FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutics)**

Semester: **I**

Course Code: **108300101**

Course Title: **Modern Pharmaceutical Analytical Techniques**

Course Objectives: Upon completion of the course the student shall be able to

1. Chemicals and Excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	**UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV – Visible Spectroscopy **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 **Spectroflourimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications	**11**
2	**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	**10**

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3	**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, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy	**10**
4	**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 g) Affinity chromatography	**10**
5	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 electric focusing b. **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.	**9**
6	**Potentiometry**: Principle, thermal transitions and instrumentation (heat flux and power compensation and designs) working, Ion selective Electrodes and Application of potentiometry. **Thermal Analysis:** Polymer behaviour, factors affecting and instrumentation, and working, application of TGA	**9**

Reference 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, Eastern press, 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 - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7	Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Pedagogy:

1. ICT tools (LCD projector, Laptop)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
40	40	10	10	0	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

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Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Explain theory and applications of various spectroscopic techniques like UV-visible, IR, fluorimetric and atomic spectroscopy	**30**
CO-2	Explain theory and applications of various chromatographic separation techniques	**20**
CO-3	Learn theory and applications of Mass and NMR spectroscopy	**30**
CO-4	Understand basic principles and applications of electrophoresis and X-ray methods	**10**
CO-5	Learn theory and applications of thermal and potentiometric methods of analysis	**10**

Curriculum Revision:	
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CVM UNIVERSITY
Aegis: Charutar Vidya Mandal (Estd.1945)

FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutics)**

Semester: **I**

Course Code: **108320102**

Course Title: **Drug Delivery Systems**

Course Objectives: Upon completion of the course, student shall be able to understand

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of delivering system
3. The formulation and evaluation of Novel drug delivery systems.

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	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.	10
2	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.	10
3	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 mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10

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4	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers	**6**
5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	**10**
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	**8**
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	**6**

Reference 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 Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4	N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5	S. P. Vyas and R. K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Pedagogy:

1. ICT based (Presentations, Audio Video Tools, software programs)
2. Traditional methods (Blackboard learning)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
20	40	16	15	8	1	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Learn the basic concepts of sustained/controlled release formulations and personalized medicines	**26**
CO-2	Apply the concept of stimuli responsive system in designing of rate-controlled drug delivery systems	**12**
CO-3	Apply the knowledge of physiological parameters, properties of drugs and polymers for various drug delivering systems	**42**
CO-4	Know the factors affecting delivery and novel formulations of biomolecules	**20**

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutics)**

Semester: **I**

Course Code: **108320103**

Course Title: **Modern Pharmaceutics**

Course Objectives: Upon completion of the course, student shall be able to understand

1. The elements of preformulation studies.
2. The Active Pharmaceutical Ingredients and Generic drug Product development
3. Industrial Management and GMP Considerations.
4. Optimization Techniques & Pilot Plant Scale Up Techniques
5. Stability Testing, sterilization process & packaging of dosage forms

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability. Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	20
2	Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10

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3	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance. Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	**10**
4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility	**10**
5	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	**10**

Reference 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 Leon 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.
7	Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8	Physical Pharmacy; By Alfred martin
9	Bentley's Textbook of Pharmaceutics – by Rawlins.
10	Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11	Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12	Drug formulation manual; By D.P.S. Kohli and D. H. Shah. Eastern publishers, New Delhi.
13	How to practice GMPs; By P. P. Sharma. Vandhana Publications, Agra.
14	Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15	Pharmaceutical Preformulations; By J.J. Wells.
16	Applied production and operations management, By Evans, Anderson, Sweeney and Williams.
17	Encyclopaedia of Pharmaceutical technology, Vol I – III.

Pedagogy:

1. ICT based (Presentations, Audio Video Tools, software programs)
2. Traditional methods (Blackboard learning)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
20	40	16	15	8	1	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

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Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Know elements of pre-formulation studies	**16**
CO-2	Understand the concept and importance of optimization techniques in development of pharmaceutical formulations	**15**
CO-3	Learn the concept of pharmaceutical calibration and validation as per regulatory guidelines	**15**
CO-4	Know the policies of current good manufacturing practices and Total Quality Management	**18**
CO-5	Understand and learn the physics of tablets compression and in vitro – in vivo evaluation	**16**
CO-6	Apply the knowledge of statistical inferences in pharmaceutical formulations	**20**

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutics)**

Semester: **I**

Course Code: **108320104**

Course Title: **Regulatory Affairs**

Course Objectives: Upon completion of the course, student shall be able to understand

1. The Concepts of innovator and generic drugs, drug development process
2. The Regulatory guidance's and guidelines for filing and approval process
3. Preparation of Dossiers and their submission to regulatory agencies in different countries
4. Post approval regulatory requirements for actives and drug products
5. Submission of global documents in CTD/ eCTD formats
6. Clinical trials requirements for approvals for conducting clinical trials
7. Pharmacovigilance and process of monitoring in clinical trials

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	a. 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. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs, ways and means of US registration for foreign drugs	15
2	CMC, post approval 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. Regulatory requirements of EU, MHRA, TGA and ROW countries.	15

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3	Non-clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	**15**
4	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	**15**

Reference Books:

1	Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2	The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and 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, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4	Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5	FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6	Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
7	www.ich.org/
8	www.fda.gov/
9	europa.eu/index_en.htm
10	https://www.tga.gov.au/tga-basics

Pedagogy:

1. ICT based (Presentations, Audio Video Tools)
2. Traditional methods (Blackboard learning)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
35	40	10	10	5	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

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Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Learn the preparation and management of documentation in pharmaceutical industry	**15**
CO-2	Understand the concept of generic drugs product development, regulatory requirement for approval and post approval	**20**
CO-3	Know the ICH guidelines and global regulatory requirements	**25**
CO-4	Prepare dossiers and investigator brochure as per regulatory agencies	**15**
CO-5	Understand and interpret the guidelines of clinical trials	**25**

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutics)**

Semester: **I**

Course Code: **108320105**

Course Title: **Pharmaceutics Practical-I**

Course Objectives: Upon completion of the course the student shall be able to

1. The analysis of drugs using different sophisticated instrumentation techniques.
2. Carry out preformulation studies and determine effect of different factors on tablet performance.
3. Formulate and evaluate different novel drug delivery systems.

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
-	-	12	6	-	-	50/20	100/40	150/60

* **J**: Jury; **V**: Viva; **P**: Practical

List of Practicals:

1	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2	Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3	Experiments based on HPLC
4	Experiments based on Gas Chromatography
5	Estimation of riboflavin/quinine sulphate by fluorimetry
6	Estimation of sodium/potassium by flame photometry
7	To perform In-vitro dissolution profile of CR/ SR marketed formulation
8	Formulation and evaluation of sustained release matrix tablets
9	Formulation and evaluation osmotically controlled DDS
10	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11	Formulation and evaluation of Mucoadhesive tablets.
12	Formulation and evaluation of transdermal patches.
13	To carry out preformulation studies of tablets.
14	To study the effect of compressional force on tablets disintegration time.
15	To study Micromeritic properties of powders and granulation.
16	To study the effect of particle size on dissolution of a tablet.
17	To study the effect of binders on dissolution of a tablet.
18	To plot Heckal plot, Higuchi and Peppas plot and determine similarity factors.

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Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Analyze pharmacopeial compounds and their formulations by modern analytical techniques	**35**
CO-2	Perform the pre-formulation studies for formulations	**27**
CO-3	Formulate and evaluate various types of dosage form i.e. tablets, patch, TDDS	**33**
CO-4	Study the model fitting for release pattern of drug	**5**

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutics)**

Semester: **I**

Course Code: **108320106**

Course Title: **Seminar/Assignment**

Course Objectives:
At completion of this course student shall be able to
1. Develop skills to collect and organize data
2. Acquire knowledge on the current topic in field Pharmaceutical science
3. Perform effective presentation and communication skill

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
-	-	8	4	-	-	100/40	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Guidelines

Seminar will be given on the current topic in the field of Pharmaceutical science. Student will gather information, compile data in the form of report and give presentation on the topic given.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Develop skills to collect and organize information for the given topic	25
CO-2	Compile data and develop write-up skill on the topic given for seminar presentation	25
CO-3	Develop communication and presentation skills	25
CO-4	Effectively respond to the queries and questions raised	25

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