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 – II

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		Theory	Practical	Theory	Practical
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	---	4	---
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	---	4	---
MPH203T	Computer Aided Drug Delivery System	4	---	4	---
MPH204T	Cosmetic and Cosmeceuticals	4	---	4	---
MPH205P	Pharmaceutics Practical - II	---	12	---	6
-	Seminar/Assignment	---	7	---	4
	Total	35		26	

SPECIALIZATION: PHARMACEUTICS (MPH)

SCHEME OF EXAMINATION

SEMESTER – II

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	3	75	25	--	--
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	3	75	25	--	--
MPH203T	Computer Aided Drug Delivery System	3	75	25	--	--
MPH204T	Cosmetic and Cosmeceuticals	3	75	25	--	--
MPH205P	Pharmaceutics Practical - II	6	--	--	100	50
-	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT : **MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)**

SUBJECT CODE : **MPH201T**

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 NTDS
- The formulation and evaluation of novel drug delivery systems.

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

- Make choice of correct approach to overcome biological barriers from each route.
- Make choice of suitable technology for drug candidate for improved bioavailability.
- Perform in vitro and ex-vivo methods of determination of biopharmaceutical properties of formulations.
- Screen formulations before in-vivo studies.
- Make choice of polymers to design economical and effective controlled release formulations.

PREREQUISITES: Pharmaceutical technology

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	
MPH201T	MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Targeted Drug Delivery Systems**	12
	• Concepts, Events and biological process involved in drug targeting. • Tumor targeting and Brain specific delivery.	
2	**Targeting Methods**:	12
	• Introduction preparation and evaluation. • **Nano Particles & Liposomes**: Types, preparation and evaluation.	
3	**Micro Capsules / Micro Spheres**	12
	• Types, preparation and evaluation, • Monoclonal Antibodies; preparation and application, • Preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	
4	**Pulmonary Drug Delivery Systems**	12
	• Aerosols, Propellants, Containers Types, preparation and evaluation, • Intra Nasal Route Delivery systems; Types, preparation and evaluation	
5	**Nucleic acid based therapeutic delivery system**	12
	• Gene therapy, introduction (ex-vivo & in-vivo gene therapy). • Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non-viral gene transfer). • Liposomal gene delivery systems. • Bio distribution and Pharmacokinetics. • knowledge of therapeutic antisense molecules and aptamers as drugs of future.	

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

SUBJECT : ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
SUBJECT CODE : MPH202T
SCOPE : This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts**.**
OBJECTIVES : Upon completion of the course, student shall be able to understand:

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutical studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutical parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

LEARNING OUTCOMES: At the end of the course the student will be able to:
Apply principles of biopharmaceutics and pharmacokinetics in drug product design.
PREREQUISITES: Anatomy and Physiology.
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	
MPH202T	ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Drug Absorption from the Gastrointestinal Tract**:	12
	Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, PH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate.	
	Gastrointestinal absorption: Role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form	
	Dissolution methods: Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.	
	Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	
2	**Biopharmaceutical considerations in drug product design and In Vitro Drug Product Performance**:	12
	Introduction, Biopharmaceutical factors affecting drug bioavailability, Rate-limiting steps in drug absorption, Physicochemical nature of the drug Formulation factors affecting drug product performance, In vitro: dissolution and drug release testing, Compendial methods of dissolution, alternative methods of dissolution testing, Meeting dissolution requirements, Problems of variable control in dissolution testing Performance of drug products. In vitro–in vivo correlation, Dissolution profile comparisons, Drug product stability, considerations in the design of a drug product	

3	**Pharmacokinetics**	12
	Basic considerations, Pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of Kmax and Vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters	
4	**Drug Product Performance, In Vivo:**	12
	Bioavailability and Bioequivalence: Drug product performance, purpose of bioavailability studies, Relative and absolute availability. Methods for assessing bioavailability, Bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, Bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), Clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	
5	**Application of Pharmacokinetics**	12
	Modified-Release Drug Products Targeted Drug Delivery Systems and Biotechnological Products Introduction to Pharmacokinetics and Pharmacodynamic drug interactions. Pharmacokinetics and Pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	

SR.NO	NAME OF BOOK/REFERENCE
1	Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2	Biopharmaceutics and Pharmacokinetics, A. Treatise, D. M. Brahmankar and Sunil B. Jaiswal., Vallabh Prakashan, Pitampura, Delhi
3	Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC, 2ndedition, Connecticut Appleton Century Crofts, 1985.
4	Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5	Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6	Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970.
7	Clinical Pharmacokinetics, Concepts and Applications 3rd Edition by Malcolm Rowland and Thom- N. Tozer, Lea and Febiger, Philadelphia, 1995
8	Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9	Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc., New York and Basel,1987.
10	Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st Edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11	Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12	Basic Pharmacokinetics, 1st Edition, Sunil S Jambhekar and Philip J Breen, Pharmaceutical press, RPS Publishing, 2009.
13	Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc., 2003.

SUBJECT : **COMPUTER AIDED DRUG DEVELOPMENT**
SUBJECT CODE : **MPH203T**
SCOPE : This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

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

- Apply computer software in design of drug delivery systems.
- Use software to optimize the formulations.
- Apply QbD approach in F & D.

PREREQUISITES: Basic computer applications

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	
MPH203T	COMPUTER AIDED DRUG DEVELOPMENT	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	a) **Computers in Pharmaceutical Research and Development**: • A General Overview: History of Computers in • Pharmaceutical Research and Development. • Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, • Statistical Parameters, Estimation, Confidence Regions, • Nonlinearity at the Optimum, • Sensitivity Analysis, Optimal Design, Population Modeling.	12
	b) **Quality-by-Design in Pharmaceutical Development**: • Introduction, • ICH Q8 guideline, • Regulatory and industry views on QbD, • Scientifically based QbD - examples of application	
2	**Computational Modeling of Drug Disposition**: • Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, • Active Transport; P-Gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12

3	❖ **Computer-Aided Formulation Development**: • Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. ❖ **Computers in Pharmaceutical Formulation:** • Development of pharmaceutical emulsions, Development of Macroemulsion drug carriers, Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	12
4	a. **Computer-aided biopharmaceutical characterization**: • Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in-vivo correlation, Biowaiver considerations **b. Computer Simulations in Pharmacokinetics and Pharmacodynamics:** • Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. **Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems**	12
5	**Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** • General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2	Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing.
3	Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.

SUBJECT : COSMETICS AND COSMECEUTICALS
SUBJECT CODE : MPH204T
SCOPE : This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.
OBJECTIVES : Upon completion of the course, student shall be able to understand:

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy

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

- Develop and design cosmetic products with healthcare aspect.
- Be aware of national and international regulatory requirements.

PREREQUISITES: Physicochemical principles of pharmaceuticals.

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	
MPH204T	COSMETICS AND COSMECEUTICALS	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Cosmetics – Regulatory**: • Definition of cosmetic products as per Indian regulation. • Indian regulatory requirements for labeling of cosmetics • Regulatory provisions relating to import of cosmetics, • Misbranded and spurious cosmetics. • Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12
2	**Cosmetics - Biological aspects**: • Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. • Structure of hair and hair growth cycle. • Common problems associated with oral cavity. • Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	12
3	**Formulation Building blocks**: Building blocks for different product formulations of cosmetics/cosmeceuticals. • Surfactants – Classification and application. • Emollients, • Rheological additives: classification and application. • Antimicrobial used as preservatives, their merits and demerits. • Factors affecting microbial preservative efficacy. • Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.	12
	Perfumes; • Classification of perfumes. • Perfume ingredients listed as allergens in EU regulation.	

	• Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	
4	**Design of cosmeceutical products**: • Sun protection, sunscreens classification and regulatory aspects. • Addressing dry skin, acne, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and • Sensitive teeth through cosmeceutical formulations.	12
5	**Herbal Cosmetics**: • Herbal ingredients used in Hair care, skin care and oral care. • Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. • Challenges in formulating herbal cosmetics.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Harry's Cosmeticology. 8th edition.
2	Poucher'sperfumecosmeticsandSoaps,10th edition.
3	Cosmetics - Formulation, Manufacture and quality control, P P. Sharma,4th edition
4	Handbook of cosmetic science and Technology A. O. Barel, M. Paye and H.I. Maibach. 3rd edition.
5	Cosmetic and Toiletries recent suppliers catalogue.
6	CTFA directory

SUBJECT : PHARMACEUTICS PRACTICALS - II
SUBJECT CODE : MPH205P
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	
MPH205P	PHARMACEUTICS PRACTICALS - II	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS

SR.NO	PRACTICAL
1.	To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2.	Preparation and evaluation of Alginate beads
3.	Formulation and evaluation of gelatin /albumin microspheres
4.	Formulation and evaluation of liposomes/Niosomes
5.	Formulation and evaluation of spherules
6.	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7.	Comparison of dissolution of two different marketed products /brands
8.	Protein binding studies of a highly protein bound drug & poorly protein bound drug
9.	Bioavailability studies of Paracetamol in animals.
10.	Pharmacokinetic and IVIVC data analysis by Winnoline® software
11.	In vitro cell studies for permeability and metabolism
12.	DoE Using Design Expert® Software
13.	Formulation data analysis Using Design Expert® Software
14.	Quality-by-Design in Pharmaceutical Development
15.	Computer Simulations in Pharmacokinetics and Pharmacodynamics
16.	Computational Modeling of Drug Disposition
17.	To develop Clinical Data Collection manual
18.	To carry out Sensitivity Analysis, and Population Modeling.
19.	Development and evaluation of Creams
20.	Development and evaluation of Shampoo and Toothpaste base
21.	To incorporate herbal and chemical actives to develop products
22.	To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

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: 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

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MASTER OF PHARMACY SYLLABUS
Effective from Session JUNE 2017

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SCHEME OF TEACHING

SEMESTER – II

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		Theory	Practical	Theory	Practical
MQA201T	Hazards and Safety Management	4	---	4	---
MQA202T	Pharmaceutical Validation	4	---	4	---
MQA203T	Audits and Regulatory Compliance	4	---	4	---
MQA204T	Pharmaceutical Manufacturing Technology	4	---	4	---
MQA205P	Pharmaceutical Quality Assurance Practical-II	---	12	---	6
---	Seminar/Assignment	---	7	---	4
	Total	35		26	

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SCHEME OF EXAMINATION

SEMESTER – II

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MQA201T	Hazards and Safety Management	3	75	25	--	--
MQA202T	Pharmaceutical Validation	3	75	25	--	--
MQA203T	Audits and Regulatory Compliance	3	75	25	--	--
MQA204T	Pharmaceutical Manufacturing Technology	3	75	25	--	--
MQA205P	Pharmaceutical Quality Assurance Practical-II	6	--	--	100	50
-	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT : **HAZARDS AND SAFETY MANAGEMENT**
SUBJECT CODE : **MQA201T**
SCOPE This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations**.**
OBJECTIVES Upon completion of the course, student shall be able to understand:

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an idea to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere

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

- Classification of hazards and safety measures required for the same.
- Knowledge of nature and handling of various types of chemicals and their safe disposal.

PREREQUISITES:
Basic knowledge about safety and handling of chemicals.
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	
MQA201T	Hazards and Safety Management	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Multidisciplinary nature of environmental studies**: • Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources • Ecosystems: Concept of an ecosystem and Structure and Function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	12
2	**Air based hazards**: • Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) • Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.	12
3	**Chemical based hazards**: • Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, • Management of over-Exposure to chemicals and TLV concept	12
4	**Fire and Explosion**:	12

	• Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, • Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system, Mechanical and chemical explosion, Multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion • Electricity Passivation, ventilation, and sprinkling, proofing, relief Systems -relief valves, flares, scrubbers.	
5	**Hazard and risk management**: • Self-protective measures against workplace hazards. • Critical training for risk management, Process of hazard management, • ICH guidelines on risk assessment and Risk management methods and Tools • Factory act and rules, fundamentals of accident prevention, • Elements of safety Programme and safety management, • Physicochemical measurements of effluents, BOD, COD, • Determination of some contaminants, Effluent treatment Procedure, • Role of emergency services.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2	Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3	Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4	Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

SUBJECT : **PHARMACEUTICAL VALIDATION**
SUBJECT CODE : **MQA202T**
SCOPE The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.
OBJECTIVES Upon completion of the course, student shall be able to understand:

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

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

- perform the analytical and bioanalytical validation of API and formulation.
- Performing qualification of various instruments.

PREREQUISITES:
Basic knowledge about quality assurance, quality control, regulatory guidelines, instrumentation

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	
MQA202T	Pharmaceutical Validation	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Introduction to validation**: • Definition of Calibration, Qualification and Validation, Scope, frequency and importance. • Difference between calibration and validation. Calibration of weights and measures. • Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. • Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).	10
2	**Qualification of manufacturing equipment**: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet compression (machine), Dry heat sterilization/tunnels, Autoclaves, Membrane filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.	10
3	**Qualification of laboratory equipments**: Hardness tester, Friability test apparatus, Tap density tester, Disintegration tester, Dissolution test apparatus, Validation of Utility systems: Pharmaceutical water system & Pure steam, HVAC system, Compressed air and nitrogen.	10
4	**Process Validation**: • Concept, Process and documentation of Process Validation. • Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations, (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.),	10

	• Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. • Analytical method validation: General principles, Validation of Analytical method as per ICH guidelines and USP.	
5	**Cleaning Validation**: • Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant. • Computerized system validation: Electronic records and digital Signature - 21 CFR Part 11 and GAMP	10
6	**General Principles of Intellectual Property**: • Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent application; patent application forms and guidelines. • Types patent applications-provisional and non-provisional, PCT and convention patent applications; • International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. • Significance of transfer technology (TOT), IP and ethics-positive and negative Aspects of IPP; Societal responsibility, avoiding unethical practices.	10

SR.NO	NAME OF BOOK/REFERENCE
1	B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2	The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3	Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4	Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, Marcel Dekker).
5	Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6	Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7	Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.
8	Validation of Pharmaceutical Processes: Sterile Products, Frederick J.
9	Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10	Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11	Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
12	LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

SUBJECT : **AUDITS AND REGULATORY COMPLIANCE**
SUBJECT CODE : **MPA 203T**
SCOPE This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries**.**
OBJECTIVES **:** Upon completion of the course, student shall be able to understand:

- To understand the importance of auditing
- To understand the methodology of auditing and to carry out the audit process
- To prepare the auditing report and to prepare the check list for auditing

LEARNING OUTCOMES: At the end of the course the student will be able to: Role of audit in Pharmaceutical industries, laboratories, purchase operation. Importance of audit in Pharmaceutical industries.
PREREQUISITES: Basic knowledge of Audit.
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	
MQA203T	Audits and Regulatory Compliance	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries	12
3	Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12
4	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12
5	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury 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.
5	Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
6	Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.

SUBJECT : **PHARMACEUTICAL MANUFACTURING TECHNOLOGY**
SUBJECT CODE : **MQA204T**
SCOPE This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.
OBJECTIVES Upon completion of the course, student shall be able to understand:

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.

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

- Concepts of various processes carried out in sterile and non-sterile manufacturing areas.
- Preparation of plant layout and production planning.

PREREQUISITES:
Basic knowledge of various operations related of Pharmaceutical industries.

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	
MQA204T	Pharmaceutical Manufacturing Technology	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Pharmaceutical industry developments**: • Legal requirements and Licenses for API and formulation industry, • Plant location- Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, Sterile and aseptic area layout. • Production planning: General principles, production systems, Calculation of standard cost, process planning, routing, loading, Scheduling, dispatching of records, production control.	12
2	**Aseptic process technology**: • Manufacturing, manufacturing flowcharts, In-process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). • Advanced sterile product manufacturing technology: Area Planning & environmental control, wall and floor treatment, Fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. • Process Automation in Pharmaceutical Industry: With specific Reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),	12
	Sterilization: Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.	

3	**Non-sterile manufacturing process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). **Advance non-sterile solid product manufacturing technology**: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, **Improved Tablet Production:** Tablet production process, Granulation and palletization equipments, Continuous and batch mixing, Rapid mixing granulators, Rota granulators, Spheronizers and marumerisers, another specialized granulation and drying equipments. Problems encountered. **Coating technology**: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.	12
4	**Containers and closures for pharmaceuticals**: Types, performance, Assuring quality of glass; Types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; Different types of closures and closure liners; Film wrapper; Blister packs; Bubble packs; Shrink packaging; Foil / plastic pouches, Bottle seals, tape seals, breakable seals and sealed tubes; Quality control of packaging material and filling equipment, Flexible packaging, Product package compatibility, Transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material	12
5	**Quality by design (QbD) and process analytical Technology (PAT)**: Current approach and its limitations. Why QBD is required? Advantages, Elements of QBD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QBD for drug products, QBD for Drug Substances, QBD for Excipients, Analytical QBD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: Quality by design (QBD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2	Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5Th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3	Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4	Banker GS, Rhodes CT. Modern Pharmaceutics, 4Th ed., Marcel Dekker Inc, New York, 2005.
5	Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai
6	Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7	British Pharmacopoeia. British Pharmacopoeia Commission Office,
8	United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
9	Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10	Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11	Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

SUBJECT : PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – II
SUBJECT CODE : MQA205P
SCOPE
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:

- Qualification of various pharma equipments and instruments.
- Analytical method validation.
- Handling of various instruments.

PREREQUISITES:
Basic theoretical knowledge of instruments and validation.
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	
MQA205P	Pharmaceutical Quality Assurance Practical-II	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS

SR.NO	PRACTICAL
1	Organic contaminants residue analysis by HPLC
2	Estimation of Metallic contaminants by Flame photometer
3	Identification of antibiotic residue by TLC
4	Estimation of Hydrogen Sulphide in Air.
5	Estimation of Chlorine in Work Environment.
6	Sampling and analysis of SO2 using Colorimetric method
7	Qualification of following Pharma equipment
	• Autoclave
	• Hot air oven
	• Powder Mixer (Dry)
	• Tablet Compression Machine
8	Validation of an analytical method for a drug
9	Validation of a processing area
10	Qualification of at least two analytical instruments
11	Cleaning validation of one equipment
12	Qualification of Pharmaceutical Testing Equipment (Dissolution testing Apparatus, Friability Apparatus, Disintegration Tester)
13	Check list for Bulk Pharmaceutical Chemicals vendors
14	Check list for tableting production.
15	Check list for sterile production area
16	Check list for Water for injection.
17	Design of plant layout: Sterile and non-sterile
18	Case study on application of QbD
19	Case study on application of PAT

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 – II

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		Theory	Practical	Theory	Practical
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	---	4	---
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	---	4	---
MRA203T	Regulatory Aspects of Medical Devices	4	---	4	---
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	---	4	---
MRA205P	Regulatory Affairs Practical-II	---	12	---	6
---	Seminar/Assignment	---	7	---	4
	Total	35		26	

SPECIALIZATION: PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER – II

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MRA201T	Regulatory Aspects of Drugs & Cosmetics	3	75	25	--	--
MRA202T	Regulatory Aspects of Herbal & Biologicals	3	75	25	--	--
MRA203T	Regulatory Aspects of Medical Devices	3	75	25	--	--
MRA204T	Regulatory Aspects of Food & Nutraceuticals	3	75	25	--	--
MRA205P	Regulatory Affairs Practical-II	6	--	--	100	50
-	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT : **REGULATORY ASPECTS OF DRUGS & COSMETICS**
SUBJECT CODE : **MRA201T**
SCOPE : This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

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

- The Process of drug discovery and development and generic product Development
- Regulatory approval process and registration procedures for API and Drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

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

- Understand process of drug discovery and development and generic product Development.
- Understand Regulatory approval process and registration procedures, cosmetic regulations in regulated and semi regulated markets across the world.
- Acquire knowledge regarding the emerging market trends of the world.

PREREQUISITES: B. Pharm. Graduates

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	
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**USA & CANADA**: • Organization structure and functions of FDA. • Federal register and Code of Federal Regulations (CFR), • History and evolution of United States • Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, • Drug Master Files (DMF) system in US, • Regulatory ApprovalProcess for Investigational New Drug (IND), • New Drug Application (NDA), • Abbreviated New Drug Application (ANDA), • Supplemental New Drug Application (SNDA); • Regulatory requirements for Orphan drugs and Combination Products, • Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, • Packaging and labeling of pharmaceuticals in USA. • Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.	12

2	**European Union & Australia**: • Organization and structure of EMA & EDQM, General guidelines, • Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD • Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). • Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, • Eudralex directives for human medicines, Variations &extensions, • Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. • Legislation and regulations for import, manufacture, distribution and sale ofcosmetics in European Union & Australia.	12
3	**Japan**: • Organization of the PMDA, Pharmaceutical Laws and regulations, Types of registration applications • DMF system in Japan, Drug regulatory approval process • Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. • Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	12
4	**Emerging Market**: • Introduction, Countries covered, Study of the world map • Study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) • WHO: WHO, GMP Regulatory Requirements for registration of drugs and Post Approval requirements in WHO through prequalification Programme • Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)	12
5	**Brazil, ASEAN, CIS and GCC Countries**: ❖ **ASIAN Countries**: • Introduction to ACTD • Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. ❖ **CIS (Commonwealth Independent States)**: • Regulatory pre-requisites related to Marketing Authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine ❖ **GCC (Gulf Cooperation Council) for Arab states**: • Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE • Legislation and regulations for import, manufacture, distributionand sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries	12

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, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3	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.
4	New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5	Guidebook for drug regulatory submissions / Sandy Weinberg by John Wiley & Sons. Inc.
6	Drugs: From Discovery to Approval, Second Edition by Rick Ng
7	New Drug Development: A Regulatory Overview, Eighth Edition by Mark Mathieu
8	Pharmaceutical Risk Management by Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9	Preparation and Maintenance of the IND Application in eCTD Format by William K. Sietsema
10	Country Specific Guidelines from official websites.
11	http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12	Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13	ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14	Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15	Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16	The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17	Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18	The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19	Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN: 13:978-1-60649-108-9
20	Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South east Asian studies, Singapore

SUBJECT : **REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS**
SUBJECT CODE : **MRA202T**
SCOPE : This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products
OBJECTIVES **:** Upon completion of the course, student shall be able to:

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations ofbiologics
- Understand the Regulatory Requirements of Blood and/or ItsComponents

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

- Gain the complete knowledge of the Regulatory Requirements for biologics, Vaccines and Blood Products in India and globally.
- To understand the Quality, safety and legislation for herbal products in India, USA and European Union.

PREREQUISITES: B. Pharm. Graduate with basic knowledge of drug approval process

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	
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**India**: • Introduction, • Applicable Regulations and Guidelines, • Principles for Development of Similar Biologics, • Data Requirements for Preclinical Studies, • Data Requirements for Clinical Trial Application, • Data Requirements for Market Authorization Application, • Post-Market Data for Similar Biologics, • Pharmacovigilance. • GMP and GDP	12
2	**USA**: • Introduction to Biologics; biologics, biological and biosimilars, different biological products, • Difference between generic drug and biosimilars, • Laws, regulations and guidance on biologics/ biosimilars, • Development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), • Pre-clinical and clinical development considerations, advertising, labelling and packing of biologics	12

3	**European Union**: • Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, • Plasma master file, TSE/ BSE evaluation, • Development and regulatory approval of biologics (Investigational medicinal products and biosimilars), • Pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU	12
4	**Vaccine regulations in India, US and European Union**: • Clinical evaluation, Marketing authorization, • Registration or licensing, • Quality assessment, Pharmacovigilance, Additional requirements **Blood and Blood Products Regulations in India, US and European Union:** • Regulatory Requirements of Blood and/or Its Components Including Blood Products, • Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)	12
5	**Herbal Products:** Quality, safety and legislation for herbal products in India, USA and European Union.	12

SR.NO	NAME OF BOOK/REFERENCE
1	FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus; Informa, 2008
2	Biological Drug Products: Development and Strategies; We Wang, Manmohan Singh; wiley, 2013
3	Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4	www.who.int/biologicals/en
5	www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInfo rmation/
6	www.ihn-org.com
7	www.isbtweb.org
8	Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9	www.cdsco.nic.in
10	www.ema.europa.eu › scientific guidelines › Biologicals
11	www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

SUBJECT : **REGULATORY ASPECTS OF MEDICAL DEVICES**
SUBJECT CODE : **MRA203T**
SCOPE This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries

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

- Basics of medical devices and IVDS, process of development, ethical and quality considerations
- Harmonization initiatives for approval and marketing of medical devices AND IVDS
- Regulatory approval process for medical devices and IVDS in India, US, Canada, EU, Japan and ASEAN
- Clinical evaluation and investigation of medical devices and IVDs

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

- Have a complete understanding of the various aspects of an emerging field of medical devices
- Understand the regulatory requirements for the approval and marketing of marketing devices and IVDs in the regulated countries.

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	
MRA203T	Regulatory Aspects of Medical Devices	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Medical Devices**: • Introduction, Definition, • Risk based classification and Essential Principles of Medical Devices andIVDs. • Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, • History of Medical Device Regulation, • Product Lifecycle of Medical Devices and Classification of Medical Devices. **IMDRF/GHTF**: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, • Summary Technical Document (STED), • Global Medical Device Nomenclature (GMDN).	12
2	**Ethics**: • Clinical Investigation of Medical Devices, • Clinical Investigation Plan for Medical Devices, • Good Clinical Practice for Clinical Investigation of medical devices (ISO	12

	14155:2011) **Quality**: Quality System Regulations of Medical Devices: ISO 13485, • Quality Risk Management of Medical Devices: ISO14971, • Validation and Verification of Medical device, • Adverse Event Reporting of Medical device	
3	**USA:** • Introduction, • Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, • Pre-Market Approval (PMA), • Investigational Device Exemption (IDE) and In vitro Diagnostics, • Quality System Requirements 21 CFR Part 820, • Labeling requirements 21 CFR Part 801, • Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.	12
4	**European Union**: • Introduction, • Classification, Regulatory approval process for Medical Devices • (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. • Basics of In vitro diagnostics, classification and approval process.	12
5	**ASEAN, China & Japan**: • Medical Devices and IVDs, • Regulatory registration procedures, • Quality System requirements and clinical evaluation and investigation. • IMDRF study groups and guidance documents.	12

SR.NO	NAME OF BOOK/REFERENCE
1	FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2	Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3	Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4	Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5	Country Specific Guidelines from official websites.

SUBJECT : **REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS**
SUBJECT CODE : **MRA204T**
SCOPE : This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.
OBJECTIVES **:** Upon completion of the course, student shall be able to:

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

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

- Have an in-depth knowledge regarding the Regulatory Aspects for nutraceuticals and food supplements in India and across the world.

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	
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Nutraceuticals**: • Introduction, • History of Food and Nutraceutical Regulations, • Meaning of Nutraceuticals, • Dietary Supplements, Functional Foods, • Medical Foods, Scope and Opportunities in Nutraceutical Market.	12
2	**Global Aspects**: • WHO guidelines on nutrition. • NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, • NSF Certification, NSF Standards for Food And Dietary • Supplements. • Good Manufacturing Practices for Nutraceuticals.	12
3	I**ndia**: • Food Safety and Standards Act, • Food Safety and Standards Authority of India: Organization and Functions, • Regulations for import, manufacture and sale of nutraceutical products in India, • Recommended Dietary Allowances (RDA) in India.	12
4	**USA**: • US FDA Food Safety Modernization Act, • Dietary Supplement Health and Education Act.	12

	• U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, • Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S.	
5	**European Union**: • European Food Safety Authority (EFSA): • Organization and Functions. • EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. • Nutrition labelling. European Regulation on Novel Foods and • Novel Food Ingredients. • Recommended Dietary Allowances (RDA) in Europe.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2	Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3	http://www.who.int/publications/guidelines/nutrition/en/
4	http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOLSTU(2015)536324_EN.pdf
5	Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6	Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7	Country Specific Guidelines from official websites (Wiley)

SUBJECT : REGULATORY AFFAIRS PRACTICAL - II
SUBJECT CODE : MRA205P
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:

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	
MRA205P	Regulatory Affairs Practical-II	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS

SR.NO	PRACTICAL
	Case studies on
1	Change Management/ Change control. Deviations
2	Corrective & Preventive Actions (CAPA)
3	Documentation of raw materials analysis as per official monographs
4	Preparation of audit checklist for various agencies
5	Preparation of submission to FDA using eCTD software
6	Preparation of submission to EMA using eCTD software
7	Preparation of submission to MHRA using eCTD software
8	Preparation of Biologics License Applications (BLA)
9	Preparation of documents required for Vaccine Product Approval
10	Comparison of Clinical Trial application requirements of US, EU and India of Biologics
11	Preparation of Checklist for Registration of Blood and Blood Products
12	Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
13	Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
14	Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market Authorization
15	Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
16	Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
17	Checklists for 510K and PMA for US market
18	Checklist for CE marking for various classes of devices for EU
19	STED Application for Class III Devices
20	Audit Checklist for Medical Device Facility
21	Clinical Investigation Plan for Medical Devices

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 – II

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		Theory	Practical	Theory	Practical
MPP201T	Principles of Quality Use of Medicines	4	---	4	---
MPP202T	Pharmacotherapeutics - II	4	---	4	---
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	---	4	---
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	---	4	---
MPP205P	Pharmacy Practice Practical - II	---	12	---	6
---	Seminar/Assignment	---	7	---	4
	Total	35		26	

SPECIALIZATION: PHARMACY PRACTICE (MPP)

SCHEME OF EXAMINATION

SEMESTER – II

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MPP201T	Principles of Quality Use of Medicines	3	75	25	--	--
MPP202T	Pharmacotherapeutics - II	3	75	25	--	--
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	3	75	25	--	--
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	3	75	25	--	--
MPP205P	Pharmacy Practice Practical - II	6	--	--	100	50
-	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT **: PRINCIPLES OF QUALITY USE OF MEDICINES**
SUBJECT CODE **: MPP201T**
SCOPE This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.
OBJECTIVES **:** Upon completion of the course, student shall be able to understand:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

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

- Understand and explain quality use of medicine in health care.
- Understand and learn Practice of evidence based medicine and rational drug use.
- Comment and explain medication error and safety-ADR.
- Understand pharmacist role role-value in quality use of medicine.
- Acquire knowledge on regulatory aspects and drug use in special population.

PREREQUISITES: Pharmacology, Pharmacotherapeutics, 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	
MPP201T	Principles of Quality Use of Medicines	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Introduction to Quality use of medicines (QUM)**: • Definition and Principles of QUM, • Key partners and responsibilities of the partners, • Building blocks in QMC, • Evaluation process in QMC, • Communication in QUM, • Cost effective prescribing.	12
2	**Concepts in QUM** • Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings Essential drugs: Definition, need, concept of essential drug, • National essential drug policy and list • Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.	12
3	**QUM in various settings**: • Hospital settings, Ambulatory care/Residential care, • Role of health care professionals in promoting the QUM,	12

	• Strategies to promote the QUM, Impact of QUM on E-health, • Integrative medicine and multidisciplinary care. **QUM in special population**: • Pediatric prescribing, • Geriatric prescribing, • Prescribing in pregnancy and lactation, • Prescribing in immune compromised and organ failure patients.	
4	**Regulatory aspects of QUM in India**: • Regulation including scheduling, • Regulation of complementary medicines, • Regulation of OTC medicines, • Professional responsibility of pharmacist, • Role of industry in QUM in medicine development.	12
5	**Medication errors**: • Definition, categorization and causes of medication errors, • Detection and prevention of medication errors, • Role of pharmacist in monitoring and management of medication errors **Pharmacovigilance**: • Definition, aims and need for pharmacovigilance, • Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, • Causality assessment of ADRs, Management of ADRs, • Role of pharmacist in pharmacovigilance.	12

SR.NO	NAME OF BOOK/REFERENCE
1	A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2	Andrews EB, Moore N. Mann's Pharmacovigilance
3	Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4	Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5	Cohen MR. Medication Errors
6	Online:
	• http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf • http://curriculum.racgp.org.au/statements/quality-use-of-medicines/ • http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7	Relevant review articles from recent medical and pharmaceutical literature.

SUBJECT : PHARMACOTHERAPEUTICS - II
SUBJECT CODE : MPP202T

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:

- Appreciate and implement rational use of medicines;
- Summarize therapeutic approach for management of disease;
- Explain and discuss controversies in therapy management and evidence based medicine;
- Able to set a goal based on diagnosis;
- Able to identify and correlate problems of therapy in patient.
- 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.
- Choose and justify appropriate drug and treatment with duration to a given patient with regard to current recommendations and patient-related factors such as other diseases, age, organ functions and another drug treatment.
- State (ab)normalities in common laboratory values and explain related to physiology, drug treatment and / or disease

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	
MPP202T	Pharmacotherapeutics-II	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Nervous system**: • Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management	12
2	**Psychiatric disorders**: • Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders	12

	Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease	
3	**Infectious diseases**: • General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, • Bacterial endocarditis, Septicemia.	12
4	**Infectious diseases**: • Meningitis, HIV and opportunistic infections, • Rheumatic fever, Dengue fever, H1N1, Helminthiasis, • Fungal infections Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.	12
5	**Oncology:** • General principles of cancer chemotherapy, • Pharmacotherapy of breast cancer, lung cancer, head & neck cancer • Hematological malignancies, • Management of nausea and vomiting, Palliative care	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 Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.

SUBJECT: CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING
SUBJECT CODE : MPP203T

SCOPE This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data**.**

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

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for pediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

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

- Discuss and Apply PK-PD principles/models to provide drug therapies that maximize efficacy (i.e., pharmacodynamics) and minimize toxicity (i.e., toxicodynamic)
- Recognize and manage PK variability for patients with significant alterations due to factors such as age, body weight, organ function, pregnancy, disease states, clinical status or drug interactions, polymorphism…
- Monitor drug therapies in patients where concentration is measured (i.e., vancomycin, cyclosporine, digoxin, Phenytoin, lithium) and correlated to response from the scientific literature.
- Analyze and interpret data of pharmacokinetics/TDM of drugs to variables and changes
- Discuss how to adjust drug dosages depending on the clinical situation.
- Differentiate the various drugs' pharmacokinetics & adjust their doses in the different clinical situations. Use data to optimize drug selection and dosing for patients including special group-pediatric, geriatric… Select a dose for special patient groups and individual patients by performing calculations.
- Analyze and interpret bioavailability and bioequivalence data.

PREREQUISITES: Human physiology and Biopharmaceutics & pharmacokinetics

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	
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS

1	**Introduction to Clinical pharmacokinetics**: • Compartmental and Non-compartmental models, • Renal and non-renal clearance, • Organ extraction and models of hepatic clearance, • Estimation and determinants of bioavailability, • Multiple dosing, Calculation of loading and maintenance doses **Designing of dosage regimens**: • Determination of dose and dosing intervals, • Conversion from intravenous to oral dosing, • Nomograms and Tabulations in designing dosage regimen.	12
2	**Pharmacokinetics of Drug Interaction**: • Pharmacokinetic drug interactions, • Inhibition and Induction of Drug metabolism, • Inhibition of Biliary Excretion **Pharmacogenetics**: • Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, • Genetic Polymorphism in Drug Transport and Drug Targets • Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations **Introduction to Pharmacometrics**: • Introduction to Bayesian Theory, • Adaptive method or Dosing with feedback, • Analysis of Population Pharmacokinetic Data.	12
3	**Non-Linier Mixed Effects Modelling**: • The Structural or Base Model, • Modeling Random Effects, • Modeling Covariate Relationships, • Mixture Model, • Estimation Methods, • Model Building Techniques, • Covariate Screening Methods, • Testing the model assumptions, • Precision of the parameter estimates and confidence intervals, • Model misspecification and violation of the model assumptions, • Model Validation, Simulation of dosing regimens and dosing recommendations, • Pharmacometrics software.	12
4	**Altered Pharmacokinetics**: • Drug dosing in the elderly, • Drug dosing in the pediatrics, • Drug dosing in the obese patients, • Drug dosing in the pregnancy and lactation, • Drug dosing in the renal failure and extracorporeal removal of drugs, • Drug dosing in the in hepatic failure.	12
5	**Therapeutic Drug monitoring**: • Introduction, • Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs),	12

	• Indications for TDM, Protocol for TDM, • Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, **TDM of drugs used in the following conditions**: • Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; • Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; • Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; • Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; • Antibiotics: Vancomycin, Gentamicin, Meropenem.	

SR.NO	NAME OF BOOK/REFERENCE
1	Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2	Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3	Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4	Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA
5	Soraya Dhillon, Andrzej Kostrzewski. Clinical Pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6	Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A. Blouin and Jane M. Pruemer. Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7	Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.
8	Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health System Pharmacists, USA.
9	Michael E. Winter. Basic Clinical Pharmacokinetics. Lippincott Williams & Wilkins, USA.
10	Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11	Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12	John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health-System Pharmacist, USA.
13	Relevant review articles from recent medical and pharmaceutical literature

SUBJECT : PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS
SUBJECT CODE : MPP204T

SCOPE This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

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

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

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

- Understand the role of pharmacoepidemiological & Pharmacoeconomics in analyzing the economic impact of pharmaceutical interventions on health care systems.
- Explain and comment various models and theories.
- Learn about different types of epidemiological and economic evaluations their use in plan and execute to perform pharmacoepidemiological Pharmacoeconomics studies
- understand the perspectives of economic evaluations and the way they might influence decision analysis and costing of drugs and services.
- analyze data from pharmacoepidemiological and Pharmacoeconomics studies
- Comment pharmacoepidemiological and Pharmacoeconomics studies.
- Understand explain outcomes and Health related "quality of life"

PREREQUISITES: Basic knowledge in area - 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	
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Introduction to Pharmacoepidemiology**: • Definition, Scope, Need, Aims & Applications; **Outcome measurement**: • Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, • Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. • **Concept of risk**: Measurement of risk, Attributable risk and	12

	relative risk, Time- risk relationship and odds ratio	
2	**Pharmacoepidemiological Methods**: **Qualitative models**: • Drug Utilization Review; • Quantitative models: case reports, case series, • Cross sectional studies, Cohort and case control studies, • Calculation of Odds' ratio, Meta-analysis models, **Drug effects study in populations**: • Spontaneous reporting, • Prescription event monitoring, • Post marketing surveillance, • Record linkage systems, • Applications of Pharmacoepidemiology	12
3	**Introduction to Pharmacoeconomics**: • Definition, history of Pharmacoeconomics, • Need of Pharmacoeconomic studies in Indian healthcare system. **Cost categorization and resources for cost estimation**: • Direct costs, Indirect costs, Intangible costs. **Outcomes and Measurements of Pharmacoeconomics**: • Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; • Quality Adjusted Life Years, Disability Adjusted Life Years • Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. • Person Time, Willingness to Pay, Time Trade Off and Discounting.	12
4	**Pharmacoeconomic evaluations**: • Definition, Steps involved, Applications, **Advantages and disadvantages of the following Pharmacoeconomic models:** • Cost Minimization Analysis (CMA), • Cost Benefit Analysis (CBA), • Cost Effective Analysis (CEA), • Cost Utility Analysis (CUA), • Cost of Illness (COI), • Cost Consequences Analysis (COA).	12
5	**Definition, Steps involved, Applications, Advantages and disadvantages of the following**: • Health related quality of life (HRQOL): • Definition, Need for measurement of HRQOL, • Common HRQOL measures. Definition, Steps involved, Applications of the following: • Decision Analysis and Decision tree, • Sensitivity analysis, Markov Modeling, • Software used in Pharmacoeconomic analysis, • Applications of Pharmacoeconomics.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.

2	Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3	Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4	Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5	George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
6	Graker, Dennis. Pharmacoeconomic and outcomes.
7	Walley, Pharmacoeconomics.
8	Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9	Relevant review articles from recent medical and pharmaceutical literature George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.

SUBJECT : PHARMACY PRACTICE PRACTICAL - II
SUBJECT CODE : MPP205P

SCOPE Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics

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:

- Effectively listen, speak and write in a manner that facilitates positive interaction with patients, health professionals and the public
- Identify selected diseases based on knowledge 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
- Choose and justify appropriate drug and treatment duration to patient about current recommendations and patient-related factors such as other diseases, age, organ functions and another drug treatment
- Choose and justify appropriate dose, dosing interval and pharmaceutical form for a given patient about age, organ functions and drug pharmacokinetics, pharmacodynamics and toxicity
- Evaluate abnormalities, efficacy of drug in common laboratory values and explain related to physiology, drug treatment and / or disease. Extract information from medical records/documents.
- Identify, evaluate and respond to basic drug-related problems from patient records and to motivate action
- Identify and priorities therapeutic/ drug-related problems and appropriately select patient specific management regimens, and requirements for monitoring and assessing response to therapy.
- Choose appropriate non-pharmacological treatment regarding the given patient and current recommendations
- Apply knowledge and skills of the core principles of pharmacy practice to simulated patient cases including ethics, forensics, confidentiality and quality use of medicines.
- Apply knowledge to access drug safety-ADR and medication error.
- Respond sufficiently to questions related to drug pricing 2. Evaluate added value of new drugs and interventions compared with available substitutes in the Jordanian market

PREREQUISITES: Completion or concurrent subjects 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	
MPP205P	Pharmacy Practice Practical-II	-	12	12	6	--	50	--	100	150

SR.NO	LIST OF PRACTICALS
1	Causality assessment of adverse drug reactions (three)
2	Detection and management of medication errors (three)
3	Rational use of medicines in special population (three)
4	Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5	Calculation of Bioavailability and Bioequivalence from the given data (two)
6	Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7	Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

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 – II

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		Theory	Practical	Theory	Practical
MPL201T	Advanced Pharmacology - II	4	--	4	--
MPL202T	Pharmacological and Toxicological Screening Methods - II	4	--	4	--
MPL203T	Principles of Drug Discovery	4	--	4	--
MPL204T	Clinical Research and Pharmacovigilance	4	--	4	--
MPL205P	Experimental Pharmacology Practical - II	--	12	---	6
--	Seminar/Assignment	--	7	--	4
	Total	35		26	

SPECIALIZATION: PHARMACOLOGY (MPL)

SCHEME OF EXAMINATION

SEMESTER – II

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
MPL201T	Advanced Pharmacology - II	3	75	25	--	--
MPL202T	Pharmacological and Toxicological Screening Methods - II	3	75	25	--	--
MPL203T	Principles of Drug Discovery	3	75	25	--	--
MPL204T	Clinical Research and Pharmacovigilance	3	75	25	--	--
MPL205P	Experimental Pharmacology Practical - II	6	--	--	100	50
--	Seminar/Assignment	--	--	--	--	100
	Total	--	300	100	100	150

SUBJECT : **ADVANCED PHARMACOLOGY - II**
SUBJECT CODE : **MPL201T**
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, the subject helps the student to understand the concepts of drug action and mechanism involved
OBJECTIVES Upon completion of the course, student shall be able to understand:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- 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:

- Treatment of endocrine disorders
- Treatment of bacterial, viral, fungal and protozoal infections
- Role of free radicals in certain diseases
- GI tract disorders and their treatment; treatment of cancer
- Treatment of certain neurodegenerative disorders

PREREQUISITES:

- Anatomy and physiology of endocrine glands, the physiological actions of hormones on body systems
- Infectious agents
- Anatomy and physiology of GI tract and secretions of GI Tract
- Cell cycle in normal and cancer cell
- Anatomy and physiology of brain

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	
MPL201T	Advanced Pharmacology - II	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Endocrine Pharmacology** • Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones • Anti-thyroid drugs, • Oral hypoglycemic agents, • Oral contraceptives, • Corticosteroids. • Drugs affecting calcium regulation	12
2	**Chemotherapy** Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs	12
3	**Chemotherapy** • Drugs used in Protozoal Infections • Drugs used in the treatment of Helminthiasis • Chemotherapy of cancer	12

	• Immunopharmacology • Cellular and biochemical mediators of inflammation and immune response. • Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. • immunosuppressant and Immunostimulants	
4	**GIT Pharmacology** • Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. • **Chronopharmacology** Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12
5	**Free radicals Pharmacology** • Generation of free radicals, • Role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. • Protective activity of certain important antioxidant • Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	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 et al.
3	Basic and Clinical Pharmacology by B.G -Katzung
4	Pharmacology by H.P. Rang and M.M. Dale.
5	Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6	Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7	Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu.
8	Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9	Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10	A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11	K. D. Tripathi. Essentials of Medical Pharmacology
12	Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

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

SUBJECT CODE : **MPL202T**

SCOPE : This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

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

- Develop and induce various diseases in rodents like rats and mice (experimental models)
- Understand national and international toxicity guidelines
- Studies required for IND approval including *in vitro* and *in vivo*

PREREQUISITES: Regulatory guideline for Toxicity studies of drugs & formulation. Toxicokinetic

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	
MPL202T	Pharmacological and Toxicological Screening Methods - II	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	• Basic definition and types of toxicology (general, mechanistic, • regulatory and descriptive) • Regulatory guidelines for conducting toxicity studies OECD, ICH, • EPA and Schedule Y • OECD principles of Good laboratory practice (GLP) • History, concept and its importance in drug development	12
2	• Acute, sub-acute and chronic- oral, dermal and inhalational Studies as per OECD guidelines. • Acute eye irritation, skin sensitization, dermal irritation & dermal Toxicity studies. • Test item characterization- importance and methods in regulatory toxicology studies	12
3	**Reproductive toxicology studies**, • Male reproductive toxicity studies, • Female reproductive studies (segment I and segment III), • Teratogenicity studies (segment II) **Genotoxicity studies** (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) • In vivo carcinogenicity studies	12
4	**IND enabling studies (IND studies**)- • Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.	12

	• Safety pharmacology studies- origin, concepts and importance of safety pharmacology. • Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	
5	**Toxicokinetic- Toxicokinetic** evaluation in preclinical studies, • Saturation kinetics Importance and applications of toxicokinetic Studies. • Alternative methods to animal toxicity testing.	12

SR.NO	NAME OF BOOK/REFERENCE
1	Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook. pdf).
2	Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3	Drugs from discovery to approval by Rick NG.
4	Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5	OECD test guidelines.
6	Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7	Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246. pdf)

SUBJECT : PRINCIPLES OF DRUG DISCOVERY
SUBJECT CODE : MPL203T
SCOPE The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process
OBJECTIVES Upon completion of the course, student shall be able to understand:

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

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

- Modern drug discovery process
- Drug Design methods
- Quantitative analysis of Structure Activity Relationship

PREREQUISITES:

- Basics of drug discovery and development process
- Concepts of lead and new drug
- Modern analytical techniques
- Concepts of Structure Activity Relationships
- Basics of genetics and proteomics

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	
MPL203T	Principles of Drug Discovery	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**An overview of modern drug discovery process**: • Target identification, • Target validation, • Lead identification and lead Optimization. • Economics of drug discovery. **Target Discovery and validation**- • Role of Genomics, Proteomics and Bioinformatics. • Role of Nucleic acid microarrays, Protein microarrays, • Antisense technologies, siRNAs, antisense oligonucleotides, • Zinc finger proteins. Role of transgenic animals in target validation.	12
2	**Lead Identification**- • Combinatorial chemistry & high throughput screening, • In silico lead discovery techniques, assay development for hit identification. • Protein structure levels of protein structure, • Domains, motifs, and folds in protein structure. **Computational prediction of protein structure**: • Threading and homology modeling methods. • Application of NMR and X-ray crystallography in protein structure prediction	12

3	**Rational Drug Design** • Traditional vs rational drug design, • Methods followed in traditional drug design, • High throughput screening, Concepts of Rational Drug Design, • Rational Drug Design Methods: Structure and Pharmacophore based approaches **Virtual Screening techniques**: • Drug likeness screening, • Concept of pharmacophore mapping and pharmacophore based Screening,	12
4	**Molecular docking**: • Rigid docking, flexible docking, manual docking; • Docking based screening. De novo drug design. • Quantitative analysis of Structure Activity Relationship • History and development of QSAR, SAR versus QSAR, • Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	12
5	**QSAR Statistical methods** – • Regression analysis, Partial least square analysis (pls) and other multivariate statistical methods. • 3d-QSAR approaches like COMFA and COMSIA • Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, • Site specific drug delivery and sustained drug action. • Rationale of prodrug design and practical consideration of prodrug design	12

SR.NO	NAME OF BOOK/REFERENCE
1	MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 umana Press Inc.
2	Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3	Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4	Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5	Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6	Abby L. Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7	J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

SUBJECT : **CLINICAL RESEARCH AND PHARMACOVIGILANCE**
SUBJECT CODE : **MPL204T**
SCOPE This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

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

- ICH-GCP guidelines and regulatory requirements for conduction of clinical trial
- Types of clinical trials (phase trials, bioequivalence trials, observational studies)
- All trial related activities
- Pharmacovigilance and methods of ADR reporting
- Pharmacovigilance programs

PREREQUISITES:

- Concepts of clinical research
- Basics of phase trials and bioequivalence trials
- Concepts of clinical trial conductions and basic requirements
- Basics Good Clinical Practice
- Concepts of Adverse Drug Reactions

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	
MPL204T	CLINICAL RESEARCH AND PHARMACOVIGILANCE	4	-	4	4	25	--	75	--	100

Course content:

CH.NO	PARTICULARS	60 HRS
1	**Regulatory Perspectives of Clinical Trials**: • Origin and Principles of International Conference on Harmonization – • Good Clinical Practice (ICH-GCP) guidelines • Ethical Committee: Institutional Review Board, • Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR • Informed Consent Process: Structure and content of an • Informed Consent Process Ethical principles governing informed consent process	12

2	**Clinical Trials**: **Types and Design Experimental Study**- RCT and Non RCT, • Observation Study: • Cohort, Case Control, Cross sectional • Clinical Trial Study Team **Roles and responsibilities of Clinical Trial Personnel**: • Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	12
3	**Clinical Trial Documentation-** • Guidelines to the preparation of documents, • Preparation of protocol, • Investigator Brochure, Case • Report Forms, Clinical Study Report Clinical Trial Monitoring- • Safety Monitoring in CT • Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. • Predictability and preventability assessment, • Management of adverse drug reactions; Terminologies of ADR.	12
4	**Basic aspects, terminologies and establishment of pharmacovigilance** • History and progress of pharmacovigilance, • Significance of safety monitoring, • Pharmacovigilance in India and international aspects, • WHO international drug monitoring programme, • WHO and Regulatory terminologies of ADR, • evaluation of medication safety, • Establishing pharmacovigilance centers in Hospitals, • Industry and National programmes related to pharmacovigilance. • Roles and responsibilities in Pharmacovigilance	12
5	**Methods, ADR reporting and tools used in Pharmacovigilance** • International classification of diseases, • International Nonproprietary names for drugs, • Passive and Active surveillance, • Comparative observational studies, • Targeted clinical investigations and Vaccine safety surveillance. • Spontaneous reporting system and Reporting to regulatory authorities, • Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, • Statistical methods for evaluating medication safety data.	12
5	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	12

SR.NO	NAME OF BOOK/REFERENCE
1	Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2	International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3	Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

4	Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5	Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6	Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7	Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes

SUBJECT : EXPERIMENTAL PHARMACOLOGY PRACTICAL - II
SUBJECT CODE : MPL205P

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

- Various in-vitro bioassay methods
- To make students familiar with toxicity guidelines

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

- in-vitro bioassay in isolated tissue
- OECD-guidelines for toxicity of drugs in human
- Protocol designing process

PREREQUISITES:

- Fundamentals of physiological salt solutions, tissue mounting, isolated tissue experiments
- Toxicity guidelines as per OECD and Schedule Y
- Basic components of clinical trial

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	
MPL205P	Experimental Pharmacology Practical - II	-	12	12	6	--	50	--	100	150

LIST OF PRACTICALS

SR.NO	PRACTICAL
1	To record the DRC of agonist using suitable isolated tissues preparation.
2	To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3	To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4	To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5	To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6	To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7	Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8	To study the effects of various drugs on isolated heart preparations
9	Recording of rat BP, heart rate and ECG.
10	Recording of rat ECG
11	Drug absorption studies by averted rat ileum preparation.
12	Acute oral toxicity studies as per OECD guidelines.
13	Acute dermal toxicity studies as per OECD guidelines.
14	Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15	Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16	Protocol design for clinical trial. (3 Nos.)
17	Design of ADR monitoring protocol.
18	In-silico docking studies. (2 Nos.)

19	In-silico pharmacophore based screening.
20	In-silico QSAR studies.
21	ADR reporting

SR.NO	NAME OF BOOK/REFERENCE
1	Fundamentals of experimental Pharmacology-by M.N.Ghosh
2	Hand book of Experimental Pharmacology-S.K.Kulakarni
3	Text book of in-vitro practical Pharmacology by Ian Kitchen
4	Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5	Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6	Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

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)	

*****