SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)
Syllabus with effect from the Academic Year 2022-2023

PROGRAMME STRUCTURE
Master of Pharmacy in Pharmaceutics
M. Pharm (Pharmaceutics) Semester: I

Programme Outcome (PO) - For M. Pharm (MPH) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: 1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. 2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. 3. Independently carry out research/investigation and development work to solve problem. 4. Write and present a substantial scientific document and technical report. 5. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.
Programme Specific Outcome (PSO) - For M. Pharm (MPH) Semester - I	After completion of the program students are able to: 1. Students will learn various analytical techniques and its application in pharmaceutical industry. The skill of instrumentation will help students to analyze active constituents from various dosage forms in their further research. 2. Students will learn the concept and design various novel drug delivery systems for its delivery. 3. Students will learn the concept of protein drug delivery and vaccine drug delivery 4. Students will also understand the need and learn the concept of various documentation used in pharmaceutical industry related to drug discovery 5. Students will understand the concept of various documentation pertaining to product approval processes and other regulatory requirements for various countries.

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M. Pharm (Pharmaceutics) Semester: I

To Pass	At least 50% Marks in the University Examination in each paper and 50% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & Research work.

Course Type	Course Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks		
						Internal	External	Total
Employability, Entrepreneurship	PP01CMAT01	Modern Pharmaceutical Analytical Techniques	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP01CMPH01	Drug Delivery System	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP01CMPH02	Modern Pharmaceutics	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP01CMPH03	Regulatory Affairs	T	4	3	25	75	100/50
Employability, Entrepreneurship, Skill development	PP01CMPH04	Pharmaceutics Practical- I	P	6	6	50	100	150/75
Employability, Skill development	PP01SMPH01	Seminar/ Assignment	S	4	-	100	-	100/50
			Total:	**26**	**-**	**250**	**400**	**650/325**

Master of Pharmacy
M. Pharm, Pharmaceutics, Semester - I

Course Code	PP01CMAT01	Title of the Course	Modern Pharmaceutical Analytical Techniques
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	1. The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. 2. The various modern analytical techniques like UV-Visible, IR, NMR, Mass are taught to enable students to understand and apply principles involved in the determination of pharmaceuticals. 3. Chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of pharmaceuticals 4. Thermal Techniques and electrophoresis are taught which are essential for the

Course Content		
Unit	**Description**	**60 Hrs**
I	**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. Multi Component Methods of analysis **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, Data Interpretation. **c. Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of the drug that can be analysed by flourimtery), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	**18**
II	**a. NMR spectroscopy**: 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. **b. 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	**12**

III	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: • High Performance Thin Layer Chromatography • Ion exchange chromatography • Column chromatography • Gas chromatography • High Performance Liquid chromatography • Ultra High Performance Liquid chromatography • Affinity chromatography • Gel Chromatography	**15**
IV	**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 **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.	**06**
V	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **Thermal Techniques**: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	**09**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Upon completion of the subject student shall be able to	
1.	Theorize the fundamentals of modern analytical techniques for the analysis of pharmaceuticals
2.	Optimize the experimental conditions of modern pharmaceutical analytical instruments
3.	Analyze or infer the results based on analytical data or observations recorded
4.	Apply modern pharmaceutical analytical techniques for the analysis of pharmaceuticals

Suggested References:	
Sr. No	**References**
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, Vol 11, Marcel. Dekker Series
8	Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi
9	Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982
10	Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	PP01CMPH01	Title of the Course	Drug Delivery System
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	
1.	The various approaches for development of novel drug delivery systems.
2.	The criteria for selection of drugs and polymers for the development of controlled delivery system
3.	The formulation and evaluation of protein and peptide drug delivery.
4.	The mucosal and Transdermal delivery of various vaccines

Course Content

Unit	Description	Hrs.
I	**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 medicines.	**12**
II	**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. Advances in oral controlled drug delivery systems.	**12**
III	**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**
IV	**Occular Drug Delivery Systems**: Barriers of drug permeation, Methods to overcome barriers	**4**
V	**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation	**10**

VI	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	**6**
VII	**Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines	**6**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	**Details of Evaluation**	**Marks**
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Upon completion of this course, students will be able to	
1.	Acquire the basic aspect of sustained and rate controlled drug delivery system in the field of pharmaceutical sciences.
2.	Interpret the formulation susceptibility, strategy and justification of available various marketed formulation of Ocular and Gastro-retentive formulations.
3.	Evaluate the element of compatibility and stability in the selection of active pharmaceutical ingredients and excipients for the development of transdermal drug delivery system.
4.	Theorize the concept, usefulness and mechanism of biological matrices like proteins, peptides and vaccines in drug delivery system.

Suggested References:	
Sr. No	**References**
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 WileyInterscience 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

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	PP01CMPH02	Title of the Course	Modern Pharmaceutics
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	1. The elements of pre-formulation studies. 2. Validation concept and its application. 3. GMP Considerations and its organizational structure, working. 4. ICH guidelines related to stability and product development 5. Principles of tablet manufacturing, various mechanisms and drug release phenomena.

Course Content

Unit	Description	Hrs.
I	**Pre-formulation studies:** Introduction/concept, Fundamental and derived properties of drug substance in Pre-formulation profiling, Role of Pre-formulation in Drug Discovery and in Drug Development Significance and methods for pre-formulation studies: a. Organoleptic properties, Particle size, shape and surface area, Solid form selection (Amourphous, Crystalline, Polymorph, Solvate, Hydrate, Co-crystal) b. Solubility studies: pH-solubility profile, solubility in pharmaceutical solvents, permeability studies, BCS classification, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. c. Stability testing studies, Hygroscopicity, Moisture/Solvent Content d. OVIs and its regulatory limits Pre-formulation protocol, Pre-formulation worksheet	**12**
II	**Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Types 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).	**10**
III	**cGMP**: cGMP guidelines according to schedule M, USFDA: Organization and personnel	**12**

	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, Good Distribution Practice. Comparative GMP of USFDA with EMEA, WHO and PIC.	
IV	**General introduction to ICH guidelines:** History of ICH, Objective of ICH, Overview of all ICH Guidelines - QSEM and Special emphasis to the Q series Guidelines. a. ICH Q1 guideline: Drug Stability for stability testing of drug substances and drug products b. ICH Q8 guideline: Quality by Design and Process development report. c. ICH Q9 guideline: Quality risk management- Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering.	**12**
V	**Principles of Tablet Manufacturing - Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles.	**07**
VI	**Principles of Drug Release, Dissolution statistics and product development-** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Similarity factors – f_2 and f_1, Higuchi and Peppas plot, Dosage form specific Pre-formulation Studies	**07**

Teaching-Learning Methodology	9. Students will be oriented about the course content in the first session of the course 10. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 11. Virtual teaching and examination will also utilized for the learners of the course. 12. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 13. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 14. Internal theory test will be conducted as a part of regular curriculum. 15. Attendance will be marked for each session as a part of overall evaluation. 16. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Upon completion of this course, students will be able to	
1.	Evaluate the pre-formulation parameters in product development

2.	Comprehend the concept of validation techniques for the pharmaceutical preparations.
3.	Prepare the cGMP aspects in Pharmaceutical Industry.
4.	Appraise the importance of significance of Quality.
5.	Theorize the basic principle of tablet compression, punching techniques and also its characteristics like dissolution parameters, diffusion parameters and pharmacokinetics study.

Suggested References:	
Sr. No	**References**
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: Parenteral medications Vol. 1-2; By Leon Lachmann
4	Modern Pharmaceutics; By Gillbert and S. Banker
5	Remington's Pharmaceutical Sciences
6	Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
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

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	PP01CMPH04	Title of the Course	Regulatory Affairs
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	6. The Concepts of innovator and generic drugs, drug development process. 7. The Regulatory guidance's and guidelines for filing and approval process. 8. Preparation of Dossiers and their submission to regulatory agencies indifferent countries. 9. Post approval regulatory requirements for actives and drug products. 10. Submission of global documents in CTD/ eCTD formats. 11. Clinical trials requirements for approvals for conducting clinical trials. 12. Various aspects of Industrial management in terms of drug production.

Course Content		
Unit	**Description**	**Hrs.**
I	**Good Documentation Practice –** Introduction, Importance, General Requirements **Documentation in Pharmaceutical industry**: Documentation in Pharmaceutical industry: a. Manufacturing and control documents: DMF, BMR, MFR and Routine Records b. Quality Assurance Documents: SOP, Audit Documents c. Store Management documents: Stock reconciliation records for Raw material, finished products and packaging material d. Maintenance and Environmental Control Related documents e. Consumer Related Documents: Product recall, complain traceability document, Preventive Maintenance record f. Exploratory Product Development Brief (EPDB) for drug product and drug substance SUPAC and its filing documents, distribution records, drug product performance, in-vitro	**12**
II	**Principles of Drug Discovery and Development:** Introduction, Drug Discovery and Development Process Outline, Clinical research and its phases, Development and informational contents of following regulatory submission documents/applications: a. Investigational New Drugs Application (IND), Investigator's Brochure (IB), Investigation Medicinal Product Dossier (IMPD) b. New Drug Application (NDA), CTD, eCTD, DMF	**12**

	c. Abbreviated New Drug Application (ANDA), d. IVIVC, BA-BE studies	
III	**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	**12**
IV	**Dossier Requirements –** Introduction and overview of dossiers, contents and organization of dossiers, Regulation for combination products and medical devices, CTD and ECTD format, ACTD, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	**12**
V	**Industrial 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.	**12**

Teaching-Learning Methodology	17. Students will be oriented about the course content in the first session of the course 18. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 19. Virtual teaching and examination will also utilized for the learners of the course. 20. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 21. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 22. Internal theory test will be conducted as a part of regular curriculum. 23. Attendance will be marked for each session as a part of overall evaluation. 24. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Upon completion of this course, students will be able to	
1.	Elucidate the concept of innovator and generic drugs, drug development process and comprehend the regulatory guidance and guidelines for filing and approval process.
2.	Categorize the preparation of dossiers and their submission to regulatory agencies in different countries in CTD/ eCTD format.
3.	Assess the post approval regulatory requirements for drug substances and drug products.
4.	Describe the concept of non-clinical drug development, regulatory requirements for conducting clinical trials and industrial management.

Suggested References:	
Sr. No	**References**
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. 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

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	PP01CMPH05	Title of the Course	Pharmaceutics Practicals- I
Total Credits of the Course	6	Hours per Week	12

Course Objectives:	1. Knowledge of various analytical instruments and its handling 2. Dissolution Profiles and Improvisation. 3. Aspects of compressional behaviour of powder 4. Knowledge of various physicochemical properties and its influence on drug performance

Course Content	
Unit	**Description**
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 Muco adhesive tablets
12	Formulation and evaluation of trans dermal 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

Teaching-Learning Methodology	1. Practical training will be facilitated by demonstrations and check-list preparation. 2. Training of instrument or equipment will be imparted with demonstration of components of equipment and standard operating procedure. 3. Students will be instructed for performance of experiment followed by recording of observation, analysis and interpretation of data and discussion on the conclusion. 4. Quiz, viva-voce and performance test will be conducted for evaluation of practical understanding.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	20
2.	Sessional Examination	30
3.	End Semester Examination	100

Course Outcomes: Upon completion of this course, students will be able to	
1.	Accomplish the assessment of the drug/s applying various spectroscopic and chromatographic techniques.
2.	Comprehend the functional aspects of various analytical instruments/equipment.
3.	Accomplish the pre-formulation, formulation and characterization of various types of the modified release drug delivery systems.
4.	Exhibit the potential effects of excipients and processing parameters on various dosage forms.
5.	Comprehend and implement the various model dependent and model independent approaches for the assessment of dosage forms.