# AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES (AUTONOMOUS)

Accredited by NAAC A+, UGC 2 (f)) (JNTU-GV Approved Research Centre)
(Approved by P.C.I, New Delhi, Recognized by the Govt. of A.P., Affiliated to JNTU-GV, Vizianagaram)
Cherukupally (Village), Chittivalasa (SO), Bhogapuram (Mandal), Vizianagaram (Dist)-531162
www.avanthipharma.ac.in, principal@avanthipharma.ac.in


## DEPARTMENT OF PHARMACY

### Course Structure

### Program– M. Pharmacy Pharmaceutical Analysis

### Regulation-R25

**I Year I Semester-Course Structure**

| S.No | Category | Course Code | Course Title | Hours per Week | | | |
|---|---|---|---|---|---|---|---|
| | | | | Lecture | Tutorial | Practical | Credits |
| 1 | PC | R25MPA101 | Modern Pharmaceutical Analytical Techniques | 4 | 0 | 0 | 4 |
| 2 | PC | R25MPA102 | Advanced Pharmaceutical Analysis | 4 | 0 | 0 | 4 |
| 3 | PC | R25MPA103 | Pharmaceutical Validation | 4 | 0 | 0 | 4 |
| 4 | PC | R25MPA104 | Food and Nutraceutical Analysis | 4 | 0 | 0 | 4 |
| 5 | PC | R25MPA105 | Modern Pharmaceutical Analytical Techniques Practical | 0 | 0 | 6 | 3 |
| 6 | PC | R25MPA106 | Food Analysis Practical | 0 | 0 | 6 | 3 |
| 7 | PC | R25MPA107 | Seminars/Assignments | 8 | 0 | 0 | 4 |
| 8 | MC | R25MPA108 | Research Paper Writing | 4 | 0 | 0 | 0 |
| Total | | | | 28 | 0 | 12 | 26 |

| Category | Courses | Credits |
|---|---|---|
| PC-Pharmacy Core Course | 7 | 26 |
| MC-Mandatory Course | 1 | 00 |

## I Year II Semester-Course Structure

| S.No | Category | Course Code | Course Title | Hours per Week | | | |
|---|---|---|---|---|---|---|---|
| | | | | Lecture | Tutorial | Practical | Credits |
| 1 | PC | R25MPA201 | Advanced Instrumental Analysis | 4 | 0 | 0 | 4 |
| 2 | PC | R25MPA202 | Modern Bio-Analytical Techniques | 4 | 0 | 0 | 4 |
| 3 | PC | R25MPA203 | Quality Control and Quality Assurance | 4 | 0 | 0 | 4 |
| 4 | PC | R25MPA204 | Herbal and Cosmetic Analysis | 4 | 0 | 0 | 4 |
| 5 | PC | R25MPA205 | Advanced Pharmaceutical Analysis Practical | 0 | 0 | 6 | 3 |
| 6 | PC | R25MPA206 | Herbal and Cosmetic Analysis Practical | 0 | 0 | 6 | 3 |
| 7 | PC | R25MPA207 | Seminars/Assignments | 8 | 0 | 0 | 4 |
| 8 | MC | R25MPA208 | Entrepreneurship Management | 4 | 0 | 0 | 0 |
| Total | | | | 28 | 0 | 12 | 26 |

| Category | Courses | Credits |
|---|---|---|
| PC-Pharmacy Core Course | 7 | 26 |
| MC-Mandatory Course | 1 | 00 |

M. pawani

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## DEPARTMENT OF PHARMACY

### Course Structure

### Program– M. Pharmacy Pharmaceutics

### Regulation-R25

### I Year I Semester-Course Structure

| S.No | Category | Course Code | Course Title | Hours per Week | | | |
|---|---|---|---|---|---|---|---|
| | | | | Lecture | Tutorial | Practical | Credits |
| 1 | PC | R25MPH101 | Modern Pharmaceutical Analytical Techniques | 4 | 0 | 0 | 4 |
| 2 | PC | R25MPH102 | Advanced Drug Delivery Systems | 4 | 0 | 0 | 4 |
| 3 | PC | R25MPH103 | Modern Pharmaceutics | 4 | 0 | 0 | 4 |
| 4 | PC | R25MPH104 | Regulatory Affairs in Product Development | 4 | 0 | 0 | 4 |
| 5 | PC | R25MPH105 | Modern Pharmaceutical Analytical Techniques Practical | 0 | 0 | 6 | 3 |
| 6 | PC | R25MPH106 | Advanced Drug Delivery Systems Practical | 0 | 0 | 6 | 3 |
| 7 | PC | R25MPH107 | Seminars/Assignments | 8 | 0 | 0 | 4 |
| 8 | MC | R25MPH108 | Research Paper Writing | 4 | 0 | 0 | 0 |
| Total | | | | 28 | 0 | 12 | 26 |

| Category | Courses | Credits |
|---|---|---|
| PC-Pharmacy Core Course | 7 | 26 |
| MC-Mandatory Course | 1 | 00 |

## I Year II Semester-Course Structure

| S.No | Category | Course Code | Course Title | Hours per Week | | | |
|---|---|---|---|---|---|---|---|
| | | | | Lecture | Tutorial | Practical | Credits |
| 1 | PC | R25MPH201 | Molecular Pharmaceutics (Nano Technology and Targeted DDS) | 4 | 0 | 0 | 4 |
| 2 | PC | R25MPH202 | Advanced Biopharmaceutics & Pharmacokinetics | 4 | 0 | 0 | 4 |
| 3 | PC | R25MPH203 | Computer Aided Drug Delivery Systems | 4 | 0 | 0 | 4 |
| 4 | PC | R25MPH204 | Product Formulation technology | 4 | 0 | 0 | 4 |
| 5 | PC | R25MPH205 | Molecular Pharmaceutics Practical | 0 | 0 | 6 | 3 |
| 6 | PC | R25MPH206 | Product Formulation technology Practical | 0 | 0 | 6 | 3 |
| 7 | PC | R25MPH207 | Seminars/Assignments | 8 | 0 | 0 | 4 |
| 8 | MC | R25MPH208 | Entrepreneurship Management | 4 | 0 | 0 | 0 |
| Total | | | | 28 | 0 | 12 | 26 |

| Category | Courses | Credits |
|---|---|---|
| PC-Pharmacy Core Course | 7 | 26 |
| MC-Mandatory Course | 1 | 00 |

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## DEPARTMENT OF PHARMACY

### Course Structure

### Program– M. Pharmacy Pharmacology

### Regulation-R25

### I Year I Semester-Course Structure

| S.No | Category | Course Code | Course Title | Hours per Week | | | |
|---|---|---|---|---|---|---|---|
| | | | | Lecture | Tutorial | Practical | Credits |
| 1 | PC | R25MPL101 | Modern Pharmaceutical Analytical Techniques | 4 | 0 | 0 | 4 |
| 2 | PC | R25MPL102 | Advanced Pharmacology-I | 4 | 0 | 0 | 4 |
| 3 | PC | R25MPL103 | Pharmacological and Toxicological Screening Methods-I | 4 | 0 | 0 | 4 |
| 4 | PC | R25MPL104 | Cellular and Molecular Pharmacology | 4 | 0 | 0 | 4 |
| 5 | PC | R25MPL105 | Analytical and Cellular Pharmacology Practical - I | 0 | 0 | 6 | 3 |
| 6 | PC | R25MPL106 | Modern Pharmacology Practical - II | 0 | 0 | 6 | 3 |
| 7 | PC | R25MPL107 | Seminars/Assignments | 8 | 0 | 0 | 4 |
| 8 | MC | R25MPL108 | Research Paper Writing | 4 | 0 | 0 | 0 |
| Total | | | | 28 | 0 | 12 | 26 |

| Category | Courses | Credits |
|---|---|---|
| PC-Pharmacy Core Course | 7 | 26 |
| MC-Mandatory Course | 1 | 00 |
| Total | 8 | 26 |

**I Year II Semester-Course Structure**

| S.No | Category | Course Code | Course Title | Hours per Week | | | |
|---|---|---|---|---|---|---|---|
| | | | | Lecture | Tutorial | Practical | Credits |
| 1 | PC | R25MPL201 | Advanced Pharmacology II | 4 | 0 | 0 | 4 |
| 2 | PC | R25MPL202 | Pharmacological and Toxicological Screening Methods-II | 4 | 0 | 0 | 4 |
| 3 | PC | R25MPL203 | Principles of drug discovery | 4 | 0 | 0 | 4 |
| 4 | PC | R25MPL204 | Clinical Research and Pharmacovigilance | 4 | 0 | 0 | 4 |
| 5 | PC | R25MPL205 | Bioassays Practical | 0 | 0 | 6 | 3 |
| 6 | PC | R25MPL206 | Pharmacological drug development Practical | 0 | 0 | 6 | 3 |
| 7 | PC | R25MPL207 | Seminars/Assignments | 8 | 0 | 0 | 4 |
| 8 | MC | R25MPL208 | Entrepreneurship Management | 4 | 0 | 0 | 0 |
| TOTAL | | | | 28 | 0 | 12 | 26 |

| Category | Courses | Credits |
|---|---|---|
| PC-Pharmacy Core Course | 7 | 26 |
| MC-Mandatory Course | 1 | 00 |

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## DEPARTMENT OF PHARMACY

### Course Structure

### Program– M. Pharmacy Pharmaceutical Technology

### Regulation-R25

**I Year I Semester-Course Structure**

| S.No | Category | Course Code | Course Title | Hours per Week | | | |
|---|---|---|---|---|---|---|---|
| | | | | Lecture | Tutorial | Practical | Credits |
| 1 | PC | R25MPT101 | Modern Pharmaceutical Analytical Techniques | 4 | 0 | 0 | 4 |
| 2 | PC | R25MPT102 | Advanced Drug Delivery Systems | 4 | 0 | 0 | 4 |
| 3 | PC | R25MPT103 | Modern Pharmaceutics | 4 | 0 | 0 | 4 |
| 4 | PC | R25MPT104 | Regulatory Affairs in Product Development | 4 | 0 | 0 | 4 |
| 5 | PC | R25MPT105 | Modern Pharmaceutical Analytical Techniques Practical | 0 | 0 | 6 | 3 |
| 6 | PC | R25MPT106 | Advanced Drug Delivery Systems Practical | 0 | 0 | 6 | 3 |
| 7 | PC | R25MPT107 | Seminars/Assignments | 8 | 0 | 0 | 4 |
| 8 | MC | R25MPT108 | Research Paper Writing | 4 | 0 | 0 | 0 |
| Total | | | | 28 | 0 | 12 | 26 |

| Category | Courses | Credits |
|---|---|---|
| PC-Pharmacy Core Course | 7 | 26 |
| MC-Mandatory Course | 1 | 00 |

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## I Year II Semester-Course Structure

| S.No | Category | Course Code | Course Title | Hours per Week | | | |
|---|---|---|---|---|---|---|---|
| | | | | Lecture | Tutorial | Practical | Credits |
| 1 | PC | R25MPT201 | Molecular Pharmaceutics (Nano Technology and Targeted DDS) | 4 | 0 | 0 | 4 |
| 2 | PC | R25MPT202 | Advanced Biopharmaceutics & Pharmacokinetics | 4 | 0 | 0 | 4 |
| 3 | PC | R25MPT203 | Computer Aided Drug Delivery Systems | 4 | 0 | 0 | 4 |
| 4 | PC | R25MPT204 | Product Formulation technology | 4 | 0 | 0 | 4 |
| 5 | PC | R25MPT205 | Molecular Pharmaceutics Practical | 0 | 0 | 6 | 3 |
| 6 | PC | R25MPT206 | Product Formulation technology Practical | 0 | 0 | 6 | 3 |
| 7 | PC | R25MPT207 | Seminars/Assignments | 8 | 0 | 0 | 4 |
| 8 | MC | R25MPT208 | Entrepreneurship Management | 4 | 0 | 0 | 0 |
| Total | | | | 28 | 0 | 12 | 26 |

| Category | Courses | Credits |
|---|---|---|
| PC-Pharmacy Core Course | 7 | 26 |
| MC-Mandatory Course | 1 | 00 |

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## R25MPA101 MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES 4 0 0 4

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

1. **To impart fundamental and advanced knowledge** on modern analytical instrumentation techniques used in pharmaceutical analysis.
2. **To provide comprehensive understanding** of the principles, instrumentation, working mechanisms, and applications of spectroscopic techniques such as UV-Visible, IR, NMR, and Mass Spectrometry.
3. **To introduce chromatographic and electrophoretic techniques** including HPLC, HPTLC, GC, and Capillary Electrophoresis, with emphasis on their role in qualitative and quantitative analysis of drugs.
4. **To familiarize students with modern hyphenated techniques** such as LC-MS, GC-MS, and their pharmaceutical applications in drug discovery, formulation development, and regulatory submissions.
5. **To develop competence in analytical method validation** as per ICH and regulatory guidelines for the quality control and quality assurance of pharmaceuticals.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO5 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO101.1 | Recall principle, operation and applications of selected instrumental spectroscopic, chromatographic analysis. | 1 | 2 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25CO101.2 | Gain knowledge on interpretation of NMR spectra for determination of molecular structure of compounds. | 1 | 2 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25CO101.3 | Build the analytical understanding in the level of ion, atom, group and molecular structure of organic and inorganic compounds with different functional groups by Mass spectroscopy and their applications in pharmacy. | 1 | 2 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25CO101.4 | Understand the concept of separation and identification of compounds by chromatographic techniques. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25CO101.5 | Categorize different anions and cations by using suitable electrophoresis techniques. Elaborate principle, theory and instruments employed for the analysis of drugs by thermal techniques | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

**b. IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.

**c. Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

**d. Flame emission spectroscopy:** Principle, Instrumentation, Interferences and Applications.

**CO's–CO1**

**Self Learning topics:** Comparative Analysis of Molecular Spectroscopy Techniques: UV-Vis vs. IR vs. Fluorescence, Role of Solvent Effects and Sample Preparation Techniques in Spectroscopic Analysis and Pharmaceutical Applications of Atomic Absorption and Flame Emission Spectroscopy in Trace Element Analysis.

**UNIT II:** **10 Hours**

**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

**CO's–CO2**

**Self Learning topics:** Understanding Quantum Numbers and Their Role in NMR Activity, Solvent Selection in NMR: Deuterated Solvents and Their Importance and Comparison Between $^{1}H$ NMR and $^{13}C$ NMR Spectroscopy.

**UNIT III:** **10 Hours**

**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.

**CO's–CO3**

**Self Learning topics:** Comparison of Ionization Techniques in Mass Spectrometry, Understanding Mass Fragmentation Patterns and the Nitrogen Rule and Role and Interpretation of Metastable Ions and Isotopic Peaks.

**UNIT IV:** **8 Hours**

**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography

**CO's–CO4**

**Self Learning topics:** Comparison of Chromatographic Techniques: Planar vs. Column Chromatography, Optimization of Resolution in HPLC and Gas Chromatography and ligand selection and elution strategies in bioseparation processes.

**UNIT V:** **7 Hours**

**a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis
c) Capillary electrophoresis d) Zone electrophoresis
e) Moving boundary electrophoresis f) Iso electricfocusing

**b. Thermal techniques: DSC, DTA, TGA:** Principle, instrumentation, factors affecting results, pharmaceutical applications.

**c. X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

**d. Immunological assays:** RIA(Radio immuno assay), ELISA, Bioluminescence assays.

**CO's-CO5**

**Self Learning topics:** real-life applications in DNA profiling, protein purification, and forensic analysis. X-ray diffraction helps in drug polymorphism, crystal habit modification, and structure-based drug design.

Board of Studies: Pharmacy
Approved in BOS No: 01, 22nd October, 2025
Approved in ACM No: 01

**Text Books**

1. Spectrometric Identification of Organic compounds –Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Easternpress, Bangalore,1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis –Modern methods –Part B- JW Munson, Volume 11, Marcel Dekker Series

**Reference Books**

1. Indian Pharmacopoeia
2. United State Pharmacopoeia

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define Beer-Lambert's law.
2. List any two applications of UV-Visible spectroscopy.
3. Name different types of molecular vibrations.
4. What is fluorescence?
5. Define chemical shift.
6. List NMR-active nuclei.
7. What are quantum numbers?
8. Define m/z ratio
9. List two ionization techniques.
10. Define retention time and resolution.
11. List types of chromatography.
12. Define isoelectric focusing.

13. What is Bragg's law?
14. List types of electrophoresis.

**L2.** Understand

1. Explain how solvent polarity affects UV spectra.
2. Describe the principle of atomic absorption spectroscopy.
3. Differentiate between dispersive and FT-IR spectrometers.
4. Explain spin-spin coupling with an example.
5. Describe the relaxation processes in NMR.
6. Explain the principle of MALDI and ESI.
7. Describe the role of quadrupole analyzer.
8. Describe how ion exchange chromatography separates analytes.
9. Explain the role of mobile and stationary phases.

**L3.** Apply

1. Calculate concentration using Beer-Lambert law.
2. Show how IR spectra can identify functional groups.
3. Use fluorescence intensity to determine analyte concentration.
4. Interpret a simple 1H NMR spectrum.
5. Apply the concept of shielding/deshielding in identifying peaks.
6. Predict fragmentation patterns for a given compound.
7. Apply mass spectral data to determine molecular weight.
8. Apply HPLC parameters to optimize peak separation.
9. Demonstrate how gas chromatography is used for volatile analytes.

**L4.** Analyze

1. Compare UV-Vis and IR spectroscopy in terms of analytical application.
2. Analyze the effect of quenchers on fluorescence output.
3. Identify factors affecting vibrational frequencies.
4. Compare 1H NMR and 13C NMR in terms of sensitivity and resolution.
5. Analyze how solvent affects chemical shifts.
6. Differentiate between TOF and quadrupole analyzers.
7. Analyze isotopic peaks in a chlorine-containing compound.
8. Compare paper chromatography and TLC.
9. Analyze how temperature affects GC resolution.
10. Compare capillary and gel electrophoresis.
11. Analyze differences between RIA and ELISA.

**L5.** Evaluate

1. Assess the usefulness of atomic absorption spectroscopy in trace metal analysis.
2. Justify the use of FT-IR over dispersive IR in analytical labs
3. Evaluate FT-NMR advantages in complex compound analysis.
4. Justify the selection of TMS as internal standard.
5. Evaluate the choice of ionization method for thermally labile molecules.
6. Critique the accuracy of molecular ion peak in EI-MS.
7. Assess the effectiveness of affinity chromatography for protein purification.
8. Justify using HPLC over column chromatography for pharmaceutical QC.
9. Evaluate the role of XRD in drug crystal structure determination.
10. Assess ELISA as a diagnostic tool.

**L6. Create**

1. Design a novel conjugated organic molecule with predictable λ_max using Woodward-Fieser, Fieser-Kuhn, and Nelson rules. Explain the rationale behind each substitution.
2. Design an IR-based experiment to distinguish between cis and trans isomers of a substituted alkene, taking into account hydrogen bonding and vibrational coupling effects.
3. Design a mass spectrometric experiment to determine the fragmentation pattern and molecular structure of a newly synthesized drug molecule.
4. Construct a procedure for integrating FT-NMR and CW-NMR data to obtain a detailed structural characterization of a synthetic drug molecule.

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**R25MPA102** **ADVANCED PHARMACEUTICAL ANALYSIS** **4 0 0 4**

**Course Objectives:**

1. **To impart fundamental and advanced knowledge** on modern analytical instrumentation techniques used in pharmaceutical analysis.
2. **To provide comprehensive understanding** of the principles, instrumentation, working mechanisms, and applications of spectroscopic techniques such as UV-Visible, IR, NMR, and Mass Spectrometry.
3. **To introduce chromatographic and electrophoretic techniques** including HPLC, HPTLC, GC, and Capillary Electrophoresis, with emphasis on their role in qualitative and quantitative analysis of drugs.
4. **To familiarize students with modern hyphenated techniques** such as LC-MS, GC-MS, and their pharmaceutical applications in drug discovery, formulation development, and regulatory submissions.
5. **To develop competence in analytical method validation** as per ICH and regulatory guidelines for the quality control and quality assurance of pharmaceuticals.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DoK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO5 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO102.1 | Gain aknowledge on comprehensive understanding of impurity and stability studies, enabling them to develop and analyze pharmaceutical products that meet regulatory requirements. | 1 | 2 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25CO102.2 | By achieving, understanding of elemental impurities and stability testing, enabling them to develop and analyze pharmaceutical products that meet regulatory requirements.. | 1 | 2 | 3 | 1 | - | - | 2 | 1 | L1, L2 |
| R25CO102.3 | To develop and analyze pharmaceutical products that meet regulatory requirements. | 1 | 2 | 3 | 1 | 3 | - | 2 | 1 | L1, L3 |
| R25CO102.4 | understanding of stability testing of phyto pharmaceuticals and immunoassays, enabling them to develop and analyze pharmaceutical products that meet regulatory requirements. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25CO102.5 | understanding of biological tests and assays, and PCR, enabling them to develop and analyze pharmaceutical products that meet regulatory requirements | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.

**Impurities in new drug products:** Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products.

**Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

**LC-MS:** Variety of mass systems available, their essential differences, strategy for qualitative and quantitative analysis of trace components, specific case studies. LC-NMR: Nature of interfaces, qualitative and quantitative applications.

**CO's–CO1**

**Self Learning topics:** ICH guidelines for impurity quantification (ICH Q3A), Analytical methods for detecting and quantifying impurities, Safety assessment of degradation products, Qualification thresholds and limits

**UNIT II:** **10 Hours**

**Elemental impurities:** Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis.

**Stability testing protocols:** Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

**CO's–CO2**

**Self Learning topics:** Classification of elemental impurities, Understanding the risks associated with elemental impurities. Strategies for controlling elemental impurities in pharmaceuticals. Regulatory guidelines for elemental impurities (e.g., ICH Q3D)

**UNIT III:** **10 Hours**

**Impurity profiling and degradant characterization:** Method development, Stability studies and concepts of validation accelerated stability testing & shelflife calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photo stability testing guidelines, ICH stability guidelines for biological products.

**CO's–CO3**

**Self Learning topics:** Method optimization and ICH guidelines for method validation (ICH Q2) Parameters , Purpose and scope of stability testing and,Types . Principles and applications of accelerated stability testing Calculation of shelf life using accelerated stability data

**UNIT IV:** **8 Hours**

**Stability testing of phytopharmaceuticals:** Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

**Immunoassays (IA):** Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications

**CO's–CO4**

**Self Learning topics:** Understanding the regulatory framework for phytopharmaceuticals Principles and applications of HPTLC fingerprinting. Understand the Basic Principles immunoassays and their applications..

**UNIT V:** **7 Hours**

Biological tests and assays of the following: a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

**CO's-CO5**

**Self Learning topics:**

Understanding the principles and procedures of biological assays ,Learning about the development and testing of vaccines , Mastering PCR techniques, Understanding the mechanisms of gene regulation.

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**Text Books:**


1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5 th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982. 102.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.

**Reference Books:**


1. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014
2. Methods of sampling and microbiological examination of water, first revision, BIS
3. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
4. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005.
5. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
6. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
7. ICH Guidelines for impurity profiles and stability studies.


**Web References:**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. *https://www.sciencedirect.com/*

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define impurities in pharmaceuticals.
2. What are the ICH guidelines for quantification of impurities?
3. Define elemental impurities.
4. What are the ICH guidelines for control of elemental impurities?
5. Define impurity profiling.
6. What are the ICH guidelines for stability testing of pharmaceuticals?

7. Define stability testing of phytopharmaceuticals.
8. Define biological tests and assays.
9. What are the basic principles of immunoassays?
10. What are the principles of PCR and its applications

**L2.** Understand

1. Explain the classification of impurities according to ICH guidelines.
2. Explain the potential sources of elemental impurities
3. Explain the importance of impurity profiling in pharmaceutical development.
4. Explain the importance of stability testing for phytopharmaceuticals
5. Explain the importance of biological tests and assays in pharmaceutical development

**L3.** Apply

1. Identify the importance of impurity profiling in pharmaceutical development.
2. Identify the importance of stability testing protocols in pharmaceutical development.
3. Identify the steps involved in impurity profiling
4. Identify the regulatory requirements for stability testing of phytopharmaceuticals.
5. Identify the types of biological tests and assays used in pharmaceutical development

**L4.** Analyzing

1. Analyze the impact of impurities on drug safety and efficacy.
2. Analyze the impact of elemental impurities on drug quality and safety.
3. Analyze the impact of degradation products on drug stability and efficacy.
4. Analyze the importance of immunoassays in pharmaceutical analysis.
5. Analyze the importance of PCR in gene regulation studies.
6. Develop a plan for using PCR in gene regulation studies.
7. Develop a plan for identifying and quantifying impurities in a new drug substance.
8. Develop a plan for controlling elemental impurities in a pharmaceutical product.
9. Develop a plan for identifying and characterizing degradation products in a pharmaceutical product.
10. Develop a plan for using immunoassays in pharmaceutical analysis.

**L5.** Evaluating

1. Evaluate the risks associated with impurities in pharmaceuticals and propose strategies for mitigating them.
2. Evaluate the risks associated with elemental impurities in pharmaceuticals and propose strategies for mitigating them
3. Evaluate the importance of photostability testing in pharmaceutical development.
4. Evaluate the importance of stability testing for phytopharmaceuticals and propose strategies for improving stability.
5. Evaluate the importance of biological tests and assays in pharmaceutical development and propose strategies for improving their use.

M. pavani

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**R25MPA103** **PHARMACEUTICAL VALIDATION** **4 0 0 4**

**Course Objectives:**

- To understand the principles and importance of validation in pharmaceutical industry.
- To learn about different types of validation, including process validation, cleaning validation, analytical method validation, and equipment validation.
- To understand the scope and merits of validation, including ICH and WHO guidelines.
- To develop skills in validation protocols, master plans, and summary reports.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO5 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO103.1 | Understand the principles and importance of qualification and validation in pharmaceutical manufacturing. | 1 | 2 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25CO103.2 | Apply the qualification and validation processes to specific equipment, instruments, and systems. | 1 | 2 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25CO103.3 | Develop a Validation Master Plan and understand the different stages of qualification. | 1 | 2 | 3 | 1 | 3 | - | 2 | 1 | L 2, L4 |
| R25CO103.4 | Understand the importance of intellectual property protection in the pharmaceutical industry. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L3, L6 |
| R25CO103.5 | Apply the knowledge and skills learned in the course to real- world scenarios in pharmaceutical manufacturing and research. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L4, L5 |

## SYLLABUS

**UNIT I:** **12 Hrs**

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

**CO's–CO1**

**Self-Learning Topics:** Regulatory Guidelines and Industry Standards, Develop a Qualification Protocol, Case Studies, Practice with Scenarios.

**UNIT II:** **12 Hrs**

**Qualification of analytical instruments:** Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.

**Qualification of Glassware:** Volumetric flask, pipette, Measuring cylinder, beakers and burette

**CO's–CO2**

**Self-Learning Topics:** Read Instrument Manuals, Watch Qualification Videos, Practice Qualification Procedures, Analyze Qualification Data, Document Qualification Results.

**UNIT III:** **12 Hrs**

**Validation of Utility systems:** Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation- Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). **CO's–CO3**

**Self-Learning Topics:** Read Regulatory Guidelines, Case Studies, Develop a Validation Protocol, Practice Validation Procedures, Analyze Validation Data.

**UNIT IV:** **12 Hrs**

**Analytical method validation:** Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP. General principles, Validation of analytical method as per ICH guidelines and USP.

**Quality by design (QbD):** Fundamentals of pharmaceutical quality by design, identification of critical quality attributes, critical material attributes, critical process parameters and quality risk management. Process analytical technology (PAT) and other control strategies for QbD.

**CO's–CO4**

**Self-Learning Topics:** Read Regulatory Guidelines, Develop a Validation Protocol, Practice Validation Procedures, Analyze Validation Data, Case Studies.

**UNIT V:** **12 Hrs**

**General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property–patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee;

Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

**CO's–CO5**

**Self-Learning Topics:** Read IP Guidelines and Regulations, Case Studies, Develop a Patent Application, Analyze IP Strategies.

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**Text Books:**

1. Textbook of Pharmaceutical Validation by Priyanka Sheetal, Chatur, and Usman: A comprehensive textbook covering pharmaceutical validation for M.Pharm students
2. Textbook of Pharmaceutical Validation by Dr. Raj Kumar Bolledula, Dr. P. Sivakumar, Prof Dr. J. Amutha Iswarya Devi, A. Sahithi, and Dr. T. Venkatachalam: A detailed guide to pharmaceutical validation
3. Textbook of Pharmaceutical Validation by A.A Kulkarni and V.S Kashikar: A book providing insights into pharmaceutical validation principles and practices
4. Pharmaceutical Calibration, Validation and Qualification: A Comprehensive Approach by Shiv Shankar Shukla: A monograph covering validation, calibration, and qualification in pharmaceuticals

**Reference Books:**

1. Indian Pharmacopoeia
2. United State Pharmacopoeia

**Web References:**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. *https://www.sciencedirect.com/*

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |

| | | |
|---|---|---|
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1: Remember**

1. Define qualification and validation in the context of pharmaceutical manufacturing.
2. List the analytical instruments that require qualification.
3. What are the parameters required for analytical method validation?
4. Describe the importance of intellectual property rights.
5. What are the steps involved in the qualification process?

**L2: Understand**

1. Explain the difference between qualification and validation.
2. Discuss the role of calibration in maintaining the qualified status of analytical instruments.
3. Describe the principles of analytical method validation.
4. Explain the importance of cleaning validation in ensuring product quality.
5. Discuss the role of intellectual property protection in the pharmaceutical industry.

**L3: Apply**

1. Develop a qualification protocol for a manufacturing equipment.
2. Create a plan for validating a computerized system.
3. Apply the analytical method validation process to a specific method.
4. Develop a validation protocol for a pharmaceutical water system.
5. Create a plan for cleaning validation of a specific equipment.

**L4: Analyze**

1. Compare and contrast the qualification requirements for different analytical instruments.
2. Analyze the impact of instrument qualification on the validity of analytical results.
3. Identify the critical steps in the qualification process for analytical instruments.
4. Analyze the impact of cleaning validation on product quality.
5. Compare and contrast the validation requirements for different utility systems.

**L5: Evaluate**

1. Evaluate the effectiveness of a qualification program for analytical instruments.
2. Justify the importance of qualification and validation in ensuring product quality.
3. Assess the impact of qualification and validation on regulatory compliance.
4. Evaluate the effectiveness of a cleaning validation program.
5. Justify the importance of intellectual property rights in ensuring return on investment in research and development.

M. Pavani

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Cherukupally (V), Bhogapuram Mandal
Vizianagaram Dt.,- 531162

**R25MPA104 FOOD AND NUTRACEUTICAL ANALYSIS 4 0 0 4**

**Course Objectives:**

- To understand the composition, classification, and nutritional importance of food carbohydrates, proteins, lipids, and vitamins.
- To apply standard analytical methods for the detection and estimation of food nutrients, additives, adulterants, and contaminants.
- To analyze the effects of food processing and storage on the quality and safety of food components.
- To evaluate the composition and quality of dairy products and fermentation-based food items.
- TO understand food safety regulations and standards such as BIS, Agmark, FDA, and apply them in ensuring food quality and compliance.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | PO1 | PO2 | PO6 | PO9 | PO10 | PSO1 | PSO2 | DOK |
|---|---|---|---|---|---|---|---|---|---|
| R25CO203.1 | Describe the classification, properties, and nutritional significance of food carbohydrates and proteins, and explain their digestion, absorption, metabolism, and analytical methods. | 1 | 2 | 1 | 1 | 1 | 2 | 1 | L1, L2 |
| R25CO203.2 | Classify and analyze lipids and vitamins in food, understand refining processes and spoilage detection, and apply appropriate methods for their analysis. | 1 | 2 | 1 | 1 | 1 | 2 | 1 | L2, L3, L4 |
| R25CO203.3 | Identify and evaluate various food additives, preservatives, pigments, and dyes, and apply analytical methods to detect permitted and non-permitted substances in food. | 1 | 2 | 1 | 1 | 1 | 2 | 1 | L3, L4, L5 |
| R25CO203.4 | Apply analytical techniques for the evaluation of milk and milk products, and fermentation-based foods like wine, beer, and vinegar, including detection of adulterants and contaminants. | 1 | 2 | 1 | 1 | 1 | 2 | 1 | L3, L4 |
| R25CO203.5 | Analyze pesticide residues in food products, explain pesticide regulations, and interpret national and international food safety standards such as BIS, Agmark, FDA, and US-FDA. | 1 | 2 | 1 | 1 | 1 | 2 | 1 | L2,L4, L6 |

## SYLLABUS

**Unit I** **12 hrs**

**Carbohydrates & Proteins: Carbohydrates:** Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates.

**Proteins:** Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

**CO's: CO 1**

**Self learning topics**: Structure and function of polysaccharides (e.g., starch, cellulose, glycogen), Glycemic Index and its nutritional significance, Protein denaturation and its impact on food, Role of dietary fiber in health and digestion.

**Unit II** **12 hrs**

**Lipids & Vitamins: Lipids:** Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

**Vitam□□** Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

**CO's: CO 2**

**Self learning topics:** Trans fats – formation, health effects, and regulations, Omega-3 and Omega-6 fatty acids – functions and dietary sources, Fat-soluble vs water-soluble vitamins: absorption and storage, Role of B-complex vitamins in metabolism.

**Unit III** **12 hrs**

**Food Additives & Pigments: Food Additives:** Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

**Pigments and synthetic dyes**: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of Detection of natural, permitted and non-permitted dyes.

**CO's: CO 3**

**Self learning topics:** Health concerns and regulatory limits of artificial sweeteners, Mechanism of action of common food preservatives, How to read food labels for additives and dyes, Impact of food additives on children's health

**Unit IV** **08 hrs**

**Unit 4: Milk and Fermentation Products:** General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

**Nutraceuticals:** Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

**CO's: CO 4**

**Self learning topics:** Pasteurization vs UHT treatment of milk, Safety standards for milk and dairy products (FSSAI/BIS).

**Unit V** **12 hrs**

**Pesticides & Regulations:** Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

**CO's: CO 5**

**Self learning topics:** Safe limits of pesticide residues in food, Comparison between Indian (FSSAI/BIS) and international (US-FDA) food laws.

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**Text Books**

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.

**Reference Books**

1. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.
2. Food Chemistry – H.-D. Belitz, W. Grosch, P. Schieberle, Springer.
3. Food Additives – A. Larry Branen et al., CRC Press.
4. Dairy Chemistry and Biochemistry – P.F. Fox, P.L.H. McSweeney, Springer.
5. Analysis of Pesticides in Food and Environmental Samples – Jose L. Tadeo, CRC Press.
6. Food Laws and Regulations – Patricia A. Curtis, Wiley.

**Web References:**

1. https://www.ncbi.nlm.nih.gov/books/
2. https://www.khanacademy.org/science/biology/biochemistry
3. https://bio.libretexts.org/Bookshelves/Biochemistry
4. https://www.aoac.org
5. https://www.fssai.gov.in
6. https://www.fao.org/fao-who-codexalimentarius
7. https://pubchem.ncbi.nlm.nih.gov

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remembering**

1. Define dietary fibre and crude fibre. Mention their importance in food analysis.
2. List the types of carbohydrates found in food.
3. Name four essential amino acids and their role in nutrition.
4. State any two methods used to detect adulteration in food.
5. What are preservatives? List any four commonly used food preservatives.
6. Define vitamins and classify them with examples.
7. List the steps in protein digestion.
8. What are the physical properties of fats and oils?
9. Write the names of any two permitted synthetic food dyes.
10. Mention any four milk constituents commonly analyzed in dairy testing.

**L2 – Understanding**

1. Describe the process of digestion and absorption of carbohydrates.
2. Explain the principle of hydrogenation of vegetable oils.
3. Describe how food processing alters carbohydrates.
4. Explain the function of antioxidants in food preservation.

5. Describe the role of microbial assay in vitamin B-complex analysis.
6. Explain how fermentation affects food composition and safety.
7. Discuss the chemical structure and classification of proteins.
8. Explain the significance of enzymatic browning during food processing.
9. Describe the method of vitamin analysis using HPLC.
10. Explain how fiber contributes to digestive health.

**L3 – Applying**

1. Apply a suitable method to detect adulteration in milk.
2. Demonstrate the analysis of artificial sweeteners in beverages.
3. Determine the vitamin C content in a fruit sample.
4. Use the Kjeldahl method to estimate protein content in food.
5. Perform a test for rancidity in edible oils.
6. Apply principles of spectroscopy in detecting synthetic dyes.
7. Estimate crude fat in a dairy sample using Soxhlet extraction.
8. Determine spoilage in fats using peroxide value.
9. Apply a method to detect pesticide residue in fruits.
10. Use a microbial assay to estimate folic acid in a vitamin supplement.

**L4 – Analyzing**

1. Differentiate between organophosphorus and organochlorine pesticides.
2. Analyze the differences between natural and synthetic food colorants.
3. Compare the analytical methods used for fat and protein analysis.
4. Examine the quality differences between raw milk and pasteurized milk.
5. Analyze the effect of food additives on product shelf life.
6. Interpret data from vitamin assay to determine nutritional quality.
7. Distinguish between BIS and Agmark quality standards.
8. Assess the effects of adulteration on nutritional quality.
9. Compare fermentation outcomes in vinegar and wine production.
10. Identify the regulatory checkpoints for ensuring food safety.

**L5 – Creating**

1. Design an experiment to determine the vitamin content in a packaged juice.
2. Develop a protocol for detecting non-permitted synthetic dyes in candies.
3. Create a food analysis report for a milk product including contaminants.
4. Formulate a food testing procedure for artificial sweeteners.
5. Design a case study on the impact of food processing on protein structure.
6. Construct a food safety checklist for pesticide-free vegetables.

7. Create a chart showing classification and function of food additives.
8. Design a standard operating procedure for adulteration testing.
9. Propose a training module for food lab technicians.
10. Develop a method to quantify spoilage in oils using titration techniques.

**L6 – Evaluating**

1. Evaluate the importance of food labelling and regulations in public health.
2. Justify the use of synthetic preservatives over natural ones.
3. Assess the health implications of excessive artificial sweetener consumption.
4. Critically evaluate the microbial assay method for vitamin estimation.
5. Judge the effectiveness of regulatory agencies like FSSAI and FDA.
6. Defend the inclusion of dietary fibre in therapeutic diets.
7. Critically compare HPLC and spectrophotometric methods in vitamin analysis.
8. Evaluate the safety risks posed by non-permitted dyes in snacks.
9. Review the pesticide analysis data of vegetables and recommend actions.
10. Assess how international standards affect food export quality.

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**R25MPA105 Modern Pharmaceutical Analytical Techniques Practical 0 0 6 3**

**Course Objectives:**

1. To provide practical training in the calibration of analytical instruments.
2. To develop a strong foundation in Good Laboratory Practices (GLP) and regulatory guidelines.
3. To enable students to perform impurity profiling of pharmaceutical substances.
4. To train students in conducting assays of official compounds.
5. To enhance proficiency in the quantitative estimation of functional groups.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO6 | PO8 | PO9 | PO11 | PSO1 | PSO2 | |
| R25CO105.1 | Able to perform the calibration of glassware and instruments | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L1, L2 |
| R25CO105.2 | Estimate the amount of impurity for the given drugs | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2, L3 |
| R25CO105.3 | Examine the purity of official compounds by instrumental techniques and titrimetric procedures | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2, L3 |
| R25CO105.4 | Identify the quantitative determination of functional groups and drugs by using different reagents | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L3, L4 |

Board of Studies: Pharmacy

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## COURSE CONTENT

| S.No | Name of the experiment | Course Outcome |
|---|---|---|
| 1. | Calibration of glass wares | CO1 |
| 2. | Calibration of pH meter | CO1 |
| 3. | Calibration of UV-Visible spectrophotometer | CO1 |
| 4. | Calibration of FTIR spectrophotometer | CO1 |
| 5. | Calibration of GC instrument | CO2 |
| 6. | Calibration of HPLC instrument | CO2 |
| 7. | Cleaning validation of any one equipment | CO2 |
| 8. | Impurity profiling of drugs | CO2 |
| 9. | Assay of official compounds by different titrations | CO3 |
| 10. | Assay of official compounds by instrumental techniques. | CO3 |
| 11. | Estimation of riboflavin/quinine sulphate by fluorimetry | CO3 |
| 12. | Estimation of sodium/potassium by flame photometry | CO3 |
| 13. | Quantitative determination of hydroxyl group. | CO4 |
| 14. | Quantitative determination of amino group | CO4 |
| 15. | Colorimetric determination of drugs by using different reagents | CO4 |

**Textbooks**


1. Analysis of drugs in Biological fluids- Joseph Chamberlain, 2 nd Edition.CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis- Doglas A Skoog, F.James Holler, Timothy A. Nieman, 5 th edition, Easternpress, Bangalore, 1998.
3. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2 nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods– Part B- JW Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2 nd Edition.


**Reference Books**


1. Indian Pharmacopoeia
2. United States Pharmacopoeia
3. ICH, USFDA & CDSCO Guidelines.


M.pawani

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**Board of Studies**



Chairperson
Board of Studies (UG)
Avanthi Institute of Pharmaceutical Sciences (A)
Cherukupally (V), Bhogapuram Mandal
Vizianagaram Dt.,- 531162

**R25MPA106** **FOOD ANALYSIS PRACTICAL** **0 0 6 3**

**Course Objectives:**

1. To impart hands-on training in the analysis of pharmacopoeial compounds and their formulations using advanced instrumental techniques such as UV-Visible, GC and HPLC.
2. To develop the analytical skills necessary for qualitative and quantitative analysis of pharmaceutical and food products.
3. To train students in the determination of physicochemical parameters such as Saponification value, iodine value, acid value, peroxide value, density of food substances.
4. To build competence in detecting food adulterants and contaminants

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO6 | PO8 | PO9 | PO11 | PSO1 | PSO2 | |
| R25CO106.1 | Estimate the drug content by using UV Spectroscopy, GC and HPLC | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L1,L2 |
| R25CO106.2 | Able to determine Carbohydrate, protein, vitamin and lipid content in food products | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2,L3 |
| R25CO106.3 | Determine Pesticides and preservative contents in food products | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L1,L2 |
| R25CO106.4 | Analysis of Vitamin content in food products | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L2,L3 |

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Approved in BOS No: 01, 22nd October, 2025
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**COURSE CONTENT**

| S.No | Name of the Experiment | Course Outcome |
|---|---|---|
| 1. | Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer | CO1 |
| 2. | Simultaneous estimation of multi component containing formulations by UV spectrophotometry | CO1 |
| 3. | Experiments based on HPLC | CO1 |
| 4. | Experiments based on Gas Chromatography | CO1 |
| 5. | Determination of total reducing sugar | CO2 |
| 6. | Determination of proteins | CO2 |

| | | |
|---|---|---|
| 7. | Determination of saponification value, Iodine value, Peroxide value, Acid value in food products | CO2 |
| 8. | Determination of fat content and rancidity in food products | CO3 |
| 9. | Analysis of natural and synthetic colors in food | CO3 |
| 10. | Determination of preservatives in food | CO3 |
| 11. | Determination of pesticide residue in food products | CO4 |
| 12. | Analysis of vitamin content in foodproducts | CO4 |
| 13. | Determination of density and specific gravity of foods | CO4 |
| 14. | Determination of food additives | CO4 |

**Textbooks:**


1. Analysis of drugs in Biological fluids- Joseph Chamberlain, 2 nd Edition.CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis- Doglas A Skoog, F.James Holler, Timothy A. Nieman, 5 th edition, Easternpress, Bangalore, 1998.
3. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2 nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods– Part B- JW Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2 nd Edition,


**Reference Books:**


1. Indian Pharmacopoeia
2. United States Pharmacopoeia
3. ICH, USFDA & CDSCO Guidelines.


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**R25MPA108** **RESEARCH PAPER WRITING** **4 0 0 0**

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

- To understand the essentials of writing skills and their level of readability.
- To learn about what to write in each section.
- To ensure qualitative presentation with linguistic accuracy.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO8 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO108.1 | Understand the significance of writing skills and the level of readability. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L1, L2 |
| R25CO108.2 | Analyze and write title, abstract, different sections in research paper | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L1, L2, L3 |
| R25CO108.3 | Develop the skills needed while writing a research paper | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L 2, L3 |
| R25CO108.4 | Able to develop and apply key academic writing skills to construct clear, concise, and impactful Titles, Abstracts, and Introductions for research papers, demonstrating the ability to attract readers, summarize core findings, and establish research context effectively. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L3, L4 |
| R25CO108.5 | Able to use appropriate academic language and style to accurately formulate the methodology, clearly present Results, logically construct Arguments, and effectively draw valid conclusions in research writing. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breakingup Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity.

**CO's–CO1**

**Self Learning topics**: Examples of effective vs. poor research paper planning, Exercises on improving word order and sentence clarity, Identifying and breaking long, complex sentences into shorter ones.

**UNIT II:** **10 Hours**

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

**CO's–CO2**

**Self Learning topics:** Common pitfalls in defining a research problem, Hedging phrases in academic writing (e.g., "suggests that", "may indicate"), Identifying plagiarism vs. acceptable paraphrasing.

**UNIT III:** **10 Hours**

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

**CO's–CO3**

**Self Learning topics:** Steps to conduct a literature review (sources, search engines, databases), Comparing qualitative vs. quantitative methodologies,Tools for data analysis (SPSS, Excel, R basics).

**UNIT IV:** **8 Hours**

Key skills needed for writing a Title, Abstract, and Introduction

**CO's–CO4**

**Self Learning topics:** Characteristics of an impactful research title, Common errors to avoid in writing an abstract, Strategies for writing a strong introduction.

**UNIT V:** **7 Hours**

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions.

**CO's-CO5**

**Self Learning topics:** Neutral and objective ways to report results, Building logical arguments with evidence, Transition words for coherence.

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**Text Books**

1. Goldbart R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I].
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press.
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman"sbook Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011.

**Web References**

1. https://cambridge-research.org/blogs/how-to-write-a-research-paper/?
2. https://www.readwritethink.org/classroom-resources/lesson-plans/scaffolding-methods-research-paper?
3. https://academicguides.waldenu.edu/writingcenter/assignments/literaturereview/matrix?

4. https://www.verywellmind.com/how-to-write-an-introduction-2794846?

**Assessment Pattern:**

1. Evaluated for a total of 100 marks.
2. A student can select 2 articles of his/her choice with a minimum of 01 review or research article per semester. Each article publication shall be evaluated by the concerned teacher for 50 marks, totaling to 100 marks.

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**R25MPA201** **ADVANCED INSTRUMENTAL ANALYSIS** **4 0 0 4**

**Course Objectives:**

1. **To impart fundamental and advanced knowledge** on modern analytical instrumentation techniques used in pharmaceutical analysis.
2. **To provide comprehensive understanding** of the principles, instrumentation, working mechanisms, and applications of spectroscopic techniques such as UV-Visible, IR, NMR, and Mass Spectrometry.
3. **To introduce chromatographic and electrophoretic techniques** including HPLC, HPTLC, GC, and Capillary Electrophoresis, with emphasis on their role in qualitative and quantitative analysis of drugs.
4. **To familiarize students with modern hyphenated techniques** such as LC-MS, GC-MS, and their pharmaceutical applications in drug discovery, formulation development, and regulatory submissions.
5. **To develop competence in analytical method validation** as per ICH and regulatory guidelines for the quality control and quality assurance of pharmaceuticals.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DoK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO5 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO201.1 | To learn the principles and instrumentation, applications of HPLC and also method development and validation in HPLC.To learn about advanced HPLC techniques, including ultra, nano, and preparative HPLC | 1 | 2 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25CO201.2 | To understand the principles, instrumentation, and applications of various chromatographic techniques, including bio chromatography, gas chromatography, and high-performancethin-layer chromatography, In pharmaceutical analysis | 1 | 2 | 3 | 1 | - | - | 2 | 1 | L1, L2, |
| R25CO201.3 | To learn the principles, instrumentation, and applications of supercritical fluid chromatography and capillary electrophoresis in pharmaceutical analysis, including method development and hyphenated techniques. | 1 | 2 | 3 | 1 | 3 | - | 2 | 1 | L3, L4 |
| R25CO201.4 | To understand the principles, instrumentation, and applications of mass spectrometry, including various ionization techniques, mass | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L4, L5 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | analyzers, and hyphenated techniques like LC-MS and MS/MS systems. | | | | | | | | | |
| R25CO201.5 | To master the principles, instrumentation, and applications of mass spectrometry, including various ionization techniques, mass analyzers, and hyphenated techniques. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L6 |

## SYLLABUS

**UNIT I:** **12 Hours**

**HPLC:** Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

**CO's–CO1**

**Self Learning topics: -** New developments in HPLC, including ultra, nano, and preparative HPLC. Immobilized polysaccharide CSP's and chiral method development.

**UNIT II:** **12 Hours**

**Bio chromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

**Gas chromatography:** Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

**Hyphenated techniques:** Introduction to GC-MS and LC-MS techniques and their applications in natural products.

**CO's–CO2**

**Self Learning topics:** principles, procedure, applications of size exclusion, ion exchange, ion pair, and affinity chromatography.

**UNIT III:** **12 Hours**

**Super critical fluid chromatography :** Principles, instrumentation, pharmaceutical applications.

**Capillary electrophoresis:** Overview of CE in pharmaceutical analysis, basic configuration, CE

characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

**CO's–CO3**

**Self Learning topics: -** Supercritical fluid chromatography including method development and validation. Capillary electrophoresis principles, basic configuration characteristics, methods, and modes of CE, including CE-MS hyphenation and the use of crown ethers as buffer additives.

**UNIT IV:** **12 Hours**

**Mass spectrometry:** Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

**CO's–CO4**

**Self Learning topics:** MS/MS systems (Tandem mass spectrometry)

**UNIT V:** **12 Hours**

**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR , 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations

**CO's-CO5**

**Self Learning topics:** Mass spectrometry principles, ionization techniques, mass analyzers, MS/MS systems, LC-MS, DART MS, and applications in pharmaceutical analysis.

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**Text Books:**

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5 th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7 th edition, CBS publishers.

4. Organic Spectroscopy - William Kemp, 3 rd edition, ELBS, 1991.

5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi. 6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3 rd Edition, CBS Publishers, New Delhi, 1997.

7.

**Reference Books:**

1. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
2. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

**Web References:**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define HPLC and its principle.
2. Define gas chromatography.
3. Define size exclusion chromatography and its applications.
4. Define supercritical fluid chromatography and its principle.
5. Define mass spectrometry and its principle.
6. Define NMR spectroscopy and its principle.
7. Define affinity chromatography.
8. Define ion-pair chromatography.
9. Define capillary electrophoresis and its types

L2. **Understand**

1. Describe the instrumentation of HPLC
2. Describe the principles of gas chromatography.
3. Describe the basic configuration of capillary electrophoresis.
4. Describe the different types of ionization techniques in mass spectrometry.
5. Describe the importance of quantum numbers in NMR.

6. Describe the procedure of ion-exchange chromatography.
7. Describe the instrumentation of mass spectroscopy.

**L3.** Apply

1. Explain the importance of peak shapes, capacity factor, and selectivity in HPLC
2. Identify the importance of peak shapes in HPLC
3. Explain the importance of stationary phases and mobile phases in biochromatography.
4. Identify the importance of stationary phases in biochromatography
5. Explain the importance of supercritical fluid chromatography in pharmaceutical analysis.
6. Explain the basic configuration of capillary electrophoresis.
7. Explain the importance of mass fragmentation and its rules in mass spectrometry.
8. Explain the importance of chemical shift and spin-spin coupling in NMR.

**L4.** Analyze

1. Discuss the role of immobilized polysaccharide CSP's in enantiomeric separations.
2. Analyze the role of capacity factor and selectivity in HPLC.
3. Discuss the applications of HPTLC in pharmaceutical analysis.
4. Analyze the applications of HPTLC in pharmaceutical analysis
5. Discuss the applications of capillary electrophoresis in pharmaceutical analysis.
6. Discuss the applications of LC-MS and MS/MS systems in pharmaceutical analysis.
7. Discuss the applications of 1D and 2D NMR techniques in pharmaceutical analysis.

**L5.** Evaluate

1. Design an HPLC method for the analysis of a pharmaceutical compound.
2. Evaluate the advantages and limitations of ultra, nano, and preparative HPLC in pharmaceutical analysis.
3. Develop a biochromatographic method for the analysis of a biomolecule.
4. Evaluate the advantages and limitations of GC and HPTLC in pharmaceutical analysis.
5. Design a supercritical fluid chromatographic method for the analysis of a pharmaceutical compound.
6. Evaluate the advantages and limitations of capillary electrophoresis in pharmaceutical analysis.
7. Develop a mass spectrometric method for the analysis of a pharmaceutical compound.
8. Evaluate the advantages and limitations of different mass analyzers and MS/MS systems.
9. Interpret an NMR spectrum and identify the structure of a compound.
10. Evaluate the advantages and limitations of NMR spectroscopy in pharmaceutical analysis.

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**R25MPA202** **MODERN BIO-ANALYTICAL TECHNIQUES** **4 0 0 4**

**Course Objectives:**

- To understand the principles and applications and learn the theoretical foundations and practical applications of various bio-analytical techniques.
- To develop analytical skills and will gain hands-on experience with instruments and techniques used in bio-analysis.
- To apply bio-analytical techniques will be able to apply bio-analytical techniques to analyze biological samples and solve problems.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO5 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO202.1 | Explain the principles and procedures involved in extracting drugs and metabolites from biological matrices using techniques such as protein precipitation, liquid-liquid extraction, and solid-phase extraction. | 1 | 2 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25CO202.2 | Understanding the BCS classification system, which categorizes drugs based on their solubility and permeability. | 1 | 2 | 3 | 1 | - | - | 2 | 1 | L1, L3, L4 |
| R25CO202.3 | Recognize and predict potential drug interactions, including PK-PD interactions, protein-binding interactions, tissue-binding interactions, and cytochrome P450-based interactions. | 1 | 2 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25CO202.4 | Isolate cells, perform subculturing, cryopreservation, and characterization of cells. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L3, 6 |
| R25CO202.5 | Design and conduct studies to identify and characterize metabolites, including sample preparation and analytical techniques. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L4, L5 |

## SYLLABUS

**UNIT I:** **12 Hrs**

**Extraction of drugs and metabolites from biological matrices:** General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid Liquid extraction and Solid phase extraction and other novel sample preparation approach.

**Bioanalytical method validation:** USFDA and EMEA guidelines.

**CO's–CO1**

**Self-Learning Topics:** Read Regulatory Guidelines and Industry Standards, Develop a Qualification Protocol, Case Studies, Practice with Scenarios.

**UNIT II:** **12 Hrs**

**Biopharmaceutical Consideration:** Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System.

**Solubility:** Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

**CO's–CO2**

**Self-Learning Topics:** Read Instrument Manuals, Watch Qualification Videos, Practice Qualification Procedures, Analyze Qualification Data, Document Qualification Results.

**UNIT III:** **12 Hrs**

**Pharmacokinetics and Toxicokinetics:** Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

**CO's–CO3**

**Self-Learning Topics:** Read Regulatory Guidelines, Case Studies, Develop a Validation Protocol, Practice Validation Procedures, Analyze Validation Data.

**UNIT IV:** **12 Hrs**

**Cell culture techniques:** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization ofcells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

**CO's–CO4**

**Self-Learning Topics:** Read Regulatory Guidelines, Develop a Validation Protocol, Practice Validation Procedures, Analyze Validation Data, Case Studies.

**UNIT V:** **12 Hrs**

**Metabolite identification:** In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met–ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

**Drug Product Performance, In-Vivo: Bioavailability and Bioequivalence:** Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

**CO's–CO5**

**Self-Learning Topics:** Read Regulatory Guidelines, Develop a Validation Protocol, Practice Validation Procedures, Analyze Validation Data, Case Studies.

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**Text Books:**

1. A Textbook of Modern Bio Analytical Technique: Dr. K. Bhavyasri, Dr. Osman Ahmed, Dr. Faris F. Aba Alkhayl, and Dr. Ashish Suresh Jain, published by Mahi Publication.
2. Modern Bioanalytical Techniques: Teja Kumar Reddy Konatham, T. Venkatachalam, P. Kalaiselvi, P. Balan, and Tarun Chaudhary, published by Walnut Publication.
3. Modern Bioanalytical Techniques: Teja Kumar Reddy Konatham, T. Venkatachalam, and P. Kalaiselvi.
4. Modern Bioanalytical Techniques: This book is written by Dr. S. Janet Beula, Kallam Sudha Divya Madhuri, Dr. Mahammad Ishaq B., M.M. Eswarudu, and Pusuluri Siva Krishna.

**Reference Books:**

1. Indian Pharmacopoeia
2. United State Pharmacopoeia

**Web References:**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

## Sample Short and Long Answers questions of Various Cognitive Levels

### L1: Remember

1. Define biopharmaceutics and its importance in drug development.
2. What is the Biopharmaceutics Classification System (BCS)?
3. Describe the principle of protein precipitation in bioanalytical methods.
4. What are the USFDA guidelines for bioanalytical method validation?
5. Define pharmacokinetics and toxicokinetics.
6. What are the basic equipment used in cell culture labs?
7. Describe the concept of metabolite identification.

### L2: Understand

1. Explain the concept of dissolution and drug release testing.
2. Describe the importance of permeability in drug absorption.
3. What are the key parameters evaluated in bioanalytical method validation?
4. Explain the concept of drug interactions and their impact on pharmacokinetics.
5. Describe the importance of toxicokinetic evaluation in preclinical studies.
6. What are the applications of flow cytometry in cell biology?
7. Explain the concept of bioequivalence and its importance in generic drug development.

### L3: Apply

1. Design an experiment to evaluate solubility.
2. Develop a plan for assessing permeability.
3. Design a protocol for extracting a drug from biological samples.
4. Develop a plan for validating a bioanalytical method.
5. Design a pharmacokinetic study to evaluate drug absorption and distribution.
6. Develop a plan for characterizing cells using flow cytometry.
7. Design a bioequivalence study to compare the bioavailability of two formulations.

### L4: Analyze

1. Analyze the relationship between solubility and bioavailability.
2. Compare the advantages and disadvantages of different dissolution testing methods.
3. Analyze the impact of matrix effects on bioanalytical method validation.
4. Compare the applications of different cell culture techniques.
5. Analyze the impact of protein-binding interactions on pharmacokinetics.
6. Compare the advantages and disadvantages of different bioequivalence study designs.
7. Analyze the relationship between metabolite identification and drug toxicity.

### L5: Evaluate

1. Evaluate the biopharmaceutical properties of a drug.
2. Justify the selection of a particular formulation strategy.
3. Evaluate the suitability of a bioanalytical method for a specific pharmaceutical compound.
4. Justify the selection of a particular animal model for toxicokinetic studies.
5. Evaluate the suitability of a cell culture model for a specific application.
6. Justify the selection of a particular bioequivalence study design.
7. Evaluate the impact of metabolite identification on drug development.

**L6: Creation/Creating**

1. Develop a new formulation strategy for a specific drug.
2. Design a new bioanalytical method for extracting and analyzing a specific drug.
3. Develop a plan for assessing the toxicokinetics of a new pharmaceutical compound.
4. Design a new cell culture protocol for evaluating cytotoxicity.
5. Develop a plan for evaluating the bioequivalence of a generic drug product.
6. Design a metabolite identification study to evaluate drug metabolism.
7. Create a protocol for validating a bioanalytical method for a specific pharmaceutical compound.

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**R25MPA203** **QUALITY CONTROL AND QUALITY ASSURANCE** **4 0 0 4**

## Course Objectives:

At the completion of this subject it is expected that the student shall be able

1. To know the CGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to Pharmaceutical industries
4. To understand the responsibilities of QA & QC departments

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO4 | PO8 | PO10 | PSO1 | PSO2 | |
| R25CO203.1 | Understand the Concept and Evolution of Quality Control and Quality Assurance. | 1 | 1 | 1 | 2 | 1 | - | 2 | 1 | L1, L2 |
| R25CO203.2 | Remember cGMP guidelines according to schedule M. | 1 | 1 | 1 | 2 | 1 | - | 2 | 1 | L1, L2, L3 |
| R25CO203.3 | Know the Analysis of raw materials finished products, packaging materials, in process quality control. | 1 | 1 | 1 | 2 | 1 | - | 2 | 1 | L 2, L3 |
| R25CO204.4 | Summarize Quality control test for containers, closures and secondary packing materials.. | 1 | 1 | 1 | 2 | 1 | - | 2 | 1 | L3, L4 |
| R25CO205.5 | Assess the Documentation process in pharmaceutical industry. Appreciate the importance of the role of Manufacturing operations and controls in product development | 1 | 1 | | 2 | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **12 Hours**

Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines-QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation **CO's–CO1**

**Self Learning topics:** Evolution and Importance of Quality Systems in Pharmaceuticals, Good Laboratory Practices (GLP) and GMP in Pharmaceutical Testing, ICH Guidelines Overview with Focus on Q-Series

**UNIT II:**

**12 Hours**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

**CO's–CO2**

**Self Learning topics:** Comparative Study of Global cGMP Guidelines, GMP-Compliant Facility Design and Environmental Control

**UNIT III:**

**12 Hours**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 andQ3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

**CO's–CO3**

**Self Learning topics:** Analysis & Specification of Raw Materials, Packaging & Finished Products, In-Process and Finished Product Quality Control (IPQC & FPQC)

**UNIT IV:**

**12 Hours**

**Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

**Standard operating procedures:** SOP on SOPs, Change control procedure, annual product review/product quality review, handling of deviations & non conformity, corrective & preventive actions (CAPA), handling of laboratory incidents and OOS test results.

**CO's–CO4**

**Self Learning topics:** Explore the importance of proper formatting and compliance with regulatory expectations, Understand how MFRs and BMRs are used to ensure batch consistency and traceability.

**UNIT V:**

**12 Hours**

**Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

**CO's-CO5**

**Self Learning topics:** Material handling procedures (charging-in), and time restrictions to avoid degradation or contamination.Gain knowledge of IPQC tests and how they control product quality in real time.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books:**


1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3 rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2 nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guidelines and Related materials, Vol I & II, 2 nd edition, WHO Publications, 1999.
4. How to Practice GMP's – PP Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F.Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines


**Reference Books:**


1. ISO 9000 and total quality management
2. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
3. QA Manual–D.H.Shah, 1 st edition, Business Horizons, 2000.
4. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H.Willig, Vol.52, 3 rd edition, Marcel Dekker Series.
5. SteinbornL. GMP/ISO Quality Audit Manual for Health care Manufacturers and Their Suppliers, Sixth Edition, (Volume1-With Check lists and Software Package). Taylor & Francis; 2003.
6. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.


**Web References:**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |

| | | |
|---|---|---|
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1-Remember**

1. Define Good Laboratory Practice (GLP).
2. List any three objectives of Quality Assurance (QA).
3. What does the abbreviation ICH stand for?
4. Name any two international cGMP regulatory bodies.
5. Define Pharmaceutical Inspection Convention (PIC/S).
6. List four key personal hygiene requirements under GMP.
7. Define in-process quality control (IPQC).
8. Name any two official pharmacopoeias.
9. List any three QC tests for capsules.
10. What are the three tiers of documentation?
11. Define SOP and BMR.
12. Define yield and process deviation.
13. List steps involved in IPQC during ointment manufacturing.

**L2- Understand**

1. Explain the function of the Quality Assurance Unit in GLP.
2. Describe the scope of GLP in non-clinical testing.
3. Discuss the importance of ICH Q10 in pharmaceutical quality systems.
4. Explain the role of CDER and CBER in USFDA.
5. Discuss the significance of Schedule M in Indian GMP regulations.
6. Describe the function of environmental control systems in sterile manufacturing
7. Explain how pharmacopoeias are referred to for quality control.
8. Describe the importance of packaging material testing.
9. Discuss the role of IPQC in maintaining product quality.
10. Explain the difference between a Master Formula Record (MFR) and a Batch Record.
11. Describe the importance of retention and retrieval of records.
12. Explain how cross-contamination is prevented in manufacturing.
13. Discuss the importance of aseptic process control.

**L3- Apply**

1. Apply GLP principles to develop a sample non-clinical testing protocol.
2. Demonstrate how quality assurance is maintained in a laboratory setting.
3. Illustrate how to maintain documentation for an animal house.
4. Apply WHO GMP guidelines to design a sanitation procedure.
5. Use Schedule M to draft layout requirements for a tablet manufacturing area.
6. Prepare a training plan for new employees on personal hygiene under GMP.
7. Apply ICH Q6A to create a specification for a new excipient.
8. Demonstrate how to test the integrity of a blister pack.
9. Use IPQC standards to evaluate a batch of tablets.
10. Apply SOP principles to write an equipment cleaning procedure.
11. Use BMR data to verify if a batch is within yield limits.
12. Calculate yield from the following data: Theoretical = 200 kg, Actual = 185 kg.

13. Apply expiry date calculation using a real-time example.

**L4-Analyze**

1. Compare GMP and GLP in terms of scope and purpose.
2. Differentiate between ICH Q8 and Q9 guidelines.
3. Analyze the importance of proper documentation in GLP compliance.
4. Analyze the differences between WHO and USFDA GMP guidelines.
5. Compare the environmental control parameters of a sterile vs non-sterile unit.
6. Break down the components of CPCSEA guidelines related to animal houses
7. Compare the IPQC parameters for tablets and ointments.
8. Analyze packaging material tests based on USP and IP standards.
9. Differentiate between raw material and finished product testing.
10. Compare electronic vs manual record-keeping in terms of accuracy.
11. Analyze the components of a quality audit report.
12. Compare the inspection procedures for tablets and parenterals.
13. Differentiate between aseptic and terminal sterilization.

**L5- Evaluate**

1. Assess the impact of poor documentation on GLP compliance.
2. Evaluate the effectiveness of ICH Q10 in ensuring product lifecycle quality.
3. Justify the need for separate QA units in GLP-regulated labs.
4. Evaluate a sample layout plan of a sterile area for GMP compliance.
5. Judge the suitability of a facility located in a high-pollution area.
6. Critically assess warehousing practices against cGMP standards.
7. Evaluate the quality of a batch using test data from IP and USP.
8. Assess a packaging material's compliance with pharmacopoeial requirements.
9. Critique a given specification sheet for completeness and accuracy
10. Evaluate the effectiveness of a documentation system during an audit.
11. Critique a poorly written SOP and suggest improvements.
12. Assess the effectiveness of packaging operations for a cream product.
13. Justify the importance of change control in manufacturing.

**L6- Create**

1. Design a basic GLP-compliant layout for a toxicology lab.
2. Develop a checklist for GLP audit preparation.
3. Create a training module for GLP implementation in a new lab.
4. Design a GMP-compliant warehouse layout.
5. Create a hygiene training checklist for pharmaceutical staff.
6. Develop a facility maintenance SOP for GMP compliance.
7. Design a QC protocol for ointment testing as per IP.
8. Develop a finished product checklist for sterile parenterals.
9. Create a flowchart showing IPQC checks during capsule filling.
10. Draft an SOP for granulation process documentation.
11. Design a document retention policy for QA records.
12. Design a production record format for a new batch of tablets.
13. Create an IPQC checklist for suppository production.

H. Jawani

**Chairperson**
**Board of Studies**

**R25MPA204 HERBAL AND COSMETIC ANALYSIS 4 0 0 4**

**Course Objectives:**

- To provide foundational knowledge on the classification, identification, and evaluation of herbal drugs using pharmacopoeial and WHO guidelines.
- To introduce various analytical techniques for the standardization, quality control, and detection of adulteration in herbal products.
- To explain formulation principles and evaluation parameters of herbal cosmetic products such as creams lotions, shampoos, and lipsticks.
- To develop understanding of stability studies, safety assessment, and toxicity evaluation of herbal and cosmetic formulations.
- To familiarize students with the national and international regulatory frameworks governing herbal and cosmetic product manufacturing and marketing.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO8 | PSO1 | PSO2 | |
| R25CO204.1 | Explain the basic principles, classification, and evaluation parameters of herbal drugs and cosmetics used in traditional and modern systems | 1 | 2 | 1 | 1 | 2 | 1 | L1,L2 |
| R25CO204.2 | Apply various standardization and quality control techniques to ensure the identity, purity, safety, and efficacy of herbal products. | 1 | 2 | 1 | 1 | 2 | 1 | L3,L4 |
| R25CO204.3 | Describe the principles and formulations of herbal cosmetics such as creams, shampoos, and lotions and evaluate them using modern analytical techniques | 1 | 2 | 1 | 1 | 2 | 1 | L2, L3,L4 |
| R25CO204.4 | Analyze and interpret the regulatory guidelines governing herbal and cosmetic products in India and globally (e.g., AYUSH, CDSCO, FDA, EMA). | 1 | 2 | 1 | 1 | 2 | 1 | L2, L4, L5 |
| R25CO204.5 | Design and evaluate formulations of herbal and cosmetic products considering safety, quality, regulatory, and consumer | 1 | 2 | 1 | 1 | 2 | 1 | L4, L5, L6 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | acceptability aspects. | | | | | | | |

## SYLLABUS

**UNIT I** **12 Hours**

**Herbal remedies- Toxicity and Regulations:** Herbals vs Conventional drugs,Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues.

**Herbal drug standardization:** WHO and AYUSH guidelines.

**CO'S-CO1**

**Self Learning topics:** Herbal Drug Toxicity and Regulatory Guidelines: Comparison of Herbals vs Conventional Drugs, Validation and Standardization of Herbal Medicines: WHO and AYUSH Perspectives.

**UNIT II** **12 Hours**

**Adulteration and Deterioration:** Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration.

Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

**Regulatory requirements for setting herbal drug industry:** Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

**CO'S-CO2**

**Self Learning topics:** Adulteration and Quality Control of Herbal Drugs: Types, Causes, Detection, and Preventive Measures,Regulatory and Legal Framework for Herbal Drug Industry: Global Marketing, Patents, and Compliance Protocols.

**UNIT III** **12 Hours**

**Testing of natural products and drugs:** Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.

**Monographs of Herbal drugs:** Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia. WHO guidelines in quality assessment of herbal drugs.

**CO'S-CO3**

**Self Learning topics:** Modern Analytical Approaches and Stability Testing of Herbal Drugs, Comparative Study of Herbal Drug Monographs and WHO Guidelines for Quality Assessment.

**UNIT IV** **12 Hours**

**Herbal drug-drug interaction:** WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

**CO'S-CO4**

**Self Learning topics:** Herbal Drug–Drug and Food Interactions: Case Studies and Safety Monitoring Approaches, WHO and AYUSH Guidelines for Pharmacovigilance and Safety Reporting of Herbal Medicines.

**UNIT V**

**12 Hours**

**Evaluation of herbal cosmetic products:** Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

**CO'S-CO5**

**Self Learning topics:** Analytical Parameters and Quality Evaluation of Cosmetic Raw Materials and Finished Products, BIS Standards and Specifications for Testing and Sampling of Cosmetics in India.

Board of Studies: Pharmacy

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Approved in ACM No: 01

**Text Books:-**

1. Pharmacognosy by Trease and Evans.
2. Pharmacognosy by Kokate, Purohit and Gokhale.
3. Quality Control Methods for Medicinal Plant, WHO, Geneva.
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar.
5. Essential of Pharmacognosy by Dr.S.H.Ansari.
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi.

**Reference Books:-**

1. Indian Standard specification, for raw materials, BIS, New Delhi. 8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi.
2. Harry's Cosmeticology 8th edition.
3. Suppliers catalogue on specialized cosmetic excipients.
4. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps

5. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition.

**Web References:**

1. https://www.ncbi.nlm.nih.gov/books/
2. https://www.khanacademy.org/science/biology/biochemistry
3. https://bio.libretexts.org/Bookshelves/Biochemistry
4. https://www.aoac.org
5. https://www.who.int/publications/guidelines
6. https://www.ayush.gov.in
7. https://www.fda.gov/cosmetics
8. https://www.sciencedirect.com/journal/journal-of-herbal-medicine
9. https://www.cosmeticsandtoiletries.com

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remembering**

1. Define herbal drug and herbal cosmetics.
2. List any five plant sources used in cosmetic preparations.
3. What are the primary ingredients in herbal shampoo?
4. Name any four herbal antiseptics and their uses.
5. Define standardization and why it is necessary in herbal products.
6. What is the role of WHO in herbal drug standardization?
7. Write the full form of BIS, AYUSH, and ICH.
8. Name any two chromatographic techniques used in herbal analysis.
9. What are primary metabolites?
10. List quality parameters for face creams.

**L2 – Understanding**

1. Explain the classification of herbal drugs based on morphology.
2. Discuss the importance of phytochemical screening in herbal formulations.
3. Describe any two evaluation parameters of lipstick.
4. Illustrate the process of formulating herbal toothpaste.
5. Differentiate between synthetic and herbal cosmetics.
6. Explain the role of antioxidants in skin care products.
7. Describe the use of UV spectroscopy in herbal drug analysis.
8. Summarize the challenges in herbal drug standardization.
9. Explain the basic principle behind HPTLC.
10. Discuss the concept of microbial load and its significance in cosmetics.

**L3 – Applying**

1. Apply suitable methods to evaluate the quality of herbal shampoo.
2. Demonstrate thin-layer chromatography in identifying herbal ingredients.
3. Formulate a herbal face pack using any five ingredients.
4. Perform physicochemical tests for a given herbal cream.
5. Develop a standard protocol for testing herbal tablets.
6. Conduct an assay for alkaloids in a crude drug.
7. Apply ICH guidelines for stability testing of a cosmetic product.
8. Use appropriate techniques for microbial analysis of herbal cream.
9. Calculate the spreadability and pH of a cosmetic gel.
10. Perform identification tests for steroids in herbal extracts.

**L4 – Analyzing**

1. Analyze the adulteration in herbal drugs using microscopy.
2. Compare traditional and modern methods of standardization.
3. Break down the steps in the preparation of herbal lipstick.
4. Identify the critical points in cosmetic product label compliance.
5. Examine the regulatory differences between AYUSH and FDA guidelines.
6. Categorize herbal drugs based on phytochemical constituents.
7. Evaluate a marketed herbal formulation for standardization parameters.
8. Distinguish between various evaluation tests used in shampoo.
9. Interpret the FTIR spectrum of a plant extract.
10. Analyze the safety profile of a herbal fairness cream.

**L5 – Evaluating**

1. Critically assess the efficacy of a herbal sunscreen formulation.
2. Justify the need for stability studies in herbal cosmetics.

3. Recommend a suitable evaluation method for herbal ointment.
4. Evaluate the claims made on a marketed herbal cosmetic product.
5. Formulate a report on comparative analysis of synthetic vs. herbal lip balms.
6. Validate a method used for flavonoid quantification.
7. Defend the use of natural colorants over synthetic ones in cosmetics.
8. Review an HPTLC profile of a plant extract and suggest improvements.
9. Recommend improvements in the quality control of herbal shampoos.
10. Evaluate the regulatory approval process for herbal drugs in India.

**L6 – Creating**

1. Design a novel herbal formulation for acne treatment.
2. Create a standard operating procedure (SOP) for herbal soap production.
3. Develop a complete quality control protocol for a herbal lotion.
4. Construct a comparative chart of various herbal cosmetic evaluation methods.
5. Formulate a research plan for evaluating antioxidant activity in herbal cosmetics.
6. Design a label for a new herbal toothpaste meeting legal requirements.
7. Build a method for validating herbal face wash ingredients using HPLC.
8. Create a protocol for simultaneous detection of multiple adulterants in herbal products.
9. Devise a regulatory checklist for exporting herbal products from India.

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**R25MPA205** **Advanced Pharmaceutical Analysis Practical** **0 0 6 3**

**Course Objectives:**

1. To develop competency in the comparison and interpretation of absorption spectra
2. To train students in the interpretation of spectral data
3. To enable students to assess the purity of pharmaceutical substances
4. To provide hands-on experience in the identification and structural elucidation of organic compounds
5. To impart knowledge on biomolecular separation and quantification techniques

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POS and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO6 | PO8 | PO9 | PO11 | PSO1 | PSO2 | |
| R25CO205A.1 | Interpretation of organic compounds by FT-IR & NMR | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L1,L2 |
| R25CO205A.2 | Determination of Purity by DSC in pharmaceutical compounds | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2,L3 |
| R25CO205A.3 | Study the quantitative analysis of Compounds by HPLC techniques | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L3,L4 |
| R25CO205A.4 | Study the protocol preparation for the conduct of BA/BE studies according to guidelines | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L3,L4 |

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## COURSE CONTENTS

| Experiment No | Name of the Experiment | Course Outcome |
|---|---|---|
| 1) | In process and finished product quality control tests for tablets, capsules, parenterals and cream Comparison of absorption spectra by UV and Wood ward – Fiesure rules | CO1 |
| 2) | Interpretation of organic compounds by FT-IR | CO1 |
| 3) | Interpretation of organic compounds by NMR | CO1 |
| 4) | Interpretation of organic compounds by MS Testing of related and foreign substances in drugs and raw materials | CO2 |

| | | |
|---|---|---|
| 5) | Determination of purity by DSC in pharmaceuticals. | CO2 |
| 6) | Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra | CO2 |
| 7) | Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis. | CO3 |
| 8) | Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques | CO3 |
| 9) | Isolation of analgesics from biological fluids (Blood serum and urine). | CO3 |
| 10) | Quantitative Protocol preparation and performance of analytical / Bioanalytical method validation. | CO4 |
| 11) | Protocol preparation for the conduct of BA/BE studies according to guidelines determination of hydroxyl group. | CO4 |

**Textbooks:**


1. Analysis of drugs in Biological fluids- Joseph Chamberlain, 2 nd Edition.CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis- Doglas A Skoog, F.James Holler, Timothy A. Nieman, 5 th edition, Easternpress, Bangalore, 1998.
3. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2 nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods– Part B- JW Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2 nd Edition,


**Reference Books:**


1. Indian Pharmacopoeia
2. United States Pharmacopoeia
3. ICH, USFDA & CDSCO Guidelines.


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**R25MPA206** **Herbal and Cosmetic Analysis Practical** **0 0 6 3**

**Course Objectives:**

1. To train students in conducting in-process and finished product quality control tests.
2. To develop practical knowledge in evaluating the quality of primary and secondary packaging materials.
3. To enable students to perform the assay and purity testing of raw materials and excipients.
4. To provide hands-on experience in detecting related substances and foreign matter.
5. To impart practical knowledge in cosmetic product evaluation.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO6 | PO8 | PO9 | PO11 | PSO1 | PSO2 | |
| R25CO205B.1 | Perform quality control test for primary and secondary packaging materials | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L1,L2 |
| R25CO205B.2 | Study the preparation of Master Formula Record | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2,L3 |
| R25CO205B.3 | Determination of quality control tests for Cosmetics | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2,L3 |
| R25CO205B.4 | Interpret Quantitative analysis of Rancidity in lipsticks and hair oil | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L3,L4 |

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

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## COURSE CONTENTS

| Experiment No | Name of the Experiment | Course Outcome |
|---|---|---|
| 1) | In process and finished product quality control tests for tablets, capsules, parenterals and creams | CO1 |

| | | |
|---|---|---|
| 2) | Quality control tests for Primary and secondary packing materials | CO1 |
| 3) | Assay of raw materials as per official monographs | CO1 |
| 4) | Testing of related and foreign substances in drugs and raw materials | CO2 |
| 5) | Preparation of Master Formula Record. | CO2 |
| 6) | Preparation of Batch Manufacturing Record | CO2 |
| 7) | Quantitative analysis of rancidity in lipsticks and hairoil | CO3 |
| 8) | Determination of aryl amine content and Developer in hair dye | CO3 |
| 9) | Determination of foam height and SLS content of Shampoo.Ferrous sulphate | CO3 |
| 10) | Determination of total fatty matter in creams (Soap, skin and hair creams) | CO4 |
| 11) | Determination of acid value and saponification value. | CO4 |
| 12) | Determination of calcium thioglycolate in depilatories Copper sulphate | CO4 |

**Textbooks:**


1. Analysis of drugs in Biological fluids- Joseph Chamberlain, 2 nd Edition.CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis- Doglas A Skoog, F.James Holler, Timothy A. Nieman, 5 th edition, Easternpress, Bangalore, 1998.
3. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2 nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods– Part B- JW Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2 nd Edition,


**Reference Books:**


1. Indian Pharmacopoeia
2. United States Pharmacopoeia
3. ICH, USFDA & CDSCO Guidelines


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R25MPA208

## ENTREPRENEURSHIP MANAGEMENT

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

4 0 0 0

**Course Objectives:**

- To impart knowledge and skills necessary to train students in entrepreneurship management.
- To enable students to understand the conceptual framework and role of enterprises in economic development.
- To develop entrepreneurial competencies such as motivation, creativity, and decision-making.
- To provide insights into launching, organizing, and managing enterprises.
- To equip students with strategies for growth, networking, and project proposal preparation.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO8 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO208.1 | Explain the role of enterprises in the national and global economy and identify different types of enterprises with their merits and demerits. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L1, L2 |
| R25CO208.2 | Analyze entrepreneurial motivation and competencies, and develop self-awareness, creativity, and interpersonal skills needed for entrepreneurship. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L1, L2, L3 |
| R25CO208.3 | Apply methods for launching and organizing enterprises, including market assessment, feasibility studies, resource mobilization, and cost/quality management. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L 2, L3 |
| R25CO208.4 | Evaluate growth strategies, networking opportunities, diversification techniques, and performance control measures for enterprises. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L3, L4 |
| R25CO208.5 | Prepare a project proposal and feasibility report for starting a new enterprise, including planning, resource mobilization, and implementation strategies. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Conceptual Frame Work:** Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government

policies and schemes for enterprise development. Institutional support in enterprise development and management.

**CO's–CO1**

**Self Learning topics:** Research government policies and schemes for enterprise development in India (e.g., Startup India, MSME schemes), Compare the role of enterprises in national vs. global economy. Study case studies of successful enterprises and analyze factors contributing to success.

**UNIT II:** **10 Hours**

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

**CO's–CO2**

**Self Learning topics:** Research traits of successful entrepreneurs and how they develop skills like creativity and assertiveness, Explore exercises for improving interpersonal skills and leadership qualities.

**UNIT III:** **10 Hours**

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

**CO's–CO3**

**Self Learning topics:** Conduct a mini-market research exercise for a hypothetical business idea, Practice preparing a SWOT analysis for an existing company or startup.

**UNIT IV:** **8 Hours**

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measure, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, coordination and feasibility study.

**CO's–CO4**

**Self Learning topics:** Explore examples of diversification and expansion in real enterprises, Research joint ventures and strategic alliances in Indian and global business.

**UNIT V:** **7 Hours**

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

**CO's-CO5**

**Self Learning topics:** Prepare a simple project proposal for a hypothetical new enterprise.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books**


1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson.


**Web References**

1. https://www.babson.edu/professional/entrepreneurship-education/what-is-babson-academy/resources-and-tips/
2. https://www.coursera.org/browse/business/entrepreneurship
3. https://ocw.mit.edu/collections/entrepreneurship/
4. https://online.hbs.edu/courses/entrepreneurship-essentials/

**Assessment Pattern:**

1. Evaluated for a total of 100 marks.
2. A student can Prepare project proposals and feasibility reports for new enterprises by planning resource mobilization, implementation, and evaluation effectively.
3. **Internal Assessment (40 Marks)**
   Class Tests / Assignments (15 Marks): Short answer / case-based questions from Units I–III. Presentations / Seminars (10 Marks): Students present on entrepreneurial case studies, government schemes, or startup ideas. Class Participation & Attendance (5 Marks):Engagement in discussions, interaction, and group activities.
   Mini Project / Report (10 Marks): A short write-up on an existing entrepreneur/startup or analysis of an enterprise's SWOT.

**2. End Semester Evaluation (60 Marks) Section A:**

Short Answer Questions (10 Marks)

5 questions × 2 marks (covering fundamental concepts from all units).

**Section B:** Medium Length Questions (30 Marks)

5 questions × 6 marks each (from Units I–IV, focusing on application and analysis).

**Section C:** Long Answer / Case Study (20 Marks)

2 questions × 10 marks each (Unit III–V: project proposal, growth strategies, resource mobilization).

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## R25MPT101 MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES 4 0 0 4

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

1. **To impart fundamental and advanced knowledge** on modern analytical instrumentation techniques used in pharmaceutical analysis.
2. **To provide comprehensive understanding** of the principles, instrumentation, working mechanisms, and applications of spectroscopic techniques such as UV-Visible, IR, NMR, and Mass Spectrometry.
3. **To introduce chromatographic and electrophoretic techniques** including HPLC, HPTLC, GC, and Capillary Electrophoresis, with emphasis on their role in qualitative and quantitative analysis of drugs.
4. **To familiarize students with modern hyphenated techniques** such as LC-MS, GC-MS, and their pharmaceutical applications in drug discovery, formulation development, and regulatory submissions.
5. **To develop competence in analytical method validation** as per ICH and regulatory guidelines for the quality control and quality assurance of pharmaceuticals.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO5 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO101.1 | Recall principle, operation and applications of selected instrumental spectroscopic, chromatographic analysis. | 1 | 2 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25CO101.2 | Gain knowledge on interpretation of NMR spectra for determination of molecular structure of compounds. | 1 | 2 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25CO101.3 | Build the analytical understanding in the level of ion, atom, group and molecular structure of organic and inorganic compounds with different functional groups by Mass spectroscopy and their applications in pharmacy. | 1 | 2 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25CO101.4 | Understand the concept of separation and identification of compounds by chromatographic techniques. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25CO101.5 | Categorize different anions and cations by using suitable electrophoresis techniques. Elaborate principle, theory and instruments employed for the analysis of drugs by thermal techniques | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

**b. IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.

**c. Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

**d. Flame emission spectroscopy:** Principle, Instrumentation, Interferences and Applications.
**CO's–CO1**

**Self Learning topics:** Comparative Analysis of Molecular Spectroscopy Techniques: UV-Vis vs. IR vs. Fluorescence, Role of Solvent Effects and Sample Preparation Techniques in Spectroscopic Analysis and Pharmaceutical Applications of Atomic Absorption and Flame Emission Spectroscopy in Trace Element Analysis.

**UNIT II:** **10 Hours**

**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.
**CO's–CO2**

**Self Learning topics:** Understanding Quantum Numbers and Their Role in NMR Activity, Solvent Selection in NMR: Deuterated Solvents and Their Importance and Comparison Between $^{1}H$ NMR and $^{13}C$ NMR Spectroscopy.

**UNIT III:** **10 Hours**

**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.
**CO's–CO3**

**Self Learning topics:** Comparison of Ionization Techniques in Mass Spectrometry, Understanding Mass Fragmentation Patterns and the Nitrogen Rule and Role and Interpretation of Metastable Ions and Isotopic Peaks.

**UNIT IV:** **8 Hours**

**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography

**CO's–CO4**

**Self Learning topics:** Comparison of Chromatographic Techniques: Planar vs. Column Chromatography, Optimization of Resolution in HPLC and Gas Chromatography and ligand selection and elution strategies in bioseparation processes.

**UNIT V:**

**7 Hours**

**a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis
c) Capillary electrophoresis d) Zone electrophoresis
e) Moving boundary electrophoresis f) Iso electricfocusing

**b. Thermal techniques: DSC, DTA, TGA:** Principle, instrumentation, factors affecting results, pharmaceutical applications.

**c. X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

**d. Immunological assays:** RIA(Radio immuno assay), ELISA, Bioluminescence assays.

**CO's-CO5**

**Self Learning topics:** real-life applications in DNA profiling, protein purification, and forensic analysis. X-ray diffraction helps in drug polymorphism, crystal habit modification, and structure-based drug design.

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**Text Books**

1. Spectrometric Identification of Organic compounds –Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Easternpress, Bangalore,1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis –Modern methods –Part B- JW Munson, Volume 11, Marcel Dekker Series

**Reference Books**

1. Indian Pharmacopoeia
2. United State Pharmacopoeia

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define Beer-Lambert's law.
2. List any two applications of UV-Visible spectroscopy.
3. Name different types of molecular vibrations.
4. What is fluorescence?
5. Define chemical shift.
6. List NMR-active nuclei.
7. What are quantum numbers?
8. Define m/z ratio
9. List two ionization techniques.
10. Define retention time and resolution.
11. List types of chromatography.
12. Define isoelectric focusing.
13. What is Bragg's law?
14. List types of electrophoresis.

## L2. Understand

1. Explain how solvent polarity affects UV spectra.
2. Describe the principle of atomic absorption spectroscopy.
3. Differentiate between dispersive and FT-IR spectrometers.
4. Explain spin-spin coupling with an example.
5. Describe the relaxation processes in NMR.
6. Explain the principle of MALDI and ESI.
7. Describe the role of quadrupole analyzer.
8. Describe how ion exchange chromatography separates analytes.
9. Explain the role of mobile and stationary phases.

## L3. Apply

1. Calculate concentration using Beer-Lambert law.
2. Show how IR spectra can identify functional groups.
3. Use fluorescence intensity to determine analyte concentration.
4. Interpret a simple 1H NMR spectrum.
5. Apply the concept of shielding/deshielding in identifying peaks.
6. Predict fragmentation patterns for a given compound.
7. Apply mass spectral data to determine molecular weight.
8. Apply HPLC parameters to optimize peak separation.
9. Demonstrate how gas chromatography is used for volatile analytes.

## L4. Analyze

1. Compare UV-Vis and IR spectroscopy in terms of analytical application.
2. Analyze the effect of quenchers on fluorescence output.
3. Identify factors affecting vibrational frequencies.
4. Compare 1H NMR and 13C NMR in terms of sensitivity and resolution.
5. Analyze how solvent affects chemical shifts.
6. Differentiate between TOF and quadrupole analyzers.
7. Analyze isotopic peaks in a chlorine-containing compound.
8. Compare paper chromatography and TLC.
9. Analyze how temperature affects GC resolution.
10. Compare capillary and gel electrophoresis.
11. Analyze differences between RIA and ELISA.

## L5. Evaluate

1. Assess the usefulness of atomic absorption spectroscopy in trace metal analysis.
2. Justify the use of FT-IR over dispersive IR in analytical labs
3. Evaluate FT-NMR advantages in complex compound analysis.
4. Justify the selection of TMS as internal standard.
5. Evaluate the choice of ionization method for thermally labile molecules.
6. Critique the accuracy of molecular ion peak in EI-MS.
7. Assess the effectiveness of affinity chromatography for protein purification.
8. Justify using HPLC over column chromatography for pharmaceutical QC.
9. Evaluate the role of XRD in drug crystal structure determination.
10. Assess ELISA as a diagnostic tool.

## L6. Create

1. Design a novel conjugated organic molecule with predictable λ_max using Woodward- Fieser, Fieser-Kuhn, and Nelson rules. Explain the rationale behind each substitution.
2. Design an IR-based experiment to distinguish between cis and trans isomers of a substituted alkene, taking into account hydrogen bonding and vibrational coupling effects.
3. Design a mass spectrometric experiment to determine the fragmentation pattern and molecular structure of a newly synthesized drug molecule.
4. Construct a procedure for integrating FT-NMR and CW-NMR data to obtain a detailed structural characterization of a synthetic drug molecule.

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**R25MPT102** **ADVANCED DRUG DELIVERY SYSTEMS** **4 0 0 4**

**Course Objectives:**

- To gain knowledge upon various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of delivering system.
- To understand the concepts of formulation and evaluation of Novel drug delivery systems.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO10 | PO11 | PSO1 | PSO2 | |
| R25MPH102.1 | Gain basic knowledge on sustained release, controlled release, polymer science and personalized medicine. | 3 | 3 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25MPH102.2 | Summarize the various approaches for development of novel drug delivery systems. | 3 | 3 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25MPH102.3 | | 3 | 3 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25MPH102.4 | Summarize the formulation and evaluation of Ocular drug delivery systems and Transdermal Drug Delivery Systems. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25MPH102.5 | Elaborate formulation of protein delivery and evaluate the formulated vaccine drug delivery systems. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

**CO's–CO1**

**Self Learning topics:** Role of 3D printing in personalized drug delivery, Real-world applications of Telepharmacy and Bioelectronic Medicine, Emerging customized dosage forms for pediatric and geriatric care.

**UNIT II:** **10 Hours**

**Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

**CO's–CO2**

**Self Learning topics:** Difference between diffusion-, dissolution-, and osmosis-based control, Osmotic pump design and case examples, Enzyme-activated drug delivery in cancer therapy, Real-time examples of pH-responsive drug release systems.

**UNIT III:** **10 Hours**

**Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit.

**Buccal Drug Delivery Systems:** Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

**Colon targeted Drug Delivery systems for local and Systemic Therapy.**

**CO's–CO3**

**Self Learning topics:** Floating vs. bioadhesive gastroretentive techniques, Approaches to modulate gastric emptying time, Buccal films vs. buccal tablets: Formulation differences, Mechanism of mucoadhesion – theories (electronic, adsorption, wetting), Evaluation parameters for buccal delivery (e.g., residence time, permeation).

**UNIT IV:** **8 Hours**

**Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.

**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

**CO's–CO4**

**Self Learning topics:** Ocular inserts and nanocarriers for eye drug delivery, Challenges in retinal drug delivery and overcoming techniques, Types of penetration enhancers used in TDDS, Microneedles and iontophoresis in transdermal delivery, Formulation and evaluation of transdermal patches – case examples.

**UNIT V:** **7 Hours**

**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

**Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

**Nucleic acid-based Delivery Systems (DNA, mRNA, siRNA-based Therapeutics).**

**CO's-CO5**

**Self Learning topics:** Routes of administration for peptide drugs (e.g., insulin), Role of nanocarriers in protein delivery (liposomes, dendrimers), Stability issues and degradation pathways of protein-based drugs, Mucosal vaccine delivery – nasal and oral vaccines, Single-shot vaccines: depot formulations and slow-release systems.

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**Text Books**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, published by Wiley Inter science Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.

**Reference Books**

1. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1. Remember**

1. Define sustained release and controlled release drug delivery systems. Mention key differences between them.
2. List the categories of patients who benefit from personalized medicine.
3. Enumerate the types of rate-controlled drug delivery systems.
4. State the barriers in ocular and transdermal drug delivery.
5. Define muco-adhesion and list the advantages of buccal drug delivery.

**L2. Understand**

1. Explain the mechanism of drug release from SR and CR formulations with suitable diagrams.
2. Describe the physicochemical and biological factors affecting SR and CR drug delivery systems.
3. Discuss the principles of feedback-regulated drug delivery systems with an example.
4. Explain the advantages and limitations of gastro-retentive drug delivery systems.

**L3. Apply**

1. Describe the structure of skin and its significance in transdermal drug delivery.
2. Apply the concept of personalized medicine in designing a dosage form for a diabetic patient.
3. Design a formulation strategy using osmotic principles for controlled release of a drug.
4. Illustrate how pH-activated drug delivery systems can be used to target drug release in the intestine.
5. Formulate a transdermal patch for a highly lipophilic drug, considering permeation enhancers.

**L4. Analyze**

1. Differentiate between pH-activated, enzyme-activated, and osmotically activated drug delivery systems with examples.
2. Analyze the factors affecting gastrointestinal transit time in gastro-retentive drug delivery systems.
3. Compare the mechanisms of drug absorption in buccal vs transdermal delivery systems.
4. Examine the formulation and evaluation differences between proteins and peptide delivery systems.

**L5. Evaluate**

1. Evaluate the advantages and disadvantages of using 3D printing technology for customized drug delivery.
2. Justify the selection of mucoadhesive polymers in buccal formulations based on mechanism of adhesion and retention time.
3. Assess the potential of single-shot vaccines in improving patient compliance and public health outcomes.
4. Critically evaluate the challenges in protein and peptide drug delivery and suggest possible solutions.

**L6: Create**

1. **Design a controlled release formulation using biodegradable polymers for a chronic** condition like hypertension.
2. Propose a novel vaccine delivery system using microneedles for painless transdermal administration.
3. Formulate a gastro-retentive dosage form for an anti-ulcer drug and outline its evaluation parameters.
4. Develop a tele pharmacy-based model for remote dispensing of personalized medications and explain its implementation challenges.

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**R25MPT103** **MODERN PHARMACEUTICS** **4 0 0 4**

**Course Objectives:**

- To impart knowledge on pre-formulation studies, dispersion systems, parenteral formulations, and nanocarrier-based stabilization strategies.
- To develop skills in applying statistical, QbD, DoE, and AI/ML-based approaches for formulation and process optimization.
- To understand validation principles, regulatory guidelines, and risk-based approaches in ensuring pharmaceutical product quality.
- To gain insights into cGMP compliance, production management, quality systems, and industrial practices for efficient pharmaceutical operations.
- To equip students with knowledge of tablet compression physics, dissolution and IVIVC, and application of statistical tools in formulation evaluation.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO10 | PO11 | PSO1 | PSO2 | |
| R25MPH103.1 | Understand preformulation studies, dispersion systems, parenteral formulations, and nanocarrier- based stabilization strategies. | 3 | 3 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25MPH103.2 | Apply statistical, QbD, DoE, and AI/ML-based approaches for formulation and process optimization. | 3 | 3 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25MPH103.3 | Analyze and implement validation principles, regulatory guidelines, and risk-based approaches in ensuring product quality. | 3 | 3 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25MPH103.4 | Apply cGMP compliance, production management, and quality systems for efficient pharmaceutical operations. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25MPH103.5 | Evaluate compression physics, dissolution, IVIVC, and apply statistical tools in formulation performance assessment. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Preformulation Concepts & Pharmaceutical Dispersions**

**Drug–excipient interactions:** Methods, kinetics of stability, stability testing.

**Theories of dispersion and pharmaceutical dispersions (Emulsions, Suspensions, SMEDDS):** Preparation and stability.

**Large and small-volume parenterals** : Physiological and formulation considerations, manufacturing and evaluation;

**Role of nanocarriers in dispersions (nanoemulsions, nanosuspensions) and their stability aspects.**

**CO's–CO1**

**Self Learning topics:** Role of forced degradation studies in predicting long-term stability, Comparison of physical vs. chemical stability testing in dispersions, Novel approaches for stabilization of SMEDDS and nanosuspensions.

**UNIT II:** **10 Hours**

**Optimization Techniques in Pharmaceutical Formulation**

Concept and parameters of optimization; Optimization techniques in formulation and processing; Statistical design, response surface method, contour designs, factorial designs, Applications in formulation development; Quality by Design (QbD) approach and Design of Experiments (DoE) in optimization; Use of artificial intelligence (AI) and machine learning (ML) tools in formulation optimization.

**CO's–CO2**

**Self Learning topics:** Application of AI & ML in predicting formulation performance, Integration of QbD with PAT (Process Analytical Technology), Recent research articles on response surface methodology in pharmaceutical optimization, Limitations of statistical designs in highly variable biological systems.

**UNIT III:** **10 Hours**

**Introduction to pharmaceutical validation:** scope & merits; Validation and calibration master plan.

ICH & WHO guidelines for calibration and validation of equipment, Validation of specific dosage forms, types of validation and analytical method validation. QbD based validation.

Government regulations, manufacturing process model, URS, DQ, IQ, OQ, PQ of facilities; Risk-based validation approaches and continuous process verification; Current FDA/EMA perspectives on process validation.

**CO's–CO3**

**Self Learning topics:** Differences between US FDA, EMA, and WHO approaches to process validation, Practical examples of validation protocols for sterile vs. non-sterile dosage forms, Case studies of failed pharmaceutical validation and lessons learned.

**UNIT IV:** **8 Hours**

Objectives and policies of current good manufacturing practices (cGMP); Layout of buildings, services, equipment, and their maintenance; Production management: organization, materials management, handling, transportation, inventory management and control.

Production and planning control, sales forecasting, budget and cost control; Industrial and personnel relationship.

Concept of Total Quality Management (TQM), Regulatory audits and data integrity in industrial practice.

**CO's–CO4**

**Self Learning topics:** Real-world examples of cGMP violations and regulatory warning letters, Lean manufacturing and Six Sigma practices in pharma, Case studies on production planning and forecasting in multinational pharmaceutical companies.

**UNIT V:** **7 Hours**

**Compression, Compaction & Pharmaceutical Evaluation Parameters**

Physics of tablet compression, consolidation, effect of friction, distribution of forces, compaction profiles;

Solubility and study of consolidation parameters; Diffusion parameters, dissolution parameters, pharmacokinetic parameters; Heckel plots, similarity factors (f2 and f1), Higuchi and Peppas plots.

Biorelevant dissolution testing and IVIVC (In vitro–In vivo correlation); Applications of advanced modelling (PBPK – Physiologically Based Pharmacokinetics) in formulation evaluation.

Linearity, concept of significance, standard deviation, chi-square test, student's t-test, ANOVA.

**CO's-CO5**

**Self Learning topics:** Case studies on tablet compression failures (capping, lamination, picking), Correlation between compaction pressure and dissolution profile, Application of Heckel analysis in understanding powder compressibility.

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**Text Books**

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leo Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.

**Reference Books**

1. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

2. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
3. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
5. Pharmaceutical Preformulations; By J.J. Wells.
6. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Write the different methods for detecting drug–excipient interactions (DSC, FTIR, XRPD) with suitable examples.
2. Write the objectives and principles of cGMP with reference to facility layout, equipment maintenance, and personnel requirements.

**L2.** Understand

1. Explain the scope, merits, and types of pharmaceutical validation with examples of dosage forms.
2. Discuss the theories of dispersion and their application in pharmaceutical emulsions and suspensions.

**L3.** Apply

1. Illustrate the preparation and evaluation of small-volume parenterals, highlighting physiological and

formulation considerations.
2. Apply factorial design and response surface methodology to optimize an oral solid dosage form.
3. Prepare a validation protocol for sterile injectable formulations incorporating URS, DQ, IQ, OQ, and PQ.
4. Demonstrate the application of Heckel plots and compaction profiles in understanding powder compressibility.

**L4.** Analyze

1. Compare OFAT (one-factor-at-a-time) and factorial design approaches in pharmaceutical formulation optimization.
2. Analyze regulatory differences in process validation between US FDA, EMA, and WHO.
3. Critically analyze case studies of FDA warning letters on cGMP violations and identify root causes.
4. Examine the correlation between compaction pressure, dissolution rate, and pharmacokinetic performance of tablets.

**L5.** Evaluate

1. Evaluate the role of nanocarriers (nanoemulsions, nanosuspensions, SMEDDS) in improving solubility and stability of drugs.
2. Critically evaluate the role of cleaning validation and data integrity (ALCOA+) in preventing cross-contamination.
3. Assess the impact of Lean Manufacturing, Six Sigma, and ERP systems on productivity and cost efficiency in pharma industries.
4. Evaluate the application of IVIVC and PBPK modeling in predicting in vivo performance and supporting regulatory submissions.

**L6: Create**

1. Design a preformulation study plan for a poorly soluble BCS Class II drug including forced degradation and stability testing.
2. Propose an AI/ML-based predictive framework for formulation optimization of nanocarrier-based systems.
3. Develop a risk-based validation master plan for a continuous manufacturing facility in line with ICH Q9.
4. Create a comprehensive evaluation protocol for a sustained-release tablet, integrating statistical methods (ANOVA, t-test, f1/f2 similarity factors).

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**R25MPT104 REGULATORY AFFAIRS IN PRODUCT DEVELOPMENT 4 0 0 4**

**Course Objectives:**

- To gain knowledge about the concepts of innovator and generic drugs, drug development process and Regulatory guidance's and guidelines for filing and approval process.
- To explain the Common Technical Document (CTD) and electronic CTD (eCTD) formats used for the submission of drug dossiers globally.
- To familiarize students with the post-approval regulatory requirement related to drug substances and drug products. To understand regulatory obligations for maintaining product quality, safety, and compliance after approval.
- To provide a detailed understanding of clinical trial guidelines, approvals, and ethical considerations. To enable students to interpret and apply regulatory requirements for conducting safe and effective clinical trials.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | DOK |
|---|---|---|---|---|---|---|---|
| | | PO1 | PO3 | PO6 | PO9 | PSO1 | |
| R25CO104.1 | Recall documentation procedure in Pharmaceutical Industry for drug approval process. | 2 | 1 | 1 | 1 | 1 | L1, L2 |
| R25CO104.2 | Understand the concepts of Regulatory guidance and guidelines for filing and approval process of drugs. | 2 | 1 | 1 | 1 | 1 | L2, L3 |
| R25CO104.3 | Summarize the process of submission of global documents in CTD/eCTD formats. Understand post approval regulatory requirements for actives and drug products. | 2 | 1 | 1 | 1 | 1 | L 3, L4 |
| R25CO104.4 | Understand the global regulatory terms related to drug approval process. | 2 | 1 | 1 | 1 | 1 | L5, L6 |
| R25CO104.5 | Understand the guidelines and requirements for approvals of conducting clinical trials. | 2 | 1 | 1 | 1 | 1 | L5, L6 |

## SYLLABUS

**UNIT I:** **12 Hours**

**Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in- vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in – vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

**CO's–CO1**

**Self Learning topics::** Understand the preparation and significance of DMF, CFR, ANDA, and NDA approvals. Learn about drug performance evaluation, bioequivalence studies, outsourcing to CROs, and post-marketing surveillance.

**UNIT II:** **12 Hours**

**Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. Regulatory requirements of EU, MHRA, TGA and ROW countries. International regulatory trends in pharmaceutical industry

**CO's–CO2**

**Self learning Concepts:** Explore regulatory pathways for APIs, biologics, and generics including NDA and ANDA submissions. Study global regulatory requirements of EU, MHRA, TGA, and ROW countries for drug registration.

**UNIT III:** **12 Hours**

**CMC, post proval regulatory affairs.** Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M.

**CO's–CO3**

**Self learning Concepts:** Learn CMC documentation, ECTD format, and regulations for combination products and medical devices. Understand ICH guidelines, industry-FDA liaison, and post-approval regulatory processes.

**UNIT IV:** **12 Hours**

**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

**Hybrid NDA:** a difference from NDA, historical background, literature based hybrid NDAs and other sources of information for hybrid NDA, examples of types of products considered under hybrid NDA.

**CO's–CO4**

**Self learning Concepts:** Study global regulatory submissions like IND, NDA, ANDA, and preparation of dossiers, IMPD, and investigator brochures.

**UNIT V:** **12 Hours**

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics

committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

**CO's-CO5**

**Self learning Concepts:** Understand clinical trial protocols, ethical approvals, informed consent, HIPAA guidelines, and pharmacovigilance in clinical trials.

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Approved in ACM No: 01

**Text Books**

1. Itkar, S. (2020). Drug Regulatory Affairs. Pune: Nirali Prakashan.
2. Kadam, M. (2021). Pharmaceutical Regulatory Affairs. Nashik: Career Publications.
3. Alkasab, A. (Ed.). (2012). Comprehensive Drug Regulatory Affairs. New York: Academic Press.
4. Berry, I. R., & Martin, R. P. (2004). The Pharmaceutical Regulatory Process. CRC Press.

**Reference Books**

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series,Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R Berryand Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5thedition, Drugs andthe Pharmaceutical Sciences,Vol.190.
4. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
5. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams.

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/

6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1: Remember**

1. Define bioequivalence (BE).
2. What is the Hatch–Waxman Act?
3. Write the full form of CFR.
4. What is the Orange Book?
5. Mention any two PK parameters used in BE studies.
6. Describe the contents of a Master Formula Record.
7. Explain the different types of DMFs and their purposes.
8. Write in detail about the Hatch–Waxman Act (1984).
9. Discuss the major parts of 21 CFR relevant to drug regulation.
10. Explain the difference between ANDA and NDA.

**L2: Understand**

1. Differentiate between in-vitro and in-vivo drug performance tests.
2. Why are distribution records important for drug recalls?
3. Explain the significance of Paragraph IV certification under Hatch–Waxman Act.
4. Why is bioequivalence testing required for generics?
5. Give reasons why many companies outsource BA/BE studies to CROs.
6. Compare the regulatory approval process of NDA and ANDA in the US.
7. Explain the registration pathway for foreign drugs in the US.

8. Discuss the regulatory roles of FDA, EMA (EU), MHRA, and TGA.
9. Summarize the steps required for the approval of biologics.
10. Explain the importance of ROW country regulations in global drug distribution.

**L3: Applying**

1. Apply the knowledge of NDA/ANDA pathways to outline how a foreign API manufacturer can register its product in the US.
2. Using an example, explain how different regulatory agencies (FDA, EMA, MHRA, TGA) may impact the global launch of a new biologic.
3. Design a step-wise regulatory strategy for a company planning to introduce a novel gene therapy in both the US and EU markets.
4. Analyze how the Hatch–Waxman Act framework supports the approval of generics and apply it to a hypothetical case of a company filing an ANDA.
5. Apply the concept of global regulatory harmonization to discuss how a drug approved in the US can be marketed in ROW countries with minimal duplication of work.
6. A company wants to change the manufacturing site for an approved drug. Apply the concept of post-approval regulatory affairs to explain the pathway they must follow.
7. A firm is developing a drug–device inhaler. Explain how it would be classified as a combination product and what regulatory steps are required.
8. A manufacturer needs to prepare a global submission for the same drug in the US, EU, and Japan. How would the CTD/eCTD format help in this process?
9. Apply the ICH Quality (Q) guidelines to explain how stability testing should be conducted before submission.
10. A biotech company is designing clinical trials for a new biologic. Which ICH E (Efficacy) guidelines apply, and how should they be used?

**L4: Analyzing**

1. Compare the regulatory pathways for medical devices vs. combination products in terms of data requirements and approval processes.
2. Analyze how post-approval regulatory changes (e.g., formulation, packaging, manufacturing site) can affect drug quality, safety, and efficacy.
3. Differentiate between the CTD and eCTD formats with respect to structure, submission process, and advantages.

4. Examine how ICH guidelines (Q, S, E, M) collectively ensure global harmonization of drug development.
5. Evaluate the role of FDA–industry liaison meetings (pre-IND, end-of-phase, pre-NDA) in reducing regulatory delays.

**L5: Evaluating**

1.Evaluate the impact of nonclinical study design on the outcome of an NDA submission: Critically evaluate how the design of nonclinical studies can impact the outcome of a New Drug Application (NDA) submission, including the potential consequences of inadequate study design.

2. Assess the role of the IMPD in ensuring the quality and safety of investigational products: Evaluate the significance of the Investigation of Medicinal Products Dossier (IMPD) in ensuring the quality and safety of investigational products, including its role in regulatory decision-making.

3. Compare and contrast the requirements for IND, NDA, and ANDA submissions: Critically compare and contrast the regulatory requirements for Investigational New Drug (IND), New Drug Application (NDA), and Abbreviated New Drug Application (ANDA) submissions, highlighting key similarities and differences.

4. Justify the importance of regular updates to the Investigator's Brochure (IB) during clinical development: Evaluate the importance of regularly updating the Investigator's Brochure (IB) during clinical development and justify the need for these updates in ensuring subject safety and informed consent.

5. Assess the impact of inadequate informed consent on clinical trial validity: Evaluate the potential consequences of inadequate informed consent on the validity and reliability of clinical trial results.

6. Evaluate the role of Institutional Review Boards (IRBs) in ensuring clinical trial ethics: Assess the significance of IRBs in ensuring that clinical trials are conducted in accordance with ethical principles and regulatory requirements.

7. Compare and contrast the requirements for HIPAA compliance in clinical trials: Evaluate the requirements for Health Insurance Portability and Accountability Act (HIPAA) compliance in clinical trials, including the implications for data management and participant confidentiality.

8. Justify the importance of pharmacovigilance in clinical trials: Assess the significance of pharmacovigilance in clinical trials, including its role in ensuring participant safety and identifying potential safety risks.

**L6: Creating**

1. Develop a comprehensive plan for compiling nonclinical data for a global IND submission: Create a detailed plan outlining the necessary steps, timelines, and resources required to compile nonclinical data for a global Investigational New Drug (IND) submission.
2. Design an IMPD dossier for a new investigational product: Create a comprehensive Investigation of Medicinal Products Dossier (IMPD) for a new investigational product, including all necessary sections and information.
3. Construct a strategy for preparing an NDA submission package: Develop a strategy for preparing a New Drug Application (NDA) submission package, including the organization of nonclinical and clinical data, and ensuring compliance with regulatory requirements.
4. Create an outline for an Investigator's Brochure (IB) for a phase II clinical trial: Design an outline for an Investigator's Brochure (IB) for a phase II clinical trial, including key sections such as product description, nonclinical and clinical data, and safety information.
5. Design a clinical trial protocol for a phase III study: Create a comprehensive clinical trial protocol for a phase III study, including the study design, objectives, inclusion and exclusion criteria, and safety monitoring plan.
6. Develop an informed consent form for a clinical trial: Create an informed consent form for a clinical trial, including all necessary information about the study, risks and benefits, and participant rights.

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**R25MPT105 Modern Pharmaceutical Analytical Techniques Practical 0 0 6 3**

**Course Objectives:**

1. To provide practical training in the calibration of analytical instruments.
2. To develop a strong foundation in Good Laboratory Practices (GLP) and regulatory guidelines.
3. To enable students to perform impurity profiling of pharmaceutical substances.
4. To train students in conducting assays of official compounds.
5. To enhance proficiency in the quantitative estimation of functional groups.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO6 | PO8 | PO9 | PO11 | PSO1 | PSO2 | |
| R25CO105.1 | Able to perform the calibration of glassware and instruments | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L1, L2 |
| R25CO105.2 | Estimate the amount of impurity for the given drugs | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2, L3 |
| R25CO105.3 | Examine the purity of official compounds by instrumental techniques and titrimetric procedures | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2, L3 |
| R25CO105.4 | Identify the quantitative determination of functional groups and drugs by using different reagents | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L3, L4 |

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## COURSE CONTENT

| S.No | Name of the experiment | Course Outcome |
|---|---|---|
| 1. | Calibration of glass wares | CO1 |
| 2. | Calibration of pH meter | CO1 |

| | | |
|---|---|---|
| 3. | Calibration of UV-Visible spectrophotometer | CO1 |
| 4. | Calibration of FTIR spectrophotometer | CO1 |
| 5. | Calibration of GC instrument | CO2 |
| 6. | Calibration of HPLC instrument | CO2 |
| 7. | Cleaning validation of any one equipment | CO2 |
| 8. | Impurity profiling of drugs | CO2 |
| 9. | Assay of official compounds by different titrations | CO3 |
| 10. | Assay of official compounds by instrumental techniques. | CO3 |
| 11. | Estimation of riboflavin/quinine sulphate by fluorimetry | CO3 |
| 12. | Estimation of sodium/potassium by flame photometry | CO3 |
| 13. | Quantitative determination of hydroxyl group. | CO4 |
| 14. | Quantitative determination of amino group | CO4 |
| 15. | Colorimetric determination of drugs by using different reagents | CO4 |

**Textbooks**


1. Analysis of drugs in Biological fluids- Joseph Chamberlain, 2 nd Edition.CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis- Doglas A Skoog, F.James Holler, Timothy A. Nieman, 5 th edition, Easternpress, Bangalore, 1998.
3. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2 nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods– Part B- JW Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2 nd Edition.


**Reference Books**


1. Indian Pharmacopoeia
2. United States Pharmacopoeia
3. ICH, USFDA & CDSCO Guidelines.


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**R25MPT106 ADVANCED DRUG DELIVERY SYSTEMS PRACTICAL 0 0 6 3**

**Course Objectives:**

- To understand the design principles and evaluation methods of various advanced drug delivery systems (SR/CR, osmotic, gastro-retentive, mucoadhesive, transdermal).
- To gain hands-on experience in the formulation and evaluation of novel and modified release dosage forms.
- To perform pre-formulation, micromeritic, and dissolution studies to establish relationships between formulation variables and drug release kinetics.
- To apply mathematical models (Higuchi, Peppas, Hixson-Crowell, etc.) to interpret in-vitro drug release data.
- To develop skills in using formulation approaches to optimize bioavailability, stability, and patient compliance.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO6 | PO8 | PO9 | PO11 | PSO1 | PSO2 | |
| R25CO106.1 | Perform in-vitro dissolution studies for controlled/sustained release formulations and interpret release patterns. | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L1, L2 |
| R25CO106.2 | Able to Formulate and Evaluate Tablets | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2, L3 |
| R25CO106.3 | Able to Formulate and Evaluate different Drug Delivery Systems. | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L1, L2 |
| R25CO106.4 | Identify the Drug Release kinetics models. | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L2, L3 |

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**COURSE CONTENT**

| S.No | Name of the Experiment | Course Outcome |
|---|---|---|
| 1. | **Perform In-vitro dissolution profile of CR/ SR marketed formulation.** | CO1 |
| 2. | **Formulation and evaluation of sustained release matrix** | CO1 |

| | | |
|---|---|---|
| | **tablets.** | |
| 3. | **Formulation and evaluation osmotically controlled DDS.** | CO2 |
| 4. | Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS. | CO2 |
| 5. | Formulation and evaluation of Muco-adhesive tablets. | CO2 |
| 6. | Formulation and evaluation of transdermal patches. | CO3 |
| 7. | Carry out pre-formulation studies of tablets and study the effect of compressional force on tablets disintegration time. | CO3 |
| 8. | Study of Micromeritic properties of powders and granulation. | CO4 |
| 9. | Study the effect of binders and the effect of particle size on dissolution of a tablet. | CO4 |
| 10. | Heckel plot, Higuchi and Peppas plot and determine similarity Factors. | CO4 |

**Textbooks:**


1. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig – The Theory and Practice of Industrial Pharmacy, CBS Publishers.
2. Y. W. Chien – Novel Drug Delivery Systems, CRC Press.
3. Vyas, S.P. & Khar, R.K. – Controlled Drug Delivery: Concepts and Advances, Vallabh Prakashan.
4. Robinson, J.R., Lee, V.H.L. – Controlled Drug Delivery: Fundamentals and Applications, Marcel Dekker.


**Reference Books:**


1. Banker, G.S. & Rhodes, C.T. – Modern Pharmaceutics, CRC Press.
2. Brahmankar, D.M. & Jaiswal, S.B. – Biopharmaceutics and Pharmacokinetics: A Treatise, Vallabh Prakashan.
3. Jain, N.K. – Controlled and Novel Drug Delivery, CBS Publishers.
4. Allen, L.V., Popovich, N.G., Ansel, H.C. – Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Williams & Wilkins.


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**R25MPT108** **RESEARCH PAPER WRITING** **4 0 0 0**

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

- To understand the essentials of writing skills and their level of readability.
- To learn about what to write in each section.
- To ensure qualitative presentation with linguistic accuracy.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO8 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO108.1 | Understand the significance of writing skills and the level of readability. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L1, L2 |
| R25CO108.2 | Analyze and write title, abstract, different sections in research paper | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L1, L2, L3 |
| R25CO108.3 | Develop the skills needed while writing a research paper | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L 2, L3 |
| R25CO108.4 | Able to develop and apply key academic writing skills to construct clear, concise, and impactful Titles, Abstracts, and Introductions for research papers, demonstrating the ability to attract readers, summarize core findings, and establish research context effectively. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L3, L4 |
| R25CO108.5 | Able to use appropriate academic language and style to accurately formulate the methodology, clearly present Results, logically construct Arguments, and effectively draw valid conclusions in research writing. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breakingup Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity.

**CO's–CO1**

**Self Learning topics**: Examples of effective vs. poor research paper planning, Exercises on improving word order and sentence clarity, Identifying and breaking long, complex sentences into shorter ones.

**UNIT II:** **10 Hours**

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

**CO's–CO2**

**Self Learning topics:** Common pitfalls in defining a research problem, Hedging phrases in academic writing (e.g., "suggests that", "may indicate"), Identifying plagiarism vs. acceptable paraphrasing.

**UNIT III:** **10 Hours**

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

**CO's–CO3**

**Self Learning topics:** Steps to conduct a literature review (sources, search engines, databases), Comparing qualitative vs. quantitative methodologies,Tools for data analysis (SPSS, Excel, R basics).

**UNIT IV:** **8 Hours**

Key skills needed for writing a Title, Abstract, and Introduction

**CO's–CO4**

**Self Learning topics:** Characteristics of an impactful research title, Common errors to avoid in writing an abstract, Strategies for writing a strong introduction.

**UNIT V:** **7 Hours**

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions.

**CO's-CO5**

**Self Learning topics:** Neutral and objective ways to report results, Building logical arguments with evidence, Transition words for coherence.

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**Text Books**

1. Goldbart R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I].
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press.
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman"sbook Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011.

**Web References**

1. https://cambridge-research.org/blogs/how-to-write-a-research-paper/?

2. https://www.readwritethink.org/classroom-resources/lesson-plans/scaffolding-methods-research-paper?
3. https://academicguides.waldenu.edu/writingcenter/assignments/literaturereview/matrix?
4. https://www.verywellmind.com/how-to-write-an-introduction-2794846?

**Assessment Pattern:**

1. Evaluated for a total of 100 marks.
2. A student can select 2 articles of his/her choice with a minimum of 01 review or research article per semester. Each article publication shall be evaluated by the concerned teacher for 50 marks, totaling to 100 marks.

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**R25MPT201 MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) 4 0 0 4**

**Course Objectives:**

- To understand the principles and biological basis of targeted drug delivery systems.
- To explore the types, preparation techniques, and evaluation methods for nanocarriers and vesicular drug delivery systems.
- To analyse strategies for site-specific drug delivery, especially to the brain and tumours.
- To understand the role of monoclonal antibodies, gene therapy, and nucleic acid-based therapeutics.
- To gain insight into pulmonary and nasal delivery platforms and their relevance in modern pharmaceutics.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO10 | PO11 | PSO1 | PSO2 | |
| R25MPH201.1 | Explain the fundamental concepts, need, and principles of targeted drug delivery | 3 | 3 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25MPH201.2 | Assess the potential of emerging nanocarriers and lipid-polymer systems. Compare traditional and next-generation nanocarriers in terms of efficiency, stability, and clinical translation. | 3 | 3 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25MPH201.3 | Illustrate the Preparation techniques and Evaluation parameters of microcapsules and microspheres, Monoclonal Antibodies etc. | 3 | 3 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25MPH201.4 | Evaluate the role of nanocarriers in enhancing pulmonary and nasal delivery efficiency. Discuss and interpret regulatory considerations and bioequivalence requirements of inhalation products. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25MPH201.5 | Assess the role of liposomal gene delivery and novel nucleic acid-based systems like siRNA, aptamers Critically discuss regulatory, ethical, and clinical trial challenges associated with gene therapy. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## AIPS|R25|MPY|R25MPT201| Molecular Pharmaceutics (Nano Technology & Targeted DDS)

### SYLLABUS

**UNIT I:** **10 Hours**

**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumour targeting and Brain specific delivery.

**CO's–CO1**

**Self Learning topics:** Recent patents in tumour-targeted nanomedicine, Role of receptors (e.g., folate, transferrin) in targeting, Mechanisms of drug release in targeted therapy.

**UNIT II:** **10 Hours**

**Targeting Methods: Active and Passive Targeting.** Introduction, preparation and Characterization of Nano Particles: Polymeric & solid lipid nanoparticles & Liposomes: Types, preparation and evaluation: Stimuli Responsive and Smart Drug Delivery Systems.

**CO's–CO2**

**Self Learning topics:** Role of PEGylation in nanocarrier stealth properties, Case studies of polymeric nanoparticles (e.g., PLGA, chitosan).

**UNIT III:** **10 Hours**

**Micro Capsules / Micro Spheres:** Types, preparation and evaluation of Monoclonal Antibodies; Preparation, Characterization and applications of Niosomes, Aquasomes, Phytosomes, Electrosomes, Transferosomes, Exosomes and Ethosomes.

**CO's–CO3**

**Self Learning topics:** Industrial scale-up techniques for microspheres, Stability concerns in vesicular systems, Thermosensitive liposomes and applications in hyperthermia.

**UNIT IV:** **8 Hours**

**Pulmonary Drug Delivery Systems:** Aerosols, propellants, Containers Types, preparation and evaluation.

**Intra Nasal Route Delivery systems:** Types, preparation and evaluation, Nanocarriers in Naso-Pulmonary Delivery. Regulatory Considerations and Bioequivalence of Inhalation Products.

**CO's–CO4**

**Self Learning topics:** Smart inhalers and digital drug delivery systems, Dry powder inhaler (DPI) formulation case studies, Role of surfactants in nasal drug absorption.

**UNIT V:** **7 Hours**

**Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Regulatory and Ethical Issues in Gene Therapy, Clinical Trial Challenges.

**Biodistribution and Pharmacokinetics:** knowledge of therapeutic antisense molecules and aptamers as drugs of future.

**CO's-CO5**

**Self Learning topics:**FDA-approved gene therapy products, Advances in mRNA delivery systems, Ethical controversies and public perception of gene editing.

## SYLLABUS

**UNIT I:** **10 Hours**

**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumour targeting and Brain specific delivery.

**CO's–CO1**

**Self Learning topics:** Recent patents in tumour-targeted nanomedicine, Role of receptors (e.g., folate, transferrin) in targeting, Mechanisms of drug release in targeted therapy.

**UNIT II:** **10 Hours**

**Targeting Methods: Active and Passive Targeting.** Introduction, preparation and Characterization of Nano Particles: Polymeric & solid lipid nanoparticles & Liposomes: Types, preparation and evaluation: Stimuli Responsive and Smart Drug Delivery Systems.

**CO's–CO2**

**Self Learning topics:** Role of PEGylation in nanocarrier stealth properties, Case studies of polymeric nanoparticles (e.g., PLGA, chitosan).

**UNIT III:** **10 Hours**

**Micro Capsules / Micro Spheres:** Types, preparation and evaluation of Monoclonal Antibodies; Preparation, Characterization and applications of Niosomes, Aquasomes, Phytosomes, Electrosomes, Transferosomes, Exosomes and Ethosomes.

**CO's–CO3**

**Self Learning topics:** Industrial scale-up techniques for microspheres, Stability concerns in vesicular systems, Thermosensitive liposomes and applications in hyperthermia.

**UNIT IV:** **8 Hours**

**Pulmonary Drug Delivery Systems:** Aerosols, propellants, Containers Types, preparation and evaluation.

**Intra Nasal Route Delivery systems:** Types, preparation and evaluation, Nanocarriers in Naso-Pulmonary Delivery. Regulatory Considerations and Bioequivalence of Inhalation Products.

**CO's–CO4**

**Self Learning topics:** Smart inhalers and digital drug delivery systems, Dry powder inhaler (DPI) formulation case studies, Role of surfactants in nasal drug absorption.

**UNIT V:** **7 Hours**

**Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Regulatory and Ethical Issues in Gene Therapy, Clinical Trial Challenges.

**Biodistribution and Pharmacokinetics:** knowledge of therapeutic antisense molecules and aptamers as drugs of future.

**CO's-CO5**

**Self Learning topics:**FDA-approved gene therapy products, Advances in mRNA delivery systems, Ethical controversies and public perception of gene editing.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
4. Torchilin V, Amiji M – Handbook of Nanoparticles for Pharmaceutical Applications.

**Reference Books**

1. Kumar MNVR – Polymeric Nanoparticles: Production, Characterization and Applications.
2. Chowdary KP, Varma KS – Pharmaceutical Technology: Novel Drug Delivery Systems.
3. Khan AY, Vyas A, Gupta S – Drug Delivery: Principles and Appiications.

**Web References**

1. https://www.journals.elsevier.com/advanced-drug-delivery-reviews
2. https://www.journals.elsevier.com/advanced-drug-delivery-reviews
3. https://www.frontiersin.org/journals/nanotechnology
4. https://www.mdpi.com/journal/pharmaceutics
5. https://www.sciencedirect.com/journal/european-journal-of-pharmaceutics-and-biopharmaceutics
6. https://www.mdpi.com/journal/genes
7. https://www.mdpi.com/journal/genes

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define targeted drug delivery systems. List different targeting strategies used in site-specific drug delivery.
2. Describe the classification of liposomes based on structure and composition.

**L2.** Understand

1. Explain the biological processes that influence the efficiency of drug targeting, with emphasis on tumour and brain-specific delivery.
2. Describe the role of polymers and surfactants in the formulation of nanoparticles and vesicular drug delivery systems.
3. Discuss the principles and process of gene therapy. Differentiate between ex vivo and in vivo approaches.

**L3. Apply**

1. Explain the step-by-step procedure for the preparation and evaluation of polymeric nanoparticles used in targeted therapy.
2. Describe the formulation of a nasal drug delivery system for systemic delivery of peptides. Include anatomical and physiological considerations.
3. Illustrate how monoclonal antibodies can be used in targeted drug delivery. Include real-world applications in cancer therapy.

**L4. Analyze**

1. Compare the mechanisms, advantages, and limitations of Aquasomes, Phytosomes, and Electrosomes in drug delivery.
2. Analyze the structural and functional differences between liposomes and niosomes and their impact on drug release.
3. Distinguish between various pulmonary delivery devices (MDI, DPI, nebulizers) in terms of formulation components and performance.

**L5. Evaluate**

1. Evaluate the impact of liposomal gene delivery systems on biodistribution and pharmacokinetics. Support your answer with examples.
2. Critically assess the challenges associated with the use of nucleic acid-based therapeutics in clinical settings.
3. Discuss the ethical and regulatory considerations of gene therapy and their influence on therapeutic development.

**L6: Create**

1. Design a multifunctional nanoparticle system for co-delivery of a chemotherapeutic drug and siRNA. Include targeting, release mechanism, and delivery route.
2. Propose a smart drug delivery system for chronic brain disease using a nanocarrier. Justify your design based on BBB permeability and targeting efficiency.
3. Construct a framework for evaluating the success of a newly developed pulmonary nanoparticle formulation intended for COPD treatment.

Mpawani

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Cherukupally (V), Bhogapuram Mandal
Vizianagaram Dt.,- 531162

**R25MPT202 ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS 4 0 0 4**

**Course Objectives:**

- To apply biopharmaceutic principles in drug formulation and product design.
- To analyze pharmacokinetic models, parameters, and drug interactions.
- To evaluate drug product performance through bioavailability and bioequivalence studies.
- To explore applications of pharmacokinetics in modified-release, targeted, and biotechnological drug products.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO10 | PO11 | PSO1 | PSO2 | |
| R25MPH202.1 | Explain the mechanisms and factors influencing gastrointestinal drug absorption, dissolution, dosage form performance, transport models, and first-pass metabolism for optimizing oral drug delivery | 3 | 3 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25MPH202.2 | Assess biopharmaceutic factors, dissolution testing, and IVIVC to optimize drug product design, stability, and in vitro performance for improved bioavailability. | 3 | 3 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25MPH202.3 | Apply pharmacokinetic models, nonlinear kinetics, and drug interaction principles for clinical use in therapeutic drug monitoring and dose optimization. | 3 | 3 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25MPH202.4 | Evaluate bioavailability, bioequivalence, BCS, and permeability studies to ensure therapeutic equivalence, regulatory compliance, and clinical relevance of drug products | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25MPH202.5 | Integrate PK/PD principles with advanced drug delivery, biotechnology products, and TDM to optimize individualized therapy and clinical outcomes. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH partition theory of drug absorption.

**Formuulation and physicochemical factors:** Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate.

**Gastrointestinal absorption:** role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.

**Transport model:** Permeability Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

**CO's–CO1**

**Self Learning topics:** Anatomy & physiology of the GIT relevant to drug absorption, Mechanisms of drug transport and factors influencing absorption, Dissolution testing methods (USP apparatus I–IV) and IVIVC, Role of first-pass metabolism in limitlng oral bioavailability.

**UNIT II:** **10 Hours**

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance.

**Drug permeability,** in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

**CO's–CO2**

**Self Learning topics:** Bioavailability & Absorption factors, In vitro testing & dissolution methods, IVIVC & dissolution profile comparison, Drug product design & stability.

**UNIT III:** **10 Hours**

**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra vascular.

**Multi compartment model:** two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of kmax and vmax.

**Drug interactions:** introduction, the effect of protein- binding interactions,the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

**Clinical applications of PK (therapeutic drug monitoring, dose adjustment)**

**CO's–CO3**

**Self Learning topics:** Pharmacokinetic models – one & two-compartment, linear vs. nonlinear, Key PK parameters – clearance, half-life, Vd, AUC, MRT, Nonlinear kinetics – Michaelis–Menten, causes of non-linearity, Drug interactions – protein binding, tissue binding, CYP450 & transporters.

**UNIT IV:** **8 Hours**

**Drug Product Performance, In Vivo:** Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, Bioequivalence of narrow therapeutic index (NTI) drugs, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

**CO's–CO4**

**Self Learning topics:** Bioavailability & Bioequivalence basics – definitions, relative vs. absolute, influencing factors, Study designs & evaluation – crossover, data analysis, regulatory aspects.

**UNIT V:** **7 Hours**

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. **Therapeutic drug monitoring (TDM) and individualized dosing strategies.** Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

**CO's-CO5**

**Self Learning topics:** PK/PD relationship & drug interactions – modeling, simulation, clinical impact, Modified-release & targeted delivery systems – design principles, applications, Pharmacokinetics of biotech drugs – proteins, peptides, mAbs, oligonucleotides, Advanced therapies – vaccines, gene therapy, immunotherapy, regulatory concerns.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books**

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi.

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts,
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book .
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982.

**Reference Books**

1. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996 12.
2. Basic Pharmacokinetics, 1 st edition, Sunil S JambhekarandPhilip J Breen, pharmaceutical press, RPS Publishing,2009.
3. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

**Web References**

1. https://www.vallabhprakashan.com/cvsABP.aspx
2. https://dulomix.com/study-material/m-pharm-pharmaceutics-study-material/
3. https://jecpublication.com/index.php/product/advanced-biopharmaceutics-pharmacokinetics/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define drug absorption.
2. List the mechanisms of drug absorption from the gastrointestinal tract.
3. State the factors affecting drug absorption.

4. Define the pH partition theory of drug absorption.
5. Recall the Noyes–Whitney equation for drug dissolution.
6. List the factors affecting the dissolution rate of drugs.
7. Name the types of dosage forms that influence gastrointestinal absorption.
8. Identify examples of solutions used as dosage forms (e.g., elixir, syrup, solution).
9. Recall the advantages of suspensions as dosage forms for absorption.
10. State the role of capsules in drug absorption.
11. Recall the role of tablets in gastrointestinal drug absorption.
12. List different dissolution methods used in drug testing.
13. State formulation and processing factors affecting drug dissolution.
14. Define in vitro–in vivo correlation (IVIVC).
15. Recall the transport model based on permeability, solubility, and charge state.
16. List the properties of the gastrointestinal tract relevant to drug absorption.
17. Define pH microclimate in the gastrointestinal environment.
18. Recall the role of intracellular pH environment in drug absorption.
19. State the significance of tight-junction complexes in drug transport.
20. Define first-pass metabolism.

**L2.** Understand

1. Explain the mechanism of drug absorption across the gastrointestinal tract.
2. Discuss the major factors affecting drug absorption from the GIT.
3. Explain the concept of pH partition theory in relation to drug absorption.
4. Summarize the role of dissolution rate in drug absorption.
5. Describe the Noyes–Whitney equation and its application in drug dissolution.
6. Explain the factors affecting the dissolution rate of drugs.
7. Differentiate between solutions, suspensions, capsules, and tablets in terms of their gastrointestinal absorption.
8. Describe the significance of dissolution methods in predicting drug absorption.
9. Explain the correlation between in vivo data and in vitro dissolution data.
10. Summarize the transport model with respect to permeability, solubility, and charge state.
11. Explain the importance of GIT properties such as pH microclimate, intracellular pH, and tight-junction complex in drug absorption.
12. Discuss biopharmaceutic factors affecting drug bioavailability.
13. Explain the rate-limiting steps in drug absorption with examples.
14. Describe how the physicochemical nature of a drug affects product performance.
15. Differentiate between compendial and alternative dissolution testing methods.
16. Explain the problems of variable control in dissolution testing.
17. Summarize the importance of in vitro–in vivo correlation (IVIVC).
18. Discuss the significance of dissolution profile comparison in drug product evaluation.
19. Explain why drug product stability is an important factor in formulation design.
20. Describe the major considerations in the design of a drug product with respect to biopharmaceutic performance

**L3. Apply**

1. Apply your knowledge of biopharmaceutic factors to explain how solubility and permeability influence the oral bioavailability of a new drug.

2. Apply the concept of rate-limiting steps to predict absorption patterns for a highly lipophilic but poorly soluble drug.
3. Given the physicochemical properties of a drug (pKa, solubility, partition coefficient), apply your knowledge to predict its in vivo performance.
4. Apply compendial and alternative dissolution methods to evaluate the performance of two different tablet formulations.
5. Given dissolution profile data, apply comparison techniques to assess equivalence between two drug products.
6. Apply the concept of IVIVC (In vitro–In vivo correlation) to predict clinical performance of a drug based on dissolution data.
7. Apply stability considerations to recommend formulation strategies for a moisture-sensitive drug.

**L4. Analyze**

1. Analyze the differences between IV bolus, IV infusion, and extravascular administration using the one-compartment model.
2. Compare one-compartment and two-compartment pharmacokinetic models in terms of drug distribution and elimination.
3. Examine the causes of non-linearity in pharmacokinetics and analyze how they impact dose–response relationships.
4. Analyze the Michaelis–Menten equation to interpret nonlinear drug kinetics and explain the significance of Vmax and Km in dosage adjustment.
5. Compare protein-binding and tissue-binding drug interactions and analyze their impact on pharmacokinetic parameters.
6. Analyze the role of cytochrome P450–based interactions in altering drug metabolism and therapeutic outcomes.

**L5. Evaluate**

1. Critically evaluate the purpose and limitations of bioavailability studies in ensuring therapeutic drug performance.
2. Assess the relative importance of absolute vs. relative bioavailability in clinical decision-making.
3. Evaluate the strengths and weaknesses of different methods used for assessing bioavailability.
4. Critically appraise the design and evaluation of bioequivalence studies, focusing on crossover study designs.
5. Judge the regulatory importance of bioequivalence data submission in the drug review process.
6. Assess the clinical significance of the Biopharmaceutics Classification System (BCS) in predicting bioavailability and guiding drug approval.
7. Evaluate the appropriateness of different permeability assessment methods (in vitro, in situ, in vivo) in drug development.
8. Critically analyze the challenges in establishing bioequivalence for generic biologics (biosimilars).

**L6: Create**

1. Design a modified-release drug product strategy for a drug with a short half-life and high first-pass metabolism, justifying formulation and pharmacokinetic considerations.
2. Evaluate the effectiveness of targeted drug delivery systems in minimizing systemic toxicity compared to conventional dosage forms.
3. Propose a pharmacokinetic–pharmacodynamic model to optimize dosing regimens for monoclonal antibodies, considering their unique absorption and clearance patterns.
4. Critically appraise the challenges of applying conventional PK principles to proteins and peptides, and recommend strategies to improve their oral bioavailability.
5. Design an integrated delivery approach for oligonucleotides or gene therapies, accounting for stability, distribution, and intracellular delivery barriers.

M. Pavani

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**R25MPT203 COMPUTER-AIDED DRUG DELIVERY SYSTEMS 4 0 0 4**

**Course Objectives**

- To introduce the use of modern computing tools in drug discovery, design, and development.
- To understand simulation, modeling, and artificial intelligence in optimizing formulations.
- To equip students with practical insights into software applications and digital innovations in drug delivery.

**Course Outcomes**

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO4 | PSO1 | PSO2 | |
| R25 CO203.1 | Explain the fundamentals of computational modeling in pharmaceutical sciences. | 3 | 2 | 2 | 1 | 2 | 1 | L1 ,L2 |
| R25 CO203.2 | Simulate and predict drug disposition parameters using software tools. | 2 | 2 | 3 | 2 | 3 | 2 | L2, L3 |
| R25 CO203.3 | Apply design of experiments and optimization in formulation development. | 2 | 3 | 3 | 2 | 3 | 2 | L2 ,L3 |
| R25 CO203.4 | Integrate in-silico tools to support biopharmaceutical and pharmacokinetic studies. | 2 | 2 | 3 | 2 | 3 | 2 | L3 ,L4 |
| R25 CO203.5 | Recognize the role of AI, robotics, and digital systems in modern drug delivery. | 1 | 2 | 3 | 2 | 3 | 3 | L4, L5, L6 |

## SYLLABUS

**Unit I:** **10 Hours**

**Introduction to Computer-Aided Drug Delivery:** Evolution and need for computational tools in pharmaceutical research. Introduction to computer-aided drug design (CADD) and drug delivery. Overview of modeling approaches: mechanistic vs empirical. Quality-by-Design (QbD) and ICH Q8–Q10 guidelines in formulation optimization. Regulatory expectations in computational submissions.

**CO's-CO1**

**Self learning Concepts:** Trace the historical development of computational tools in drug discovery and delivery. Investigate key milestones in pharmaceutical computational technology.

**Unit II:** **8 Hours**

**Computational Pharmacokinetics and ADME Prediction:** In-silico prediction of ADME properties. Modeling tools for absorption, metabolism, transporters (e.g., P-gp, BCRP). Basics of pharmacokinetic software (e.g., GastroPlus™, Simcyp™ – case study-based). Use of simplified case examples for software simulations.

**CO's-CO2**

**Self learning Concepts:** Explore computational methods and free online tools (Swiss ADME, pkCSM) for predicting drug absorption, metabolism, and excretion properties. Study the role of transporters like P-gp and BCRP in drug disposition and how modeling predicts their effect on bioavailability.

**Unit III:** **8 Hours**

**Formulation Design and Optimization using Software Tools:** Introduction to software like Design Expert™, JMP™, Minitab™, Factorial designs, response surface methodology, Box-Behnken design. Case studies on optimization of nanoparticles, emulsions, tablets. Inclusion of recent trends: 3D printing-assisted formulation design.

**CO's-CO3**

**Self learning Concepts:** Study the features and applications of Design Expert™, JMP™, and Minitab™ for implementing Design of Experiments in pharmaceutical formulations. DoE Techniques: Learn factorial designs, response surface methodology, and Box-Behnken design for optimizing formulation variables. Recent Trends in Design: Explore 3D printing-assisted formulation design and its integration with modern optimization techniques.

**Unit IV:** **10 Hours**

**In-Silico Biopharmaceutics and Virtual Trials:** Biopharmaceutics Classification System (BCS) and bioavailability modeling, Virtual bioequivalence trials and biowaivers, IVIVC concepts with simulation examples, Integration with eCTD submissions.

**CO's-CO4**

**Self learning Concepts:** BCS and Bioavailability Modeling: Learn the principles of the Biopharmaceutics Classification System (BCS) and how in-silico tools model oral drug absorption and bioavailability. Virtual Bioequivalence & Biowaivers: Explore the concept of virtual bioequivalence trials, regulatory requirements, and conditions for biowaivers. IVIVC with Simulations: Understand in-vitro/in-vivo correlation (IVIVC) models and perform simulation-based examples for drug dissolution and absorption prediction. Integration with eCTD: Study how in-silico biopharmaceutics data is compiled and integrated into electronic Common Technical Document (eCTD) submissions for regulatory approval.

**Unit V:** **10 Hours**

**Artificial Intelligence, Machine Learning & Automation in Drug Delivery:** Basics of AI/ML in drug design and DDS. Case studies on Chat GPT, DeepMind, Alpha Fold in pharma.

Introduction to pharmaceutical robotics and automation tools. Computational Fluid Dynamics (CFD) and applications in drug delivery systems. Real-world examples from pharmaceutical industries and startups.

**CO's-CO5**

**Self learning concepts:** AI/ML in Drug Design: Understand the basic principles of artificial intelligence and machine learning applications in drug discovery and delivery systems. Pharma Case Studies: Explore how tools like ChatGPT, DeepMind, and AlphaFold are transforming pharmaceutical research and drug development. Pharmaceutical Robotics & Automation: Learn about robotic systems and automated tools used in drug manufacturing and formulation processes. Computational Fluid Dynamics (CFD): Study CFD principles and their applications in modeling drug delivery systems such as inhalers and injectables. Industry Applications: Review real-world examples where AI, ML, and automation are implemented in pharmaceutical industries and startups.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Recommended Books & Resources**

1. Sean Ekins – Computer Applications in Pharmaceutical R&D.
2. Jelena Djuris – Computer-Aided Applications in Pharmaceutical Technology.
3. Novel Drug Delivery Systems – Y. W. Chien.
4. Modern Pharmaceutics – Banker & Rhodes.
5. Artificial Intelligence in Drug Discovery – Nathan Brown (new addition).

**Web References:**

1. https://www.simulations-plus.com/software/gastroplus/
2. https://www.certara.com/software/simcyp-simulator/
3. https://www.open-systems-pharmacology.org/
4. https://www.statease.com/software/design-expert/
5. https://www.minitab.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remember**

1. Define computer-aided drug design (CADD).
2. What is Quality-by-Design (QbD)?
3. Mention two pharmacokinetic simulation tools.
4. Name any two statistical software used in formulation optimization.
5. List the BCS classification system classes.
6. Describe the basic modeling approaches used in pharmaceutical research.

**L2 – Understand**

1. Explain the role of transmembrane transporters like P-gp in drug absorption.
2. Differentiate between mechanistic and empirical modeling.
3. Describe how software like GastroPlus™ aids in drug development.
4. Explain the concept of IVIVC.
5. Discuss the applications of in-silico ADME prediction in preclinical drug development.

**L3 – Apply**

1. Apply Design Expert™ to optimize a tablet formulation.
2. Demonstrate the use of Box-Behnken design in drug formulation.
3. Use a case study to show application of CFD in drug delivery.
4. Using a software simulation (real or hypothetical), illustrate how virtual trials are conducted for bioequivalence testing.

**L4 – Analyze**

1. Analyze the difference between GastroPlus™ and Simcyp™.
2. Evaluate the significance of QbD in formulation development.
3. Classify various AI tools used in drug design.
4. Analyze the impact of 3D printing technology on the development of personalized drug delivery systems.

**L5 – Evaluate**

1. Justify the use of AI/ML in pharmaceutical R&D.
2. Assess the limitations of in-silico models in real-time bioavailability prediction.
3. Critically evaluate the use of computational tools in regulatory submission.
4. Compare and contrast conventional optimization methods with AI-driven formulation design approaches.

**L6 – Create**

1. Design a hypothetical workflow integrating QbD and simulation for a new DDS.
2. Propose a software-based framework for predicting drug–food interactions.
3. Develop a basic protocol for using CFD in nasal drug delivery system design.
4. Create a case-based simulation plan using Gastro Plus™ to demonstrate the pharmacokinetics of a new oral formulation under fed and fasted conditions.

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**R25MPT204** **PRODUCT FORMULATION TECHNOLOGY** **4 0 0 4**

**Course Objectives:**

- To understand Preformulation Studies and to enable students to gain knowledge about molecular optimization, crystal morphology, drug-excipient compatibility, and determination methods essential for formulation development.
- To Learn about Formulation Additives and to provide in-depth understanding of various formulation additives, their roles in product development, and the design of experiments for process optimization.
- To familiarize students with solubility enhancement techniques, dissolution mechanisms, and testing models to improve bioavailability and product performance.
- To train students in stability testing methods, degradation kinetics, ICH guidelines, and shelf-life determination of pharmaceutical products.
- To formulate and Evaluate Cosmetic Product and to impart knowledge on the formulation, evaluation, and packaging of various cosmetic products, including creams, gels, shampoos, and baby care products.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO4 | PO8 | PO9 | PO10 | PSO1 | PSO2 | |
| R25CO204.1 | To analyze API properties, crystal morphology, and drug-excipient compatibility to optimiz formulation development. | 2 | 1 | 1 | 1 | 1 | 2 | 1 | L 1, L2 |
| R25CO204.2 | Students will understand the role of excipients, factors influencing their incorporation, and design experiments for effective product and process development. | 2 | 1 | 1 | 1 | 1 | 2 | 1 | L1,L2 |
| R25CO204.3 | Students will learn solubility enhancement techniques, dissolution testing models, and correlate in-vitro and in-vivo data for improved drug bioavailability. | 2 | 1 | 1 | 1 | 1 | 2 | 1 | L 2, L3 |
| R25CO204.4 | Students will evaluate degradation kinetics, conduct stability testing as per ICH guidelines, and predict product shelf life effectively. | 2 | 1 | 1 | 1 | 1 | 2 | 1 | L3, L4 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| R25CO204.5 | To gain skills to formulate, evaluate, and package various cosmetic products, ensuring quality, safety, and regulatory compliance. | 2 | 1 | 1 | 1 | 1 | 2 | | L5,L6 |

## SYLLABUS

### Unit I — 12 Hours

**Preformulation Studies:** Fundamentals of preformulation studies and their significance in drug development. Molecular optimization of APIs: physicochemical properties and their role in formulation. Crystal morphology and polymorphism – implications in bioavailability. Powder flow properties and evaluation techniques. Structure modification for enhanced solubility. Drug-excipient compatibility studies: methods (DSC, FTIR, etc.). Analytical techniques for preformulation characterization. Role of complexation, rheology, micromeritics and dissolution in design of dosage form.

**Solubility & Dissolution**: Solubility and its importance in drug absorption and bioavailability. Experimental methods for solubility determination and enhancement. Advanced solubility improvement strategies: Salt formation Solid dispersion, Micellar solubilization, Nanocrystals, Lipid-based formulations,

**Dissolution:** principles, theories, and in vitro testing, Dissolution apparatus: design, calibration, and method development, IVIVC (In vitro–In vivo correlation): levels and applications, Role of biorelevant dissolution media in predicting in vivo performance. Biowaviers in drug development.

**CO'S-CO1**

**Self-Learning Concepts:** Latest approaches in predictive preformulation tools using computational methods. Role of QbD (Quality by Design) in preformulation studies. Recent research on co-crystals and amorphous solid dispersions for solubility enhancement. Regulatory considerations for preformulation studies in ANDA and NDA submissions.

### Unit II — 12 Hours

**Formulation Additives:** Classification of pharmaceutical excipients and their functional roles. Factors influencing excipient selection and compatibility. Recent developments in novel excipients and their regulatory acceptance. Role of excipients in controlled release, taste masking, and stability. Qbd, Design of experiments (DOE) and factorial design in formulation optimization. Excipients for biologics and nanotechnology-based formulations.

**CO'S-CO2**

**Self-Learning Concepts:** Current trends in green excipients and sustainable formulation practices. Role of co-processed excipients for improving tableting properties. IPEC guidelines for excipient quality and safety. Case studies on excipient failures and their impact on product recalls.
**CO'S-CO2**

### Unit III — 12 Hours

**Quality by design (QbD):** Fundamentals of pharmaceutical quality by design, identification of critical quality attributes, critical material attributes, critical process parameters and quality risk management.

**Methods of optimization** – OVAT and Design of experiments (DOE). Experimental designs, screening designs, factorial designs, composite designs, mixture designs, response surface methodology. Applications of systematic optimization techniques.

Process analytical technology (PAT) and other control strategies for QbD.

**CO'S-CO3**

**Self-Learning Concepts:** ICH guidelines: Q8(R2), Q9, Q10, Make a diagram showing QbD workflow from QTPP to control strategy.

**Unit IV:** **12 Hours**

**Product stability:** Stability concepts: degradation pathways, kinetics, and shelf-life prediction. Factors affecting stability: temperature, humidity, light, and pH. Stability studies: real-time and accelerated protocols as per ICH guidelines. Current ICH guidelines (Q1A–Q1F). Stability indicating methods and analytical validation. Interpretation of kinetic data (Arrhenius plot, Q10 method). Stability testing for biologics and novel drug delivery systems. Solid-state stability, packaging considerations, and labelling.

**CO'S-CO4**

**Self-Learning Concepts:** WHO recommendations for stability testing. Impact of climatic zones on stability requirements. Stability testing of nanomedicines and biologics. Case studies on stability-related product recalls.

**Unit V** **12 Hours**

**Cosmetics:** Regulatory framework for cosmetic products (FDA, BIS, EU). Formulation, evaluation, and packaging of cosmetics:Dentifrices (toothpaste, gels), Nail care (nail polish, nail removers), Lip care (lipstick, lip balms), Eye cosmetics (mascara, eyeliner), Baby care products, Skin care (moisturizers, vanishing cream, cold cream), Hair care (shampoos, conditioners), Stability testing of cosmetic formulations.

**CO'S-CO5**

**Self-Learning Concepts:** Role of natural ingredients and herbal extracts in cosmetics. Concept of **cosmeceuticals** and their regulatory challenges. Nanotechnology in cosmetics (nanoemulsions, liposomes). Ethical considerations: animal testing bans and alternatives.

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**Text Books:**

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nded., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore,1999.13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
6. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.
7. Harry's Cosmeticology. 8th edition.

8. Poucher's perfume cosmetics and Soaps,10th edition.
9. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
10. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd Edition.

**Reference Books:**

1. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
2. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
3. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
4. Encyclopedia of Pharm. Technology, Vol I – III.

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1: Remember**

1. List the physicochemical properties considered in preformulation studies.
2. What is crystal polymorphism
3. Identify two analytical techniques used for preformulation characterization.
4. Recall the role of drug-excipient compatibility studies.
5. Name any two regulatory submissions related to preformulation studies
6. List the functional roles of pharmaceutical excipients.
7. Recall the factors influencing excipient selection.
8. Identify the role of excipients in taste masking.
9. List different types of excipients used in nanotechnology-based formulations.
10. Mention any two IPEC guidelines for excipient quality and safety

**L2: Understand**

1. Explain the significance of preformulation studies in drug development.

2. Differentiate between DSC and FTIR methods used in compatibility studies.
3. Describe the role of QbD in improving preformulation process.
4. Describe the factors influencing the compatibility of excipients in formulations.
5. Summarize the role of excipients in controlled drug release and stability.
6. Explain the importance of DOE and factorial design in formulation optimization.
7. Describe the regulatory acceptance process of novel excipients.
8. Classify various solubility enhancement techniques and give one example for each.
9. Interpret the role of lipid-based formulations in enhancing drug solubility.
10. Compare micellar solubilization and solid dispersion techniques in terms of mechanism.

**L3: Apply**

1. Demonstrate how you would design an experiment to determine the solubility of a new API.
2. Apply the concept of IVIVC to predict in vivo performance from in vitro dissolution data for an immediate-release tablet.
3. Calculate the solubility improvement when converting a drug into its salt form, given experimental data.
4. Select an appropriate dissolution apparatus for testing a controlled-release formulation and justify your choice.
5. Apply the principle of solid dispersion to formulate a poorly water-soluble drug for oral delivery.
6. Design a method using micellar solubilization for a drug with low aqueous solubility.
7. Choose suitable biorelevant media for dissolution testing of a lipid-based drug delivery system and explain why.
8. Develop a step-by-step protocol for calibrating a USP Type II (paddle) dissolution apparatus.
9. Propose a solubility enhancement strategy for a BCS Class II drug and explain its mechanism.
10. Interpret dissolution data from an in vitro study and predict possible in vivo absorption trends.
11. Apply the concept of degradation kinetics to calculate the shelf life of a drug product stored at 40°C.
12. How would you design an accelerated stability study for a new pharmaceutical product according to ICH guidelines?
13. Demonstrate how zero-order and first-order kinetics impact the stability of pharmaceutical formulations.

**L4: Analyze**

1. Analyze the difference between real-time stability testing and accelerated stability testing.
2. Compare the significance of Arrhenius equation and Q10 method in predicting product shelf life.

3. Examine how environmental factors (temperature, humidity, light) influence the degradation of pharmaceutical products.Differentiate between the regulatory pathways of NDA and ANDA.

**L5 – Evaluate**

1. Evaluate the effectiveness of different packaging materials for preserving cosmetic product stability.
2. Justify the selection of preservatives in a cosmetic formulation to ensure microbial safety.
3. Critically assess the role of Good Manufacturing Practices (GMP) in ensuring cosmetic product quality.

**L6 – Create**

1. Design a novel cosmetic formulation for an anti-aging cream, considering regulatory and safety requirements.
2. Develop a quality evaluation protocol for a newly developed herbal cosmetic product.
3. Create a packaging strategy for a cosmetic lotion to maintain product integrity during transportation and storage.

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**R25MPT205 MOLECULAR PHARMACEUTICS PRACTICAL 0 0 6 3**

**Course Objectives:**

- To develop knowledge and practical skills in designing, preparing, and characterizing novel drug delivery systems such as microcapsules, alginate beads, microspheres, liposomes, niosomes, and spherules.
- To understand and apply techniques for improving drug performance, including enhancement of solubility, dissolution, bioavailability, and bioequivalence, as well as comparison of marketed formulations.
- To evaluate pharmacokinetic and pharmacodynamic aspects of drug formulations, including protein binding studies and determination of pharmacokinetic parameters for optimizing therapeutic efficacy.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | PO1 | PO2 | PO3 | PO4 | PO11 | PSO1 | PSO2 | DOK |
|---|---|---|---|---|---|---|---|---|---|
| R25MPH205.1 | Develop the ability to design, prepare, and optimize various novel drug delivery systems (e.g., microcapsules, alginate beads, microspheres). | 3 | 3 | 3 | 2 | 3 | 3 | 2 | L1,L2 |
| R25MPH205.2 | Demonstrate proficiency in advanced drug delivery techniques by preparing and evaluating liposomes, niosomes, and spherules | 3 | 3 | 3 | 3 | 3 | 3 | 2 | L2,L3 |
| R25MPH205.3 | Apply formulation strategies such as solid dispersion and comparative dissolution testing to enhance solubility, dissolution, and therapeutic performance of drugs | 3 | 3 | 3 | 2 | 3 | 3 | 2 | L2,L6 |
| R25MPH205.4 | Evaluate pharmacokinetic and pharmacodynamic properties by determining bioavailability, bioequivalence, and protein-binding characteristics of drugs. | 3 | 2 | 2 | 2 | 3 | 3 | 2 | L4,L5 |

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## COURSE CONTENT

The course helps to provide students with **practical knowledge and hands-on training** in modern drug delivery techniques, dissolution enhancement methods, bioavailability studies, and pharmacokinetic data analysis, bridging the gap between formulation development and therapeutic efficacy.

| Experiment No | Name of the Experiment | CO |
|---|---|---|
| 1. | To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation | CO1 |
| 2. | Preparation and evaluation of Alginate beads | CO2 |
| 3. | Formulation and evaluation of gelatin /albumin microspheres | CO2 |
| 4. | Formulation and evaluation of liposomes/niosomes | CO2 |
| 5. | Formulation and evaluation of spherules | CO2 |
| 6. | Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique. | CO2 |
| 7. | Comparison of dissolution of two different marketed products/brands. | CO3 |
| 8. | Protein binding studies of a highly protein bound drug & poorly protein bound drug | CO3 |
| 9. | Determination of bioavailability and bioequivalence. | CO4 |
| 10. | Determination of Pharmacokinetic parameters. | CO4 |

**Text Books:**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

**Reference Books:**

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.

3. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi Harry's Cosmeticology. 8th edition.

4. Poucher's perfume cosmetics and Soaps,10th edition

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**R25MPT206 PRODUCT FORMULATION TECHNOLOGY PRACTICAL 0 0 6 3**

**Course Objectives:**

- To train students in computational and experimental techniques for drug delivery and pharmaceutical product development.
- To enable hands-on skills in formulation, evaluation, and comparison of cosmetic and therapeutic dosage forms.
- To develop proficiency in quality by design (QbD) approaches for pharmaceutical products.
- To strengthen students' ability to analyze clinical and preclinical data through simulations and modeling tools.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | PO1 | PO2 | PO8 | PO9 | PO10 | PSO1 | PSO2 | DOK |
|---|---|---|---|---|---|---|---|---|---|
| R25CO107.1 | Perform computer simulations in pharmacokinetics & pharmacodynamics using software tools. | 3 | 2 | 3 | 3 | 2 | 2 | 1 | L2,L3 |
| R25CO107.2 | Formulate and evaluate cosmetic products (toothpaste, anti-dandruff shampoo) and compare with marketed samples. | 2 | - | 3 | 3 | 2 | 2 | 1 | L2,L3 |
| R25CO107.3 | Develop nutraceutical formulations (multi-vitamin syrups, herbal creams) and evaluate their quality. | 3 | 2 | 3 | 3 | 2 | 2 | 2 | L3,L4 |
| R25CO107.4 | Prepare a clinical data collection manual and interpret preclinical/clinical findings for pharmaceutical R&D. | 2 | - | 3 | 3 | 2 | 2 | 1 | L2,L5 |

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## COURSE CONTENT

| Experiment No | Name of the Experiment | CO |
|---|---|---|
| 1. | Computer simulations in pharmacokinetics and pharmacodynamics. | CO1 |
| 2. | Preparation and evaluation of toothpaste formulation. | CO2 |
| 3. | Preparation and evaluation of anti-dandruff shampoo. | CO2 |
| 4. | Evaluation of prepared shampoo formulations and comparison with marketed shampoos. | CO2 |
| 5. | Formulation and evaluation of multi-purpose herbal cream. | CO2 |
| 6. | Formulation and evaluation of multi-vitamin syrup. | CO2 |
| 7. | Quality by Design (QbD) in pharmaceutical product development. | CO3 |
| 8. | Computational modeling of drug deposition & release kinetics. | CO3 |
| 9. | Development of a clinical data collection manual for pharmaceutical R&D. | CO4 |
| 10. | In-silico ADME/Tox modeling using open-source software for predicting drug-likeness. | CO4 |

**Textbooks:**

- Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig – The Theory and Practice of Industrial Pharmacy, CBS Publishers.
- Y. Anjaneyulu, C. Chandrasekhar – Laboratory Manual of Industrial Pharmacy.
- Raymond C. Rowe, Paul J. Sheskey, Marian E. Quinn – Handbook of Pharmaceutical Excipients.

**Reference Books:**

- Patrick J. Sinko – Martin's Physical Pharmacy and Pharmaceutical Sciences.
- Michael E. Aulton – Aulton's Pharmaceutics: The Design and Manufacture of Medicines.
- Larry L. Augsburger – Pharmaceutical Dosage Forms: Tablets.

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**R25MPT208** **ENTREPRENEURSHIP MANAGEMENT** **4 0 0 0**

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

- To impart knowledge and skills necessary to train students in entrepreneurship management.
- To enable students to understand the conceptual framework and role of enterprises in economic development.
- To develop entrepreneurial competencies such as motivation, creativity, and decision-making.
- To provide insights into launching, organizing, and managing enterprises.
- To equip students with strategies for growth, networking, and project proposal preparation.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO8 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO208.1 | Explain the role of enterprises in the national and global economy and identify different types of enterprises with their merits and demerits. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L1, L2 |
| R25CO208.2 | Analyze entrepreneurial motivation and competencies, and develop self-awareness, creativity, and interpersonal skills needed for entrepreneurship. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L1, L2, L3 |
| R25CO208.3 | Apply methods for launching and organizing enterprises, including market assessment, feasibility studies, resource mobilization, and cost/quality management. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L 2, L3 |
| R25CO208.4 | Evaluate growth strategies, networking opportunities, diversification techniques, and performance control measures for enterprises. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L3, L4 |
| R25CO208.5 | Prepare a project proposal and feasibility report for starting a new enterprise, including planning, resource mobilization, and implementation strategies. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Conceptual Frame Work:** Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government

policies and schemes for enterprise development. Institutional support in enterprise development and management.

**CO's–CO1**

**Self Learning topics:** Research government policies and schemes for enterprise development in India (e.g., Startup India, MSME schemes), Compare the role of enterprises in national vs. global economy. Study case studies of successful enterprises and analyze factors contributing to success.

**UNIT II:** **10 Hours**

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

**CO's–CO2**

**Self Learning topics:** Research traits of successful entrepreneurs and how they develop skills like creativity and assertiveness, Explore exercises for improving interpersonal skills and leadership qualities.

**UNIT III:** **10 Hours**

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

**CO's–CO3**

**Self Learning topics:** Conduct a mini-market research exercise for a hypothetical business idea, Practice preparing a SWOT analysis for an existing company or startup.

**UNIT IV:** **8 Hours**

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measure, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, coordination and feasibility study.

**CO's–CO4**

**Self Learning topics:** Explore examples of diversification and expansion in real enterprises, Research joint ventures and strategic alliances in Indian and global business.

**UNIT V:** **7 Hours**

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

**CO's-CO5**

**Self Learning topics:** Prepare a simple project proposal for a hypothetical new enterprise.

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**Text Books**

1. Akhauri, M. M. P (1990): Entrepreneurship for Women in India, NIESBUD, New Delhi

2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson.

**Web References**

1. https://www.babson.edu/professional/entrepreneurship-education/what-is-babson-academy/resources-and-tips/
2. https://www.coursera.org/browse/business/entrepreneurship
3. https://ocw.mit.edu/collections/entrepreneurship/
4. https://online.hbs.edu/courses/entrepreneurship-essentials/

**Assessment Pattern:**

1. Evaluated for a total of 100 marks.
2. A student can Prepare project proposals and feasibility reports for new enterprises by planning resource mobilization, implementation, and evaluation effectively.

3. **Internal Assessment (40 Marks)**
Class Tests / Assignments (15 Marks): Short answer / case-based questions from Units I–III. Presentations / Seminars (10 Marks): Students present on entrepreneurial case studies, government schemes, or startup ideas.
Class Participation & Attendance (5 Marks):Engagement in discussions, interaction, and group activities.Mini Project / Report (10 Marks): A short write-up on an existing entrepreneur/startup or analysis of an enterprise's SWOT.

**2. End Semester Evaluation (60 Marks)**
**Section A:** Short Answer Questions (10 Marks)
5 questions × 2 marks (covering fundamental concepts from all units).
**Section B:** Medium Length Questions (30 Marks)
5 questions × 6 marks each (from Units I–IV, focusing on application and analysis).
**Section C:** Long Answer / Case Study (20 Marks)
2 questions × 10 marks each (Unit III–V: project proposal, growth strategies, resource mobilization).

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**R25MPH101 MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES** **4 0 0 4**

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

1. **To impart fundamental and advanced knowledge** on modern analytical instrumentation techniques used in pharmaceutical analysis.
2. **To provide comprehensive understanding** of the principles, instrumentation, working mechanisms, and applications of spectroscopic techniques such as UV-Visible, IR, NMR, and Mass Spectrometry.
3. **To introduce chromatographic and electrophoretic techniques** including HPLC, HPTLC, GC, and Capillary Electrophoresis, with emphasis on their role in qualitative and quantitative analysis of drugs.
4. **To familiarize students with modern hyphenated techniques** such as LC-MS, GC-MS, and their pharmaceutical applications in drug discovery, formulation development, and regulatory submissions.
5. **To develop competence in analytical method validation** as per ICH and regulatory guidelines for the quality control and quality assurance of pharmaceuticals.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO5 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO101.1 | Recall principle, operation and applications of selected instrumental spectroscopic, chromatographic analysis. | 1 | 2 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25CO101.2 | Gain knowledge on interpretation of NMR spectra for determination of molecular structure of compounds. | 1 | 2 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25CO101.3 | Build the analytical understanding in the level of ion, atom, group and molecular structure of organic and inorganic compounds with different functional groups by Mass spectroscopy and their applications in pharmacy. | 1 | 2 | 3 | 1 | 3 | - | 2 | 1 | L2, L3 |
| R25CO101.4 | Understand the concept of separation and identification of compounds by chromatographic techniques. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25CO101.5 | Categorize different anions and cations by using suitable electrophoresis techniques. Elaborate principle, theory and instruments employed for the analysis of drugs by thermal techniques | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

**b. IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.

**c. Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

**d. Flame emission spectroscopy:** Principle, Instrumentation, Interferences and Applications.

**CO's–CO1**

**Self Learning topics:** Comparative Analysis of Molecular Spectroscopy Techniques: UV-Vis vs. IR vs. Fluorescence, Role of Solvent Effects and Sample Preparation Techniques in Spectroscopic Analysis and Pharmaceutical Applications of Atomic Absorption and Flame Emission Spectroscopy in Trace Element Analysis.

**UNIT II:** **10 Hours**

**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

**CO's–CO2**

**Self Learning topics:** Understanding Quantum Numbers and Their Role in NMR Activity, Solvent Selection in NMR: Deuterated Solvents and Their Importance and Comparison Between $^{1}H$ NMR and $^{13}C$ NMR Spectroscopy.

**UNIT III:** **10 Hours**

**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.

**CO's–CO3**

**Self Learning topics:** Comparison of Ionization Techniques in Mass Spectrometry, Understanding Mass Fragmentation Patterns and the Nitrogen Rule and Role and Interpretation of Metastable Ions and Isotopic Peaks.

**UNIT IV:** **8 Hours**

**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography

CO's–CO4

**Self Learning topics:** Comparison of Chromatographic Techniques: Planar vs. Column Chromatography, Optimization of Resolution in HPLC and Gas Chromatography and ligand selection and elution strategies in bioseparation processes.

**UNIT V:**

**7 Hours**

**a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis
c) Capillary electrophoresis d) Zone electrophoresis
e) Moving boundary electrophoresis f) Iso electricfocusing

**b. Thermal techniques: DSC, DTA, TGA:** Principle, instrumentation, factors affecting results, pharmaceutical applications.

**c. X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

**d. Immunological assays:** RIA(Radio immuno assay), ELISA, Bioluminescence assays.

**CO's-CO5**

**Self Learning topics:** real-life applications in DNA profiling, protein purification, and forensic analysis. X-ray diffraction helps in drug polymorphism, crystal habit modification, and structure-based drug design.

Board of Studies: Pharmacy
Approved in BOS No: 01, 22nd October, 2025
Approved in ACM No: 01

**Text Books**

1. Spectrometric Identification of Organic compounds –Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Easternpress, Bangalore,1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis –Modern methods –Part B- JW Munson, Volume 11, Marcel Dekker Series

**Reference Books**

1. Indian Pharmacopoeia
2. United State Pharmacopoeia

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define Beer-Lambert's law.
2. List any two applications of UV-Visible spectroscopy.
3. Name different types of molecular vibrations.
4. What is fluorescence?
5. Define chemical shift.
6. List NMR-active nuclei.
7. What are quantum numbers?
8. Define m/z ratio
9. List two ionization techniques.
10. Define retention time and resolution.
11. List types of chromatography.
12. Define isoelectric focusing.

13. What is Bragg's law?
14. List types of electrophoresis.

**L2.** Understand

1. Explain how solvent polarity affects UV spectra.
2. Describe the principle of atomic absorption spectroscopy.
3. Differentiate between dispersive and FT-IR spectrometers.
4. Explain spin-spin coupling with an example.
5. Describe the relaxation processes in NMR.
6. Explain the principle of MALDI and ESI.
7. Describe the role of quadrupole analyzer.
8. Describe how ion exchange chromatography separates analytes.
9. Explain the role of mobile and stationary phases.

**L3.** Apply

1. Calculate concentration using Beer-Lambert law.
2. Show how IR spectra can identify functional groups.
3. Use fluorescence intensity to determine analyte concentration.
4. Interpret a simple 1H NMR spectrum.
5. Apply the concept of shielding/deshielding in identifying peaks.
6. Predict fragmentation patterns for a given compound.
7. Apply mass spectral data to determine molecular weight.
8. Apply HPLC parameters to optimize peak separation.
9. Demonstrate how gas chromatography is used for volatile analytes.

**L4.** Analyze

1. Compare UV-Vis and IR spectroscopy in terms of analytical application.
2. Analyze the effect of quenchers on fluorescence output.
3. Identify factors affecting vibrational frequencies.
4. Compare 1H NMR and 13C NMR in terms of sensitivity and resolution.
5. Analyze how solvent affects chemical shifts.
6. Differentiate between TOF and quadrupole analyzers.
7. Analyze isotopic peaks in a chlorine-containing compound.
8. Compare paper chromatography and TLC.
9. Analyze how temperature affects GC resolution.
10. Compare capillary and gel electrophoresis.
11. Analyze differences between RIA and ELISA.

**L5.** Evaluate

1. Assess the usefulness of atomic absorption spectroscopy in trace metal analysis.
2. Justify the use of FT-IR over dispersive IR in analytical labs
3. Evaluate FT-NMR advantages in complex compound analysis.
4. Justify the selection of TMS as internal standard.
5. Evaluate the choice of ionization method for thermally labile molecules.
6. Critique the accuracy of molecular ion peak in EI-MS.
7. Assess the effectiveness of affinity chromatography for protein purification.
8. Justify using HPLC over column chromatography for pharmaceutical QC.
9. Evaluate the role of XRD in drug crystal structure determination.
10. Assess ELISA as a diagnostic tool.

**L6. Create**

1. Design a novel conjugated organic molecule with predictable λ_max using Woodward-Fieser, Fieser-Kuhn, and Nelson rules. Explain the rationale behind each substitution.
2. Design an IR-based experiment to distinguish between cis and trans isomers of a substituted alkene, taking into account hydrogen bonding and vibrational coupling effects.
3. Design a mass spectrometric experiment to determine the fragmentation pattern and molecular structure of a newly synthesized drug molecule.
4. Construct a procedure for integrating FT-NMR and CW-NMR data to obtain a detailed structural characterization of a synthetic drug molecule.

M. pavani

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**Board of Studies**

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Board of Studies (AIPS)
Avanthi Institute of Pharmaceutical Sciences (A)
Cherukupally (V), Bhogapuram Manda
Vizianagaram Dt.,- 531162

**R25MPH102** **ADVANCED DRUG DELIVERY SYSTEMS** **4 0 0 4**

**Course Objectives:**

- To gain knowledge upon various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of delivering system.
- To understand the concepts of formulation and evaluation of Novel drug delivery systems.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO10 | PO11 | PSO1 | PSO2 | |
| R25MPH102.1 | Gain basic knowledge on sustained release, controlled release, polymer science and personalized medicine. | 3 | 3 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25MPH102.2 | Summarize the various approaches for development of novel drug delivery systems. | 3 | 3 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25MPH102.3 | Remember the development of formulations of gastro retentive drug delivery systems and Muco-adhesion and Buccal drug delivery systems. | 3 | 3 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25MPH102.4 | Summarize the formulation and evaluation of Ocular drug delivery systems and Transdermal Drug Delivery Systems. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25MPH102.5 | Elaborate formulation of protein delivery and evaluate the formulated vaccine drug delivery systems. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

**CO's–CO1**

**Self Learning topics:** Role of 3D printing in personalized drug delivery, Real-world applications of Telepharmacy and Bioelectronic Medicine, Emerging customized dosage forms for pediatric and geriatric care.

**UNIT II:** **10 Hours**

**Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

**CO's–CO2**

**Self Learning topics:** Difference between diffusion-, dissolution-, and osmosis-based control, Osmotic pump design and case examples, Enzyme-activated drug delivery in cancer therapy, Real-time examples of pH-responsive drug release systems.

**UNIT III:** **10 Hours**

**Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit.

**Buccal Drug Delivery Systems:** Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

**Colon targeted Drug Delivery systems for local and Systemic Therapy.**

**CO's–CO3**

**Self Learning topics:** Floating vs. bioadhesive gastroretentive techniques, Approaches to modulate gastric emptying time, Buccal films vs. buccal tablets: Formulation differences, Mechanism of mucoadhesion – theories (electronic, adsorption, wetting), Evaluation parameters for buccal delivery (e.g., residence time, permeation).

**UNIT IV:** **8 Hours**

**Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.

**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

**CO's–CO4**

**Self Learning topics:** Ocular inserts and nanocarriers for eye drug delivery, Challenges in retinal drug delivery and overcoming techniques, Types of penetration enhancers used in TDDS, Microneedles and iontophoresis in transdermal delivery, Formulation and evaluation of transdermal patches – case examples.

**UNIT V:** **7 Hours**

**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

**Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

**Nucleic acid-based Delivery Systems (DNA, mRNA, siRNA-based Therapeutics).**

**CO's-CO5**

**Self Learning topics:** Routes of administration for peptide drugs (e.g., insulin), Role of nanocarriers in protein delivery (liposomes, dendrimers), Stability issues and degradation pathways of protein-based drugs, Mucosal vaccine delivery – nasal and oral vaccines, Single-shot vaccines: depot formulations and slow-release systems.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, published by Wiley Inter science Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.

**Reference Books**

1. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1. Remember**

1. Define sustained release and controlled release drug delivery systems. Mention key differences between them.
2. List the categories of patients who benefit from personalized medicine.
3. Enumerate the types of rate-controlled drug delivery systems.
4. State the barriers in ocular and transdermal drug delivery.
5. Define muco-adhesion and list the advantages of buccal drug delivery.

**L2. Understand**

1. Explain the mechanism of drug release from SR and CR formulations with suitable diagrams.
2. Describe the physicochemical and biological factors affecting SR and CR drug delivery systems.
3. Discuss the principles of feedback-regulated drug delivery systems with an example.
4. Explain the advantages and limitations of gastro-retentive drug delivery systems.

**L3. Apply**

1. Describe the structure of skin and its significance in transdermal drug delivery.
2. Apply the concept of personalized medicine in designing a dosage form for a diabetic patient.
3. Design a formulation strategy using osmotic principles for controlled release of a drug.
4. Illustrate how pH-activated drug delivery systems can be used to target drug release in the intestine.
5. Formulate a transdermal patch for a highly lipophilic drug, considering permeation enhancers.

**L4. Analyze**

1. Differentiate between pH-activated, enzyme-activated, and osmotically activated drug delivery systems with examples.
2. Analyze the factors affecting gastrointestinal transit time in gastro-retentive drug delivery systems.
3. Compare the mechanisms of drug absorption in buccal vs transdermal delivery systems.
4. Examine the formulation and evaluation differences between proteins and peptide delivery systems.

**L5. Evaluate**

1. Evaluate the advantages and disadvantages of using 3D printing technology for customized drug delivery.
2. Justify the selection of mucoadhesive polymers in buccal formulations based on mechanism of adhesion and retention time.
3. Assess the potential of single-shot vaccines in improving patient compliance and public health outcomes.
4. Critically evaluate the challenges in protein and peptide drug delivery and suggest possible solutions.

**L6: Create**

1. **Design a controlled release formulation using biodegradable polymers for a chronic** condition like hypertension.
2. Propose a novel vaccine delivery system using microneedles for painless transdermal administration.
3. Formulate a gastro-retentive dosage form for an anti-ulcer drug and outline its evaluation parameters.
4. Develop a tele pharmacy-based model for remote dispensing of personalized medications and explain its implementation challenges.

M. Pavani

**Chairperson**
**Board of Studies**

Chairperson
Board of Studies (AIPS)

**R25MPH103** **MODERN PHARMACEUTICS** **4 0 0 4**

**Course Objectives:**

- To impart knowledge on pre-formulation studies, dispersion systems, parenteral formulations, and nanocarrier-based stabilization strategies.
- To develop skills in applying statistical, QbD, DoE, and AI/ML-based approaches for formulation and process optimization.
- To understand validation principles, regulatory guidelines, and risk-based approaches in ensuring pharmaceutical product quality.
- To gain insights into cGMP compliance, production management, quality systems, and industrial practices for efficient pharmaceutical operations.
- To equip students with knowledge of tablet compression physics, dissolution and IVIVC, and application of statistical tools in formulation evaluation.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO10 | PO11 | PSO1 | PSO2 | |
| R25MPH103.1 | Understand preformulation studies, dispersion systems, parenteral formulations, and nanocarrier-based stabilization strategies. | 3 | 3 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25MPH103.2 | Apply statistical, QbD, DoE, and AI/ML-based approaches for formulation and process optimization. | 3 | 3 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25MPH103.3 | Analyze and implement validation principles, regulatory guidelines, and risk-based approaches in ensuring product quality. | 3 | 3 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25MPH103.4 | Apply cGMP compliance, production management, and quality systems for efficient pharmaceutical operations. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25MPH103.5 | Evaluate compression physics, dissolution, IVIVC, and apply statistical tools in formulation performance assessment. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Preformulation Concepts & Pharmaceutical Dispersions**

**Drug–excipient interactions:** Methods, kinetics of stability, stability testing.

**Theories of dispersion and pharmaceutical dispersions (Emulsions, Suspensions, SMEDDS):** Preparation and stability.

**Large and small-volume parenterals :** Physiological and formulation considerations, manufacturing and evaluation;

**Role of nanocarriers in dispersions (nanoemulsions, nanosuspensions) and their stability aspects.**

**CO's–CO1**

**Self Learning topics:** Role of forced degradation studies in predicting long-term stability, Comparison of physical vs. chemical stability testing in dispersions, Novel approaches for stabilization of SMEDDS and nanosuspensions.

**UNIT II:** **10 Hours**

**Optimization Techniques in Pharmaceutical Formulation**

Concept and parameters of optimization; Optimization techniques in formulation and processing; Statistical design, response surface method, contour designs, factorial designs, Applications in formulation development; Quality by Design (QbD) approach and Design of Experiments (DoE) in optimization; Use of artificial intelligence (AI) and machine learning (ML) tools in formulation optimization.

**CO's–CO2**

**Self Learning topics:** Application of AI & ML in predicting formulation performance, Integration of QbD with PAT (Process Analytical Technology), Recent research articles on response surface methodology in pharmaceutical optimization, Limitations of statistical designs in highly variable biological systems.

**UNIT III:** **10 Hours**

**Introduction to pharmaceutical validation:** scope & merits; Validation and calibration master plan.

ICH & WHO guidelines for calibration and validation of equipment, Validation of specific dosage forms, types of validation and analytical method validation. QbD based validation.

Government regulations, manufacturing process model, URS, DQ, IQ, OQ, PQ of facilities; Risk-based validation approaches and continuous process verification; Current FDA/EMA perspectives on process validation.

**CO's–CO3**

**Self Learning topics:** Differences between US FDA, EMA, and WHO approaches to process validation, Practical examples of validation protocols for sterile vs. non-sterile dosage forms, Case studies of failed pharmaceutical validation and lessons learned.

**UNIT IV:** **8 Hours**

Objectives and policies of current good manufacturing practices (cGMP); Layout of buildings, services, equipment, and their maintenance; Production management: organization, materials management, handling, transportation, inventory management and control.

Production and planning control, sales forecasting, budget and cost control; Industrial and personnel relationship.

Concept of Total Quality Management (TQM), Regulatory audits and data integrity in industrial practice.

**CO's–CO4**

**Self Learning topics:** Real-world examples of cGMP violations and regulatory warning letters, Lean manufacturing and Six Sigma practices in pharma, Case studies on production planning and forecasting in multinational pharmaceutical companies.

**UNIT V:** **7 Hours**

**Compression, Compaction & Pharmaceutical Evaluation Parameters**

Physics of tablet compression, consolidation, effect of friction, distribution of forces, compaction profiles;

Solubility and study of consolidation parameters; Diffusion parameters, dissolution parameters, pharmacokinetic parameters; Heckel plots, similarity factors (f2 and f1), Higuchi and Peppas plots.

Biorelevant dissolution testing and IVIVC (In vitro–In vivo correlation); Applications of advanced modelling (PBPK – Physiologically Based Pharmacokinetics) in formulation evaluation.

Linearity, concept of significance, standard deviation, chi-square test, student's t-test, ANOVA.

**CO's-CO5**

**Self Learning topics:** Case studies on tablet compression failures (capping, lamination, picking), Correlation between compaction pressure and dissolution profile, Application of Heckel analysis in understanding powder compressibility.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books**

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leo Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.

**Reference Books**

1. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
2. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
3. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.

5. Pharmaceutical Preformulations; By J.J. Wells.
6. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1. Remember**

1. Write the different methods for detecting drug–excipient interactions (DSC, FTIR, XRPD) with suitable examples.
2. Write the objectives and principles of cGMP with reference to facility layout, equipment maintenance, and personnel requirements.

**L2. Understand**

1. Explain the scope, merits, and types of pharmaceutical validation with examples of dosage forms.
2. Discuss the theories of dispersion and their application in pharmaceutical emulsions and suspensions.

**L3. Apply**

1. Illustrate the preparation and evaluation of small-volume parenterals, highlighting physiological and formulation considerations.
2. Apply factorial design and response surface methodology to optimize an oral solid dosage form.
3. Prepare a validation protocol for sterile injectable formulations incorporating URS, DQ, IQ, OQ, and PQ.
4. Demonstrate the application of Heckel plots and compaction profiles in understanding powder compressibility.

**L4. Analyze**

1. Compare OFAT (one-factor-at-a-time) and factorial design approaches in pharmaceutical formulation optimization.
2. Analyze regulatory differences in process validation between US FDA, EMA, and WHO.
3. Critically analyze case studies of FDA warning letters on cGMP violations and identify root causes.
4. Examine the correlation between compaction pressure, dissolution rate, and pharmacokinetic performance of tablets.

**L5. Evaluate**

1. Evaluate the role of nanocarriers (nanoemulsions, nanosuspensions, SMEDDS) in improving solubility and stability of drugs.
2. Critically evaluate the role of cleaning validation and data integrity (ALCOA+) in preventing cross-contamination.
3. Assess the impact of Lean Manufacturing, Six Sigma, and ERP systems on productivity and cost efficiency in pharma industries.
4. Evaluate the application of IVIVC and PBPK modeling in predicting in vivo performance and supporting regulatory submissions.

**L6: Create**

1. Design a preformulation study plan for a poorly soluble BCS Class II drug including forced degradation and stability testing.
2. Propose an AI/ML-based predictive framework for formulation optimization of nanocarrier-based systems.
3. Develop a risk-based validation master plan for a continuous manufacturing facility in line with ICH Q9.
4. Create a comprehensive evaluation protocol for a sustained-release tablet, integrating statistical methods (ANOVA, t-test, f1/f2 similarity factors).

M. Pavani

**Chairperson**
**Board of Studies**

Chairperson
Board of Studies (AIPS)
Avanthi Institute of Pharmaceutical Sciences (A)
Cherukupally (V), Bhogapuram Mandal
Vizianagaram Dt.,- 531162

**R25MPH104 REGULATORY AFFAIRS IN PRODUCT DEVELOPMENT 4 0 0 4**

**Course Objectives:**

- To gain knowledge about the concepts of innovator and generic drugs, drug development process and Regulatory guidance's and guidelines for filing and approval process.
- To explain the Common Technical Document (CTD) and electronic CTD (eCTD) formats used for the submission of drug dossiers globally.
- To familiarize students with the post-approval regulatory requirement related to drug substances and drug products. To understand regulatory obligations for maintaining product quality, safety, and compliance after approval.
- To provide a detailed understanding of clinical trial guidelines, approvals, and ethical considerations. To enable students to interpret and apply regulatory requirements for conducting safe and effective clinical trials.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | DOK |
|---|---|---|---|---|---|---|---|
| | | PO1 | PO3 | PO6 | PO9 | PSO1 | |
| R25CO104.1 | Recall documentation procedure in Pharmaceutical Industry for drug approval process. | 2 | 1 | 1 | 1 | 1 | L1, L2 |
| R25CO104.2 | Understand the concepts of Regulatory guidance and guidelines for filing and approval process of drugs. | 2 | 1 | 1 | 1 | 1 | L2, L3 |
| R25CO104.3 | Summarize the process of submission of global documents in CTD/eCTD formats. Understand post approval regulatory requirements for actives and drug products. | 2 | 1 | 1 | 1 | 1 | L 3, L4 |
| R25CO104.4 | Understand the global regulatory terms related to drug approval process. | 2 | 1 | 1 | 1 | 1 | L5, L6 |
| R25CO104.5 | Understand the guidelines and requirements for approvals of conducting clinical trials. | 2 | 1 | 1 | 1 | 1 | L5, L6 |

## SYLLABUS

**UNIT I:** **12 Hours**

**Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in- vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in – vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

**CO's–CO1**

**Self Learning topics::** Understand the preparation and significance of DMF, CFR, ANDA, and NDA approvals. Learn about drug performance evaluation, bioequivalence studies, outsourcing to CROs, and post-marketing surveillance.

**UNIT II:** **12 Hours**

**Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. Regulatory requirements of EU, MHRA, TGA and ROW countries. International regulatory trends in pharmaceutical industry

**CO's–CO2**

**Self learning Concepts:** Explore regulatory pathways for APIs, biologics, and generics including NDA and ANDA submissions. Study global regulatory requirements of EU, MHRA, TGA, and ROW countries for drug registration.

**UNIT III:** **12 Hours**

**CMC, post proval regulatory affairs.** Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M.

**CO's–CO3**

**Self learning Concepts:** Learn CMC documentation, ECTD format, and regulations for combination products and medical devices. Understand ICH guidelines, industry-FDA liaison, and post-approval regulatory processes.

**UNIT IV:** **12 Hours**

**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

**Hybrid NDA:** a difference from NDA, historical background, literature based hybrid NDAs and other sources of information for hybrid NDA, examples of types of products considered under hybrid NDA.

**CO's–CO4**

**Self learning Concepts:** Study global regulatory submissions like IND, NDA, ANDA, and preparation of dossiers, IMPD, and investigator brochures.

**UNIT V:** **12 Hours**

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics

committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

**CO's-CO5**

**Self learning Concepts:** Understand clinical trial protocols, ethical approvals, informed consent, HIPAA guidelines, and pharmacovigilance in clinical trials.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books**

1. Itkar, S. (2020). Drug Regulatory Affairs. Pune: Nirali Prakashan.
2. Kadam, M. (2021). Pharmaceutical Regulatory Affairs. Nashik: Career Publications.
3. Alkasab, A. (Ed.). (2012). Comprehensive Drug Regulatory Affairs. New York: Academic Press.
4. Berry, I. R., & Martin, R. P. (2004). The Pharmaceutical Regulatory Process. CRC Press.

**Reference Books**

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series,Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R Berryand Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5thedition, Drugs andthe Pharmaceutical Sciences,Vol.190.
4. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
5. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams.

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1: Remember**

1. Define bioequivalence (BE).
2. What is the Hatch–Waxman Act?
3. Write the full form of CFR.
4. What is the Orange Book?
5. Mention any two PK parameters used in BE studies.
6. Describe the contents of a Master Formula Record.
7. Explain the different types of DMFs and their purposes.
8. Write in detail about the Hatch–Waxman Act (1984).
9. Discuss the major parts of 21 CFR relevant to drug regulation.
10. Explain the difference between ANDA and NDA.

**L2: Understand**

1. Differentiate between in-vitro and in-vivo drug performance tests.
2. Why are distribution records important for drug recalls?
3. Explain the significance of Paragraph IV certification under Hatch–Waxman Act.
4. Why is bioequivalence testing required for generics?
5. Give reasons why many companies outsource BA/BE studies to CROs.
6. Compare the regulatory approval process of NDA and ANDA in the US.
7. Explain the registration pathway for foreign drugs in the US.
8. Discuss the regulatory roles of FDA, EMA (EU), MHRA, and TGA.
9. Summarize the steps required for the approval of biologics.
10. Explain the importance of ROW country regulations in global drug distribution.

**L3: Applying**

1. Apply the knowledge of NDA/ANDA pathways to outline how a foreign API manufacturer can register its product in the US.
2. Using an example, explain how different regulatory agencies (FDA, EMA, MHRA, TGA) may impact the global launch of a new biologic.
3. Design a step-wise regulatory strategy for a company planning to introduce a novel gene therapy in both the US and EU markets.
4. Analyze how the Hatch–Waxman Act framework supports the approval of generics and apply it to a hypothetical case of a company filing an ANDA.
5. Apply the concept of global regulatory harmonization to discuss how a drug approved in the US can be marketed in ROW countries with minimal duplication of work.
6. A company wants to change the manufacturing site for an approved drug. Apply the concept of post-approval regulatory affairs to explain the pathway they must follow.
7. A firm is developing a drug–device inhaler. Explain how it would be classified as a combination product and what regulatory steps are required.
8. A manufacturer needs to prepare a global submission for the same drug in the US, EU, and Japan. How would the CTD/eCTD format help in this process?
9. Apply the ICH Quality (Q) guidelines to explain how stability testing should be conducted before submission.
10. A biotech company is designing clinical trials for a new biologic. Which ICH E (Efficacy) guidelines apply, and how should they be used?

**L4: Analyzing**

1. Compare the regulatory pathways for medical devices vs. combination products in terms of data requirements and approval processes.
2. Analyze how post-approval regulatory changes (e.g., formulation, packaging, manufacturing site) can affect drug quality, safety, and efficacy.
3. Differentiate between the CTD and eCTD formats with respect to structure, submission process, and advantages.
4. Examine how ICH guidelines (Q, S, E, M) collectively ensure global harmonization of drug development.
5. Evaluate the role of FDA–industry liaison meetings (pre-IND, end-of-phase, pre-NDA) in reducing regulatory delays.

**L5: Evaluating**

1. Evaluate the impact of nonclinical study design on the outcome of an NDA submission: Critically evaluate how the design of nonclinical studies can impact the outcome of a New

Drug Application (NDA) submission, including the potential consequences of inadequate study design.

2. Assess the role of the IMPD in ensuring the quality and safety of investigational products: Evaluate the significance of the Investigation of Medicinal Products Dossier (IMPD) in ensuring the quality and safety of investigational products, including its role in regulatory decision-making.
3. .Compare and contrast the requirements for IND, NDA, and ANDA submissions: Critically compare and contrast the regulatory requirements for Investigational New Drug (IND), New Drug Application (NDA), and Abbreviated New Drug Application (ANDA) submissions, highlighting key similarities and differences.
4. Justify the importance of regular updates to the Investigator's Brochure (IB) during clinical development: Evaluate the importance of regularly updating the Investigator's Brochure (IB) during clinical development and justify the need for these updates in ensuring subject safety and informed consent.
5. Assess the impact of inadequate informed consent on clinical trial validity: Evaluate the potential consequences of inadequate informed consent on the validity and reliability of clinical trial results.
6. Evaluate the role of Institutional Review Boards (IRBs) in ensuring clinical trial ethics: Assess the significance of IRBs in ensuring that clinical trials are conducted in accordance with ethical principles and regulatory requirements.
7. Compare and contrast the requirements for HIPAA compliance in clinical trials: Evaluate the requirements for Health Insurance Portability and Accountability Act (HIPAA) compliance in clinical trials, including the implications for data management and participant confidentiality.
8. Justify the importance of pharmacovigilance in clinical trials: Assess the significance of pharmacovigilance in clinical trials, including its role in ensuring participant safety and identifying potential safety risks.

**L6: Creating**

1. Develop a comprehensive plan for compiling nonclinical data for a global IND submission: Create a detailed plan outlining the necessary steps, timelines, and resources required to compile nonclinical data for a global Investigational New Drug (IND) submission.
2. Design an IMPD dossier for a new investigational product: Create a comprehensive Investigation of Medicinal Products Dossier (IMPD) for a new investigational product, including all necessary sections and information.

3. Construct a strategy for preparing an NDA submission package: Develop a strategy for preparing a New Drug Application (NDA) submission package, including the organization of nonclinical and clinical data, and ensuring compliance with regulatory requirements.
4. Create an outline for an Investigator's Brochure (IB) for a phase II clinical trial: Design an outline for an Investigator's Brochure (IB) for a phase II clinical trial, including key sections such as product description, nonclinical and clinical data, and safety information.
5. Design a clinical trial protocol for a phase III study: Create a comprehensive clinical trial protocol for a phase III study, including the study design, objectives, inclusion and exclusion criteria, and safety monitoring plan.
6. Develop an informed consent form for a clinical trial: Create an informed consent form for a clinical trial, including all necessary information about the study, risks and benefits, and participant rights.

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**R25MPH105 Modern Pharmaceutical Analytical Techniques Practical 0 0 6 3**

**Course Objectives:**

1. To provide practical training in the calibration of analytical instruments.
2. To develop a strong foundation in Good Laboratory Practices (GLP) and regulatory guidelines.
3. To enable students to perform impurity profiling of pharmaceutical substances.
4. To train students in conducting assays of official compounds.
5. To enhance proficiency in the quantitative estimation of functional groups.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO6 | PO8 | PO9 | PO11 | PSO1 | PSO2 | |
| R25CO105.1 | Able to perform the calibration of glassware and instruments | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L1, L2 |
| R25CO105.2 | Estimate the amount of impurity for the given drugs | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2, L3 |
| R25CO105.3 | Examine the purity of official compounds by instrumental techniques and titrimetric procedures | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2, L3 |
| R25CO105.4 | Identify the quantitative determination of functional groups and drugs by using different reagents | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L3, L4 |

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## COURSE CONTENT

| S.No | Name of the experiment | Course Outcome |
|---|---|---|
| 1. | Calibration of glass wares | CO1 |
| 2. | Calibration of pH meter | CO1 |

| | | |
|---|---|---|
| 3. | Calibration of UV-Visible spectrophotometer | CO1 |
| 4. | Calibration of FTIR spectrophotometer | CO1 |
| 5. | Calibration of GC instrument | CO2 |
| 6. | Calibration of HPLC instrument | CO2 |
| 7. | Cleaning validation of any one equipment | CO2 |
| 8. | Impurity profiling of drugs | CO2 |
| 9. | Assay of official compounds by different titrations | CO3 |
| 10. | Assay of official compounds by instrumental techniques. | CO3 |
| 11. | Estimation of riboflavin/quinine sulphate by fluorimetry | CO3 |
| 12. | Estimation of sodium/potassium by flame photometry | CO3 |
| 13. | Quantitative determination of hydroxyl group. | CO4 |
| 14. | Quantitative determination of amino group | CO4 |
| 15. | Colorimetric determination of drugs by using different reagents | CO4 |

**Textbooks**


1. Analysis of drugs in Biological fluids- Joseph Chamberlain, 2 nd Edition.CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis- Doglas A Skoog, F.James Holler, Timothy A. Nieman, 5 th edition, Easternpress, Bangalore, 1998.
3. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2 nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods– Part B- JW Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2 nd Edition.


**Reference Books**


1. Indian Pharmacopoeia
2. United States Pharmacopoeia
3. ICH, USFDA & CDSCO Guidelines.


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## R25MPH106 ADVANCED DRUG DELIVERY SYSTEMS PRACTICAL 0 0 6 3

**Course Objectives:**

- To understand the design principles and evaluation methods of various advanced drug delivery systems (SR/CR, osmotic, gastro-retentive, mucoadhesive, transdermal).
- To gain hands-on experience in the formulation and evaluation of novel and modified release dosage forms.
- To perform pre-formulation, micromeritic, and dissolution studies to establish relationships between formulation variables and drug release kinetics.
- To apply mathematical models (Higuchi, Peppas, Hixson-Crowell, etc.) to interpret in-vitro drug release data.
- To develop skills in using formulation approaches to optimize bioavailability, stability, and patient compliance.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO6 | PO8 | PO9 | PO11 | PSO1 | PSO2 | |
| R25CO106.1 | Perform in-vitro dissolution studies for controlled/sustained release formulations and interpret release patterns. | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L1, L2 |
| R25CO106.2 | Able to Formulate and Evaluate Tablets | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L2, L3 |
| R25CO106.3 | Able to Formulate and Evaluate different Drug Delivery Systems. | 3 | 2 | 1 | 3 | - | 1 | 2 | 1 | L1, L2 |
| R25CO106.4 | Identify the Drug Release kinetics models. | 3 | 2 | 1 | 3 | - | - | 2 | 1 | L2, L3 |

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### COURSE CONTENT

| S.No | Name of the Experiment | Course Outcome |
|---|---|---|
| 1. | **Perform In-vitro dissolution profile of CR/ SR marketed formulation.** | CO1 |
| 2. | **Formulation and evaluation of sustained release matrix** | CO1 |

| | | |
|---|---|---|
| | tablets. | |
| 3. | **Formulation and evaluation osmotically controlled DDS.** | CO2 |
| 4. | Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS. | CO2 |
| 5. | Formulation and evaluation of Muco-adhesive tablets. | CO2 |
| 6. | Formulation and evaluation of transdermal patches. | CO3 |
| 7. | Carry out pre-formulation studies of tablets and study the effect of compressional force on tablets disintegration time. | CO3 |
| 8. | Study of Micromeritic properties of powders and granulation. | CO4 |
| 9. | Study the effect of binders and the effect of particle size on dissolution of a tablet. | CO4 |
| 10. | Heckel plot, Higuchi and Peppas plot and determine similarity Factors. | CO4 |

**Textbooks:**


1. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig – The Theory and Practice of Industrial Pharmacy, CBS Publishers.
2. Y. W. Chien – Novel Drug Delivery Systems, CRC Press.
3. Vyas, S.P. & Khar, R.K. – Controlled Drug Delivery: Concepts and Advances, Vallabh Prakashan.
4. Robinson, J.R., Lee, V.H.L. – Controlled Drug Delivery: Fundamentals and Applications, Marcel Dekker.


**Reference Books:**


1. Banker, G.S. & Rhodes, C.T. – Modern Pharmaceutics, CRC Press.
2. Brahmankar, D.M. & Jaiswal, S.B. – Biopharmaceutics and Pharmacokinetics: A Treatise, Vallabh Prakashan.
3. Jain, N.K. – Controlled and Novel Drug Delivery, CBS Publishers.
4. Allen, L.V., Popovich, N.G., Ansel, H.C. – Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Williams & Wilkins.


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**R25MPH108** **RESEARCH PAPER WRITING** **4 0 0 0**

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

- To understand the essentials of writing skills and their level of readability.
- To learn about what to write in each section.
- To ensure qualitative presentation with linguistic accuracy.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO8 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO108.1 | Understand the significance of writing skills and the level of readability. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L1, L2 |
| R25CO108.2 | Analyze and write title, abstract, different sections in research paper | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L1, L2, L3 |
| R25CO108.3 | Develop the skills needed while writing a research paper | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L 2, L3 |
| R25CO108.4 | Able to develop and apply key academic writing skills to construct clear, concise, and impactful Titles, Abstracts, and Introductions for research papers, demonstrating the ability to attract readers, summarize core findings, and establish research context effectively. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L3, L4 |
| R25CO108.5 | Able to use appropriate academic language and style to accurately formulate the methodology, clearly present Results, logically construct Arguments, and effectively draw valid conclusions in research writing. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breakingup Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity.

**CO's–CO1**

**Self Learning topics**: Examples of effective vs. poor research paper planning, Exercises on improving word order and sentence clarity, Identifying and breaking long, complex sentences into shorter ones.

**UNIT II:** **10 Hours**

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

**CO's–CO2**

**Self Learning topics:** Common pitfalls in defining a research problem,. Hedging phrases in academic writing (e.g., "suggests that", "may indicate"), Identifying plagiarism vs. acceptable paraphrasing.

**UNIT III:** **10 Hours**

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

**CO's–CO3**

**Self Learning topics:** Steps to conduct a literature review (sources, search engines, databases), Comparing qualitative vs. quantitative methodologies,Tools for data analysis (SPSS, Excel, R basics).

**UNIT IV:** **8 Hours**

Key skills needed for writing a Title, Abstract, and Introduction

**CO's–CO4**

**Self Learning topics:** Characteristics of an impactful research title, Common errors to avoid in writing an abstract, Strategies for writing a strong introduction.

**UNIT V:** **7 Hours**

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions.

**CO's-CO5**

**Self Learning topics:** Neutral and objective ways to report results, Building logical arguments with evidence, Transition words for coherence.

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**Text Books**

1. Goldbart R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I].
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press.
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman"sbook Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011.

**Web References**

1. https://cambridge-research.org/blogs/how-to-write-a-research-paper/?
2. https://www.readwritethink.org/classroom-resources/lesson-plans/scaffolding-methods-research-paper?
3. https://academicguides.waldenu.edu/writingcenter/assignments/literaturereview/matrix?

4. https://www.verywellmind.com/how-to-write-an-introduction-2794846?

**Assessment Pattern:**

1. Evaluated for a total of 100 marks.
2. A student can select 2 articles of his/her choice with a minimum of 01 review or research article per semester. Each article publication shall be evaluated by the concerned teacher for 50 marks, totaling to 100 marks.

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R25MPH201 MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) 4 0 0 4

**Course Objectives:**

- To understand the principles and biological basis of targeted drug delivery systems.
- To explore the types, preparation techniques, and evaluation methods for nanocarriers and vesicular drug delivery systems.
- To analyse strategies for site-specific drug delivery, especially to the brain and tumours.
- To understand the role of monoclonal antibodies, gene therapy, and nucleic acid-based therapeutics.
- To gain insight into pulmonary and nasal delivery platforms and their relevance in modern pharmaceutics.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO10 | PO11 | PSO1 | PSO2 | |
| R25MPH201.1 | Explain the fundamental concepts, need, and principles of targeted drug delivery | 3 | 3 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25MPH201.2 | Assess the potential of emerging nanocarriers and lipid-polymer systems. Compare traditional and next-generation nanocarriers in terms of efficiency, stability, and clinical translation. | 3 | 3 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25MPH201.3 | Illustrate the Preparation techniques and Evaluation parameters of microcapsules and microspheres, Monoclonal Antibodies etc. | 3 | 3 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25MPH201.4 | Evaluate the role of nanocarriers in enhancing pulmonary and nasal delivery efficiency. Discuss and interpret regulatory considerations and bioequivalence requirements of inhalation products. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25MPH201.5 | Assess the role of liposomal gene delivery and novel nucleic acid-based systems like siRNA, aptamers. Critically discuss regulatory, ethical, and clinical trial challenges associated with gene therapy. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumour targeting and Brain specific delivery.

**CO's–CO1**

**Self Learning topics:** Recent patents in tumour-targeted nanomedicine, Role of receptors (e.g., folate, transferrin) in targeting, Mechanisms of drug release in targeted therapy.

**UNIT II:** **10 Hours**

**Targeting Methods: Active and Passive Targeting.** Introduction, preparation and Characterization of Nano Particles: Polymeric & solid lipid nanoparticles & Liposomes: Types, preparation and evaluation: Stimuli Responsive and Smart Drug Delivery Systems.

**CO's–CO2**

**Self Learning topics:** Role of PEGylation in nanocarrier stealth properties, Case studies of polymeric nanoparticles (e.g., PLGA, chitosan).

**UNIT III:** **10 Hours**

**Micro Capsules / Micro Spheres:** Types, preparation and evaluation of Monoclonal Antibodies; Preparation, Characterization and applications of Niosomes, Aquasomes, Phytosomes, Electrosomes, Transferosomes, Exosomes and Ethosomes.

**CO's–CO3**

**Self Learning topics:** Industrial scale-up techniques for microspheres, Stability concerns in vesicular systems, Thermosensitive liposomes and applications in hyperthermia.

**UNIT IV:** **8 Hours**

**Pulmonary Drug Delivery Systems:** Aerosols, propellants, Containers Types, preparation and evaluation.

**Intra Nasal Route Delivery systems:** Types, preparation and evaluation, Nanocarriers in Naso-Pulmonary Delivery.

Regulatory Considerations and Bioequivalence of Inhalation Products.

**CO's–CO4**

**Self Learning topics:** Smart inhalers and digital drug delivery systems, Dry powder inhaler (DPI) formulation case studies, Role of surfactants in nasal drug absorption.

**UNIT V:** **7 Hours**

**Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Regulatory and Ethical Issues in Gene Therapy, Clinical Trial Challenges.

**Biodistribution and Pharmacokinetics:** knowledge of therapeutic antisense molecules and aptamers as drugs of future.

**Self Learning topics:**FDA-approved gene therapy products, Advances in mRNA delivery systems, Ethical controversies and public perception of gene editing. **CO's-CO5**

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**Text Books**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
4. Torchilin V, Amiji M – Handbook of Nanoparticles for Pharmaceutical Applications.

**Reference Books**

1. Kumar MNVR – Polymeric Nanoparticles: Production, Characterization and Applications.
2. Chowdary KP, Varma KS – Pharmaceutical Technology: Novel Drug Delivery Systems.
3. Khan AY, Vyas A, Gupta S – Drug Delivery: Principles and Applications.

**Web References**

1. https://www.journals.elsevier.com/advanced-drug-delivery-reviews
2. https://www.journals.elsevier.com/advanced-drug-delivery-reviews
3. https://www.frontiersin.org/journals/nanotechnology
4. https://www.mdpi.com/journal/pharmaceutics
5. https://www.sciencedirect.com/journal/european-journal-of-pharmaceutics-and-biopharmaceutics
6. https://www.mdpi.com/journal/genes
7. https://www.mdpi.com/journal/genes

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |

| | | |
|---|---|---|
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define targeted drug delivery systems. List different targeting strategies used in site-specific drug delivery.
2. Describe the classification of liposomes based on structure and composition.

**L2.** Understand

1. Explain the biological processes that influence the efficiency of drug targeting, with emphasis on tumour and brain-specific delivery.
2. Describe the role of polymers and surfactants in the formulation of nanoparticles and vesicular drug delivery systems.
3. Discuss the principles and process of gene therapy. Differentiate between ex vivo and in vivo approaches.

**L3.** Apply

1. Explain the step-by-step procedure for the preparation and evaluation of polymeric nanoparticles used in targeted therapy.
2. Describe the formulation of a nasal drug delivery system for systemic delivery of peptides. Include anatomical and physiological considerations.
3. Illustrate how monoclonal antibodies can be used in targeted drug delivery. Include real-world applications in cancer therapy.

**L4.** Analyze

1. Compare the mechanisms, advantages, and limitations of Aquasomes, Phytosomes, and Electrosomes in drug delivery.
2. Analyze the structural and functional differences between liposomes and niosomes and their impact on drug release.
3. Distinguish between various pulmonary delivery devices (MDI, DPI, nebulizers) in terms of formulation components and performance.

**L5.** Evaluate

1. Evaluate the impact of liposomal gene delivery systems on biodistribution and pharmacokinetics. Support your answer with examples.
2. Critically assess the challenges associated with the use of nucleic acid-based therapeutics in clinical settings.
3. Discuss the ethical and regulatory considerations of gene therapy and their influence on therapeutic development.

**L6: Create**

1. Design a multifunctional nanoparticle system for co-delivery of a chemotherapeutic drug and siRNA. Include targeting, release mechanism, and delivery route.
2. Propose a smart drug delivery system for chronic brain disease using a nanocarrier. Justify your design based on BBB permeability and targeting efficiency.
3. Construct a framework for evaluating the success of a newly developed pulmonary nanoparticle formulation intended for COPD treatment.
4.

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**R25MPH202 ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS 4 0 0 4**

**Course Objectives:**

- To apply biopharmaceutic principles in drug formulation and product design.
- To analyze pharmacokinetic models, parameters, and drug interactions.
- To evaluate drug product performance through bioavailability and bioequivalence studies.
- To explore applications of pharmacokinetics in modified-release, targeted, and biotechnological drug products.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO10 | PO11 | PSO1 | PSO2 | |
| R25MPH202.1 | Explain the mechanisms and factors influencing gastrointestinal drug absorption, dissolution, dosage form performance, transport models, and first-pass metabolism for optimizing oral drug delivery | 3 | 3 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25MPH202.2 | Assess biopharmaceutic factors, dissolution testing, and IVIVC to optimize drug product design, stability, and in vitro performance for improved bioavailability. | 3 | 3 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25MPH202.3 | Apply pharmacokinetic models, nonlinear kinetics, and drug interaction principles for clinical use in therapeutic drug monitoring and dose optimization. | 3 | 3 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25MPH202.4 | Evaluate bioavailability, bioequivalence, BCS, and permeability studies to ensure therapeutic equivalence, regulatory compliance, and clinical relevance of drug products | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25MPH202.5 | Integrate PK/PD principles with advanced drug delivery, biotechnology products, and TDM to optimize individualized therapy and clinical outcomes. | 3 | 3 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH partition theory of drug absorption.

**Formuulation and physicochemical factors:** Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate.

**Gastrointestinal absorption:** role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.

**Transport model:** Permeability Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

**CO's–CO1**

**Self Learning topics:** Anatomy & physiology of the GIT relevant to drug absorption, Mechanisms of drug transport and factors influencing absorption, Dissolution testing methods (USP apparatus I–IV) and IVIVC, Role of first-pass metabolism in limiting oral bioavailability.

**UNIT II:** **10 Hours**

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance.

**Drug permeability,** in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

**CO's–CO2**

**Self Learning topics:** Bioavailability & Absorption factors, In vitro testing & dissolution methods, IVIVC & dissolution profile comparison, Drug product design & stability.

**UNIT III:** **10 Hours**

**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra vascular.

**Multi compartment model:** two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of kmax and vmax.

**Drug interactions:** introduction, the effect of protein- binding interactions,the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

**Clinical applications of PK (therapeutic drug monitoring, dose adjustment)**

**CO's–CO3**

**Self Learning topics:** Pharmacokinetic models – one & two-compartment, linear vs. nonlinear, Key PK parameters – clearance, half-life, Vd, AUC, MRT, Nonlinear kinetics – Michaelis–Menten, causes of non-linearity, Drug interactions – protein binding, tissue binding, CYP450 & transporters.

**UNIT IV:** **8 Hours**

**Drug Product Performance, In Vivo:** Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, Bioequivalence of narrow therapeutic index (NTI) drugs, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

**CO's–CO4**

**Self Learning topics:** Bioavailability & Bioequivalence basics – definitions, relative vs. absolute, influencing factors, Study designs & evaluation – crossover, data analysis, regulatory aspects.

**UNIT V:** **7 Hours**

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. **Therapeutic drug monitoring (TDM) and individualized dosing strategies.** Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

**CO's-CO5**

**Self Learning topics:** PK/PD relationship & drug interactions – modeling, simulation, clinical impact, Modified-release & targeted delivery systems – design principles, applications, Pharmacokinetics of biotech drugs – proteins, peptides, mAbs, oligonucleotides, Advanced therapies – vaccines, gene therapy, immunotherapy, regulatory concerns.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books**

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts,

4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book .
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982.

**Reference Books**

1. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996 12.
2. Basic Pharmacokinetics, 1 st edition, Sunil S JambhekarandPhilip J Breen, pharmaceutical press, RPS Publishing,2009.
3. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

**Web References**

1. https://www.vallabhprakashan.com/cvsABP.aspx
2. https://dulomix.com/study-material/m-pharm-pharmaceutics-study-material/
3. https://jccpublication.com/index.php/product/advanced-biopharmaceutics-pharmacokinetics/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define drug absorption.
2. List the mechanisms of drug absorption from the gastrointestinal tract.
3. State the factors affecting drug absorption.
4. Define the pH partition theory of drug absorption.
5. Recall the Noyes–Whitney equation for drug dissolution.

6. List the factors affecting the dissolution rate of drugs.
7. Name the types of dosage forms that influence gastrointestinal absorption.
8. Identify examples of solutions used as dosage forms (e.g., elixir, syrup, solution).
9. Recall the advantages of suspensions as dosage forms for absorption.
10. State the role of capsules in drug absorption.
11. Recall the role of tablets in gastrointestinal drug absorption.
12. List different dissolution methods used in drug testing.
13. State formulation and processing factors affecting drug dissolution.
14. Define in vitro–in vivo correlation (IVIVC).
15. Recall the transport model based on permeability, solubility, and charge state.
16. List the properties of the gastrointestinal tract relevant to drug absorption.
17. Define pH microclimate in the gastrointestinal environment.
18. Recall the role of intracellular pH environment in drug absorption.
19. State the significance of tight-junction complexes in drug transport.
20. Define first-pass metabolism.

**L2.** Understand

1. Explain the mechanism of drug absorption across the gastrointestinal tract.
2. Discuss the major factors affecting drug absorption from the GIT.
3. Explain the concept of pH partition theory in relation to drug absorption.
4. Summarize the role of dissolution rate in drug absorption.
5. Describe the Noyes–Whitney equation and its application in drug dissolution.
6. Explain the factors affecting the dissolution rate of drugs.
7. Differentiate between solutions, suspensions, capsules, and tablets in terms of their gastrointestinal absorption.
8. Describe the significance of dissolution methods in predicting drug absorption.
9. Explain the correlation between in vivo data and in vitro dissolution data.
10. Summarize the transport model with respect to permeability, solubility, and charge state.
11. Explain the importance of GIT properties such as pH microclimate, intracellular pH, and tight-junction complex in drug absorption.
12. Discuss biopharmaceutic factors affecting drug bioavailability.
13. Explain the rate-limiting steps in drug absorption with examples.
14. Describe how the physicochemical nature of a drug affects product performance.
15. Differentiate between compendial and alternative dissolution testing methods.
16. Explain the problems of variable control in dissolution testing.
17. Summarize the importance of in vitro–in vivo correlation (IVIVC).
18. Discuss the significance of dissolution profile comparison in drug product evaluation.
19. Explain why drug product stability is an important factor in formulation design.
20. Describe the major considerations in the design of a drug product with respect to biopharmaceutic performance

**L3.** Apply

1. Apply your knowledge of biopharmaceutic factors to explain how solubility and permeability influence the oral bioavailability of a new drug.
2. Apply the concept of rate-limiting steps to predict absorption patterns for a highly lipophilic but poorly soluble drug.

3. Given the physicochemical properties of a drug (pKa, solubility, partition coefficient), apply your knowledge to predict its in vivo performance.
4. Apply compendial and alternative dissolution methods to evaluate the performance of two different tablet formulations.
5. Given dissolution profile data, apply comparison techniques to assess equivalence between two drug products.
6. Apply the concept of IVIVC (In vitro–In vivo correlation) to predict clinical performance of a drug based on dissolution data.
7. Apply stability considerations to recommend formulation strategies for a moisture-sensitive drug.

**L4. Analyze**

1. Analyze the differences between IV bolus, IV infusion, and extravascular administration using the one-compartment model.
2. Compare one-compartment and two-compartment pharmacokinetic models in terms of drug distribution and elimination.
3. Examine the causes of non-linearity in pharmacokinetics and analyze how they impact dose–response relationships.
4. Analyze the Michaelis–Menten equation to interpret nonlinear drug kinetics and explain the significance of Vmax and Km in dosage adjustment.
5. Compare protein-binding and tissue-binding drug interactions and analyze their impact on pharmacokinetic parameters.
6. Analyze the role of cytochrome P450–based interactions in altering drug metabolism and therapeutic outcomes.

**L5. Evaluate**

1. Critically evaluate the purpose and limitations of bioavailability studies in ensuring therapeutic drug performance.
2. Assess the relative importance of absolute vs. relative bioavailability in clinical decision-making.
3. Evaluate the strengths and weaknesses of different methods used for assessing bioavailability.
4. Critically appraise the design and evaluation of bioequivalence studies, focusing on crossover study designs.
5. Judge the regulatory importance of bioequivalence data submission in the drug review process.
6. Assess the clinical significance of the Biopharmaceutics Classification System (BCS) in predicting bioavailability and guiding drug approval.
7. Evaluate the appropriateness of different permeability assessment methods (in vitro, in situ, in vivo) in drug development.
8. Critically analyze the challenges in establishing bioequivalence for generic biologics (biosimilars).

**L6: Create**

1. Design a modified-release drug product strategy for a drug with a short half-life and high first-pass metabolism, justifying formulation and pharmacokinetic considerations.

2. Evaluate the effectiveness of targeted drug delivery systems in minimizing systemic toxicity compared to conventional dosage forms.
3. Propose a pharmacokinetic–pharmacodynamic model to optimize dosing regimens for monoclonal antibodies, considering their unique absorption and clearance patterns.
4. Critically appraise the challenges of applying conventional PK principles to proteins and peptides, and recommend strategies to improve their oral bioavailability.
5. Design an integrated delivery approach for oligonucleotides or gene therapies, accounting for stability, distribution, and intracellular delivery barriers.

M. pavani

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Cherukupally (V), Bhogapuram Mandal
Vizianagaram Dt.,- 531162

**R25MPH203 COMPUTER-AIDED DRUG DELIVERY SYSTEMS 4 0 0 4**

**Course Objectives**

- To introduce the use of modern computing tools in drug discovery, design, and development.
- To understand simulation, modeling, and artificial intelligence in optimizing formulations.
- To equip students with practical insights into software applications and digital innovations in drug delivery.

**Course Outcomes**

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO4 | PSO1 | PSO2 | |
| R25 CO203.1 | Explain the fundamentals of computational modeling in pharmaceutical sciences. | 3 | 2 | 2 | 1 | 2 | 1 | L1 ,L2 |
| R25 CO203.2 | Simulate and predict drug disposition parameters using software tools. | 2 | 2 | 3 | 2 | 3 | 2 | L2, L3 |
| R25 CO203.3 | Apply design of experiments and optimization in formulation development. | 2 | 3 | 3 | 2 | 3 | 2 | L2 ,L3 |
| R25 CO203.4 | Integrate in-silico tools to support biopharmaceutical and pharmacokinetic studies. | 2 | 2 | 3 | 2 | 3 | 2 | L3 ,L4 |
| R25 CO203.5 | Recognize the role of AI, robotics, and digital systems in modern drug delivery. | 1 | 2 | 3 | 2 | 3 | 3 | L4, L5, L6 |

## SYLLABUS

**Unit I:** **10 Hours**

**Introduction to Computer-Aided Drug Delivery:** Evolution and need for computational tools in pharmaceutical research. Introduction to computer-aided drug design (CADD) and drug delivery. Overview of modeling approaches: mechanistic vs empirical. Quality-by-Design (QbD) and ICH Q8–Q10 guidelines in formulation optimization. Regulatory expectations in computational submissions.

**CO's-CO1**

**Self learning Concepts:** Trace the historical development of computational tools in drug discovery

and delivery. Investigate key milestones in pharmaceutical computational technology.

**Unit II:** **8 Hours**

**Computational Pharmacokinetics and ADME Prediction:** In-silico prediction of ADME properties. Modeling tools for absorption, metabolism, transporters (e.g., P-gp, BCRP). Basics of pharmacokinetic software (e.g., GastroPlus™, Simcyp™ – case study-based). Use of simplified case examples for software simulations.

**CO's-CO2**

**Self learning Concepts:** Explore computational methods and free online tools (Swiss ADME, pkCSM) for predicting drug absorption, metabolism, and excretion properties. Study the role of transporters like P-gp and BCRP in drug disposition and how modeling predicts their effect on bioavailability.

**Unit III:** **8 Hours**

**Formulation Design and Optimization using Software Tools:** Introduction to software like Design Expert™, JMP™, Minitab™, Factorial designs, response surface methodology, Box-Behnken design. Case studies on optimization of nanoparticles, emulsions, tablets. Inclusion of recent trends: 3D printing-assisted formulation design.

**CO's-CO3**

**Self learning Concepts:** Study the features and applications of Design Expert™, JMP™, and Minitab™ for implementing Design of Experiments in pharmaceutical formulations. DoE Techniques: Learn factorial designs, response surface methodology, and Box-Behnken design for optimizing formulation variables. Recent Trends in Design: Explore 3D printing-assisted formulation design and its integration with modern optimization techniques.

**Unit IV:** **10 Hours**

**In-Silico Biopharmaceutics and Virtual Trials:** Biopharmaceutics Classification System (BCS) and bioavailability modeling, Virtual bioequivalence trials and biowaivers, IVIVC concepts with simulation examples, Integration with eCTD submissions.

**CO's-CO4**

**Self learning Concepts:** BCS and Bioavailability Modeling: Learn the principles of the Biopharmaceutics Classification System (BCS) and how in-silico tools model oral drug absorption and bioavailability. Virtual Bioequivalence & Biowaivers: Explore the concept of virtual bioequivalence trials, regulatory requirements, and conditions for biowaivers. IVIVC with Simulations: Understand in-vitro/in-vivo correlation (IVIVC) models and perform simulation-based examples for drug dissolution and absorption prediction. Integration with eCTD: Study how in-silico biopharmaceutics data is compiled and integrated into electronic Common Technical Document (eCTD) submissions for regulatory approval.

**Unit V:** **10 Hours**

**Artificial Intelligence, Machine Learning & Automation in Drug Delivery:** Basics of AI/ML in drug design and DDS. Case studies on Chat GPT, DeepMind, Alpha Fold in pharma. Introduction to pharmaceutical robotics and automation tools. Computational Fluid Dynamics (CFD) and applications in drug delivery systems. Real-world examples from pharmaceutical industries and startups.

**CO's-CO5**

**Self learning concepts:** AI/ML in Drug Design: Understand the basic principles of artificial intelligence and machine learning applications in drug discovery and delivery systems. Pharma Case Studies: Explore how tools like ChatGPT, DeepMind, and AlphaFold are transforming pharmaceutical research and drug development. Pharmaceutical Robotics & Automation: Learn about robotic systems and automated tools used in drug manufacturing and formulation processes. Computational Fluid Dynamics (CFD): Study CFD principles and their applications in modeling drug delivery systems such as inhalers and injectables. Industry Applications: Review real-world examples where AI, ML, and automation are implemented in pharmaceutical industries and startups.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Recommended Books & Resources**

1. Sean Ekins – Computer Applications in Pharmaceutical R&D.
2. Jelena Djuris – Computer-Aided Applications in Pharmaceutical Technology.
3. Novel Drug Delivery Systems – Y. W. Chien.
4. Modern Pharmaceutics – Banker & Rhodes.
5. Artificial Intelligence in Drug Discovery – Nathan Brown (new addition).

**Web References:**

1. https://www.simulations-plus.com/software/gastroplus/
2. https://www.certara.com/software/simcyp-simulator/
3. https://www.open-systems-pharmacology.org/
4. https://www.statease.com/software/design-expert/
5. https://www.minitab.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |

| | | |
|---|---|---|
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remember**

1. Define computer-aided drug design (CADD).
2. What is Quality-by-Design (QbD)?
3. Mention two pharmacokinetic simulation tools.
4. Name any two statistical software used in formulation optimization.
5. List the BCS classification system classes.
6. Describe the basic modeling approaches used in pharmaceutical research.

**L2 – Understand**

1. Explain the role of transmembrane transporters like P-gp in drug absorption.
2. Differentiate between mechanistic and empirical modeling.
3. Describe how software like GastroPlus™ aids in drug development.
4. Explain the concept of IVIVC.
5. Discuss the applications of in-silico ADME prediction in preclinical drug development.

**L3 – Apply**

1. Apply Design Expert™ to optimize a tablet formulation.
2. Demonstrate the use of Box-Behnken design in drug formulation.
3. Use a case study to show application of CFD in drug delivery.
4. Using a software simulation (real or hypothetical), illustrate how virtual trials are conducted for bioequivalence testing.

**L4 – Analyze**

1. Analyze the difference between GastroPlus™ and Simcyp™.
2. Evaluate the significance of QbD in formulation development.
3. Classify various AI tools used in drug design.
4. Analyze the impact of 3D printing technology on the development of personalized drug delivery systems.

**L5 – Evaluate**

1. Justify the use of AI/ML in pharmaceutical R&D.
2. Assess the limitations of in-silico models in real-time bioavailability prediction.
3. Critically evaluate the use of computational tools in regulatory submission.

4. Compare and contrast conventional optimization methods with AI-driven formulation design approaches.

**L6 – Create**

1. Design a hypothetical workflow integrating QbD and simulation for a new DDS.
2. Propose a software-based framework for predicting drug–food interactions.
3. Develop a basic protocol for using CFD in nasal drug delivery system design.
4. Create a case-based simulation plan using Gastro Plus™ to demonstrate the pharmacokinetics of a new oral formulation under fed and fasted conditions

M. Pavani

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Avanthi Institute of Pharmaceutical Sciences (A)
Cherukupally (V), Bhogapuram Mandal
Vizianagaram Dt.,- 531162

**R25MPH204 PRODUCT FORMULATION TECHNOLOGY 4 0 0 4**

**Course Objectives:**

- To understand Preformulation Studies and to enable students to gain knowledge about molecular optimization, crystal morphology, drug-excipient compatibility, and determination methods essential for formulation development.
- To Learn about Formulation Additives and to provide in-depth understanding of various formulation additives, their roles in product development, and the design of experiments for process optimization.
- To familiarize students with solubility enhancement techniques, dissolution mechanisms, and testing models to improve bioavailability and product performance.
- To train students in stability testing methods, degradation kinetics, ICH guidelines, and shelf-life determination of pharmaceutical products.
- To formulate and Evaluate Cosmetic Product and to impart knowledge on the formulation, evaluation, and packaging of various cosmetic products, including creams, gels, shampoos, and baby care products.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO4 | PO8 | PO9 | PO10 | PSO1 | PSO2 | |
| R25CO204.1 | To analyze API properties, crystal morphology, and drug-excipient compatibility to optimizeformulation development. | 2 | 1 | 1 | 1 | 1 | 2 | 1 | L 1, L2 |
| R25CO204.2 | Students will understand the role of excipients, factors influencing their incorporation, and design experiments for effective product and process development. | 2 | 1 | 1 | 1 | 1 | 2 | 1 | L1,L2 |
| R25CO204.3 | Students will learn solubility enhancement techniques, dissolution testing models, and correlate in-vitro and in-vivo data for improved drug bioavailability. | 2 | 1 | 1 | 1 | 1 | 2 | 1 | L 2, L3 |
| R25CO204.4 | Students will evaluate degradation kinetics, conduct stability testing as per ICH guidelines, and predict product shelf life effectively. | 2 | 1 | 1 | 1 | 1 | 2 | 1 | L3, L4 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| R25CO204.5 | To gain skills to formulate, evaluate, and package various cosmetic products, ensuring quality, safety, and regulatory compliance. | 2 | 1 | 1 | 1 | 1 | 2 | | L5,L6 |

## SYLLABUS

### Unit I

**12 Hours**

**Preformulation Studies:** Fundamentals of preformulation studies and their significance in drug development. Molecular optimization of APIs: physicochemical properties and their role in formulation. Crystal morphology and polymorphism – implications in bioavailability. Powder flow properties and evaluation techniques. Structure modification for enhanced solubility. Drug-excipient compatibility studies: methods (DSC, FTIR, etc.). Analytical techniques for preformulation characterization. Role of complexation, rheology, micromeritics and dissolution in design of dosage form.

**Solubility & Dissolution**: Solubility and its importance in drug absorption and bioavailability. Experimental methods for solubility determination and enhancement. Advanced solubility improvement strategies: Salt formation Solid dispersion, Micellar solubilization, Nanocrystals, Lipid-based formulations,

Dissolution: principles, theories, and in vitro testing, Dissolution apparatus: design, calibration, and method development, IVIVC (In vitro–In vivo correlation): levels and applications, Role of biorelevant dissolution media in predicting in vivo performance. Biowaviers in drug development.

**CO'S-CO1**

**Self-Learning Concepts:** Latest approaches in predictive preformulation tools using computational methods. Role of QbD (Quality by Design) in preformulation studies. Recent research on co-crystals and amorphous solid dispersions for solubility enhancement. Regulatory considerations for preformulation studies in ANDA and NDA submissions.

### Unit II

**12 Hours**

**Formulation Additives:** Classification of pharmaceutical excipients and their functional roles. Factors influencing excipient selection and compatibility. Recent developments in novel excipients and their regulatory acceptance. Role of excipients in controlled release, taste masking, and stability. Qbd, Design of experiments (DOE) and factorial design in formulation optimization. Excipients for biologics and nanotechnology-based formulations.

**CO'S-CO2**

**Self-Learning Concepts:** Current trends in green excipients and sustainable formulation practices. Role of co-processed excipients for improving tableting properties. IPEC guidelines for excipient quality and safety. Case studies on excipient failures and their impact on product recalls.

**CO'S-CO2**

### Unit III

**12 Hours**

**Quality by design (QbD):** Fundamentals of pharmaceutical quality by design, identification of critical quality attributes, critical material attributes, critical process parameters and quality risk management.

**Methods of optimization** – OVAT and Design of experiments (DOE). Experimental designs, screening designs, factorial designs, composite designs, mixture designs, response surface methodology. Applications of systematic optimization techniques.

Process analytical technology (PAT) and other control strategies for QbD.

**CO'S-CO3**

**Self-Learning Concepts:** ICH guidelines: Q8(R2), Q9, Q10, Make a diagram showing QbD workflow from QTPP to control strategy.

**Unit IV:** **12 Hours**

**Product stability**: Stability concepts: degradation pathways, kinetics, and shelf-life prediction. Factors affecting stability: temperature, humidity, light, and pH. Stability studies: real-time and accelerated protocols as per ICH guidelines. Current ICH guidelines (Q1A–Q1F). Stability indicating methods and analytical validation. Interpretation of kinetic data (Arrhenius plot, Q10 method). Stability testing for biologics and novel drug delivery systems. Solid-state stability, packaging considerations, and labelling.

**CO'S-CO4**

**Self-Learning Concepts:** WHO recommendations for stability testing. Impact of climatic zones on stability requirements. Stability testing of nanomedicines and biologics. Case studies on stability-related product recalls.

**Unit V** **12 Hours**

**Cosmetics**: Regulatory framework for cosmetic products (FDA, BIS, EU). Formulation, evaluation, and packaging of cosmetics:Dentifrices (toothpaste, gels), Nail care (nail polish, nail removers), Lip care (lipstick, lip balms), Eye cosmetics (mascara, eyeliner), Baby care products, Skin care (moisturizers, vanishing cream, cold cream), Hair care (shampoos, conditioners), Stability testing of cosmetic formulations.

**CO'S-CO5**

**Self-Learning Concepts:** Role of natural ingredients and herbal extracts in cosmetics. Concept of **cosmeceuticals** and their regulatory challenges. Nanotechnology in cosmetics (nanoemulsions, liposomes). Ethical considerations: animal testing bans and alternatives.

**Text Books:**


1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nded., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore,1999.13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
6. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.
7. Harry's Cosmeticology. 8th edition.
8. Poucher's perfume cosmetics and Soaps,10th edition.
9. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
10. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd Edition.

**Reference Books:**

1. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
2. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
3. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
4. Encyclopedia of Pharm. Technology, Vol I – III.

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1: Remember**

1. List the physicochemical properties considered in preformulation studies.
2. What is crystal polymorphism
3. Identify two analytical techniques used for preformulation characterization.
4. Recall the role of drug-excipient compatibility studies.
5. Name any two regulatory submissions related to preformulation studies
6. List the functional roles of pharmaceutical excipients.
7. Recall the factors influencing excipient selection.
8. Identify the role of excipients in taste masking.
9. List different types of excipients used in nanotechnology-based formulations.
10. Mention any two IPEC guidelines for excipient quality and safety

**L2: Understand**

1. Explain the significance of preformulation studies in drug development.
2. Differentiate between DSC and FTIR methods used in compatibility studies.
3. Describe the role of QbD in improving preformulation process.
4. Describe the factors influencing the compatibility of excipients in formulations.

5. Summarize the role of excipients in controlled drug release and stability.
6. Explain the importance of DOE and factorial design in formulation optimization.
7. Describe the regulatory acceptance process of novel excipients.
8. Classify various solubility enhancement techniques and give one example for each.
9. Interpret the role of lipid-based formulations in enhancing drug solubility.
10. Compare micellar solubilization and solid dispersion techniques in terms of mechanism.

**L3: Apply**

1. Demonstrate how you would design an experiment to determine the solubility of a new API.
2. Apply the concept of IVIVC to predict in vivo performance from in vitro dissolution data for an immediate-release tablet.
3. Calculate the solubility improvement when converting a drug into its salt form, given experimental data.
4. Select an appropriate dissolution apparatus for testing a controlled-release formulation and justify your choice.
5. Apply the principle of solid dispersion to formulate a poorly water-soluble drug for oral delivery.
6. Design a method using micellar solubilization for a drug with low aqueous solubility.
7. Choose suitable biorelevant media for dissolution testing of a lipid-based drug delivery system and explain why.
8. Develop a step-by-step protocol for calibrating a USP Type II (paddle) dissolution apparatus.
9. Propose a solubility enhancement strategy for a BCS Class II drug and explain its mechanism.
10. Interpret dissolution data from an in vitro study and predict possible in vivo absorption trends.
11. Apply the concept of degradation kinetics to calculate the shelf life of a drug product stored at 40°C.
12. How would you design an accelerated stability study for a new pharmaceutical product according to ICH guidelines?
13. Demonstrate how zero-order and first-order kinetics impact the stability of pharmaceutical formulations.

**L4: Analyze**

1. Analyze the difference between real-time stability testing and accelerated stability testing.
2. Compare the significance of Arrhenius equation and Q10 method in predicting product shelf life.
3. Examine how environmental factors (temperature, humidity, light) influence the degradation of pharmaceutical products.Differentiate between the regulatory pathways of NDA and ANDA.

**L5 – Evaluate**

1. Evaluate the effectiveness of different packaging materials for preserving cosmetic product stability.
2. Justify the selection of preservatives in a cosmetic formulation to ensure microbial safety.
3. Critically assess the role of Good Manufacturing Practices (GMP) in ensuring cosmetic product quality.

**L6 – Create**

1. Design a novel cosmetic formulation for an anti-aging cream, considering regulatory and safety requirements.
2. Develop a quality evaluation protocol for a newly developed herbal cosmetic product.
3. Create a packaging strategy for a cosmetic lotion to maintain product integrity during transportation and storage.

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**R25MPH205 MOLECULAR PHARMACEUTICS PRACTICAL 0 0 6 3**

**Course Objectives:**

- To develop knowledge and practical skills in designing, preparing, and characterizing novel drug delivery systems such as microcapsules, alginate beads, microspheres, liposomes, niosomes, and spherules.
- To understand and apply techniques for improving drug performance, including enhancement of solubility, dissolution, bioavailability, and bioequivalence, as well as comparison of marketed formulations.
- To evaluate pharmacokinetic and pharmacodynamic aspects of drug formulations, including protein binding studies and determination of pharmacokinetic parameters for optimizing therapeutic efficacy.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | PO1 | PO2 | PO3 | PO4 | PO11 | PSO1 | PSO2 | DOK |
|---|---|---|---|---|---|---|---|---|---|
| R25MPH205.1 | Develop the ability to design, prepare, and optimize various novel drug delivery systems (e.g., microcapsules, alginate beads, microspheres). | 3 | 3 | 3 | 2 | 3 | 3 | 2 | L1,L2 |
| R25MPH205.2 | Demonstrate proficiency in advanced drug delivery techniques by preparing and evaluating liposomes, niosomes, and spherules | 3 | 3 | 3 | 3 | 3 | 3 | 2 | L2,L3 |
| R25MPH205.3 | Apply formulation strategies such as solid dispersion and comparative dissolution testing to enhance solubility, dissolution, and therapeutic performance of drugs | 3 | 3 | 3 | 2 | 3 | 3 | 2 | L2,L6 |
| R25MPH205.4 | Evaluate pharmacokinetic and pharmacodynamic properties by determining bioavailability, bioequivalence, and protein-binding characteristics of drugs. | 3 | 2 | 2 | 2 | 3 | 3 | 2 | L4,L5 |

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## COURSE CONTENT

The course helps to provide students with **practical knowledge and hands-on training** in modern drug delivery techniques, dissolution enhancement methods, bioavailability studies, and pharmacokinetic data analysis, bridging the gap between formulation development and therapeutic efficacy.

| Experiment No | Name of the Experiment | CO |
|---|---|---|
| 1. | To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation | CO1 |
| 2. | Preparation and evaluation of Alginate beads | CO2 |
| 3. | Formulation and evaluation of gelatin /albumin microspheres | CO2 |
| 4. | Formulation and evaluation of liposomes/niosomes | CO2 |
| 5. | Formulation and evaluation of spherules | CO2 |
| 6. | Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique. | CO2 |
| 7. | Comparison of dissolution of two different marketed products/brands. | CO3 |
| 8. | Protein binding studies of a highly protein bound drug & poorly protein bound drug | CO3 |
| 9. | Determination of bioavailability and bioequivalence. | CO4 |
| 10. | Determination of Pharmacokinetic parameters. | CO4 |

**Text Books:**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

**Reference Books:**

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.

3. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi Harry's Cosmeticology. 8th edition.

4. Poucher's perfume cosmetics and Soaps,10th edition

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**R25MPH206 PRODUCT FORMULATION TECHNOLOGY PRACTICAL 0 0 6 3**

**Course Objectives:**

- To train students in computational and experimental techniques for drug delivery and pharmaceutical product development.
- To enable hands-on skills in formulation, evaluation, and comparison of cosmetic and therapeutic dosage forms.
- To develop proficiency in quality by design (QbD) approaches for pharmaceutical products.
- To strengthen students' ability to analyze clinical and preclinical data through simulations and modeling tools.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | PO1 | PO2 | PO8 | PO9 | PO10 | PSO1 | PSO2 | DOK |
|---|---|---|---|---|---|---|---|---|---|
| R25CO107.1 | Perform computer simulations in Pharmacokinetics& pharmacodynamics using software tools. | 3 | 2 | 3 | 3 | 2 | 2 | 1 | L2,L3 |
| R25CO107.2 | Formulate and evaluate cosmetic products (toothpaste, anti- dandruff shampoo) and compare with marketed samples. | 2 | - | 3 | 3 | 2 | 2 | 1 | L2,L3 |
| R25CO107.3 | Develop nutraceuticals formulations (multi-vitamin syrups, herbal creams) and evaluate their quality. | 3 | 2 | 3 | 3 | 2 | 2 | 2 | L3,L4 |
| R25CO107.4 | Prepare a clinical data collection manual and interpret preclinical/clinical findings for pharmaceutical R&D. | 2 | - | 3 | 3 | 2 | 2 | 1 | L2,L5 |

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## COURSE CONTENT

| Experiment No | Name of the Experiment | CO |
|---|---|---|
| 1. | Computer simulations in pharmacokinetics and pharmacodynamics. | CO1 |
| 2. | Preparation and evaluation of toothpaste formulation. | CO2 |
| 3. | Preparation and evaluation of anti-dandruff shampoo. | CO2 |
| 4. | Evaluation of prepared shampoo formulations and comparison with marketed shampoos. | CO2 |
| 5. | Formulation and evaluation of multi-purpose herbal cream. | CO2 |
| 6. | Formulation and evaluation of multi-vitamin syrup. | CO2 |
| 7. | Quality by Design (QbD) in pharmaceutical product development. | CO3 |
| 8. | Computational modeling of drug deposition & release kinetics. | CO3 |
| 9. | Development of a clinical data collection manual for pharmaceutical R&D. | CO4 |
| 10. | In-silico ADME/Tox modeling using open-source software for predicting drug-likeness. | CO4 |

**Textbooks:**

- Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig – The Theory and Practice of Industrial Pharmacy, CBS Publishers.
- Y. Anjaneyulu, C. Chandrasekhar – Laboratory Manual of Industrial Pharmacy.
- Raymond C. Rowe, Paul J. Sheskey, Marian E. Quinn – Handbook of Pharmaceutical Excipients.

**Reference Books:**

- Patrick J. Sinko – Martin's Physical Pharmacy and Pharmaceutical Sciences.
- Michael E. Aulton – Aulton's Pharmaceutics: The Design and Manufacture of Medicines.
- Larry L. Augsburger – Pharmaceutical Dosage Forms: Tablets.

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**R25MPH208** **ENTREPRENEURSHIP MANAGEMENT** **4 0 0 0**

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

- To impart knowledge and skills necessary to train students in entrepreneurship management.
- To enable students to understand the conceptual framework and role of enterprises in economic development.
- To develop entrepreneurial competencies such as motivation, creativity, and decision-making.
- To provide insights into launching, organizing, and managing enterprises.
- To equip students with strategies for growth, networking, and project proposal preparation.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO8 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO208.1 | Explain the role of enterprises in the national and global economy and identify different types of enterprises with their merits and demerits. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L1, L2 |
| R25CO208.2 | Analyze entrepreneurial motivation and competencies, and develop self-awareness, creativity, and interpersonal skills needed for entrepreneurship. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L1, L2, L3 |
| R25CO208.3 | Apply methods for launching and organizing enterprises, including market assessment, feasibility studies, resource mobilization, and cost/quality management. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L 2, L3 |
| R25CO208.4 | Evaluate growth strategies, networking opportunities, diversification techniques, and performance control measures for enterprises. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L3, L4 |
| R25CO208.5 | Prepare a project proposal and feasibility report for starting a new enterprise, including planning, resource mobilization, and implementation strategies. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Conceptual Frame Work:** Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government

policies and schemes for enterprise development. Institutional support in enterprise development and management.

**CO's–CO1**

**Self Learning topics:** Research government policies and schemes for enterprise development in India (e.g., Startup India, MSME schemes), Compare the role of enterprises in national vs. global economy. Study case studies of successful enterprises and analyze factors contributing to success.

**UNIT II:** **10 Hours**

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

**CO's–CO2**

**Self Learning topics:** Research traits of successful entrepreneurs and how they develop skills like creativity and assertiveness, Explore exercises for improving interpersonal skills and leadership qualities.

**UNIT III:** **10 Hours**

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

**CO's–CO3**

**Self Learning topics:** Conduct a mini-market research exercise for a hypothetical business idea, Practice preparing a SWOT analysis for an existing company or startup.

**UNIT IV:** **8 Hours**

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measure, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, coordination and feasibility study.

**CO's–CO4**

**Self Learning topics:** Explore examples of diversification and expansion in real enterprises, Research joint ventures and strategic alliances in Indian and global business.

**UNIT V:** **7 Hours**

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

**CO's-CO5**

**Self Learning topics:** Prepare a simple project proposal for a hypothetical new enterprise.

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**Text Books**


1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson.


**Web References**

1. https://www.babson.edu/professional/entrepreneurship-education/what-is-babson-academy/resources-and-tips/
2. https://www.coursera.org/browse/business/entrepreneurship
3. https://ocw.mit.edu/collections/entrepreneurship/
4. https://online.hbs.edu/courses/entrepreneurship-essentials/

**Assessment Pattern:**

1. Evaluated for a total of 100 marks.
2. A student can Prepare project proposals and feasibility reports for new enterprises by planning resource mobilization, implementation, and evaluation effectively.
3. **Internal Assessment (40 Marks)**
   Class Tests / Assignments (15 Marks): Short answer / case-based questions from Units I–III.Presentations / Seminars (10 Marks): Students present on entrepreneurial case studies, government schemes, or startup ideas.
   Class Participation & Attendance (5 Marks):Engagement in discussions, interaction, angroup activities. Mini Project / Report (10 Marks): A short write-up on an existing entrepreneur/startup or analysis of an enterprise's SWOT.

**2. End Semester Evaluation (60 Marks)**

**Section A:** Short Answer Questions (10 Marks)
5 questions × 2 marks (covering fundamental concepts from all units).

**Section B:** Medium Length Questions (30 Marks)
5 questions × 6 marks each (from Units I–IV, focusing on application and analysis).

**Section C:** Long Answer / Case Study (20 Marks)
2 questions × 10 marks each (Unit III–V: project proposal, growth strategies, resource mobilization).

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## R25MPL101 MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES 4 0 0 4

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

1. **To impart fundamental and advanced knowledge** on modern analytical instrumentation techniques used in pharmaceutical analysis.
2. **To provide comprehensive understanding** of the principles, instrumentation, working mechanisms, and applications of spectroscopic techniques such as UV-Visible, IR, NMR, and Mass Spectrometry.
3. **To introduce chromatographic and electrophoretic techniques** including HPLC, HPTLC, GC, and Capillary Electrophoresis, with emphasis on their role in qualitative and quantitative analysis of drugs.
4. **To familiarize students with modern hyphenated techniques** such as LC-MS, GC-MS, and their pharmaceutical applications in drug discovery, formulation development, and regulatory submissions.
5. **To develop competence in analytical method validation** as per ICH and regulatory guidelines for the quality control and quality assurance of pharmaceuticals.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO5 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO101.1 | Recall principle, operation and applications of selected instrumental spectroscopic, chromatographic analysis. | 1 | 2 | 3 | 1 | 1 | - | 2 | 1 | L1, L2 |
| R25CO101.2 | Gain knowledge on interpretation of NMR spectra for determination of molecular structure of compounds. | 1 | 2 | 3 | 1 | - | - | 2 | 1 | L1, L2, L3 |
| R25CO101.3 | Build the analytical understanding in the level of ion, atom, group and molecular structure of organic and inorganic compounds with different functional groups by Mass spectroscopy and their applications in pharmacy. | 1 | 2 | 3 | 1 | 3 | - | 2 | 1 | L 2, L3 |
| R25CO101.4 | Understand the concept of separation and identification of compounds by chromatographic techniques. | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L3, L4 |
| R25CO101.5 | Categorize different anions and cations by using suitable electrophoresis techniques. Elaborate principle, theory and instruments employed for the analysis of drugs by thermal techniques | 1 | 2 | 3 | - | 1 | - | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

**b. IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.

**c. Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

**d. Flame emission spectroscopy:** Principle, Instrumentation, Interferences and Applications.

**CO's–CO1**

**Self Learning topics:** Comparative Analysis of Molecular Spectroscopy Techniques: UV-Vis vs. IR vs. Fluorescence, Role of Solvent Effects and Sample Preparation Techniques in Spectroscopic Analysis and Pharmaceutical Applications of Atomic Absorption and Flame Emission Spectroscopy in Trace Element Analysis.

**UNIT II:** **10 Hours**

**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

**CO's–CO2**

**Self Learning topics:** Understanding Quantum Numbers and Their Role in NMR Activity, Solvent Selection in NMR: Deuterated Solvents and Their Importance and Comparison Between $^{1}H$ NMR and $^{13}C$ NMR Spectroscopy.

**UNIT III:** **10 Hours**

**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.

**CO's–CO3**

**Self Learning topics:** Comparison of Ionization Techniques in Mass Spectrometry, Understanding Mass Fragmentation Patterns and the Nitrogen Rule and Role and Interpretation of Metastable Ions and Isotopic Peaks.

**UNIT IV:** **8 Hours**

**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography

**CO's–CO4**

**Self Learning topics:** Comparison of Chromatographic Techniques: Planar vs. Column Chromatography, Optimization of Resolution in HPLC and Gas Chromatography and ligand selection and elution strategies in bioseparation processes.

**UNIT V:**

**7 Hours**

**a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis
c) Capillary electrophoresis d) Zone electrophoresis
e) Moving boundary electrophoresis f) Iso electricfocusing

**b. Thermal techniques: DSC, DTA, TGA:** Principle, instrumentation, factors affecting results, pharmaceutical applications.

**c. X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

**d. Immunological assays:** RIA(Radio immuno assay), ELISA, Bioluminescence assays.

**CO's-CO5**

**Self Learning topics:** real-life applications in DNA profiling, protein purification, and forensic analysis. X-ray diffraction helps in drug polymorphism, crystal habit modification, and structure-based drug design.

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**Text Books**

1. Spectrometric Identification of Organic compounds –Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Easternpress, Bangalore,1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis –Modern methods –Part B- JW Munson, Volume 11, Marcel Dekker Series

**Reference Books**

1. Indian Pharmacopoeia
2. United State Pharmacopoeia

**Web References**

1. https://www.pharmacytimes.com/
2. https://nptel.ac.in/
3. https://ipc.gov.in/
4. https://www.pharmacopoeia.com/
5. https://www.usp.org/
6. https://www.sciencedirect.com/

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1.** Remember

1. Define Beer-Lambert's law.
2. List any two applications of UV-Visible spectroscopy.
3. Name different types of molecular vibrations.
4. What is fluorescence?
5. Define chemical shift.
6. List NMR-active nuclei.
7. What are quantum numbers?
8. Define m/z ratio
9. List two ionization techniques.
10. Define retention time and resolution.
11. List types of chromatography.
12. Define isoelectric focusing.

13. What is Bragg's law?
14. List types of electrophoresis.

**L2.** Understand

1. Explain how solvent polarity affects UV spectra.
2. Describe the principle of atomic absorption spectroscopy.
3. Differentiate between dispersive and FT-IR spectrometers.
4. Explain spin-spin coupling with an example.
5. Describe the relaxation processes in NMR.
6. Explain the principle of MALDI and ESI.
7. Describe the role of quadrupole analyzer.
8. Describe how ion exchange chromatography separates analytes.
9. Explain the role of mobile and stationary phases.

**L3.** Apply

1. Calculate concentration using Beer-Lambert law.
2. Show how IR spectra can identify functional groups.
3. Use fluorescence intensity to determine analyte concentration.
4. Interpret a simple 1H NMR spectrum.
5. Apply the concept of shielding/deshielding in identifying peaks.
6. Predict fragmentation patterns for a given compound.
7. Apply mass spectral data to determine molecular weight.
8. Apply HPLC parameters to optimize peak separation.
9. Demonstrate how gas chromatography is used for volatile analytes.

**L4.** Analyze

1. Compare UV-Vis and IR spectroscopy in terms of analytical application.
2. Analyze the effect of quenchers on fluorescence output.
3. Identify factors affecting vibrational frequencies.
4. Compare 1H NMR and 13C NMR in terms of sensitivity and resolution.
5. Analyze how solvent affects chemical shifts.
6. Differentiate between TOF and quadrupole analyzers.
7. Analyze isotopic peaks in a chlorine-containing compound.
8. Compare paper chromatography and TLC.
9. Analyze how temperature affects GC resolution.
10. Compare capillary and gel electrophoresis.
11. Analyze differences between RIA and ELISA.

**L5.** Evaluate

1. Assess the usefulness of atomic absorption spectroscopy in trace metal analysis.
2. Justify the use of FT-IR over dispersive IR in analytical labs
3. Evaluate FT-NMR advantages in complex compound analysis.
4. Justify the selection of TMS as internal standard.
5. Evaluate the choice of ionization method for thermally labile molecules.
6. Critique the accuracy of molecular ion peak in EI-MS.
7. Assess the effectiveness of affinity chromatography for protein purification.
8. Justify using HPLC over column chromatography for pharmaceutical QC.
9. Evaluate the role of XRD in drug crystal structure determination.
10. Assess ELISA as a diagnostic tool.

## L6. Create

1. Design a novel conjugated organic molecule with predictable λ_max using Woodward-Fieser, Fieser-Kuhn, and Nelson rules. Explain the rationale behind each substitution.
2. Design an IR-based experiment to distinguish between cis and trans isomers of a substituted alkene, taking into account hydrogen bonding and vibrational coupling effects.
3. Design a mass spectrometric experiment to determine the fragmentation pattern and molecular structure of a newly synthesized drug molecule.
4. Construct a procedure for integrating FT-NMR and CW-NMR data to obtain a detailed structural characterization of a synthetic drug molecule.

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**R25MPL102** **ADVANCED PHARMACOLOGY -I** **4 0 0 4**

**Course Objectives:**

- To Discuss the pathophysiology and pharmacotherapy of certain diseases.
- To Explain the mechanism of drug actions at cellular and molecular level
- To Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO4 | PO9 | PSO1 | PSO2 | |
| R25 CO102.1 | Gain basic knowledge on pharmacokinetics and Pharmacodynamics modeling, parameters and its determination. | 2 | 1 | 1 | 2 | 1 | 2 | 1 | L 1, L2 |
| R25 CO102.2 | Summarize the mechanism and effects of neurotransmission and understand the pharmacology of Systemic and Autonomic Pharmacology | 2 | 1 | 1 | 2 | 1 | 2 | 1 | L1, L2, L3 |
| R25 CO102.3 | Remember the pharmacology of drugs acting on Central nervous system and Understand the pharmacology of neurodegenerative diseases. | 2 | 1 | 1 | 2 | 1 | 2 | 1 | L 2, L3 |
| R25 CO102.4 | Categorize the drugs acting on Cardiovascular system and understand its pharmacology. | 2 | 1 | 1 | 2 | 1 | 2 | 1 | L3, L4 |
| R25 CO102.5 | Elaborate pharmacology of drugs used to treat allergic reactions. | 2 | 1 | 1 | 2 | 1 | 2 | 1 | L4, L5,L6 |

## SYLLABUS

**Unit I:** **12 Hours**

**General Pharmacology**

a. **Pharmacokinetics:** Introduction to ADME. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b. **Pharmacodynamics:** Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

**CO's-CO1**

**Self-Learning Topics:** Role of first-pass metabolism in drug action, Drug-receptor theories (Occupancy vs. Rate theory)

**Unit II:** **12 Hours**

**Neurotransmission**

a. General aspects and steps involved in neurotransmission.
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline and their receptor types and responses
c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].
d. Non adrenergic non cholinergic transmission (NANC). Cotransmission Systemic Pharmacology A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems Autonomic Pharmacology
e. Para sympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

**CO's-CO2**

**Self-Learning Topics:** Role of second messengers in neurotransmission, Dopamine pathways and their clinical implications (Parkinson's, schizophrenia), Differences between sympathetic and parasympathetic blockade

**Unit III:** **12 Hours**

**Central nervous system Pharmacology**

a. General and local anesthetics,
b. Sedatives and hypnotics, anxiolytics
c. Depression, psychosis, mania, epilepsy, neurodegenerative diseases.
d. Narcotic and non-narcotic analgesics.
e. CNS stimulants and their misuse

**CO's-CO3**

**Self-Learning Topics:** Mechanism of action of antiepileptic drugs, Role of serotonin in mood disorders, Classification of CNS stimulants and their misuse

**Unit IV** **12 Hours**

**Cardiovascular Pharmacology**

a. Diuretics, antihypertensives, antianginal, anti- arrhythmics, drugs for heart failure and hyperlipidemia.
b. Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs

**CO's-CO4**

**Self-Learning Topics:** Renin-Angiotensin-Aldosterone System (RAAS) and its pharmacological targets Monitoring parameters for anticoagulant therapy, Pharmacotherapy of hypertension in pregnancy

**Unit V:** **12 Hours**

**Autocoid Pharmacology**

a. The physiological and pathological role of Histamine (H1 and H2), Serotonin, Kinins
b. Prostaglandins Opioid autocoids.
c. Pharmacology of antihistamines, 5HT antagonists.

**Self-Learning Topics:** Role of prostaglandins in inflammation and labor, Histamine in allergy and gastric secretion, Role of Immuno modulators in hypersensitive reactions.

**Text Books:**

1.The Pharmacological Basis of Therapeutics, Goodman and Gillman's

2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

3. Basic and Clinical Pharmacology by B.G Katzung.

4.KD.Tripathi. Essentials of Medical Pharmacology.

5.Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E.,Lippincott Publishers.

6.Basic and Clinical Pharmacology by B.G Katzung

7. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

8. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

9. Graham Smith. Oxford textbook of Clinical Pharmacology.

10. Avery Drug Treatment

11. Dipiro Pharmacology, Pathophysiological approach.

12. Green Pathophysiology for Pharmacists.

13. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)

**Web References:**

**1.MedlinePlus – U.S. National Library of Medicine**

**https://medlineplus.gov/druginformation.html**

**2.Khan Academy – Pharmacology**

**https://www.khanacademy.org/science/health-and-medicine/advanced-physiology**

**3.British Pharmacological Society**

**https://www.bps.ac.uk**

**4. Merck Manual – Professional Version**

**https://www.merckmanuals.com/professional**

**5. Pharmacology Education Project (by IUPHAR)**

**https://www.pharmacologyeducation.org**

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |

| | | |
|---|---|---|
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remember**

1. Define pharmacodynamics.
2. What is the full form of ADME?
3. Name two types of cholinergic receptors.
4. List any four CNS neurotransmitters.
5. What is a partial agonist?
6. Name the major hormone secreted by the adrenal medulla.
7. Define cardiac output.
8. List any four autacoids studied in the syllabus.

**L2 – Understand**

1. Explain the mechanism of drug-receptor interaction.
2. Describe the steps involved in neurotransmission.
3. What is the difference between local and general anesthetics?
4. Explain the physiological role of serotonin.
5. Describe how antihypertensives lower blood pressure.
6. Explain the classification of diuretics.
7. Illustrate the difference between sympathetic and parasympathetic nervous systems.
8. Describe how prostaglandins act as inflammatory mediators.

**L3 – Apply**

1. Apply the concept of protein binding to explain why drug dosage is adjusted in liver disease.
2. Classify analgesic drugs and give one example of each type.
3. A patient with asthma is given a β2-agonist. Explain the rationale.
4. Choose a suitable drug for hypertension in a diabetic patient and justify.
5. Identify a drug used for serotonin syndrome and explain its use.
6. How would you treat a patient with opioid overdose?

7. Recommend a CNS stimulant for treating ADHD and explain its mechanism.
8. Design a basic regimen for peptic ulcer using pharmacological principles.

**L4 – Analyze**

1. Compare parasympathomimetics and parasympatholytics in terms of action and uses.
2. Analyze the pharmacological differences between morphine and naloxone.
3. Differentiate between the actions of H1 and H2 antihistamines.
4. How does GABA differ from glutamate in terms of CNS function?
5. Analyze the impact of drug metabolism on drug bioavailability.
6. Explain how different receptors influence heart rate.
7. Compare the action of beta-blockers with calcium channel blockers.
8. How do prostaglandin analogs differ from NSAIDs in inflammation?

**L5 – Evaluate**

1. Evaluate the effectiveness of SSRIs vs. tricyclic antidepressants.
2. Assess the risks of polypharmacy in elderly patients.
3. Justify the use of combination therapy in tuberculosis.
4. Critically evaluate the role of coagulants in post-operative patients.
5. Recommend an antipsychotic for schizophrenia and defend your choice.
6. Critique the use of opioids in chronic pain management.
7. Evaluate the cardiovascular risks of long-term NSAID use.
8. Justify using ACE inhibitors in diabetic nephropathy.

**L6 – Create**

1. Create a flowchart showing pharmacokinetic processes of a drug.
2. Design a simple protocol for treating epilepsy.
3. Propose a combination therapy for heart failure with rationale.
4. Develop a comparative chart of neurotransmitters and their actions.
5. Construct a case scenario involving serotonin syndrome and suggest a treatment approach.
6. Formulate an emergency drug list for myocardial infarction.
7. Design a patient counseling outline for beta-blocker therapy.
8. Propose a project to study the effects of receptor mutations on drug efficacy.

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Vizianagaram Dt.,- 531162

## R25MPL103 PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I 4 0 0 4

### Course Objectives:

- To Appraise the regulations and ethical requirement for the usage of experimental animals.
- To Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- To Describe the various newer screening methods involved in the drug discovery process
- To Appreciate and correlate the preclinical data to humans

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO3 | PO8 | PO9 | PSO1 | PSO2 | |
| R25 CO103.1 | Gain basic knowledge on rules and CPSCEA guidelines of handling laboratory animals. Understand the production of transgenic animals and GLP. | 1 | 3 | 2 | 1 | 2 | 1 | L1, L2 |
| R25 CO103.2 | Outline General principles of *in-vivo, in-vitro* preclinical screening techniques for drugs acting on CNS and ANS. | 1 | 3 | 2 | 1 | 2 | - | L1, L2, L3 |
| R25 CO103.3 | Identify the newer screening methods for drug acting on respiratory, reproductive systems and Gastro-intestinal system. | 1 | 3 | 2 | 1 | 2 | - | L2, L3 |
| R25 CO103.4 | Understand the principles of *in-vivo, in-vitro* preclinical screening techniques for drugs acting on Cardiovascular system. | 1 | 3 | 2 | 1 | 2 | - | L3, L4 |
| R25 CO103.5 | Understand General principles of preclinical screening techniques for Immunomodulators, Immunosuppressants. Outline general principles of immunoassay and extrapolation of in vitro/preclinical data to human. | 1 | 3 | 2 | 1 | 2 | 1 | L4, L5, L6 |

## SYLLABUS

**Unit I:** **10 Hours**

**Laboratory Animals:** Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals- Techniques and ethical aspects. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods.

**CO's- CO1**

**Self-learning topics:** Virtual simulations for animal experiments and ethical replacements. Innovations in automated bioassay technologies. 3Rs (Replacement, Reduction, Refinement) in animal research.

**Unit II:** **10 Hours**

a. **Preclinical screening** of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening.
b. **CNS Pharmacology:** behavioural and Motor coordination, CNS stimulants and depressants, anxiolytics, antipsychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis. Drugs acting on Autonomic Nervous System.

**CO's- CO2**

**Self-learning topics:** Current trends in anti-epileptic drug development. Nootropic drugs and their mechanisms in experimental models. Use of zebrafish in neurological screening.

**Unit III:** **10 Hours**

a. **Preclinical screening** of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
b. **Respiratory Pharmacology**: anti-asthmatics, drugs for COPD and anti allergics.
c. **Reproductive Pharmacology:** Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents.
d. **Gastrointestinal drugs:** anti-ulcer, anti -emetic, anti- diarrheal, laxatives and Purgatives.

**CO's- CO3**

**Self-learning topics:** Evaluation of male and female antifertility agents in rodents. Hormonal regulation of reproductive cycles – experimental insights. Experimental approaches for asthma drug development.

**Unit IV** **10 Hours**

a. **Preclinical screening** of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
b. **Cardiovascular Pharmacology:** antihypertensives, antiarrhythmics, antianginal, antiatherosclerosis agents and diuretics. Drugs for metabolic disorders like antidiabetic, antidyslipidemic agents. Anti Malignant agents. Hepatoprotective screening methods

**CO's- CO4**

**Self-learning topics:** Tumor xenograft models for anticancer drug screening. Role of gene editing (CRISPR) in cardiovascular research. Non-invasive imaging in cardiac and metabolic studies.

**Unit V:** **10 Hours**

a. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
b. Iimmunomodulators, Immunosuppressants and immunostimulants
c. General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems.
d. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin.
e. Limitations of animal experimentation and alternate animal experiments.
f. Extrapolation of in vitro data to preclinical and preclinical to humans.

**CO's- CO5**

**Self-learning topics:** Emerging non-animal methods for immunotoxicity testing. Translational challenges in immunomodulator development. AI and machine learning in extrapolating preclinical to human responses.

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**Text Books:**

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni

**Web References:**

- CPCSEA – Committee for the Purpose of Control and Supervision of Experiments on Animals https://cpcsea.nic.in
- NC3Rs – National Centre for the Replacement, Refinement and Reduction of Animals in Research https://www.nc3rs.org.uk
- IUPHAR/BPS Guide to Pharmacology https://www.guidetopharmacology.org
- ScienceDirect – Pharmacology Journals https://www.sciencedirect.com/journal/european-

journal-of-pharmacology.

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 Remember**

1. Define transgenic animals.
2. What is the function of CPCSEA?
3. List common species used in laboratory experiments.
4. Define bioassay.
5. What is the purpose of GLP?
6. Name any two anesthetic agents used in laboratory animals.
7. State any two limitations of bioassays.
8. Mention different methods of euthanasia in lab animals.

**L2 Understand**

1. Explain the importance of CPCSEA guidelines.
2. Describe the process of maintaining a laboratory animal facility.
3. Discuss the objectives of GLP.
4. Differentiate between inbred and outbred strains.
5. Explain the principles of bioassay.
6. Describe the ethical aspects of animal handling.
7. What is the role of transgenic animals in drug testing?
8. How does protein binding affect pharmacokinetics?

**L3 Apply**

1. Apply GLP principles to set up a basic lab facility.
2. Demonstrate the protocol for proper animal housing.

3. Choose a suitable animal model for analgesic testing.
4. Use CPCSEA norms to design an experiment.
5. Implement a bioassay to measure the potency of a new drug.
6. Perform basic animal handling techniques.
7. Devise a method to monitor breeding patterns.
8. Apply animal welfare rules in experiment design.

**L4 Analyze**

1. Analyze pros and cons of in vivo vs in vitro models.
2. Compare anesthesia techniques in small and large animals.
3. Examine ethical concerns in animal-based experiments.
4. Classify different types of bioassays.
5. Analyze differences between laboratory animal species.
6. Differentiate between GLP and non-GLP studies.
7. Interpret the variability in bioassay results.
8. Evaluate CPCSEA approval procedures.

**L5 Evaluate**

1. Critique the use of animal testing in pharmacological studies.
2. Justify the use of transgenic animals in genetic disorders.
3. Evaluate ethical alternatives to animal testing.
4. Assess GLP compliance in a given experimental setup.
5. Judge the effectiveness of various euthanasia methods.
6. Recommend animal models for CNS disorder studies.
7. Review an animal facility for adherence to CPCSEA.
8. Appraise the limitations of bioassays for drug toxicity.

**L6 Create**

1. Design a protocol for screening antiepileptic drugs.
2. Create a training module on ethical animal handling.
3. Develop a digital monitoring system for GLP compliance.
4. Formulate a plan to set up a new animal house facility.
5. Construct SOPs for anesthesia administration.
6. Draft a breeding schedule for genetically modified rats.
7. Propose a new in vitro alternative to reduce animal testing.
8. Design a virtual simulation to teach animal dissection.

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**R25MPL104** **CELLULAR AND MOLECULAR PHARMACOLOGY-I** **4 0 0 4**

**Course Objectives:**

- To Explain the receptor signal transduction processes.
- To Explain the molecular pathways affected by drugs.
- To Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- To Demonstrate molecular biology techniques as applicable for pharmacology

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO4 | PO5 | PO6 | PSO1 | PSO2 | |
| R25 CO104.1 | Understand the basic structure and functions of cell and genome in the living organisms. Summarize various phases of cell cycle, apoptosis, necrosis and autophagy. | 2 | 2 | 2 | 1 | 2 | 1 | L 1, L2 |
| R25 CO104.2 | Remember the pathways of cell signaling and know the importance of primary and secondary messengers. | 2 | 2 | 2 | 1 | 2 | 1 | L1, L2, L3 |
| R25 CO104.3 | Understand the principles and applications of genomic and proteonomic tools and Know the principles of rDNA technology and gene therapy. | 2 | 2 | 2 | 1 | 2 | 1 | L 2, L3 |
| R25 CO104.4 | Elaborate the significance of Pharmacogenomics and immunotherapeutics. | 2 | 2 | 2 | 1 | 2 | 1 | L3, L4 |
| R25 CO104.5 | Design various cell culture techniques. Understand the applications of biosimilars. | 2 | 2 | 2 | 1 | 2 | 1 | L4, L5,L6 |

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## SYLLABUS

**Unit I:** **12 Hours**

**Cell biology**

a. Structure and functions of cell and its organelles
b. Genome organization. Gene expression and its regulation, importance of siRNA and micro-RNA, gene mapping and gene sequencing
c. Cell cycles and its regulation.

d. Cell death mechanisms: Apoptosis (intrinsic and extrinsic pathways), necrosis, pyroptosis, and autophagy

**CO's-CO1**

**Self-learning topics:** Role of microRNA in post-transcriptional gene regulation. Compare and contrast apoptosis, necrosis, and autophagy, Therapeutic applications of siRNA in genetic disorders.

**Unit II:** **12 Hours**

**Cell signalling**

a. Intercellular and intracellular signaling pathways.
b. Types of Receptors: ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
c. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.
d. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

**CO's-CO2**

**Self-learning topics:** Role of calcium ions in neurotransmitter release, Pharmacological importance of second messengers, MAPK vs. JAK/STAT signaling: differences in mechanism and function.

**Unit III:** **12 Hours**

a. Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy
b. Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and ethical concerns of gene editing, recent advances in gene therapy.

**CO's-CO3**

**Self-learning topics:** Real-time PCR vs. RT-PCR: Applications in diagnostics. CRISPR/Cas9 gene editing – principles and controversies. Proteomics in identifying disease biomarkers.

**Unit IV** **12 Hours**

**Pharmacogenomics**

a. Gene mapping and cloning of disease gene.
b. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism
c. Genetic variation in drug transporters
d. Genetic variation in G protein coupled receptors
e. Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics

f. Application of Immunostimulants and immunosuppressant's in organ transplantation, humanization antibody therapy,
g. Immunotherapeutic in clinical practice

**CO's-CO4**

**Self-learning topics:** How genetic polymorphisms influence warfarin metabolism. Nutrigenomics and its role in diet-based therapeutics. Impact of pharmacogenomics in personalized cancer therapy.

**Unit V:** **12 Hours**

**Cell culture techniques**

a. Basic equipment's used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.
b. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays
c. 3D Cell culture and organoid model
d. Principles and applications of flow cytometry, Biosimilars

**CO's-CO5**

**Self-learning topics:** Differences between 2D and 3D cell culture: Research implications., Applications of organoids in disease modelling.

**Text Books:**

1.The Cell, A Molecular Approach. Geoffrey M Cooper.

2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong

3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

**Web References:**

- https://www.ncbi.nlm.nih.gov
- https://www.nature.com/nrm/
- https://www.biointeractive.org/
- https://www.thermofisher.com/in/en/home/life-science/learning-center.html

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remember**

1. Define apoptosis.
2. List organelles of a typical cell.
3. What is siRNA?
4. Name two secondary messengers.
5. State the function of ribosomes.
6. Mention any two types of Immunotherapeutics.
7. Define necrosis.
8. What is a biosimilar?
9. Describe the structure and functions of the cell organelles.
10. Explain the different types of cell death with examples.

**L2 – Understand**

1. Explain gene regulation using microRNA.
2. Describe the function of tyrosine kinase receptors.
3. How does cyclic AMP mediate cell signaling?
4. Explain cryopreservation in cell culture.
5. Discuss the difference between apoptosis and autophagy.
6. Describe the MAPK pathway in cell signaling.
7. Illustrate the concept of gene mapping.
8. What is the role of ELISA in diagnostics?
9. Discuss the mechanisms of cell death and their physiological significance.
10. Explain the different intracellular signaling pathways with examples.

**L3 – Apply**

1. Suggest an experiment using PCR for gene detection.
2. Apply ELISA to detect a viral antigen.
3. Design a Western blot to identify a protein marker.
4. Demonstrate the application of calcium influx assays.
5. How would you identify drug metabolism polymorphisms in patients?
6. Apply knowledge of GPCRs in designing targeted therapies.

7. Use proteomics in diagnosing metabolic disorders.
8. Demonstrate gene expression in a lab using real-time PCR.
9. Design an experimental protocol to assess the efficacy of a new gene therapy.
10. Describe how pharmacogenomics is applied to patient-specific drug responses.

**L4 – Analyze**

1. Analyze the impact of mutated G-protein receptors on drug response.
2. Break down the steps of apoptosis and identify points of regulation.
3. Compare and contrast intrinsic and extrinsic apoptosis pathways.
4. Evaluate differences in DNA vs RNA viral responses in gene therapy.
5. Differentiate between necrosis and apoptosis at the molecular level.
6. Analyze the data from a Western blot for protein expression.
7. Interpret calcium influx assay results in neuronal signaling.
8. Compare various immunoassay techniques.
9. Analyze how defects in JAK-STAT signaling pathway may lead to cancer.
10. Compare intracellular signaling pathways and their implications in therapy.

**L5 – Evaluate**

1. Evaluate the use of flow cytometry vs ELISA in immune profiling.
2. Critique a gene therapy technique for treating a genetic disorder.
3. Assess the reliability of a PCR assay in diagnosing COVID-19.
4. Judge the efficacy of siRNA in silencing oncogenes.
5. Recommend a suitable immunotherapeutic for autoimmune disease.
6. Appraise the significance of biosimilars in modern therapeutics.
7. Evaluate proteomics over genomics in clinical diagnostics.
8. Debate the ethics of transgenic animal models.
9. Evaluate the limitations and benefits of animal models in drug development.
10. Assess the role of pharmacogenomics in reducing adverse drug reactions.

**L6 – Create**

1. Propose a model for screening anticancer drugs using cell culture.
2. Formulate a method to improve cell viability in long-term cultures.
3. Develop a flowchart for selecting gene delivery systems.
4. Create a new protocol for a multiplex ELISA.
5. Invent a biosensor to detect secondary messengers.
6. Plan a recombinant DNA experiment to express insulin in bacteria.
7. Compose a decision-tree for signaling pathway analysis.
8. Devise a CRISPR-based therapy strategy for genetic blindness.
9. Design a complete protocol for personalized drug therapy using genomic data.
10. Create a detailed cell culture experimental setup to test anti-apoptotic drugs.

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**R25MPL105 ANALYTICAL AND CELLULAR PHARMACOLOGY PRACTICAL-I 0 0 6 3**

**Course Objectives:**

1. To develop competence in instrumental analytical techniques Train students in the analysis of pharmacoepocial compounds and formulations using UV-Vis spectrophotometry, HPLC, Gas Chromatography, fluorimetry, and flame photometry for pharmaceutical quality control.
2. To build practical skills in animal handling and ethical laboratory practices Familiarize students with the proper handling of laboratory animals, including drug administration routes, blood collection, anaesthesia, and euthanasia, following CCSEA guidelines.
3. To evaluate pharmacological effects using standard in vivo models Enable students to carry out preclinical screening for CNS activity (stimulants, depressants, anxiolytics), analgesic, anti-inflammatory, diuretic, ocular, and anti-ulcer activities, along with tests like the Functional Observation Battery and Oral Glucose Tolerance Test.
4. To integrate analytical and pharmacological knowledge for drug evaluation Encourage correlation between instrumental drug analysis and biological activity studies, supporting comprehensive understanding of drug action, dosage, and efficacy in pharmaceutical research.

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping With POs and PSOs | | | | | | | Dok |
|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO8 | PS01 | PSO2 | |
| R25CO105.1 | Identify the concentration of test compounds using HPLC, UV, GC, fluorimetry and flame photometry. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L1,L2 |
| R25CO105.2 | Estimate the amount of drug by different analytical techniques. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L2,L3 |
| R25CO105.3 | Estimate DNA, RNA and proteins by qualitative and quantitative methods. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L5,L6 |
| R25CO105.4 | Determine cell migration, apoptosis and cell viability assays. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L1,L4 |

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Approved in BOS No: 01, 22nd October, 2025

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## COURSE CONTENT

| S.No | Name of the Experiment | CO's |
|---|---|---|
| 01 | Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer | CO1 |
| 02 | Experiments based on HPLC | CO1 |
| 03 | Estimation of riboflavin by fluorimetry | CO1 |
| 04 | Estimation of quinine sulphate by fluorimetry | CO1 |
| 05 | Estimation of sodium and potassium by flame photometry | CO2 |
| 06 | Estimation of potassium by flame photometry | CO2 |
| 07 | Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion,Goat liver). | CO2 |
| 08 | Isolation of RNA from yeast | CO2 |
| 09 | Estimation of proteins by Braford/Lowry's in biological samples. | CO2 |
| 10 | Estimation of RNA by UV Spectroscopy | CO3 |
| 11 | Estimation of DNA by UV Spectroscopy | CO3 |
| 12 | Gene amplification by PCR. | CO3 |
| 13 | Protein quantification Western Blotting | CO3 |
| 14 | Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase). | CO4 |
| 15 | Cell viability assays (MTT/Trypan blue/SRB). | CO4 |
| 16 | DNA fragmentation assay by agarose gel electrophoresis. | CO4 |
| 17 | DNA damage study by Comet assay. | CO4 |
| 18 | Apoptosis determination by fluorescent imaging studies. | CO4 |

**Reference Books**

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

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Vizianagaram Dt.,- 531162

**R25MPL106** **MODERN PHARMACOLOGY PRACTICAL-II** **0 0 6 3**

**Course Objectives:**

1. To impart practical skills in the isolation and quantification of biomolecules Enable students to perform isolation and identification of DNA and RNA from various sources, and carry out quantitative estimation of proteins, RNA, and DNA using methods like UV spectroscopy, Bradford/Lowry's assay, and Western blotting.
2. To introduce core molecular biology techniques and assays Provide hands-on experience in gene amplification by PCR, enzyme-based in vitro assays (e.g., MPO, AChE, α-amylase, α-glucosidase), and apoptotic and DNA damage studies using fluorescent imaging, comet assay, and gel electrophoresis.
3. To develop competence in cellular and enzymatic evaluation techniques Train students in cell viability assays (MTT, SRB, Trypan blue), enzyme inhibition and induction studies, and apply these to assess drug or molecule effects on biological systems.
4. To apply analytical and pharmacokinetic tools for drug estimation and modeling Equip students with skills to extract and estimate drugs from biological fluids using UV and HPLC techniques, and perform pharmacokinetic studies and data analysis using software-based simulation tools.

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping With POs and PSOs | | | | | | | Dok |
|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO8 | PS01 | PSO2 | |
| R25CO106.1 | Examine diuretic, antiulcer activities and to analyse Oral glucose tolerance test. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L1,L2 |
| R25CO106.2 | Evaluate various pharmacological activities by *in-vitro* or *in-vivo* methods. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L2,L3 |
| R25CO106.3 | Examine pharmacokinetic studies of drugs by using softwares. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L2,L3 |
| R25CO106.4 | Extract drug from biological samples by using UV and HPLC. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L3 |

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## COURSE CONTENT:

| S.No | Name of the Experiment | CO's |
|---|---|---|
| 01 | Various routes of drug administration. | CO2 |
| 02 | Techniques of blood sampling, anesthesia and euthanasia of experimental animals. | CO2 |
| 03 | Functional observation battery tests (modified Irwin test) | CO2 |
| 04 | Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity. | CO2 |
| 05 | Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity. | CO4 |
| 06 | Evaluation of diuretic activity. | CO4 |
| 07 | Evaluation of antiulcer activity by pylorus ligation method. | CO4 |
| 08 | Oral glucose tolerance test. | CO4 |
| 09 | Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares | CO2 |
| 10 | Enzyme inhibition and induction activity | CO2 |
| 11 | Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV) | CO2 |
| 12 | Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC) | CO2 |

**Reference Books**

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

M. Jawani

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**R25MPL108** **RESEARCH PAPER WRITING** **4 0 0 0**

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

- To understand the essentials of writing skills and their level of readability.
- To learn about what to write in each section.
- To ensure qualitative presentation with linguistic accuracy.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO8 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO108.1 | Understand the significance of writing skills and the level of readability. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L1, L2 |
| R25CO108.2 | Analyze and write title, abstract, different sections in research paper | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L1, L2, L3 |
| R25CO108.3 | Develop the skills needed while writing a research paper | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L 2, L3 |
| R25CO108.4 | Able to develop and apply key academic writing skills to construct clear, concise, and impactful Titles, Abstracts, and Introductions for research papers, demonstrating the ability to attract readers, summarize core findings, and establish research context effectively. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L3, L4 |
| R25CO108.5 | Able to use appropriate academic language and style to accurately formulate the methodology, clearly present Results, logically construct Arguments, and effectively draw valid conclusions in research writing. | 1 | 2 | 3 | - | - | 2 | 2 | 1 | L4, L5, L6 |

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## SYLLABUS

**UNIT I:** **10 Hours**

Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breakingup Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity.

**CO's–CO1**

**Self Learning topics:** Examples of effective vs. poor research paper planning, Exercises on improving word order and sentence clarity, Identifying and breaking long, complex sentences into shorter ones.

**UNIT II:** **10 Hours**

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

**CO's–CO2**

**Self Learning topics:** Common pitfalls in defining a research problem, Hedging phrases in academic writing (e.g., "suggests that", "may indicate"), Identifying plagiarism vs. acceptable paraphrasing.

**UNIT III:** **10 Hours**

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

**CO's–CO3**

**Self Learning topics:** Steps to conduct a literature review (sources, search engines, databases), Comparing qualitative vs. quantitative methodologies,Tools for data analysis (SPSS, Excel, R basics).

**UNIT IV:** **8 Hours**

Key skills needed for writing a Title, Abstract, and Introduction

**CO's–CO4**

**Self Learning topics:** Characteristics of an impactful research title, Common errors to avoid in writing an abstract, Strategies for writing a strong introduction.

**UNIT V:** **7 Hours**

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions.

**CO's-CO5**

**Self Learning topics:** Neutral and objective ways to report results, Building logical arguments with evidence, Transition words for coherence.

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**Text Books**

1. Goldbart R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I].
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press.
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman"sbook Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011.

**Web References**

1. https://cambridge-research.org/blogs/how-to-write-a-research-paper/?
2. https://www.readwritethink.org/classroom-resources/lesson-plans/scaffolding-methods-research-paper?
3. https://academicguides.waldenu.edu/writingcenter/assignments/literaturereview/matrix?
4. https://www.verywellmind.com/how-to-write-an-introduction-2794846?

**Assessment Pattern:**

1. Evaluated for a total of 100 marks.
2. A student can select 2 articles of his/her choice with a minimum of 01 review or research article per semester. Each article publication shall be evaluated by the concerned teacher for 50 marks, totaling to 100 marks.

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**R25MPL201** **ADVANCED PHARMACOLOGY – II** **4 0 0 4**

**Course Objectives:**

Upon completion of the course the student shall be able to:

- To explain the mechanism of drug actions at cellular and molecular level
- To discuss the Pathophysiology and pharmacotherapy of certain diseases
- To understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO8 | PO9 | PO10 | PSO1 | PSO2 | |
| R25 CO201.1 | Relate functions of hormones and to list out drugs acting on endocrine system. | 2 | 1 | 1 | 2 | 1 | 2 | 2 | 1 | L 1, L2 |
| R25 CO201.2 | Outline the principles of chemotherapy and illustrate the mechanism of action of antibiotics, Antifungal, antiviral, and anti-TB drugs . | 2 | 1 | 1 | 2 | 1 | 2 | 2 | - | L2, L3 |
| R25 CO201.3 | Identify the chemotherapeutic agents for Protozoal and Helimenthetic infections. And Understand the chemotherapy of cancer, Immunosuppressants, Immunostimulants and pharmacotherapy of Asthma and COPD. | 2 | 1 | 1 | 2 | 1 | 2 | 2 | - | L 2, L3 |
| R25 CO201.4 | Assess the mechanism of drugs acting on GIT and applications of chrono pharmacology to treat disorders. | 2 | 1 | 1 | 2 | 1 | 2 | 2 | - | L3, L4 |
| R25 CO201.5 | Elaborate the role of free radicals in etiopathology of various diseases and adapt the recent advances in treatment of various diseases. | 2 | 1 | 1 | 2 | 1 | 2 | 2 | 1 | L5, L6 |

## SYLLABUS

**UNIT 1. Endocrine Pharmacology** **12Hours**

a. Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones.
b. Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.
c. Drugs affecting calcium Homeostasis.

CO's -CO1

**Self-Learning Topics** : Comparative study of first-generation vs second-generation oral hypoglycemic agents.,Clinical uses and limitations of long-term corticosteroid therapy,Role of calcium-homeostatic drugs in osteoporosis management.

**UNIT 2 Chemotherapy** **12Hours**

Cellular and molecular mechanism of actions, uses, Adverse effects ,Drug interactions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

CO's -CO2

**Self-Learning Topics** :Mechanisms of antimicrobial resistance (AMR) and WHO strategies to combat it. Emerging antifungal drugs and their clinical applications.

**UNIT 3 Chemotherapy** **12Hours**

a. Drugs used in Protozoal Infections.
b. Drugs used in the treatment of Helminthiasis.
c. Chemotherapy of cancer Immunopharmacology.
d. Cellular and biochemical mediators of inflammation and immune response.
e. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.
f. Immunosuppressants and Immunostimulants.
g. Recent advances in monoclonal antibodies and targeted immunotherapies

**CO's -CO3**

**Self-Learning Topics** :Applications of immunosuppressants in Organ transplantation.Role of cytokines in inflammation and their therapeutic targeting.Advances in cancer immunotherapy (checkpoint inhibitors, CAR-T cells).

**UNIT 4 GIT Pharmacology** **12Hours**

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

**Chronopharmacology**

a. Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.
b. Emerging role of microbiota-targeted therapy in GIT disorders

**CO's -CO4**

**Self-Learning Topics :**Comparative study of proton pump inhibitors , Acid Neutralizers and Antacids ,Influence of gut microbiome on drug absorption and therapeutic response.

**UNIT 5 Free radicals Pharmacology** **12Hours**

a. Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.
b. Protective activity of certain important antioxidants, Invitro, Invivo anti oxidant parameters of free radicals.

**Recent Advances in Treatment:**

Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

**CO's -CO5**

**Self-Learning Topics :**Role of oxidative stress in neurodegeneration (case study in Alzheimer's and Parkinson's).Nanotechnology-based approaches in cancer and diabetes therapy.

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**Text Books:**

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.

11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

**Web References:**

- https://pubmed.ncbi.nlm.nih.gov/39002024/
- https://www.cdc.gov/antibiotic-use/hcp/data-research/stewardship-report.html
- https://pmc.ncbi.nlm.nih.gov/articles/PMC7551545/
- https://www.sciencedirect.com/science/article/abs/pii/S1044532322000161
- https://www.mdpi.com/2571-6980/6/1/9

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 25% |
| L4 | -- | 35% |
| L5 | -- | 25% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remember**

1. Define the mechanism of action of insulin.
2. List two oral contraceptives.
3. Name drugs that affect calcium regulation.
4. Mention the functions of growth hormone.
5. Identify an anti-thyroid drug.

**L2 – Understanding**

1. Explain why corticosteroids are used in inflammatory conditions.
2. Describe the feedback mechanism of thyroid hormone secretion.
3. Differentiate between type 1 and type 2 diabetes treatment strategies.
4. Explain the physiological role of prolactin.
5. Why are oral hypoglycemic agents preferred over insulin in some patients?
6. Explain why quinolones are effective against urinary tract infections.
7. Describe bacterial resistance mechanisms to β-lactams.

8. Differentiate between bactericidal and bacteriostatic agents.
9. Explain the mechanism of antifungal drug resistance.
10. Why are antiviral drugs difficult to design compared to antibiotics
11. Explain the mechanism of chloroquine in malaria.
12. Differentiate between immunostimulants and immunosuppressants.
13. Describe the role of inflammatory mediators in asthma.
14. Why are corticosteroids used in hypersensitivity reactions?
15. Explain the mechanism of resistance in cancer chemotherapy.

**L3 – Apply**

1. Which drug would you prescribe for a patient with TB and HIV coinfection?
2. Apply knowledge of quinolones in urinary tract infection treatment.
3. Select a macrolide for a patient allergic to penicillin.
4. How would you manage candidiasis with antifungal therapy?
5. Which antimicrobial agent would you use for resistant TB strains?
6. Select a drug for giardiasis.
7. Which drug would you prescribe for hookworm infection?
8. Apply the role of bronchodilators in asthma management.
9. How would you manage a patient with chemotherapy-induced nausea?
10. Which immunosuppressant would you use in kidney transplant?

**L4 – Analyze**

1. Compare proton pump inhibitors and H2 blockers.
2. Analyze the role of serotonin in prokinetic drugs.
3. Distinguish between acute and chronic diarrhea management.
4. Compare the application of chronotherapy in diabetes vs. asthma.
5. Analyze the differences between stimulant and bulk-forming laxatives.

**L5 – Evaluate**

1. Evaluate the benefits of PPIs over H2 blockers.
2. Judge the effectiveness of chronotherapy in cardiovascular diseases.
3. Assess the safety of long-term laxative use.
4. Critically evaluate the role of antiemetics in chemotherapy-induced nausea.
5. Evaluate the importance of circadian rhythm in clinical practice
6. Evaluate the benefits of antioxidants in neurodegenerative diseases.
7. Judge the importance of free radical research in modern pharmacology.
8. Assess the clinical significance of antioxidants in diabetes.
9. Evaluate the risks of antioxidant overuse.

10. Critically evaluate the role of recent advances in cancer pharmacotherapy.

**L6 – Create**

1. Design a new antioxidant-based therapy for Alzheimer's disease.
2. Propose a clinical trial for antioxidant therapy in diabetes.
3. Develop a strategy to target free radicals in cancer.
4. Create a new neuroprotective antioxidant.
5. Suggest a personalized therapy plan using antioxidants for Parkinson's disease.

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**R25MPL202 PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II 4 0 0 4**

**Course Objectives:**

Upon completion of the course the student shall be able to:

- To explain the various types of toxicity studies.
- To appreciate the importance of ethical and regulatory requirements for toxicity studies.
- To demonstrate the practical skills required to conduct the preclinical toxicity studies

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO3 | PO8 | PO9 | PO10 | PSO1 | PSO2 | |
| R25 CO202.1 | Appreciate the importance of ethical and regulatory guide lines for conducting toxicity studies. | 1 | 3 | 2 | 1 | 2 | 2 | 1 | L 1, L2 |
| R25 CO202.2 | Illustrate Acute, sub-acute and chronic- oral, dermal and inhalational toxicity studies as per OECD guidelines. | 1 | 3 | 2 | 1 | 2 | 2 | - | L1, L2 |
| R25 CO202.3 | Construct reproductive toxicology, tearatogenicity studies. And Demonstrate the practical skills to conduct Genotoxicity studies and Carcinogenicity studies. | 1 | 3 | 2 | 1 | 2 | 2 | - | L3, L4 |
| R25 CO202.4 | Categorize IND enabling studies. Appraise the importance of Safety pharmacology. | 1 | 3 | 2 | 1 | 2 | 2 | - | L3, L4 |
| R25 CO202.5 | Compile the importance and applications of Toxicokinetic studies and alternative methods to animal toxicity testing. | 1 | 3 | 2 | 1 | 2 | 2 | 1 | L5,L6 |

## SYLLABUS

**UNIT 1.** **12 Hours**

a. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
b. Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and
c. Schedule Y
d. OECD principles of Good laboratory practice (GLP)
e. History, concept and its importance in drug development

CO's -CO1

**Self-Learning Topics:**Recent advances in toxicogenomics and its role in predictive toxicology.Case studies of regulatory toxicology failures and lessons learned.Comparative overview of GLP requirements across OECD, USFDA, and EMA.

**UNIT 2** **12 Hours**

a. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per
b. OECD guidelines.
c. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
d. Test item characterization- importance and methods in regulatory toxicology studies.

**CO's -CO2**

**Self-Learning Topics:**Application of computational toxicology tools in preclinical safety assessment.Ethical concerns and refinement strategies in repeated dose toxicity studies.OECD case studies of dermal and inhalation toxicity guidelines.

**UNIT 3** **12 Hours**

a. Reproductive toxicology studies, Male reproductive toxicity studies, female
b. reproductive studies (segment I and segment III), teratogenecity studies (segment II)
c. Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)
d. In vivo carcinogenicity studies
e. Advances in stem-cell based and organ-on-chip models for reproductive and genotoxicity testing.

**CO's -CO3**

**Self-Learning Topics:**Limitations of traditional animal models in reproductive toxicity testing.Applications of organ-on-chip models in genotoxicity and carcinogenicity testing.Regulatory acceptance of alternative models in genotoxicity testing.

**UNIT 4** **12 Hours**

a. IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.

b. Safety pharmacology studies- origin, concepts and importance of safety pharmacology.
c. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies.
d. Incorporation of computational cardiotoxicity models and AI-based safety pharmacology prediction.

CO's -CO4

**Self-Learning Topics:**FDA vs EMA perspectives on IND-enabling toxicology studies.Role of hERG assays in cardiac safety evaluation of new drugs.Advances in AI-driven models for predicting CNS and respiratory toxicity.

**UNIT 5** **12 Hours**

a. Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics
b. Importance and applications of toxicokinetic studies.
c. Alternative methods to animal toxicity testing.

**CO's -CO5**

**Self-Learning Topics:**Case studies on toxicokinetic-pharmacokinetic (TK-PK) correlation in drug discovery.Application of microdosing and human-on-chip approaches in toxicology.Regulatory acceptance of alternative models (EURL-ECVAM, OECD guidance).

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**Text Books:**

1.Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).

2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi

3. Drugs from discovery to approval by Rick NG.

4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan

5. OECD test guidelines.

6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals

**Web References:**

- https://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm
- **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3241981/**
- **https://www.epa.gov/comptox**
- **https://www.nature.com/articles/s41578-019-0107-0**
- **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9052050/**

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 35% |
| L4 | -- | 35% |
| L5 | -- | 15% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remember**

- Define toxicology.
- List the types of toxicology.
- What does OECD stand for?
- State the importance of Good Laboratory Practice (GLP).
- Name two international regulatory agencies involved in toxicity testing
- Define acute toxicity.
- List the different routes used in toxicity testing.
- What is meant by test item characterization?
- Mention two OECD guidelines used in dermal toxicity testing.
- State one method used to study eye irritation.

**L2 – Understand**

- Explain the difference between mechanistic and descriptive toxicology.
- Describe the role of ICH guidelines in toxicology studies.
- Summarize the key principles of GLP.
- Explain why regulatory toxicology is important in drug development.
- Differentiate between OECD and Schedule Y guidelines.
- Explain the difference between acute, sub-acute, and chronic toxicity studies.
- Describe the importance of test item characterization in regulatory toxicology.
- Explain how inhalation toxicity is assessed.
- Discuss the significance of dermal irritation studies in safety evaluation.
- Compare oral and dermal toxicity testing methods.

**L3 – Apply**

- Apply the principles of the Ames test to evaluate the mutagenic potential of a new drug candidate.
- Demonstrate how a micronucleus assay can be used to detect chromosomal damage.
- Use a case study to explain how teratogenicity testing is conducted in animals.
- Show how male and female reproductive toxicity studies differ in design and endpoints.
- Apply OECD guidelines to design a protocol for in vivo carcinogenicity studies.
- Apply FDA requirements to prepare a checklist of toxicity studies needed for IND submission.

- Demonstrate how hERG assay data can be used to assess cardiac safety of a new molecule.
- Apply Tier 1 safety pharmacology guidelines to evaluate CNS safety in preclinical models.
- Use OECD guidance to design a respiratory safety pharmacology study.
- Show how safety pharmacology studies are integrated into the IND application process.

**L4 -Analyze**

- Compare the utility of in vitro and in vivo genotoxicity assays.
- Analyze the limitations of animal models in reproductive toxicity studies.
- Differentiate between Segment I, Segment II, and Segment III reproductive toxicity studies.
- Examine the role of genotoxicity studies in predicting carcinogenic potential.
- Critically analyze why some carcinogens show negative results in Ames tests but positive in in vivo studies.
- Differentiate between Tier 1 and Tier 2 safety pharmacology studies with examples.
- Analyze the significance of cardiac, CNS, and respiratory safety studies in preclinical drug development.
- Examine the impact of missing IND-enabling studies on drug approval timelines.
- Compare FDA and EMA perspectives on safety pharmacology requirements.
- Critically evaluate the role of safety pharmacology in reducing late-stage drug failures.

**L5 -Evaluate**

- Critically evaluate the role of toxicokinetic studies in interpreting preclinical safety data.
- Assess the advantages and limitations of saturation kinetics in toxicological assessments.
- Judge the effectiveness of 3D organoids compared to animal models in predicting human toxicity.
- Evaluate the regulatory acceptance of alternative testing models such as organ-on-chip systems.
- Appraise the role of toxicokinetic-pharmacokinetic (TK-PK) correlation in drug development.

**L6 -Create**

- Design a toxicokinetic study plan for a new anticancer drug candidate.
- Create a framework integrating microdosing and in-silico models to replace animal testing.
- Propose a novel organ-on-chip experiment to assess renal toxicity of a drug.
- Develop a regulatory submission strategy incorporating alternative toxicity testing methods.
- Formulate a research project combining toxicokinetics, computational toxicology, and AI for predictive safety assessment.

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**R25MPL203** **PRINCIPLES OF DRUG DISCOVERY** **4 0 0 4**

**Course Objectives:**

Upon completion of the course the student shall be able to:

- To explain the various stages of drug discovery.
- To appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- To explain various targets for drug discovery.
- To explain various lead seeking method and lead optimization
- To appreciate the importance of the role of computer aided drug design in drug discovery

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO4 | PO9 | PSO1 | PSO2 | |
| R25 CO203.1 | Understand the various stages of drug discovery. Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery. | 1 | 2 | 1 | 2 | 1 | 2 | 1 | L 1, L2 |
| R25 CO203.2 | Illustrate various targets for drug discovery. Explain Insilco discovery techniques, levels of protein structure, domains and applications of NMR and X-ray crystallography | 1 | 2 | 1 | 2 | 1 | 2 | - | L1, L2 |
| R25 CO203.3 | Know the various approaches for rational drug design and Summarize various virtual screening techniques for lead discovery. | 1 | 2 | 1 | 2 | 1 | 2 | - | L3, L4 |
| R25 CO203.4 | Assess the molecular docking studies for drug discovery. | 1 | 2 | 1 | 2 | 1 | 2 | - | L3, L4 |
| R25 CO203.5 | Appreciate the importance of the role of computer aided drug design in drug discovery . | 1 | 2 | 1 | 2 | 1 | 2 | 1 | L5,L6 |

## SYLLABUS

**UNIT 1.** **12 Hours**

a. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.
b. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.
c. AI approaches in target identification and prediction.

CO's-CO1

**Self-Learning Topics:** Case study: CRISPR technology in drug target validation. Role of bioinformatics databases (PDB, KEGG, UniProt) in target discovery. Emerging role of AI-driven drug discovery platforms (e.g., AlphaFold).

**UNIT 2** **12 Hours**

a. Lead Identification- combinatorial chemistry & high throughput screening, insilico lead discovery techniques, Assay development for hit identification.
b. Protein structure
c. Levels of protein structure, Domains, motifs, and folds in protein structure.
d. Computational prediction of protein structure: Threading and homology modelling methods. Application of NMR and X-ray crystallography in protein structure prediction.
e. AlphaFold and DeepMind AI applications in protein folding prediction.

CO's-CO2

**Self-Learning Topics:** Applications of AlphaFold in drug discovery. Case study on virtual screening pipelines for antiviral drugs

**UNIT 3** **12 Hours**

a. Rational Drug Design
b. Traditional vs rational drug design, Methods followed in traditional drug design,
c. High throughput screening, Concepts of Rational Drug Design, Rational Drug
d. Design Methods: Structure and Pharmacophore based approaches
e. Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.

CO's-CO3

**Self-Learning Topics:**Explore Lipinski's Rule of Five in drug-likeness.Role of predictive AI tools in accelerating rational design.

**UNIT 4** **12 Hours**

a. Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship

b. History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

CO's-CO4

**Self-Learning Topics:** Comparison of AutoDock, GOLD, and Schrödinger Glide software. Applications of molecular dynamics in validating docking studies. Case study: Docking in COVID-19 drug repurposing.

**UNIT 5** **12 Hours**

a. QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

b. Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

CO's-CO5

**Self-Learning Topics:**Study how QSAR models are used in predicting ADMET properties.Role of deep learning in enhancing 3D-QSAR predictions.Explore databases (ChEMBL, PubChem) for QSAR model development.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books:**

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.

2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.

3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.

4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.

7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

**Web References:**

- https://www.sciencedirect.com/science/article/pii/S2095177925001741
- https://mmrjournal.biomedcentral.com/articles/10.1186/s40779-023-00446-y
- https://www.nature.com/articles/s41591-024-03434-4
- https://pmc.ncbi.nlm.nih.gov/articles/PMC10302890/
- https://pmc.ncbi.nlm.nih.gov/articles/PMC10380192/

**Internal Assessment Pattern**

| CognitiveLevel | InternalAssessment#1(%) | InternalAssessment#2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 35% |
| L4 | -- | 35% |
| L5 | -- | 15% |
| L6 | | 15% |
| Total(%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remember**

- Define target identification in the drug discovery process.
- List the major steps involved in modern drug discovery.
- What is the role of proteomics in target validation?
- Name two examples of antisense technologies used in drug discovery.
- State the importance of transgenic animals in target validation.
- Define combinatorial chemistry in the context of lead identification.
- List the different levels of protein structure.
- Name two computational methods used for protein structure prediction.
- What is high-throughput screening?
- State the role of NMR in protein structure prediction

**L2 – Understand**

- Explain the difference between target identification and target validation.
- Describe how genomics contributes to drug target discovery.
- Explain the principle of nucleic acid microarrays in drug discovery.
- Differentiate between siRNA and antisense oligonucleotides in gene silencing.
- Summarize the economic challenges of modern drug discovery.
- Differentiate between threading and homology modeling.
- Explain how combinatorial chemistry accelerates the lead discovery process.
- Describe the role of in-silico methods in lead identification.
- Explain the concept of protein domains and motifs.
- Discuss how X-ray crystallography is applied in protein structure determination.

**L3 – Apply**

- Apply Lipinski's Rule of Five to evaluate the drug-likeness of a new compound.
- Demonstrate how pharmacophore mapping can be used in virtual screening.
- Illustrate with an example how structure-based drug design can improve drug potency.
- Use a case study to show how high-throughput screening identifies lead molecules.
- Apply pharmacophore-based screening in designing anti-cancer drug candidates.
- Perform a docking study on a known protein target and interpret binding affinity scores.
- Apply Hansch analysis to predict the biological activity of a given set of compounds.
- Use Free–Wilson analysis to evaluate substituent effects in a drug series.
- Demonstrate how rigid docking differs from flexible docking with an example.
- Apply QSAR parameters to predict lipophilicity and activity of a lead compound.

**L4 – Analyze**

- Compare traditional and rational drug design with suitable examples.
- Analyze the differences between structure-based and pharmacophore-based drug design approaches.
- Examine the role of virtual screening in reducing time and cost in drug discovery.
- Critically evaluate how rational drug design has impacted the development of antiviral drugs.
- Break down the workflow of a rational drug design pipeline and identify its strengths and limitations.

- Differentiate between SAR and QSAR approaches in drug design with examples.
- Analyze the strengths and weaknesses of rigid vs flexible docking methods.
- Examine the relationship between physicochemical parameters and biological activity.
- Compare Hansch and Free–Wilson analyses in QSAR.
- Critically evaluate the role of docking in virtual screening workflows.

**L5 – Evaluate**

- Critically evaluate the advantages and limitations of regression analysis in QSAR modeling.
- Assess the reliability of COMFA and COMSIA approaches in predicting drug activity.
- Evaluate the role of multivariate statistical methods in handling large chemical datasets.
- Judge the accuracy of QSAR models when applied to ADMET (Absorption, Distribution, Metabolism, Excretion, Toxicity) predictions.
- Appraise the contribution of AI and deep learning in enhancing QSAR models compared to traditional methods.

**L6 – Create**

- Design a 3D-QSAR study to predict the activity of a new series of anticancer drugs.
- Create a machine-learning based QSAR model integrating cheminformatics data for antibiotic drug discovery.
- Develop a predictive pipeline combining COMFA, COMSIA, and deep learning for toxicity prediction.
- Propose a novel workflow that integrates pharmacophore mapping with QSAR for hit-to-lead optimization.
- Formulate a research project using QSAR and AI tools to identify potential drug candidates for neurodegenerative diseases.

M. Pavani

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**R25MPL204** **CLINICAL RESEARCH AND PHARMACOVIGILANCE** **4 0 0 4**

**Course Objectives:**

Upon completion of the course, the student shall be able to

- To explain the regulatory requirements for conducting clinical trial
- To demonstrate the types of clinical trial designs
- To explain the responsibilities of key players involved in clinical trials
- To execute safety monitoring, reporting and close-out activities
- To explain the principles of Pharmacovigilance
- To detect new adverse drug reactions and their assessment
- To perform the adverse drug reaction reporting systems and communication in pharmacovigilance

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DoK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO8 | PO9 | PO10 | PSO1 | PSO2 | |
| R25CO204.1 | Understand various regulatory requirements for conducting clinical trials. | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 1 | L 1, L2 |
| R25CO204.2 | Demonstrate the types of clinical trial designs and explain the responsibilities of key players involved in clinical trials. | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 1 | L1, L2 |
| R25CO204.3 | Construct the documentation process of clinical trials. Detect new adverse drug reactions and their assessment | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 1 | L 3, L4 |
| R25CO204.4 | Basic aspects, terminology and establishment of pharmacovigilance and contrast the roles and responsibilities of Pharmacovigilance. | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 1 | L3, L4 |
| R25CO204.5 | Appraise various methods of ADR reporting and tools used in Pharmacovigilance and Predict principles and concepts of Pharmacoepidemiology, Pharmacoeconomics and Safety pharmacology. | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 1 | L5, L6 |

**UNIT 1.** 12 Hours

a. Regulatory Perspectives of Clinical Trials:
b. Origin and Principles of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR
c. Informed Consent Process: Structure and content of an Informed Consent
d. Process Ethical principles governing informed consent process.

CO's-CO1

**Self-Learning Topics:** Case studies on ethical issues in clinical trials (Tuskegee Syphilis Study, HeLa cells),Recent updates in Schedule Y regulations,Role of ICMR guidelines in Indian clinical research

**UNIT 2** 12 Hours

a. Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional
b. Clinical Trial Study Team
c. Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

CO's-CO2

**Self-Learning Topics:** Role of Artificial Intelligence in clinical trial design and patient recruitment, Recent trends in virtual/decentralized clinical trials, Case study: Adaptive design used in COVID-19 vaccine trials

**UNIT 3** 12 Hours

a. Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT
b. Adverse Drug Reactions: Definition and types. Detection and reporting methods.
c. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions;
d. Terminologies of ADR.

CO's-CO3

**Self-Learning Topics:** Prepare a mock clinical trial protocol for a hypothetical new drug, Use of eCRFs and EDC in modern clinical trials. Role of Data Safety Monitoring Boards (DSMBs) in CTs

**UNIT 4** 12 Hours

a. Basic aspects, terminologies and establishment of pharmacovigilance
b. History and progress of pharmacovigilance, Significance of safety monitoring,
c. Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance.
d. Roles and responsibilities in Pharmacovigilance.
e. Adverse drug reactions; Terminologies of ADR.

CO's-CO4

**Self-Learning Topics:** Compare India's PvPI with WHO-UMC's pharmacovigilance frame work, Case study on a major drug withdrawn due to ADRs (e.g., Rofecoxib/Vioxx) Role of hospitals in pharmacovigilance centres.

**UNIT 5** 12 Hours

**A.** Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance.

Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

**B.** Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

CO's-CO5

**Self-Learning Topics:** Explore WHO-VigiBase as a global ADR monitoring platform Use of AI in detecting hidden ADR signals Case study: Pharmacovigilance of COVID-19 vaccines Case study on cost-effectiveness of a recently approved drug Application of pharmacoepidemiology in post-marketing safety

Board of Studies: Pharmacy
Approved in BOS No: 01, 22nd October, 2025
Approved in ACM No: 01

**Text Books:**

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.

2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.

7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynessign, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

**Web References:**

- https://www.ppd.com/our-solutions/clinical/clinical-development-consulting/adaptive-trial-designs
- https://www.finenessinstitute.com/pv-softwares/
- https://www.biomapas.com/selecting-a-pharmacovigilance-drug-safety-database
- https://en.wikipedia.org/wiki/VigiBase

**Internal Assessment Pattern**

| Cognitive Level | Internal Assessment #1(%) | Internal Assessment #2(%) |
|---|---|---|
| L1 | 35% | -- |
| L2 | 40% | -- |
| L3 | 25% | 35% |
| L4 | -- | 35% |
| L5 | -- | 15% |
| L6 | | 15% |
| Total (%) | 100% | 100% |

**Sample Short and Long Answers questions of Various Cognitive Levels**

**L1 – Remember**

- Define Good Clinical Practice (GCP).
- What is Schedule Y?
- List the main principles of ICH-GCP guidelines.
- What is an Institutional Review Board (IRB)?
- State two ethical principles governing informed consent.
- List the types of clinical trial designs.
- Define randomized controlled trial (RCT).
- Identify two examples of observational studies.
- Who is a study sponsor in a clinical trial?
- Mention the role of a Contract Research Organization (CRO).

**L2 – Understand**

- Explain the importance of ethical committees in clinical trials.
- Describe the structure and essential components of an informed consent form.
- Discuss how ICMR guidelines influence biomedical research in India.
- Compare the role of ICH-GCP and Schedule Y in clinical research regulation.
- Explain why informed consent is essential in human trials.
- Explain the difference between RCT and Non-RCT.
- Describe the responsibilities of a study coordinator.
- Compare cohort and case-control studies with examples.
- Discuss the role of a CRO in clinical trial management.
- Explain why observational studies are important in clinical research

**L3 – Apply**

- Apply the principles of GCP to design the outline of a clinical trial protocol.
- Demonstrate how to prepare a Case Report Form (CRF) for recording adverse events.
- Use the concept of adverse drug reaction (ADR) classification to categorize a given case scenario.
- Illustrate the steps for reporting a suspected adverse drug reaction in a hospital setting.
- Apply the criteria of severity and seriousness to evaluate a sample ADR case
- Apply the concept of pharmacovigilance to design a simple ADR reporting system for a hospital.
- Demonstrate how WHO-UMC causality assessment can be used for an ADR case study.
- Illustrate the role of PvPI in ensuring drug safety in India with an example.
- Apply pharmacovigilance principles to identify risks in a newly launched drug.
- Use ADR terminologies to classify a real-world adverse reaction case.

**L4 – Analyze**

- Analyze the differences between Investigator Brochure, Protocol, and Clinical Study Report.
- Compare the effectiveness of paper-based CRFs vs. electronic data capture (EDC) systems.
- Examine the strengths and limitations of different ADR detection methods.
- Differentiate between predictable and unpredictable ADRs with examples.
- Analyze a clinical trial case where monitoring failure led to serious adverse outcomes.
- Analyze the differences between Indian (PvPI) and European (EudraVigilance) pharmacovigilance systems.
- Compare the roles of hospitals, industry, and regulators in pharmacovigilance centres.
- Examine how WHO international drug monitoring programme supports global drug safety.
- Differentiate between ADR evaluation methods used in India vs. USA (FDA MedWatch).
- Analyze a real-world example of a drug withdrawn due to pharmacovigilance data (e.g., Rofecoxib)

**L5 – Evaluate**

- Evaluate the strengths and weaknesses of spontaneous reporting systems compared to active surveillance.
- Critically assess the effectiveness of Argus, ArisG, and VigiFlow in ensuring regulatory compliance.
- Judge the reliability of statistical methods used in signal detection for ADR reporting.
- Evaluate the challenges in vaccine safety surveillance during mass immunization programs.
- Critically appraise the role of Big Data and AI in modern pharmacovigilance signal detection
- Evaluate the usefulness of pharmacoepidemiological studies in post-marketing surveillance.
- Critically assess the cost-effectiveness of a recently approved drug using pharmacoeconomic models.

**L6 – Create**

- Design a pharmacovigilance workflow for a multi-specialty hospital.
- Create an ADR reporting form tailored for community pharmacists.
- Propose a new digital tool to improve spontaneous ADR reporting among healthcare professionals.
- Develop a framework for integrating VigiBase data into national pharmacovigilance systems.
- Design a comparative study protocol to evaluate the effectiveness of two PV reporting methods.
- Design a pharmacoepidemiology study to investigate ADR patterns in elderly patients.
- Create a pharmacoeconomic model to compare two antidiabetic drugs in terms of cost-effectiveness.

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**R25MPL205** **BIOASSAYS PRACTICAL** **0 0 6 3**

**Course Objectives:**

- To record and analyze dose–response curves (DRCs) of agonists and antagonists using suitable isolated tissue preparations, including determination of $PA_2$ values.
- To determine the potency of unknown drug samples by applying bioassay methods such as matching, interpolation, bracketing, and multiple-point bioassays.
- To evaluate the pharmacological effects of various drugs on isolated organ systems, with emphasis on isolated tissue and heart preparations.
- To record and interpret cardiovascular parameters such as blood pressure, heart rate, and ECG in experimental animals for drug response studies.

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping With POs and PSOs | | | | | | | DOk |
|---|---|---|---|---|---|---|---|---|---|
| | | PO1 | PO2 | PO3 | PO6 | PO8 | PS01 | PSO2 | |
| R25CO205.1 | Record the DRC of agonist using suitable isolated tissues preparation. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L5,L2 |
| R25CO205.2 | Determine the strength of unknown sample by interpolation bioassay by using suitable tissue preparation | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L5,L3 |
| R25CO205.3 | Recording of rat BP, heart rate and ECG. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L1,L2 |
| R25CO205.4 | Estimation of PA2 values of various antagonists using suitable isolated tissue preparations. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L5,L3 |

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

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## COURSE CONTENT:

| S.No | Name of the Experiment | CO's |
|---|---|---|
| 01 | To record the DRC of agonist using suitable isolated tissues preparation. | CO1 |
| 02 | To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation. | CO2 |
| 03 | To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation. | CO2 |
| 04 | To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation | CO2 |
| 05 | To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation | CO4 |
| 06 | To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation. | CO4 |
| 07 | Estimation of PA2 values of various antagonists using suitable isolated tissue preparations. | CO4 |
| 08 | To study the effects of various drugs on isolated heart preparations | CO1 |
| 09 | Recording of rat BP, heart rate and ECG | CO3 |
| 10 | Recording of rat ECG | CO3 |

**Reference Books**

1.Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

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**R25MPL206 PHARMACOLOGICAL DRUG DEVELOPMENT PRACTICAL 0 0 6 3**

**Course Objectives:**

1. To train students in conducting preclinical studies including drug absorption using everted rat ileum, acute oral and dermal toxicity, and repeated dose toxicity with biochemical, hematological, urine, functional, and histopathological evaluations.
2. To enable students to assess drug-induced genotoxicity through mice bone-marrow chromosomal aberration test.
3. To develop competency in designing clinical trial protocols, preparing ADR monitoring protocols, and practicing ADR reporting as per regulatory guidelines.
4. To provide skills in applying in-silico approaches such as molecular docking, pharmacophore-based screening, and QSAR studies for drug discovery and development.

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping With POs and PSOs | | | | | | | DOk |
|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO4 | PO6 | PO8 | PS01 | PSO2 | |
| R25CO206.1 | Study the acute oral and dermal toxicity studies as per OECD guidelines. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L4 |
| R25CO206.2 | Study the drug absorption studies by averted rat ileum preparation. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L1,L3 |
| R25CO206.3 | Design the clinical trail and ADR monitoring protocols. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L4, L6 |
| R25CO206.4 | Interpret *in-silico* pharmacophore based screening and QSAR studies by using software. | 2 | 2 | 2 | 1 | 3 | 2 | 1 | L1 |

Board of Studies: Pharmacy

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## COURSE CONTENT:

| S.No | Name of the Experiment | CO's |
|---|---|---|
| 01 | Drug absorption studies by averted rat ileum preparation. | CO2 |
| 02 | Acute oral toxicity studies as per OECD guidelines. | CO1 |
| 03 | Acute dermal toxicity studies as per OECD guidelines. | CO1 |
| 04 | Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies. | CO2 |
| 05 | Drug mutagenicity study using mice bone-marrow chromosomal aberration test. | CO2 |
| 06 | Protocol design for clinical trial.(3 Nos.) | CO3 |
| 07 | Design of ADR monitoring protocol. | CO3 |
| 08 | In-silico docking studies. (2 Nos.) | CO4 |
| 09 | In-silico Pharmacophore based screening. | CO4 |
| 10 | In-silico QSAR studies. | CO4 |
| 11 | ADR reporting | CO3 |

**Reference Books**

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

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**R25MPL208** **ENTREPRENEURSHIP MANAGEMENT** **4 0 0 0**

(M.PHARM COMMON FOR ALL SPECIALIZATIONS)

**Course Objectives:**

- To impart knowledge and skills necessary to train students in entrepreneurship management.
- To enable students to understand the conceptual framework and role of enterprises in economic development.
- To develop entrepreneurial competencies such as motivation, creativity, and decision-making.
- To provide insights into launching, organizing, and managing enterprises.
- To equip students with strategies for growth, networking, and project proposal preparation.

**Course Outcomes**

At the end of the course, students will be able to:

| Course Code | Course Outcomes (COs) | Mapping with POs and PSOs | | | | | | | | DOK |
|---|---|---|---|---|---|---|---|---|---|---|
| | | PO2 | PO3 | PO8 | PO4 | PO5 | PO11 | PSO1 | PSO2 | |
| R25CO208.1 | Explain the role of enterprises in the national and global economy and identify different types of enterprises with their merits and demerits. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L1, L2 |
| R25CO208.2 | Analyze entrepreneurial motivation and competencies, and develop self-awareness, creativity, and interpersonal skills needed for entrepreneurship. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L1, L2, L3 |
| R25CO208.3 | Apply methods for launching and organizing enterprises, including market assessment, feasibility studies, resource mobilization, and cost/quality management. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L 2, L3 |
| R25CO208.4 | Evaluate growth strategies, networking opportunities, diversification techniques, and performance control measures for enterprises. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L3, L4 |
| R25CO208.5 | Prepare a project proposal and feasibility report for starting a new enterprise, including planning, resource mobilization, and implementation strategies. | 1 | 2 | 3 | - | - | 2 | 2 | 3 | L4, L5, L6 |

## SYLLABUS

**UNIT I:** **10 Hours**

**Conceptual Frame Work:** Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government

policies and schemes for enterprise development. Institutional support in enterprise development and management.

**CO's–CO1**

**Self Learning topics**: Research government policies and schemes for enterprise development in India (e.g., Startup India, MSME schemes), Compare the role of enterprises in national vs. global economy. Study case studies of successful enterprises and analyze factors contributing to success.

**UNIT II:** **10 Hours**

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

**CO's–CO2**

**Self Learning topics:** Research traits of successful entrepreneurs and how they develop skills like creativity and assertiveness, Explore exercises for improving interpersonal skills and leadership qualities.

**UNIT III:** **10 Hours**

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

**CO's–CO3**

**Self Learning topics:** Conduct a mini-market research exercise for a hypothetical business idea, Practice preparing a SWOT analysis for an existing company or startup.

**UNIT IV:** **8 Hours**

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measure, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, coordination and feasibility study.

**CO's–CO4**

**Self Learning topics:** Explore examples of diversification and expansion in real enterprises, Research joint ventures and strategic alliances in Indian and global business.

**UNIT V:** **7 Hours**

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

**CO's-CO5**

**Self Learning topics:** Prepare a simple project proposal for a hypothetical new enterprise.

Board of Studies: Pharmacy

Approved in BOS No: 01, 22nd October, 2025

Approved in ACM No: 01

**Text Books**


1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson.


**Web References**

1. https://www.babson.edu/professional/entrepreneurship-education/what-is-babson-academy/resources-and-tips/
2. https://www.coursera.org/browse/business/entrepreneurship
3. https://ocw.mit.edu/collections/entrepreneurship/
4. https://online.hbs.edu/courses/entrepreneurship-essentials/

**Assessment Pattern:**

1. Evaluated for a total of 100 marks.
2. A student can Prepare project proposals and feasibility reports for new enterprises by planning resource mobilization, implementation, and evaluation effectively.
3. **Internal Assessment (40 Marks)**

Class Tests / Assignments (15 Marks): Short answer / case-based questions from Units I–III.

Presentations / Seminars (10 Marks): Students present on entrepreneurial case studies, government schemes, or startup ideas.

Class Participation & Attendance (5 Marks):Engagement in discussions, interaction, and group activities.

Mini Project / Report (10 Marks): A short write-up on an existing entrepreneur/startup or analysis of an enterprise's SWOT.

**2. End Semester Evaluation (60 Marks)**

**Section A:** Short Answer Questions (10 Marks)

5 questions × 2 marks (covering fundamental concepts from all units).

**Section B:** Medium Length Questions (30 Marks)

5 questions × 6 marks each (from Units I–IV, focusing on application and analysis).

**Section C:** Long Answer / Case Study (20 Marks)

2 questions × 10 marks each (Unit III–V: project proposal, growth strategies, resource mobilization).

M. pavani

**Chairperson**
**Board of Studies**

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