dossier for global submission of a New Drug Application (NDA) by organizing the required modules and regulatory documents.	10	5	3
4	Explain the role of Institutional Review Boards / Independent Ethics Committees in protecting human participants during clinical trials.	10	6	5
5	Explain the importance of pharmacovigilance safety monitoring systems in detecting and managing adverse drug reactions during clinical trials.	10	4	5
6	Explain the Chemistry, Manufacturing and Controls (CMC) requirements and outline their role in regulatory submissions for drug approval.	10	3	2
7	List and explain the steps involved in the Abbreviated New Drug Application (ANDA) regulatory approval process in the United States.	10	5	1

SECTION – B

ANSWER ANY FIVE QUESTIONS **(5 X 5M = 25 Marks)**

Q. No.	Questions	Marks	CO	BL
8	Define Master Formula Record and list its importance in pharmaceutical manufacturing documentation.	5	3	1
9	Classify medical devices based on regulatory risk categories and explain their approval requirements.	5	2	2
10	Develop an outline for preparing an Investigational Medicinal Product Dossier (IMPD) required for regulatory submission in clinical research.	5	3	3
11	Explain the importance of ICH guidelines in harmonizing international pharmaceutical regulations.	5	3	3
12	Justify the importance of the informed consent process in protecting the rights and safety of clinical trial participants.	5	6	5
13	Illustrate the structure and components of CTD and eCTD formats used for global regulatory dossier submission.	5	5	2
14	What is post-marketing surveillance and why is it important for drug safety monitoring?	5	4	1

****All the Best ****