KADI SARVA VISHWAVIDYALAYA
K. B. INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
MASTER OF PHARMACY SYLLABUS
Effective from Session JUNE 2017

SPECIALIZATION: PHARMACEUTICS (MPH)
SCHEME OF TEACHING
SEMESTER-I

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
MPH101T	Modern Pharmaceutical Analytical Techniques	4	---	4	---
MPH102T	Drug Delivery System	4	---	4	---
MPH103T	Modern Pharmaceutics	4	---	4	---
MPH104T	Regulatory Affair	4	---	4	---
MPH105P	Pharmaceutics Practical - I	---	12	---	6
---	Seminar/Assignment	---	7	---	4
	Total	35		26	

SPECIALIZATION: PHARMACEUTICS (MPH)
SCHEME OF EXAMINATION
SEMESTER-I

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MPH101T	Modern Pharmaceutical Analytical Techniques	3	75	25	--	--
MPH102T	Drug Delivery System	3	75	25	--	--
MPH103T	Modern Pharmaceutics	3	75	25	--	--
MPH104T	Regulatory Affair	3	75	25	--	--
MPH105P	Pharmaceutics Practical - I	6	--	--	100	50
---	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT : **MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**
SUBJECT CODE : **MPH101T**
SCOPE : This subject deal with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
OBJECTIVES : Upon completion of the course, student shall be able to understand:

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Discuss characteristic features of each analytical methods.
- Discuss applications of all analytical methods in pharmaceuticals.
- Interprete the spectra obtained.
- Estimate API purity, Impurity profile of drugs and intermediates.
- Estimate plasma drug concentrations from in vivo samples.

PREREQUISITES: Basic pharmaceutical analysis and related calculations.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPH101T	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**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 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.	11
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	11

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	11
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) Isoelectric focusing	11
	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	
6	**Immunological Assays**: • RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5

SR.NO	NAME OF BOOK/REFERENCE
1	Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th 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, Vol11, Marcel. Dekker Series
8	Spectroscopy of Organic Compounds, 2nd edition, P.S/Kalsi, Wiley Estern Ltd., Delhi.
9	Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

SUBJECT **: DRUG DELIVERY SYSTEMS**
SUBJECT CODE **: MPH102T**
SCOPE **:** This course is designed to impart knowledge on the area of advances in novel drug delivery systems.
OBJECTIVES **:** Upon completion of the course, student shall be able to understand:

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

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Apply pharmacokinetic parameters for designing DDS.
- Mathematically compute release rate from DDS.
- Predict release profiles and mechanism of drug release from DDS
- Use clear objectives for designing any DDS through any route of administration.

PREREQUISITES: Pharmaceutical technology for different dosage forms

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPH102T	DRUG DELIVERY SYSTEMS	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Sustained Release(SR) and Controlled Release (CR) formulations**	10
	❖ 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, Tele pharmacy	
2	**Rate Controlled Drug Delivery Systems**	10
	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.	
3	**Gastro-Retentive Drug Delivery Systems**	10
	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.	
4	**Ocular Drug Delivery Systems**:	6
	Barriers of drug permeation, Methods to overcome barriers	
5	**Transdermal Drug Delivery Systems**:	10
	Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation	
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

SR.NO	NAME OF BOOK/REFERENCE
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, NC., 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, 1st Edition 1997 (reprint in 2001).
5	S.P. Vyas and R. K. Khar, Controlled Drug Delivery - Concepts and Advances, Vallabh Prakashan, New Delhi, 1st Edition 2002.
	JOURNALS
	1. Indian Journal of Pharmaceutical Sciences (IPA)
	2. Indian drugs (IDMA)
	3. Journal of controlled release (Elsevier Sciences) desirable
	4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

SUBJECT : MODERN PHARMACEUTICS
SUBJECT CODE : MPH103T
SCOPE : Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries
OBJECTIVES : Upon completion of the course, student shall be able to understand:

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

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Design the steps of generic product development based on process variables and formulation variables.
- Determine screening criteria for successful products.
- Design dosage form development of all types of dosage forms.
- Identify factors influencing development of successful drug product.

PREREQUISITES: Principles of physical pharmaceutics.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPH103T	MODERN PHARMACEUTICS	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Preformation Concepts**	10
	• 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.	
2	**Optimization techniques in Pharmaceutical Formulation**	10
	• 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	
3	**Validation**	10
	• 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.	
4	**cGMP & Industrial Management**	10
	• 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.	
5	**Compression and compaction:**	10
	• Physics of tablet compression, consolidation, • Effect of friction, distribution of forces, compaction profiles. • Effect on Solubility.	
6	**Study of consolidation parameters:**	10
	• 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.	

SR.NO	NAME OF BOOK/REFERENCE
1	Theory and Practice of Industrial Pharmacy by Lachman and Liebermann
2	Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachman.
3	Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4	Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
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	Encyclopedia of Pharmaceutical technology, Vol I – III.

SUBJECT : **REGULATORY AFFAIRS**
SUBJECT CODE : **MPH104T**
SCOPE : Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA, to know the approval process, to know the chemistry, manufacturing controls and their regulatory importance, to learn the documentation requirements for IND, NDA and ANDA.

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

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

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Use drug and excipients s' regulatory requirements effectively in F&D.
- Prepare documents as per different guidelines.
- Manage results of each batch of formulations and properly interpret the same

PREREQUISITES: **NONE**

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPH104T	REGULATORY AFFAIRS	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**a. Documentation in Pharmaceutical industry:**	12
	• 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	
2	**Post approval regulatory affairs.**	12
	• CMC • 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.	
3	**Non-Clinical drug development:**	12
	• Global submission of IND, NDA, ANDA. • Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	
4	**Clinical Trials:**	12
	• 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.	

SR.NO	NAME OF BOOK/REFERENCE
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	www.europa.eu/index_en.htm
10	https://www.tga.gov.au/tga-basics

SUBJECT : PHARMACEUTICS PRACTICALS - I
SUBJECT CODE : MPH105P
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPH105P	PHARMACEUTICS PRACTICALS - I	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS

SR.NO	PRACTICAL
1.	To perform In-vitro dissolution profile of CR/ SR marketed formulation
2.	Formulation and evaluation of sustained release matrix tablets
3.	Formulation and evaluation osmotically controlled DDS
4.	Preparation and evaluation of Floating DDS- hydrodynamically balanced DDS
5.	Formulation and evaluation of Mucoadhesive tablets.
6.	Formulation and evaluation of trans dermal patches.
7.	To carry out pre-formulation studies of tablets.
8.	To study the effect of compressional force on tablets disintegration time.
9.	To study Micromeritics Properties of powders and granulation.
10.	To study the effect of Particle size on dissolution of a tablet.
11.	To study the effect of binders on dissolution of a tablet.
12.	To plot Heckel Plot, Higuchi and Peppas Plot and determine similarity factors.
13.	Analysis of pharmacopoeial compounds and their formulations by UV-Vis Spectrophotometer
14.	Simultaneous estimation of multi-component containing formulations by UV Spectrophotometry
15.	Experiments based on HPLC
16.	Experiments based on Gas Chromatography.
17.	Estimation of riboflavin/quinine sulphate by fluorimetry
18.	Estimation of sodium/potassium by flame photometry

SUBJECT **: SEMINAR/ASSIGNMENT**

RATIONALE : This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: NONE

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
---	SEMINAR/ASSIGNMENT	-	7	7	4	--	100	--	--	100

KADI SARVA VISHWA VIDYALAYA
K. B. INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
MASTER OF PHARMACY SYLLABUS
Effective from Session JUNE 2017
SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE (MQA)
SCHEME OF TEACHING
SEMESTER-I

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
MQA101T	Modern Pharmaceutical Analytical Techniques	4	---	4	---
MQA102T	Quality Management System	4	---	4	---
MQA103T	Quality Control and Quality Assurance	4	---	4	---
MQA104T	Product Development and Technology Transfer	4	---	4	---
MQA105P	Pharmaceutical Quality Assurance Practical-I	---	12	---	6
---	Seminar/Assignment	---	7	---	4
	Total	35		26	

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE (MQA)
SCHEME OF EXAMINATION
SEMESTER-I

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (Hrs)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MQA101T	Modern Pharmaceutical Analytical Techniques	3	75	25	--	--
MQA102T	Quality Management System	3	75	25	--	--
MQA103T	Quality Control and Quality Assurance	3	75	25	--	--
MQA104T	Product Development and Technology Transfer	3	75	25	--	--
MQA105P	Pharmaceutical Quality Assurance Practical-I	6	--	--	100	50
---	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150
-						

SUBJECT : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
SUBJECT CODE : MQA101T
SCOPE : This subject deal with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
OBJECTIVES : Upon completion of the course, student shall be able to understand:

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Discuss characteristic features of each analytical methods.
- Discuss applications of all analytical methods in pharmaceuticals.
- Interprete the spectra obtained.
- Estimate API purity, Impurity profile of drugs and intermediates.
- Estimate plasma drug concentrations from in vivo samples.

PREREQUISITES: Basic pharmaceutical analysis and related calculations.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MQA101T	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**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. Difference- Derivative 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, Data interpretation. **c. Spectroflourimetry:** • Theory of Fluorescence, • Factors affecting fluorescence, Quenchers, • Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy**: • Principle, Instrumentation, Interferences and Applications.	12
2	**NMR spectroscopy:** • Quantum numbers and their role in NMR, • Principle, • Instrumentation, • Solvent requirement in NMR,	12

	• 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.	
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	12
4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra-High-Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography	12
5	**a. Electrophoresis**: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis b) Capillary electrophoresis c) Zone electrophoresis d) Moving boundary electrophoresis e) Isoelectric 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	12
6	**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.	12

SR.NO	NAME OF BOOK/REFERENCE
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, Vol11, Marcel. Dekker Series
8	Spectroscopy of Organic Compounds, 2nd Edition, P.S/Kalsi, Wiley Estern Ltd., Delhi.
9	Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

SUBJECT : **QUALITY MANAGEMENT SYSTEMS**
SUBJECT CODE : **MQA102T**
SCOPE : This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.
OBJECTIVES Upon completion of this course, student shall be able to understand:

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Understand various guidelines related to quality, stability of pharmaceuticals, various statistical process controls for optimization of methodology.
- Developing and validating various inspection models for quality systems.

PREREQUISITES:
Basic knowledge of various Quality Assurance Guidelines and basics of quality management.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MQA102T	Quality Management Systems	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Introduction to Quality**: • Evolution of Quality, Definition of Quality, Dimensions of Quality • Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality • Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies. • Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, optimizing costs, Preventing cost of quality.	12
2	**Pharmaceutical quality Management**: • Basics of Quality Management, Total Quality Management (TQM), Principles of Six-Sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, • Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. • OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	12

3	**Six System Inspection model**: • Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. • Concept of self-inspection. • Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	12
4	**Drug Stability**: • ICH guidelines for stability testing of drug substances and drug products. • Study of ICH Q8, Quality by Design and Process development report • Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	12
5	**Statistical Process control (SPC):** • Definition and Importance of SPC, • Quality measurement in manufacturing, • Statistical control charts - concepts and general aspects, Advantages of statistical control, • Process capability, Estimating Inherent or potential capability from a control chart analysis, • Measuring process control and quality improvement, Pursuit of decreased process variability.	8
6	**Regulatory Compliance** through Quality Management and development of Quality Culture • Benchmarking: Definition of benchmarking, • Reasons for benchmarking, • Types of Benchmarking, Benchmarking process, • Advantages of benchmarking, Limitations of benchmarking.	4

SR.NO	NAME OF BOOK/REFERENCE
1	Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2	Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3	Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4	Corporate Culture and the Quality Organization By James W. FairfieldSonn, Quorum Books, 2001
5	The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6	The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7	Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8	Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

SUBJECT : **QUALITY CONTROL AND QUALITY ASSURANCE**
SUBJECT CODE : **MQA103T**
SCOPE This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

OBJECTIVES &
LEARNING OUTCOMES: At the end of the course the student will be able to:

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

PREREQUISITES: Basic knowledge of GMP, GLP and documentation.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MQA103T	Quality Control and Quality Assurance	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	❖ Introduction: Concept and evolution and scopes 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. CPCSEA guidelines	12
2	• cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(Pic), • Who and Emera 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.	12
3	❖ Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. ❖ In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	12
4	**Documentation in pharmaceutical industry:** • Three tier documentation, Policy, Procedures and Work instructions, and records (Formats),	12

	• Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit Plan and reports. • Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators. • DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.	
5	**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, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. • Concept of trade mark, copyright and patents.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2	Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3	Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4	How to Practice GMP's – P P 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
8	ISO 9000 and total quality management
9	The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10	QA Manual - D.H. Shah, 1st edition, Business Horizons, 2000.
11	Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12	Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13	Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14	Packaging of Pharmaceuticals.
15	Schedule M and Schedule N.

SUBJECT : **PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER**
SUBJECT CODE : **MQA104T**
SCOPE : This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places
OBJECTIVES Upon completion of the course, student shall be able to understand:
Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Understanding various aspects of process of product development like pre-formulation, stability, technology transfer.
- Transfer of technology from laboratory to pilot plant set-up.

PREREQUISITES:
Basic knowledge about pre-formulation study of API, raw materials and packaging material.
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MQA104T	Product Development and Technology Transfer	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Principles of Drug discovery and development**: • Introduction, Clinical research process. • Development and informational content for Investigational New Drugs Application (IND), • New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), • Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post Approval changes (BACPAC), Post marketing surveillance, • Product registration guidelines – CDSCO, USFDA.	12
2	**Pre-formulation studies**: • Introduction/concept, Organoleptic properties, purity, impurity profiles, Particle size, shape and surface area. • Solubility, Methods to improve solubility of Drugs • Surfactants & its importance, co-solvency. • Techniques for the study of Crystal properties and polymorphism. • Pre-formulation protocol, Stability testing during product development.	12
3	**Pilot plant scale up**: • Concept, Significance, design, layout of pilot plant scale up study, operations, • Large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. • New era of drug products: opportunities and challenges	12

4	**Pharmaceutical packaging**: • Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, • Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	12
5	**Technology transfer**: • Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, • Qualitative and quantitative technology models. • Documentation in technology transfer: Development report, technology transfer plan and Exhibit batch.	12

SR.NO	NAME OF BOOK/REFERENCE
1	The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2	Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3	Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumba
4	Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5	Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6	Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7	Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8	Remingtons Pharmaceutical Sciences, by Alfonso &Gennaro, 19th Edn. (1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9	The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10	Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

SUBJECT : PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL - I
SUBJECT CODE : MQA105P
SCOPE
OBJECTIVES : Upon completion of the course, student shall be able to understand:

- Proper handling and operation of various instruments like UV- visible spectrophotometer, Spectrofluorimeter, HPLC, HPTLC etc.
- Awareness regarding documentation related to quality control of raw materials and finished product.

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Proper handling, operation and troubleshooting of various instruments like UV- visible spectrophotometer, Spectrofluorimeter, HPLC, HPTLC etc.
- Preparation of documents related to quality control of raw materials and finished product.

PREREQUISITES:
Basic theoretical and practical knowledge of components of various instruments.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPH105P	Pharmaceutical Quality Assurance Practical-I	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS

SR.NO	PRACTICAL
1	Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2	Simultaneous estimation of multi-drug 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 or AAS
7	Case studies on Total Quality Management, Six Sigma, Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Corrective & Preventive Actions (CAPA), Deviations.
8	Development of Stability study protocol
9	Estimation of process capability
10	In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11	Assay of raw materials as per official monographs
12	Testing of related and foreign substances in drugs and raw materials
13	To carry out pre-formulation study for tablets, parenterals (2 experiment).
14	To study the effect of pH on the solubility of drugs, (1 experiment)
15	Quality control tests for Primary and secondary packaging materials
16	Accelerated stability studies (1 experiment)
17	Improved solubility of drugs using surfactant systems (1 experiment)
18	Improved solubility of drugs using co-solvency method (1 experiment)
19	Determination of pKa and Log P of drugs.

SUBJECT **: SEMINAR/ASSIGNMENT**

SUBJECT CODE **:**

RATIONALE : This unit is complementary to compensate the boundary-less content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: NONE

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
---	SEMINAR/ASSIGNMENT	-	7	7	4	--	100	--	--	100

KADI SARVA VISHWAVIDYALAYA
K. B. INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
MASTER OF PHARMACY SYLLABUS
Effective from Session JUNE 2017

SPECIALIZATION: PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SCHEME OF TEACHING

SEMESTER-I

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
MRA101T	Good Regulatory Practices	4	---	4	---
MRA102T	Documentation and Regulatory Writing	4	---	4	---
MRA103T	Clinical Research Regulations	4	---	4	---
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights	4	---	4	---
MRA105P	Regulatory Affairs Practical-I	---	12	---	6
---	Seminar/Assignment	---	7	---	4
	Total	35		26	

SPECIALIZATION: REGULATORY AFFAIRS (MRA)

SCHEME OF EXAMINATION

SEMESTER-I

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (Hrs)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MRA101T	Good Regulatory Practices	3	75	25	--	--
MRA102T	Documentation and Regulatory Writing	3	75	25	--	--
MRA103T	Clinical Research Regulations	3	75	25	--	--
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights	3	75	25	--	--
MRA105P	Regulatory Affairs Practical-I	6	--	--	100	50
---	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT : **GOOD REGULATORY PRACTICES**
SUBJECT CODE : **MRA101T**
SCOPE This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

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

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries.
- Prepare for the readiness and conduct of audits and inspections.

LEARNING OUTCOMES: At the end of the course the student will be able to:

- To produce and maintain the good Quality of Pharmaceutical raw materials, finished products and allied materials by adopting Good Laboratory, Good Automated Laboratory and Good Manufacturing Practices in the Industry.
- To maintain all the GLP, GLAP and GMP related records by as per the requirement of the industry by adopting Good Documentation Practices**.**
- To implement Good Regulatory Practices in the Healthcare and related Industries and also the student will be prepared to be able to conduct audits and inspections.

PREREQUISITES:

- B. Pharm. Graduate

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MRA101T	Good Regulatory Practices	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Current Good Manufacturing Practices**: • Introduction, • US cGMP Part 210 and Part 211.EC • Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; • Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs.	12
2	**Good Laboratory Practices:** • Introduction, • USFDA GLP Regulations (Subpart A to Subpart K), • Controlling the GLP inspection process, • Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, • Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards	12

3	**Good Automated Laboratory Practices**: • Introduction to GALP, Principles of GALP, • GALP Requirements, sops of GALP, • Training Documentation,21 CFR Part 11, • General check list of 21CFR Part 11, • Software Evaluation checklist, relevant ISO and QCI Standards	12
4	**Good Distribution Practices**: • Introduction to GDP, • Legal GDP requirements put worldwide, • Principles, Personnel, Documentation, Premises and Equipment, • Deliveries to Customers, Returns, Self-Inspection, Provision of information, • Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12
5	**Quality management systems**: • Concept of Quality, Total Quality Management, • Quality by design, Six Sigma concept, • Out of Specifications (OOS), • Change control. ❖ **Validation:** • Types of Validation, • Types of Qualification, • Validation master plan (VMP), • Analytical Method Validation. • Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. ❖ **The International Conference on Harmonization (ICH)** process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2	Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3	Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner, Wiley Publication.
4	How to practice GLP by PP Sharma, Vandana Publications.
5	Laboratory Auditing for Quality and Regulatory compliance by Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6	Drugs & Cosmetics Act, Rules & Amendments

SUBJECT : **DOCUMENTATION AND REGULATORY WRITING**
SUBJECT CODE : **MRA102T**
SCOPE This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies**.**
OBJECTIVES Upon completion of the course, student shall be able to:

- ❖ Know the various documents pertaining to drugs in pharmaceutical industry
- ❖ Understand the basics of regulatory compilation
- ❖ Create and assemble the regulation submission as per the requirements of agencies
- ❖ Follow up the submissions and post approval document requirements

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Describe the contents and requirements for filling INDA, NDA and ANDA in accordance with current guidelines of different approving authorities globally.
- To understand types of Documentation in pharmaceutical industry required for, Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record, Certificate of Analysis (COA), Site Master File and Drug Master Files (DMF), etc.
- Have in-depth knowledge of dossier preparations and submissions, audits, inspection and also the knowledge of product life cycle management.

PREREQUISITES:
B. Pharm. Graduate

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MRA102T	Documentation and Regulatory Writing	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Documentation in pharmaceutical industry**: • Exploratory Product Development Brief (EPDB) for Drug substance and Drug Product, • Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, • Batch Packaging Records, • Print pack specifications, • Distribution records, • Certificate of Analysis (COA), Site Master File and Drug Master Files (DMF).	12
2	**Dossier preparation and submission**: • Introduction and overview of dossiers, • Contents and organization of dossier, binders and sections, • Compilation and review of dossier. • Paper submissions, • Overview and modules of CTD, • Electronic CTD submissions; • Electronic submission: Planning electronic submission,	12

	• Requirements for submission, • Regulatory bindings and requirements, • Tool and Technologies, • Electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). • Non ECTD electronic submissions (NEES), • Asian CTD formats (ACTD) submission. • Organizing, process and validation of submission. • Submission in Sugam system of CDSCO.	
3	**Audits**: • Introduction, Definition, Summary, Types of audits, • GMP compliance audit, • Audit policy, Internal and External Audits, Second Party Audits, • External third-party audits, Auditing strategies, • Preparation and conducting audit, Auditing strategies, audit analysis, • Audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. • Timelines for audits/inspection. • GHTF study group 4 guidance document.ISO 13485.	12
4	**Inspections**: • Pre-approval inspections, • Inspection of pharmaceutical manufacturers, • Inspection of drug distribution channels, • Quality systems requirements for national good manufacturing practice inspectorates, • Inspection report, model certificate of good manufacturing practices, • Root cause analysis, Corrective and Preventive action (CAPA).	12
5	**Product life cycle management**: • Prior approval supplement (pas), post approval changes [SUPAC], • Changes being effected in 30 days (CBE-30), • Annual report, • Post marketing • Reporting requirements, • Post approval labeling changes, • Life cycle management, • FDA inspection and enforcement, • Establishment inspection report (EIR), • Warning letters, recalls, seizure and injunctions. • ISO risk Management Standard	12

SR.NO	NAME OF BOOK/REFERENCE
1	Compliance auditing for Pharmaceutical Manufacturers. Karen Gins bury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2	Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3	Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.

4	Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5	Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6	Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7	Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8	Corporate Culture and the Quality Organization By James W. Fairfield- onn, Quorum Books, 2001
9	The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10	The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11	Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12	Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13	International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

SUBJECT : **CLINICAL RESEARCH REGULATIONS**
SUBJECT CODE : **MRA103T**
SCOPE This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

OBJECTIVES

- History, origin and ethics of clinical and biomedical research andevaluation
- Clinical drug, medical device development process and different typesand phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Understand the role of Ethics in Clinical Research
- To acquire in-depth knowledge of Clinical Drug development process, Regulations and guidelines related to Clinical Trials in India and globally.
- Understand of GCPs requirements for Sponsors, Monitors, and Investigators, Significance of protocol and case report form development for all phases of clinical research.

PREREQUISITES:

- B. Pharm. Graduate

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MRA103T	Clinical Research Regulations	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Clinical Drug Development Process** • Different types of Clinical Studies • Phases of clinical trials, Clinical Trial Protocol Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points • Phase II studies (proof of concept or principle studies to establish efficacy) • Phase III studies (Multi ethnicity, global clinical trial, registration studies) • Phase IV studies (Post Marketing Studies; PSUR) **Clinical Investigation and Evaluation of Medical Devices &IVDs** • Different Types of Studies • Key Concepts of Medical Device Clinical Evaluation • Key concepts of Clinical Investigation	12
2	**Ethics in Clinical Research:** • Historical Perspectives: Nuremberg Code, Thalidomide study Nazis Trials, Tuskegee Syphilis Study, • The Belmont Report, • The declaration of Helsinki • Origin of International Conference on Harmonization - Good	12

	• Clinical Practice (ICH-GCP) guidelines. • The ethics of randomized clinical trials • The role of placebo in clinical trials • Ethics of clinical research in special population • Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data • Data safety monitoring boards. • Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research • Ethical principles governing informed consent process • Patient Information Sheet and Informed Consent Form • The informed consent process and documentation	
3	**Regulations governing Clinical Trials** • India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA) • NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) • NDA 505(b)(2) of the FD&C Act (Application for approval of a • new drug that relies, at least in part, on data not developed by the applicant) • ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) • FDA Guidance for Industry - Acceptance of Foreign Clinical Studies • FDA Clinical Trials Guidance Document: Good Clinical Practice • EU: Clinical Research regulations in European Union (EMA)	12
4	**Clinical Research Related Guidelines** • Good Clinical Practice Guidelines (ICH GCP E6) • Indian GCP Guidelines • ICMR Ethical Guidelines for Biomedical Research • CDSCO guidelines • GHTF study group 5 guidance documents • Regulatory Guidance on Efficacy and Safety ICH Guidance's • E4 – Dose Response Information to support Drug Registration • E7 – Studies in support of General Population: Geriatrics • E8 – General Considerations of Clinical Trials • E10 – Choice of Control Groups and Related Issues in Clinical Trials, • E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population • General biostatics principle applied in clinical research	12
5	**USA & EU Guidance** ❖ USA: FDA Guidance • CFR 21Part 50: Protection of Human Subjects • CFR 21Part 54: Financial Disclosure by Clinical Investigators • CFR 21Part 312: IND Application • CFR 21Part 314: Application for FDA Approval to Market a New Drug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational Device Exemptions • CFR 21Part 822: Post-market surveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies FDA Med Watch	12

	❖ Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment ❖ European Union: EMA Guidance • EU Directives 2001 • EudraLex (EMEA) Volume 3 – Scientific guidelines for • medicinal products for human use • EU Annual Safety Report (ASR) • Volume 9A – Pharmacovigilance for Medicinal Products for • Human Use • EU MDD with respect to clinical research • ISO 14155	

SR.NO	NAME OF BOOK/REFERENCE
1	Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
2	HIPAA and Human Subjects Research: A Question and Answer Reference Guide by Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3	Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene.
4	Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie a Speers; Karlberg, Johan Petter Einar, Hong Kong.
5	International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6	New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7	FDA Regulatory Affairs: A Guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA.
8	Country Specific Guidelines from official websites.

RECOMMENDED WEBSITES:

SR.NO	NAME OF BOOK/REFERENCE/website
1	EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2	Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts /cdrh /cfdocs/cfcfr/cfrsearch.cfm
3	Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html
4	Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5	FDA New Drug application:http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
6	Medicines and Healthcare Products Regulatory Agency: http://www.mhra.gov.uk
7	Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
8	ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf
9	EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf

SUBJECT **:REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS**

SUBJECT CODE **: MRA104T**

SCOPE This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

OBJECTIVES Upon completion of the course, student shall be able to:

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticalsindustry in India.
- Understand the approval process and regulatory requirements forDrugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food& Nutraceuticals

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Acquire knowledge of Product Registration, License and product approval procedure for manufacturing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food and Nutraceuticals in India and Globally.
- Have understanding regarding various Pharmacopoeial and other relevant Standards, Regulatory Requirements for Bioequivalence study and guidelines for the preclinical study.
- Have understanding regarding the Intellectual Property rights, Indian Patient scenario and will be able to correlate IPR and Regulatory affairs.

PREREQUISITES: B. Pharm. Graduate

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Biologicals & Herbals, and Food & Nutraceuticals** **Acts and Rules (with latest amendments):** • Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA • Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & • Nutraceuticals in India **Other relevant Acts**: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; • Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955;	12

	• Prevention of Cruelty to Animals Act.	
2	**Regulatory requirements and approval procedures for Drugs & cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals** • CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities • Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, • Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals • Format and contents of Regulatory dossier filing Clinical Trial/ Investigations	12
3	**Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards**	12
4	• Bioavailability and Bioequivalence data (BA & BE), • BCS Classification of Drugs, • Regulatory Requirements for Bioequivalence study **Stability requirements**: ICH and WHO **Guidelines for Drug testing in animals/Preclinical Studies** • Animal testing: Rationale for conducting studies, CPCSEA Guidelines • Ethical guidelines for human participants • ICMR-DBT Guidelines for Stem Cell Research	12
5	**Intellectual Property Rights**: • Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, • Indian Patent Scenario • IPR Vs Regulatory Affairs	12

SR.NO	NAME OF BOOK/REFERENCE
1	Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2	Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer.
3	Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4	Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5	CPCSEA Guidelines for Laboratory Animal Facility by Committee for control and supervision on experiments on animals (CPCSEA) Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
6	Principles and Practice of Clinical Trial Medicine by Richard Chin and ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonized Tripartite
7	Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organization)
8	Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials /BE studies by CDSCO.
9	Guidelines for Import and Manufacture of Medical Devices by CDSCO.
10	Guidelines from official website of CDSCO ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonized Tripartite

SUBJECT : REGULATORY AFFAIRS PRACTICAL - I
SUBJECT CODE : MRA105P
SCOPE
OBJECTIVES :
LEARNING OUTCOMES : At the end of the course the student will be able to:

- Prepare various documents required for the registration and submission to various regulatory bodies in India and globally.

PREREQUISITES: B. Pharm. Graduate.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MRA105P	Regulatory Affairs Practical - I	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS

SR.NO	PRACTICAL
1	Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2	Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3	Preparation of SOPs, Analytical reports (Stability and validation)
4	Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5	Labeling comparison between brand & generics.
6	Preparation of clinical trial protocol for registering trial in India
7	Registration for conducting BA/ BE studies in India
8	Import of drugs for research and developmental activities
9	Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10	Registering for different Intellectual Property Rights in India
11	GMP Audit Requirements as per CDSCO
12	Preparation and documentation for Indian Patent application.
13	Preparation of checklist for registration of IND as per ICH CTD format.
14	Preparation of checklist for registration of NDA as per ICH CTD format.
15	Preparation of checklist for registration of ANDA as per ICH CTD format.
16	Case studies on response with scientific rationale to USFDA Warning Letter
17	Preparation of submission checklist of IMPD for EU submission.
16	Comparison study of marketing authorization procedures in EU.
19	Comparative study of DMF system in US, EU and Japan
20	Preparation of regulatory submission using eCTD software
21	Preparation of Clinical Trial Application (CTA) for US submission
22	Preparation of Clinical Trial Application (CTA) for EU submission
23	Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24	Regulatory requirements checklist for conducting clinical trials in India.
25	Regulatory requirements checklist for conducting clinical trials in Europe.
26	Regulatory requirements checklist for conducting clinical trials in USA

SUBJECT : **SEMINAR/ASSIGNMENT**
SUBJECT CODE :
RATIONALE : This unit is complementary to compensate the boundary less content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: NONE

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
---	SEMINAR/ASSIGNMENT	-	7	7	4	--	100	--	--	100

KADI SARVA VISHWA VIDYALAYA
K. B. INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
MASTER OF PHARMACY SYLLABUS
Effective from Session JUNE 2017
SPECIALIZATION: PHARMACY PRACTICE (MPP)
SCHEME OF TEACHING
SEMESTER-I

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
MPP101T	Clinical Pharmacy Practice	4	---	4	---
MPP102T	Pharmacotherapeutics - I	4	---	4	---
MPP103T	Hospital & Community Pharmacy	4	---	4	---
MPP104T	Clinical Research	4	---	4	---
MPP105P	Pharmacy Practice Practical - I	---	12	---	6
---	Seminar/Assignment	---	7	---	4
	Total	35		26	

SPECIALIZATION: PHARMACY PRACTICE (MPP)
SCHEME OF EXAMINATION
SEMESTER-I

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (Hrs)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MPP101T	Clinical Pharmacy Practice	3	75	25	--	--
MPP102T	Pharmacotherapeutics - I	3	75	25	--	--
MPP103T	Hospital & Community Pharmacy	3	75	25	--	--
MPP104T	Clinical Research	3	75	25	--	--
MPP105P	Pharmacy Practice Practical-I	6	--	--	100	50
---	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT : **CLINICAL PHARMACY PRACTICE**
SUBJECT CODE : **MPP101T**
SCOPE This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.
OBJECTIVES Upon completion of the course, student shall be able to:

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Explain clinical pharmacy services in health care.
- Demonstrate knowledge and ability to integrate basic principles of clinical pharmacy needed for the application of these sciences to drug therapy and human health
- Design and practice Clinical Pharmacy Service
- State investigations that are of value for the diagnosis and monitoring of drug therapy in selected disease areas evaluate and Interpret laboratory result
- Critically evaluate information and provide information

PREREQUISITES: Basic pharmacy Subject Knowledge During Graduation.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPP101T	Clinical Pharmacy Practice	4	-	4	3	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Introduction to Clinical Pharmacy**: • Definition, evolution and scope of clinical pharmacy, • International and national scenario of clinical pharmacy practice, Pharmaceutical care Clinical Pharmacy Services: • Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)	12
2	**Clinical Pharmacy Services**: • Patient medication history interview, • Basic concept of medicine and poison information services, • Basic concept of pharmacovigilance, • Hemovigilance, Materiovigilance and AEFI, • Patient medication counselling, • Drug utilization evaluation, • Documentation of clinical pharmacy services,	12

	• Quality assurance of clinical pharmacy services	
3	**Patient Data Analysis:** • Patient Data & Practice Skills: Patient's case history - its • structure and significances in drug therapy management, • Common medical abbreviations and terminologies used in clinical practice, • Communication skills: verbal and non-verbal communications, its applications in patient care services. • Lab Data Interpretation: Hematological tests, • Renal function tests, Liver function tests	12
4	**Lab Data Interpretation**: • Tests associated with cardiac disorders, • Pulmonary function tests, • Thyroid function tests, • Fluid and electrolyte balance, • Microbiological culture sensitivity tests	12
5	**Medicines & Poison Information Services** • Medicine Information Service: Definition and need for medicine information service, • Medicine information resources, Systematic approach in answering medicine information queries, • Preparation of verbal and written response, • Establishing a drug information Centre. • Poison Information Service: Definition, need, organization and functions of poison information Centre.	12

SR.NO	NAME OF BOOK/REFERENCE
1	A Textbook of Clinical Pharmacy Practice – Essential concepts and skills –Parthasarathy G, Karin Nyfort-Hansen and Milap Nahata
2	Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3	Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.,
4	Relevant review articles from recent medical and pharmaceutical literature.

SUBJECT : **PHARMACOTHERAPEUTICS-I**
SUBJECT CODE : **MPP102T**
SCOPE : This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines
OBJECTIVES Upon completion of the course, student shall be able to understand:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

LEARNING OUTCOMES: At the end of the course the student will be able to:

- identify selected diseases based on knowledge of pathology and motivate with given symptoms and laboratory values
- state investigations that are of value for the diagnosis and monitoring of drug therapy in selected disease areas
- evaluate abnormalities in common laboratory values and explain related to physiology, drug treatment and / or disease
- Forward to Implement rational drug therapy
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis and to perform clinical pharmacy services.

PREREQUISITES: Pharmacology

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPP102T	**Pharmacotherapeutics - I**	**4**	**-**	**4**	**3**	25	--	75	--	**100**

Course content:

CH.NO	PARTICULARS	60 HRS
	Etiopathogenesis and pharmacotherapy of diseases associated with following systems	
1	**Cardiovascular system**: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.	12
2	**Respiratory system**: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases	12
3	**Gastrointestinal system**: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis	12

4	• Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease • Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders	12
5	**Bone and joint disorders**: • Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis **Dermatological Diseases**: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders **Ophthalmology**: Conjunctivitis, Glaucoma	12

SR.NO	NAME OF BOOK/REFERENCE
1	Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2	Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3	Robins SL. Pathologic basis of disease -W.B. Saunders publication
4	Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5	Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6	Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7	Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8	Harrison's. Principles of Internal Medicine - McGraw Hill
9	Relevant review articles from recent medical and pharmaceutical literature

SUBJECT : **HOSPITAL & COMMUNITY PHARMACY**
SUBJECT CODE : **MPP103T**
SCOPE : This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.
OBJECTIVES : Upon completion of the course, student shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Acquire knowledge and importance of health, hospital and hospital & community pharmacy.
- Explain/demonstrate knowledge in hospital and community pharmacy.
- Perform functions and responsibilities in various committees at hospital level.
- Manage-procurement, dispensing and distribution of medicine –including special formulations/medicine, radio and nuclear pharmacy- hospital pharmacy
- Management of community pharmacy – principles and practices of services and medicine their in.
- Acquire knowledge and perform prescription processing and function in health promotion.

PREREQUISITES: Basic subjective knowledge –Graduation- Pharmaceutical practice, Basic clinical pharmacy

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPP103T	**Hospital & Community Pharmacy**	**4**	**-**	**4**	**3**	25	--	75	--	**100**

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Introduction to Hospitals** – • Definition, classification, organizational structure • Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, • Organizational structure, legal requirements, work load statistics, Infrastructural requirements, • Hospital Pharmacy Budget and Hospital Pharmacy management • Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH	12
2	**Hospital Formulary Guidelines** and its development, • Developing Therapeutic guidelines, • Drug procurement process, and methods of Inventory control, • Methods of Drug distribution, Intravenous admixtures, • Hospital Waste Management	12

3	**Education and training**: • Training of technical staff, • Training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, • Formal and informal meetings and lectures, • Drug and therapeutics newsletter. • Community Pharmacy Practice: Definition, roles & Responsibilities of community pharmacists, and their relationship with other health care providers.	12
	Community Pharmacy management: • Legal requirements to start community pharmacy, site selection, lay out & design, • Drug display, super drug store model, accounts and audits, • Good dispensing practices, • Different software & databases used in community pharmacies • Entrepreneurship in community pharmacy.	
4	**Prescription** – • Legal requirements & interpretation, prescription related problems Responding to symptoms of minor ailments: Head ache, • Pyrexia, menstrual pains, food and drug allergy, OTC medication: Rational use of over the counter medications • Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence • Patient referrals to the doctors • ADR monitoring in community pharmacies	12
5	**Health Promotion** – • Definition and health promotion activities, • Family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, • Smoking cessation, Child & mother care • National Health Programs- Role of Community Pharmacist in Malaria and TB control programs • Home Medicines review program – Definition, objectives, Guidelines, method and outcomes • Research in community pharmacy Practice	12

SR.NO	NAME OF BOOK/REFERENCE
1	Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2	Textbook of hospital pharmacy - Allwood MC and Blackwell.
3	Avery's Drug Treatment, Adis International Limited.
4	Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5	Remington Pharmaceutical Sciences.
6	Relevant review articles from recent medical and pharmaceutical literature

SUBJECT **: CLINICAL RESEARCH**
SUBJECT CODE **: MPP104T**
SCOPE This course aims to provide the students an opportunity to learn drug Development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.
OBJECTIVES Upon completion of the course, student shall be able to understand:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Explain and comment on drug development process and core area there in.
- Conduct the clinical trial activities
- Perform and comment safety issues and its reporting in clinical trials.
- Manage the trial coordination.

PREREQUISITES: **Drug laws**
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPP104T	**Clinical Research**	**4**	**-**	**4**	**3**	25	--	75	--	**100**

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Drug development process**: • Introduction, various approaches to drug discovery, • Investigational new drug application submission **Ethics in Biomedical Research**: Ethical Issues in Biomedical • Research – Principles of ethics in biomedical research, • Ethical committee [institutional review board] - its constitution and functions, • Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, • Drug Safety Reporting.	12
2	**Types and Designs used in Clinical Research:** • Planning and execution of clinical trials, • Various Phases of clinical trials, • Bioavailability and Bioequivalence studies, • Randomization techniques (Simple randomization, restricted randomization, Blocking method and stratification), • Types of research designs based on Controlling	12

	Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), • Sampling methods (Cohort study, case Control study and cross-sectional study), • Health outcome measures (Clinical & Physiological, Humanistic and economic) • Clinical Trial Study team: Roles and responsibilities of: • Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.	
3	**Clinical trial Documents**: • Guidelines to the preparation of following documents: • Protocols, Investigator's Brochure, Informed Consent Form, • Case report forms, Contracts and agreements, • Dairy Cards **Clinical Trial Start up activities**: Site Feasibility Studies, • Site/Investigator selection, Pre-study visit, Investigator meeting, • Clinical trial agreement execution, • Ethics committee document preparation and submission	12
4	**Investigational Product:** • Procurement and Storage of investigation product • Filing procedures: Essential documents for clinical trial, • Trial Master File preparation and maintenance, • Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up **Clinical Trial Monitoring and Close out**: • Preparation and conduct of monitoring visit: • Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, • Study Procedure, EC communications, Safety reporting, • Monitoring visit reporting and follow-up • Close-Out visit: Study related documents collection, • Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.	12
5	**Quality Assurance and Quality Control in Clinical Trials**: • Types of audits, • Audit criteria, • Audit process, • Responsibilities of stakeholders in audit process, • Audit follow-up and documentation, • Audit resolution and Preparing for FDA inspections, Fraud and • misconduct management • Data Management **Infrastructure and System Requirement for Data Management**: • Electronic data capture systems, • Selection and implementation of new systems, • System validation and test procedures, • Coding dictionaries, • Data migration and archival	12

	Clinical Trial Data Management: • Standard Operating Procedures, • Data management plan, CRF & Data base design considerations, • Study set-up, Data entry, CRF tracking and corrections, • Data cleaning, Managing laboratory and ADR data, • Data transfer and database lock, • Quality Control and Quality Assurance in CDM, Data mining and warehousing.	

SR.NO	NAME OF BOOK/REFERENCE
1	Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Aadrew J. Flether Anthony W Fos, Peter D Sloaier Publisher: Wiley;
2	Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3	Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4	Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5	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.
6	Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7	Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8	Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9	Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10	Relevant review articles from recent medical and pharmaceutical literature

SUBJECT : **PHARMACY PRACTICE PRACTICAL – I**
SUBJECT CODE : **MPP105P**
SCOPE : Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.
OBJECTIVES Upon completion of the course, student shall be able to understand:

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Communicate, Extract, interpret and record important data.
- Review medication/treatment charts/documents.
- Comment and design appropriate pharmacological and non-pharmacological treatment about the given patient and current recommendations
- Perform Clinical Pharmacy Service and integrated-association workout viz preparation of PIL.
- Present, comment and forward pharmaceutical care with evidence based medicine.
- Prepare and comment research study process and documents.
- Disseminate drug and poison information.
- Comment & exercise inventory control and hospital formulary.
- Formulate I/V admixture.
- Identify, evaluate and respond to basic drug-related problems from patient records and to motivate action.
- Use of observational, analytical and critical thinking skills to develop, implement and evaluate solutions that solve real-world problems.

PREREQUISITES: Completion or concurrent subjects Knowledge and student.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPP105P	Pharmacy Practice Practical-I	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS:

SR.NO	PRACTICAL
1	Treatment Chart Review (one)
2	Medication History Interview (one)
3	Patient Medication Counseling (two)
4	Drug Information Query (two)
5	Poison Information Query (one)
6	Lab Data Interpretation (two)
7	Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8	ABC Analysis of a given list of medications (one)
9	Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10	Formulation and dispensing of a given IV admixtures (one)
11	Preparation of a patient information leaflet (two)
12	Preparation of Study Protocol (one)
13	Preparation of Informed Consent Form (one)

SUBJECT **: SEMINAR/ASSIGNMENT**

SUBJECT CODE **:**

RATIONALE **:** This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES **:** At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: Subject knowledge, basic presentation skills with students

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
--	Seminar/Assignment	-	7	7	4	--	100	--	--	100

KADI SARVA VISHWA VIDYALAYA
K. B. INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
MASTER OF PHARMACY SYLLABUS
Effective from Session JUNE 2017
SPECIALIZATION: PHARMACOLOGY (MPL)
SCHEME OF TEACHING
SEMESTER-I

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
MPL101T	Modern Pharmaceutical Analytical Techniques	4	--	4	--
MPL102T	Advanced Pharmacology - I	4	--	4	--
MPL103T	Pharmacological and Toxicological Screening Methods - I	4	--	4	--
MPL104T	Cellular and Molecular Pharmacology	4	--	4	--
MPL105P	Experimental Pharmacology Practical - I	--	12	--	6
--	Seminar/Assignment	--	7	--	4
	Total	35		26	

SPECIALIZATION: PHARMACOLOGY (MPL)
SCHEME OF EXAMINATION
SEMESTER-I

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MPL101T	Modern Pharmaceutical Analytical Techniques	3	75	25	--	--
MPL102T	Advanced Pharmacology - I	3	75	25	--	--
MPL103T	Pharmacological and Toxicological Screening Methods - I	3	75	25	--	--
MPL104T	Cellular and Molecular Pharmacology	3	75	25	--	--
MPL105P	Experimental Pharmacology Practical - I	6	--	--	100	50
--	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT : **MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**
SUBJECT CODE : **MPL101T**
SCOPE : This subject deal with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
OBJECTIVES : Upon completion of the course, student shall be able to understand:

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Discuss characteristic features of each analytical methods.
- Discuss applications of all analytical methods in pharmaceuticals.
- Interprete the spectra obtained.
- Estimate API purity, Impurity profile of drugs and intermediates.
- Estimate plasma drug concentrations from in vivo samples.

PREREQUISITES: Basic pharmaceutical analysis and related calculations.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPL101T	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
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, Difference/ Derivative 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, Data Interpretation. **Spectroflourimetry**: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	10
2	**NMR spectroscopy:** 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
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**: • Chromatography: Principle, apparatus, instrumentation,	10

	• chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra-High-Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography	
5	**a. Electrophoresis**: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis b) Capillary electrophoresis c) Zone electrophoresis d) Moving boundary electrophoresis e) Isoelectric focusing	10
	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	
6	**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.	10

SR.NO	NAME OF BOOK/REFERENCE
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, Vol11, 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.

SUBJECT : **ADVANCED PHARMACOLOGY - I**
SUBJECT CODE : **MPL102T**
SCOPE : The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

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

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Define and explain the various terminologies pertaining to the subject.
- Explain the basic principles of Pharmacokinetics and pharmacodynamics
- Narrate the principle involved in measurement of drug effects
- Classify the drugs according to pharmacological classes
- Explain the mechanism of action, pharmacodynamic and pharmacokinetic effects of drugs, adverse effects, contraindications and therapeutic application of various classes of drugs.

PREREQUISITES:

- Knowledge of Human Anatomy and Physiology, Health Education, Biochemistry and basic physics and chemistry.
- Basics of pharmacology

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPL102T	Advanced Pharmacology - I	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**General Pharmacology** a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. 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.	12
2	**Neurotransmission** a. General aspects and steps involved in neurotransmission. b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline). 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	12
	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 • Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	
3	**Central nervous system Pharmacology** • General and local anesthetics • Sedatives and hypnotics, drugs used to treat anxiety. • Depression, psychosis, mania, epilepsy, neurodegenerative diseases. • Narcotic and non-narcotic analgesics	12
4	**Cardiovascular Pharmacology** Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. Haematinics, coagulants, anticoagulants, fibrinolytic and antiplatelet drugs	12
5	**Autacoid Pharmacology** • The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autacoids. • Pharmacology of antihistamines, 5HT antagonists.	12

SR.NO	NAME OF BOOK/REFERENCE
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	Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5	Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu.
6	Graham Smith. Oxford textbook of Clinical Pharmacology.
7	Avery Drug Treatment
8	Dipiro Pharmacology, Pathophysiological approach.
9	Green Pathophysiology for Pharmacists.
10	Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11	A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12	KD.Tripathi. Essentials of Medical Pharmacology.
13	Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14	Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15	Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16	Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

SUBJECT : **PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I**

SUBJECT CODE : **MPL 103T**

SCOPE This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Decide the miniaturization of human dose in respective animal model.
- Justify the model for either pharmacokinetic study or pharmacodynamic study.
- Prepare animal study protocol with details about grouping of animals, parameters for estimating direct or indirect activity of drug, reference standards and controls.

PREREQUISITES:

- Basic pharmacology.
- Basic concepts of animal experiments

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPL103T	Pharmacological and Toxicological Screening Methods - I	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**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. • Maintenance and breeding of laboratory animals. • CPCSEA guidelines to conduct experiments on animals • Good laboratory practice. • Bioassay-Principle, scope and limitations and methods	12
2	**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**. • CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. • Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis. • Drugs acting on Autonomic Nervous System.	12

3	**Preclinical screening** of new substances for the pharmacological activity using in vivo, in vitro, and possible animal alternative models. • Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. • Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. • Gastrointestinal drugs: anti-ulcer, anti -emetic, antidiarrheal and laxatives	12
4	**Preclinical screening** of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. • Cardiovascular Pharmacology: antihypertensive, antiarrhythmic, Antianginal, ant atherosclerotic agents and diuretics. • Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. • Anti-cancer agents. • Hepatoprotective screening methods.	12
5	**Preclinical screening of** new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. • Immunomodulatory, Immunosuppressant's and immunostimulants **General principles of immunoassay**: • Theoretical basis and optimization of immunoassay, • Heterogeneous and homogenous immunoassay systems. • Immunoassay methods evaluation; protocol outline, objectives and preparation. • immunoassay for digoxin and insulin • Limitations of animal experimentation and alternate animal experiments. • Extrapolation of in vitro data to preclinical and preclinical to humans	12

SR.NO	NAME OF BOOK/REFERENCE
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, S. K. Kulkarni
11	Practical Pharmacology and Clinical Pharmacy, S. K. Kulkarni, 3rd Edition.
12	David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13	Screening Methods in Pharmacology, Robert A. Turner.
14	Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee.
15	Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

SUBJECT : **CELLULAR AND MOLECULAR PHARMACOLOGY**
SUBJECT CODE : **MPL104T**
SCOPE The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.
OBJECTIVES Upon completion of the course, student shall be able to understand:

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for Pharmacology

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Cell biology concepts
- Concepts of Pharmacogenomics, proteomics
- Cell culture techniques

PREREQUISITES:

- Cell biology, Cellular level organization
- Basics of genetics
- Basics of microbiology
- Basic of modern analytical techniques

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPL104T	Cellular and Molecular Pharmacology	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Cell biology** • Structure and functions of cell and its organelles • Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing • Cell cycles and its regulation. • Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. • Necrosis and autophagy	12
2	**Cell signaling** • Intercellular and intracellular signaling pathways. • Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. • Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1, 4,5-trisphosphate, (IP3), NO, and diacylglycerol. **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.	12
3	**Principles and applications of genomic and proteomic tools**	12

	• 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 • 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 recent advances in gene therapy.	
4	**Pharmacogenomics** • Gene mapping and cloning of disease gene. • Genetic variation and its role in health/ pharmacology • Polymorphisms affecting drug metabolism • Genetic variation in drug transporters • Genetic variation in G protein coupled receptors • Applications of proteomics science: Genomics, proteomics, metabolomics, function omics, nutrigenomics Immunotherapeutics • Types of immunotherapeutic, humanization antibody therapy, • Immunotherapeutic in clinical practice	12
5	**a. 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 of cells and their application. • Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays • Principles and applications of flow cytometry **b. Biosimilars**	12

SR.NO	NAME OF BOOK/REFERENCE
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 protocols in molecular biology Vol I to VI edited by Frederick M. Ausuvel et la.

SUBJECT : EXPERIMENTAL PHARMACOLOGICAL PRACTICAL - I
SUBJECT CODE : MPL105P

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

- Experimental animals
- Guidelines for use of animals in laboratory
- Animal handling and experiments
- Modern analytical methods knowledge

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Handling of laboratory animals like rats and mice
- Basics of experimental techniques like blood collection, drug administration in animals
- Basic knowledge of modern analytical techniques

PREREQUISITES:

- Basic knowledge of various analytical techniques
- Animal physiology and housing of animals

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
MPL105P	Experimental Pharmacology Practical - I	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS

SR.NO	PRACTICAL
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
	Handling of laboratory animals.
1	Various routes of drug administration.
2	Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3	Functional observation battery tests (modified Irwin test)
4	Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5	Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6	Evaluation of diuretic activity.
7	Evaluation of antiulcer activity by pylorus ligation method.
8	Oral glucose tolerance test.
9	Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10	Isolation of RNA from yeast
11	Estimation of proteins by Braford/Lowry's in biological samples.
12	Estimation of RNA/DNA by UV Spectroscopy
13	Gene amplification by PCR.
14	Protein quantification Western Blotting.
15	Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16	Cell viability assays (MTT/Trypan blue/SRB)

17	DNA fragmentation assay by agarose gel electrophoresis.
18	DNA damage study by Comet assay.
19	Apoptosis determination by fluorescent imaging studies.
20.	Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21	Enzyme inhibition and induction activity
22	Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23	Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

SR.NO	NAME OF BOOK/REFERENCE
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

SUBJECT **: SEMINAR/ASSIGNMENT**
SUBJECT CODE **:**
RATIONALE : This unit is complementary to compensate the boundary less content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

- Develop knowledge to refer literature for given topic. Literature search include key words,
- Library use and internet use.
- Develop presentation skills.
- Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

- Find any reference related to the theme.
- Have presentation skills in terms of precise and contented, relevant presentation.
- Identify current perspectives related to the subject.

PREREQUISITES: None

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME (HRS)			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL		Theory	Practical	Theory	Practical	
--	Seminar/Assignment	-	7	7	4	--	100	--	--	100

EXAM NO _____

KADI SARVA VISHWAVIDYALAYA

SEMESTER END EXAMINATION (MONTH-YEAR)

M. PHARM SEM - (NEW)

(SUBJECT CODE) SUBJECT NAME

DATE: **TIME: 3 HRS** **MARKS: 75**

NOTE: 1) Attempt ALL the Questions from each section.
2) Tie both the Sections Separately.

SECTION-I **[40]**

Q.1	Answer the following questions (MCQs/fill in blanks/Objective/ T/F) one Marks each	[10]
Q.2	LONG Answer the following	[10]
	OR//	
Q.2	LONG Answer the following	[10]
Q.3	Short Answer the following [ANY FOUR]	[20]
	1)	
	2)	
	3)	
	4)	
	5)	

SECTION-II **[35]**

Q.4	Answer the following questions (MCQs/fill in blanks/Objective/ T/F) marks each	[10]
Q.5	LONG Answer the following	[10]
	OR//	
Q.5	LONG Answer the following	[10]
Q.6	Short Answer the following [ANY THREE]	[15]
	1)	
	2)	
	3)	
	4)	

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