2.6: Student Performance and Learning Outcomes

2.6.1: Programme and course outcomes for all Programmes offered by the institution are stated and displayed on website and communicated to teachers and students.

Pune District Education Association's

Shankarrao Ursal College of Pharmaceutical Sciences & Research Centre, Kharadi, Pune-14.

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A. Programme Outcomes (POs)

PROGRAMME OUTCOMES

1. **PO1: Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
2. **PO2: Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
3. **PO3: Problem Analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
4. **PO4: Modern Tool Usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
5. **PO5: Leadership Skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well- being.
6. **PO6: Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
7. **PO7: Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
8. **PO8: Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

9. **PO9: The Pharmacist and Society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
10. **PO10: Environment and Sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
11. **PO11: Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self- assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

(Dr. V. U. Baig)
Coordinator

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B. Course Outcomes (COs) for B. Pharm and M. Pharm Programmes (A.Y. 2023-24)

Course Outcomes F. Y. B. Pharm (Semester-I)
Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course student will be able to
1.	Human Anatomy and Physiology-I (2019 Pattern)	BP101T	BP101T1	Define and explain the anatomy and physiology, various levels oforganizations basic homeostatic mechanism.
			BP101T2	Explain the morphology, physiology of skeletal system along with the physiology of muscle contraction in co-ordination with the joints, their articulation and skin.
			BP101T3	Explain and describe the composition, function of various bodyfluids like blood and lymph, their significance and related disorders.
			BP101T4	Classify the peripheral nervous system, nerves and morphology ofspecial senses.
			BP101T5	Explain the anatomy and physiology and parameters related to CVS and related disorders.
2.	Human Anatomy and Physiology-I (2019 Pattern)	BP107P	BP107P1	Utilize effectively the microscope for microscopic study of varioustissues.
			BP107P2	Identify axial and appendicular bones of human skeleton.
			BP107P3	Explain the gross morphology, structure and functions of variousorgans of human body.
			BP107P4	Identify different tissues and organs of different systems of human body.
			BP107P5	Perform the haematological tests like blood cell count, haemoglobin estimation, bleeding/clotting time, etc.
			BP107P6	Record the blood pressure, heart rate, pulse rate and respiratory volume.
3.	Pharmaceutical Analysis I (2019 Pattern)	BP102T	BP102T1	Understand fundamentals of analytical chemistry, principles of volumetric and electrochemical analysis. Carry out various volumetric and electrochemical titrations. Develop analytical skills.
			BP102T2	Differentiate between various types of volumetric titrations like acid base titration, precipitation titration, complexometric titration,

				redox titration as well as able to perform Gravimetric quantitative determination method.
			BP102T3	Illustrate about different electro chemical methods of analysis like conductometry, potentiometry, polarography, refractometry.
4.	Pharmaceutical Analysis I (2019 Pattern)	BP108P	BP108P1	Acquire knowledge about how to carry out various volumetric and electrochemical titrations.
			BP108P2	Perform standardization of various secondary standard substances
			BP108P3	Perform assays of compounds based on different types of volumetric titrations.
			BP108P4	Utilize equipments like conductivity meter, potentiometer, refractometer etc. for the determination of normality and refractive index.
5.	Pharmaceutics I (2019 Pattern)	BP103T	BP103T1	Know the history of profession of pharmacy.
			BP103T2	Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations.
			BP103T3	Understand the professional way of handling the prescription.
			BP103T4	Prepare various conventional dosage forms.
6.	Pharmaceutics I (2019 Pattern)	BP109P	BP109P1	State the correct use of various equipments in Pharmaceutics laboratory relevant to practicals.
			BP109P2	Explain formulation, evaluation and labelling of aromatic water, glycerides, syrups, elixirs and powder preparations.
			BP109P3	Perform pharmaceutical calculations to determine evaluation parameters like density, viscosity, specific gravity, angle of repose, Carr's index, Hausner ratio of preparations.
			BP109P4	Describe use of ingredients in formulation and category of formulation & Perform pharmaceutical calculations.
			BP109P5	Use equipments and apparatus needed for the preparation as per SOP, select the suitable packaging material (container-closure) for the preparation and draw the labels in neat way including all the component/parts.
			BP109P6	Summarize the principles of formulation and evaluation, predict the special requirements of preparations regarding the use, handling and storage conditions.
7.	Pharmaceutical Inorganic Chemistry	BP104T	BP104T1	Understand sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals.

	(2019 Pattern)		BP104T2	Understand the basic concepts of acidity /basicity, buffers and tonicity applicable in pharmaceuticals.
			BP104T3	Understand the medicinal and pharmaceutical applications of inorganic compounds.
			BP104T4	Understand the concepts and principles of radiopharmaceuticals.
8	Pharmaceutical Inorganic Chemistry (2019 Pattern)	BP110P	BP110P1	Develop skills to perform limit test and for given sample.
			BP110P2	Perform identification of different inorganic compounds through various qualitative tests.
			BP110P3	Perform tests for purity for different compounds as per official compendia.
			BP110P4	Acquire knowledge and skills to prepare inorganic salts such as boric acid, potash alum and ferrous sulphate.
9	Communication Skills (2019 Pattern)	BP105T	BP105T1	Understand the behavioural needs for a Pharmacist to function effectively in the areas of pharmaceutical operation.
			BP105T2	Communicate effectively (Verbal and Non Verbal).
			BP105T3	Effectively manage the team as a team player.
			BP105T4	Develop interview skills.
			BP105T5	Develop Leadership qualities and essentials.
11.	Remedial Biology (2019 Pattern)	BP106 RBT	BP106RBT1	Understand the components of living world.
			BP106RBT2	Know the classification and salient features of five kingdoms of life.
			BP106RBT3	Understand the basic components of anatomy & physiology of plant.
			BP106RBT4	Illustrate the basic components of anatomy & physiology animal with special reference to
12	Remedial Biology (2019 Pattern)	BP112RBP	BP112RBP1	Understand the components of living Cell.
			BP112RBP2	Know the classification and salient features of cell and its types.
			BP112RBP3	Understand the basic components of anatomy & physiology of plant.
			BP112RBP4	Illustrate the basic components of anatomy & physiology animal with special reference to human.
13.	Remedial Mathematics (2019 Pattern)	BP106RMT	BP106RMT1	Know the theory and their application in Pharmacy.
			BP106RMT2	Solve the different types of problems by applying theory.
			BP106RMT3	Appreciate the important application of mathematics in Pharmacy.

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Course Outcomes F. Y. B. Pharm (Semester-II)
Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course student will be able to
1	Human Anatomy and Physiology-II (2019 Pattern)	BP201T	BP201T1	Explain the anatomy and physiology and parameters related to digestive system and related disorders.
			BP201T2	Explain the anatomy and physiology and parameters related to nervous system and ANS.
			BP201T3	Explain the anatomy and physiology and parameters related to Urinary system.
			BP201T4	Explain the anatomy and physiology and parameters related Endocrine system.
			BP201T5	Explain the anatomy and physiology and parameters related Reproductive system.
			BP201T6	Explain the anatomy and physiology and parameters related Respiratory system.
2	Human Anatomy and Physiology-II (2019 Pattern)	BP207P	BP207P1	Record the body temperature and Basal Mass Index.
			BP207P2	Explain Reflex and Visual activity.
			BP207P3	Explain positive and negative feedback mechanism.
			BP207P4	Explain the gross morphology, structure and functions of various organs system of human body.
			BP207P5	Perform the hematological test like total blood count.
			BP207P6	Perform the tidal volume and vital capacity.
3	Pharmaceutical Organic Chemistry-I (2019 Pattern)	BP202T	BP202T1	Understand the basic principles of organic chemistry and Classification, IUPAC Nomenclature of organic compounds and Structural Isomerism
			BP202T2	Gain knowledge about different types of elimination and substitution reactions of alkenes, alkyl halides and conjugated dienes
			BP202T3	Gain the knowledge about reactivity & stability of different organic compounds

			BP202T4	Understand qualitative tests, structure, and uses of different organic compounds like alcohols, aldehydes, ketones, carboxylic acids and amines.
4	Pharmaceutical Organic Chemistry-I (2019 Pattern)	BP208P	BP208P1	Understand safety measures in an organic chemistry laboratory.
			BP208P2	Differentiate in between techniques like M.P, B.P determination, crystallization and various types of distillation.
			BP208P3	Perform the qualitative analysis of given organic compound.
			BP208P4	Perform synthesis of the selected organic compounds and understand the reaction mechanism involved in it.
			BP208P5	Understand the concept of building of molecular models of structures containing various functional groups.
5	Biochemistry (2019 Pattern)	BP203T	BP203T1	Understand classification, chemical nature, biological role and metabolism of biomolecules.
			BP203T2	Understand the metabolism of nutrient molecules in physiological and pathological conditions.
			BP203T3	Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.
			BP203T4	Understand the catalytic role of enzymes and importance of enzyme in biochemical process
6	Biochemistry (2019 Pattern)	BP209P	BP208P1	Learn quantitative analysis test of carbohydrates, amino acids and proteins
			BP208P2	Understand qualitative analysis of urine for normal and abnormal constituents.
			BP208P3	Study procedure and principle for determination of serum total cholesterol, blood sugar and blood creatinine.
			BP208P4	Understand preparation of buffer solution and measurement of pH.
			BP208P5	Understand the effect of temperature and substrate concentration on salivary amylase activity.
7	Pathophysiology (2019 Pattern)	BP204T	BP204T1	Describe the etiology and pathogenesis of disease.
			BP204T2	Understand the sign and symptoms of disease with its pathophysiological mechanism.
			BP204T3	Understand the pharmacological treatment of disease.
			BP204T4	Discuss about laboratory techniques and diagnostic test.
8	Computer Applications in Pharmacy	BP205T	BP205T1	Know the various types of application of computers in pharmacy.
			BP205T2	Know the various types of databases.

	(2019 Pattern)		BP205T3	Know the various applications of databases in pharmacy.
9.	Computer Applications in Pharmacy (2019 Pattern)	BP210P	BP210P1	Create a HTML web page to show personal information.
			BP210P2	Design a form in MS Access to view, add, delete and modify the patient record in the data base.
			BP210P3	Create and work with the queries in MS Access and export tables, queries, forms and reports to web pages.
10	Environmental Sciences (2019 Pattern)	BP206T	BP206T1	Elaborate the natural resources available, their advantages and disadvantages on the human and animal health and plants.
			BP206T2	Explain the ecology, energy flow and various ecosystems in the environment describing the biodiversity of state and India.
			BP206T3	Describe various environmental pollution, roll of individual in the pollution and disaster management.

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Course Outcomes S. Y. B. Pharm (Semester-III)
Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course, student will be able to
1	Pharmaceutical Organic Chemistry-II (2019 Pattern)	BP301T	BP301T1	Write the structure, name and the type of isomerism of the organic compound.
			BP301T2	Write the reaction, name the reaction and orientation of reactions
			BP301T3	Account for reactivity/stability of compounds.
			BP301T4	Prepare small organic compounds.
2	Pharmaceutical Organic Chemistry-II (2019 Pattern)	BP305P	BP305P1	Recall the various laboratory techniques involved in the synthesis process.
			BP305P2	Perform experiment with the separation of organic binary mixture.
			BP305P3	Determine the saponification value of oils.
			BP305P4	Perform synthesis, recrystallization and understand reaction mechanisms involved in synthesis of important organic compounds such as Benzanilide, Benzil etc.
3	Physical Pharmaceutics I (2019 Pattern)	BP302T	BP302T1	Ability to apply the knowledge of solubility, diffusion and distribution in pharmaceutical preparations.
			BP302T2	Investigate and apply various theories, laws and equations related to different states of matter.
			BP302T3	Demonstrate use of physicochemical properties of drugs in the formulation development and evaluation of dosage forms.
			BP302T4	Apply the concept of interfacial phenomena in pharmaceutical preparations.
			BP302T5	Distinguish the principles of complexation/ protein binding & to use them for calculations of drug release and stability constant.
			BP302T6	Understand the importance of pH, buffers and tonicity in pharmaceutical and biological system.
4	Physical Pharmaceutics I (2019 Pattern)	BP306P	BP306P1	Determine physicochemical properties of drugs in the formulation development and evaluation of dosage forms.
			BP306P2	Determine and apply the concept of interfacial phenomena in pharmaceutical preparations.

			BP306P3	Distinguish the principles of complexation/ protein binding & to use them for calculations of drug release and stability constant.
			BP306P4	Determine thermodynamic parameters using solubility studies.
5	Pharmaceutical Microbiology (2019 Pattern)	BP303T	BP303T1	Understand methods of identification, cultivation and preservation of various microorganisms.
			BP303T2	Understand the importance and implementation of sterilization in pharmaceutical processing and industry.
			BP303T3	Learn sterility testing of pharmaceutical products.
			BP303T4	Perform microbiological standardization of Pharmaceuticals.
			BP303T5	Understand the cell culture technology and its applications in pharmaceutical industries.
6	Pharmaceutical Microbiology (2019 Pattern)	BP307P	BP307P1	Understand mechanism of equipments.
			BP307P2	Students will be able to formulate culture media.
			BP307P3	Students will be able to identify bacteria by staining method.
			BP307P4	Students will be able to isolate bacteria along with motility determination and assay of antibiotics.
7	Pharmaceutical Engineering (2019 Pattern)	BP304T	BP304T1	Know various unit operations used in pharmaceutical industries.
			BP304T2	Understand the material handling techniques.
			BP304T3	Perform various processes involved in the pharmaceutical manufacturing process.
			BP304T4	Carry out various test to prevent environmental pollution, appreciate and comprehend significance of plant lay out design for optimum use of resources.
			BP304T5	Appreciate the various preventive methods used for corrosion control in pharmaceutical industries.
8	Pharmaceutical Engineering (2019 Pattern)	BP308P	BP308P1	Understand the overall heat transfer coefficient, efficiency of steam distillation.
			BP308P2	Perform construction of drying rate curve, determination of moisture content and loss on drying.
			BP308P3	Perform tablet analysis, (size analysis) by sieving method.
			BP308P4	Understand the construction, working, application of pharmaceutical machinery such as Rotary tablet machine, Autoclave, Hot Air Oven.

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Course Outcomes S. Y. B. Pharm (Semester-IV)
Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course student will be able to
1	Pharmaceutical organic chemistry-III (2019 Pattern)	BP401T	BP401T1	Understand the concept of stereoisomerism, resolution of racemic mixture and asymmetric synthesis
			BP401T2	Elaborate principle of geometrical isomerism, stereospecific and stereoselective reactions.
			BP401T3	Explain the synthesis, reactions and medicinal uses pyrrole, furan, and thiophene derivatives
			BP401T4	Explain the synthesis, reactions and medicinal Pyrazole, Imidazole, Oxazole and Thiazole Pyridine, Quinoline, Isoquinoline, Acridine and Indole derivatives.
			BP401T5	Explain the principle and pharmaceutical application of metal hydride reduction, Clemmensen reduction, Birch reduction, Wolff Kishner reduction, Oppenauer-oxidation, Dakin, Beckmanns rearrangement, Schmidt rearrangement and Claisen-Schmidt condensation reactions.
2	Medicinal Chemistry-I (2019 Pattern)	BP402T	BP402T1	Understand and relate the physicochemical properties of drug molecules with drug activity.
			BP402T2	Explain the concept of Drug Metabolism.
			BP402T3	Discuss biosynthesis of Adrenaline and Acetyl choline, ANS agonist and antagonist with respect to their structure, IUPAC nomenclature, SAR, mode of action, metabolism, synthesis and rational development.
			BP402T4	Know rational development of various categories of drugs like CNS stimulants and depressant, psychotherapeutic drugs and General anaesthetic agents.
			BP402T5	Acquire knowledge about centrally acting analgesics (Narcotic, non-narcotic, anti-inflammatory agents) with respect to structure, IUPAC nomenclature, SAR, mode of action, metabolism, synthesis and rational development.
3	Medicinal Chemistry-I	BP406P	BP406P1	Develop skills in various purification techniques of solvents/liquids used in synthesis.

	(2019 Pattern)		BP406P2	Perform synthesis, recrystallization and understand reaction mechanisms involved in synthesis of medicinally important organic compounds such as Benzocaine, Phenytoin etc.
			BP406P3	Perform the Purification of synthesized compounds by Column chromatography.
			BP406P4	Determine the partition coefficient and Ionisation constant of medicinal compounds.
4	Physical Pharmaceutics II (2019 Pattern)	BP403T	BP403T1	Relate various physicochemical properties of drug and excipient molecules in designing the dosage forms.
			BP403T2	Apply the concept of rheology and deformation in pharmaceutical formulation.
			BP403T3	Distinguish the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations.
			BP403T4	Investigate and apply micromeritic in pharmaceutical dosage forms.
5	Physical Pharmaceutics II (2019 Pattern)	BP407P	BP407P1	Investigate and apply micromeritic in pharmaceutical dosage forms.
			BP407P2	Determine and apply the concept of rheology in pharmaceutical preparations.
			BP407P3	Study rate of reaction for stability testing and determination of expiry date of formulations.
			BP407P4	Determine physiochemical properties and stability of excipients and drug for preparation dosage form.
6	Pharmacology- I (2019 Pattern)	BP404T	BP404T1	Define the fundamental concepts of pharmacology and pharmacokinetics.
			BP404T2	Understand the basics of pharmacodynamics, adverse reactions, drug interactions and drug discovery.
			BP404T3	Identify the role of neurohumoral transmission and drugs acting on peripheral nervous system.
			BP404T4	Analyse the functions of neurotransmitters and drugs acting on central nervous system.
			BP404T5	Appraise the pharmacology of Psychopharmacological agents.
			BP404T6	Predict the effects of drugs against neurodegenerative disorders and to elaborate the concepts of drug addiction/abuse/tolerance/ dependence.
7	Pharmacology- I (2019 Pattern)	BP408P	BP408P1	Learn about basic instruments, common laboratory animals used in experimental pharmacology and to organize animal house as per the CPCSEA guidelines.
			BP408P2	Demonstrate the common laboratory techniques like routes of administration, blood withdrawal, anaesthetics and euthanasia used for animal studies.

			BP408P3	Interpret the effects of various drugs on rabbit eye and ciliary motility of frog oesophagus in correlation with humans.
			BP408P4	Analyse the effect of drugs acting as enzyme inducers, skeletal muscle relaxants and affecting locomotor activity in laboratory animals.
			BP408P5	Evaluate the stereotype and anticatatonic activity of drugs in rats/mice.
			BP408P6	Predict various screening models for anticonvulsant and anxiolytic activity.
8	Pharmacognosy and Phytochemistry-I (2019 Pattern)	BP405T	BP405T1	Understand fundamentals of Pharmacognosy like scope, classification of crude drugs.
			BP405T2	Describe techniques in the cultivation and production of crude drugs.
			BP405T3	Identify crude drugs and explain their uses and chemical nature.
			BP405T4	Understand evaluation techniques for the herbal drugs.
9	Pharmacognosy and Phytochemistry-I (2019 Pattern)	BP409P	BP409P1	Understand fundamentals of Pharmacognosy with the evaluation techniques for the herbal drugs.
			BP409P2	Carry out the microscopic and morphological evaluation of crude drugs.
			BP409P3	Explain concept of adulteration of crude drugs and its identification.
			BP409P4	Illustrate handling and uses of instruments required for evaluation of the herbal drugs.

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Course Outcomes T. Y. B. Pharm (Semester-V)
Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course student will be able to
1	Medicinal Chemistry-II (2019 Pattern)	BP501T	BP501T1	Understand the chemistry of drugs with respect to their pharmacological activity.
			BP501T2	Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs.
			BP501T3	Know the Structural Activity Relationship of different class of drugs.
			BP501T4	Study the chemical synthesis of selected drugs.
2	Formulative Pharmacy (2019 Pattern)	BP502T	BP502T1	Describe various factors to be considered in development of pharmaceutical dosage forms
			BP502T2	Formulate solid, liquid, semisolid dosage forms and evaluate them for their quality.
			BP502T3	Formulate cosmetic preparations, Pharmaceutical Aerosols and evaluate them for their quality.
			BP502T4	Describe stability aspects and quality control tests of packaging materials.
3	Formulative Pharmacy (2019 Pattern)	BP506 P	BP506P1	Illustrate various pharmaceutical dosage forms and their manufacturing techniques.
			BP506P2	Describe various factors to be considered in development of pharmaceutical dosage forms.
			BP506P3	Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality.
			BP506P4	Formulate cosmetics and evaluate them for their quality.
4	Pharmacology- II (2019 Pattern)	BP503T	BP503T1	Explain the pharmacology of drugs acting on Cardiovascular system for various conditions.
			BP503T2	Explain the pharmacology of drugs acting on Urinary System.
			BP503T3	Explain the various autocoids and drugs acting on endocrine system.
			BP503T4	Explain Bioassays.
5	Pharmacology- II (2019 Pattern)	BP507P	BP507P1	Handle the laboratory equipment's and apply techniques used in experimental pharmacology. N=Introduction to Physiological Salt Solution
			BP507P2	Understand the Effect of drugs on isolated frog heart, blood pressure and heart rate of dog and diuretic activity of drugs using rats/mice.

			BP507P3	Perform recording of CRC/DRC of Acetylcholine/Histamine on suitable isolated tissue preparation.
			BP507P4	Explain and perform matching point, bracketing and interpolation bioassay to find unknown concentration of Acetylcholine/histamine.
			BP507P5	Explain Clinical Case study.
6	Pharmacognosy and Phytochemistry-II (2019 Pattern)	BP504T	BP504T1	Understand the concept of Biosynthesis in formation of secondary metabolites and Radioactive tracer techniques used in plants for determining the Process of formation of secondary metabolites.
			BP504T2	Study chemistry, classification, and uses of secondary metabolites along with the medicinal plants associated with it.
			BP504T3	Know the modern techniques associated with extraction, characterization and identification of phytoconstituents.
			BP504T4	Study different methods of isolation, separation and spectroscopically methods used for the structural elucidation of the phytoconstituents.
7	Pharmacognosy and Phytochemistry-II (2019 Pattern)	BP508P	BP508P1	Evaluate crude drugs by its Morphological, Microscopical and powder Characteristics.
			BP508P2	Study different methods of Extraction of phytoconstituents and volatile oil.
			BP508P3	Study the principle and procedure for separation and isolation of phytoconstituents by chromatography.
			BP508P4	Study the principle and procedure for separation and isolation of phytoconstituents by non-chromatography methods.
8	Pharm. Jurisprudence (2019 Pattern)	BP505T	BP505T1	Understand pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
			BP505T2	Study various Indian pharmaceutical Acts and Laws.
			BP505T3	Acquire knowledge of regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
			BP505T4	Follow code of ethics during the pharmaceutical practice.

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Course Outcomes T. Y. B. Pharm (Semester-VI)
Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course, student will be able to
1	Medicinal Chemistry-III (2019 Pattern)	BP601T	BP601T1	Explain the Drugs used for various infectious diseases caused by pathogens.
			BP601T2	Explain the Drugs used for the treatment of cancer.
			BP601T3	Explain physicochemical properties related to QSAR.
			BP601T4	Describe various approaches and designing of drug molecules including prodrug and Combinatorial chemistry.
2	Medicinal Chemistry-III (2019 Pattern)	BP607P	BP607P1	Perform synthesis, recrystallization understand reaction mechanisms involved in the synthesis of medicinally important compounds.
			BP607P2	Comprehend the techniques of microwave-assisted synthesis and explain applications of microwave-assisted synthesis in pharmaceutical research.
			BP607P3	Draw structures and reactions using Chem draw.
			BP607P4	Determine physicochemical properties such as logP, clogP, MR, Molecular weight.
			BP607P5	Handle drug design software.
3	Pharmacology-III (2019 Pattern)	BP602T	BP602T1	Understand the essential pharmacotherapy and pharmacological features of common and important drugs used in respiratory disorders.
			BP602T2	Explain pharmacology of various drugs used in treatment of GI disorders.
			BP602T3	Explain pharmacology of drugs used in the treatment of various infectious diseases and Immunopharmacology.
			BP602T4	Discuss the various principles and management of toxicology, and concept of Chrono pharmacology.
4	Pharmacology-III (2019 Pattern)	BP608P	BP608P1	Recall the dose calculations in pharmacological experiments, and to relate the antiallergic activity / anti-ulcer activity in rat models.
			BP608P2	Demonstrate of effect of drugs on gastrointestinal motility and the effect of agonists/antagonists on guinea pig ileum.

			BP608P3	Construct serum biochemical parameters by using semi auto analyzer.
			BP608P4	Analyze effect of saline purgative on frog intestine, insulin hypoglycemic effect and test for pyrogens using rabbit method.
			BP608P5	Evaluate acute oral toxicity (LD50), acute skin irritation / corrosion and acute eye irritation/corrosion of a test substance.
			BP608P6	Predict the pharmacokinetic parameters and adapt the biostatistics methods in experimental pharmacology.
5	Herbal Drug Technology (2019 Pattern)	BP603T	BP603T1	Understand the concept of herbs as a source of raw materials, concept of Biodynamic farming and principals involved in different traditional systems of Medicines.
			BP603T2	Gain knowledge about Herbal cosmetics, Natural sweeteners and Nutraceuticals.
			BP603T3	Acquaint with guidelines framed by W.H.O., I.C.H, and G.M.P for evaluation herbal drugs.
			BP603T4	Gain knowledge about herbal Industry and understand the importance of patenting of herbal drugs.
6	Herbal Drug Technology (2019 Pattern)	BP609P	BP609P1	Understand concept of extraction and preliminary phytochemical screening of Phytoconstituents.
			BP609P2	Understand concept for extraction and preliminary phytochemical screening of Phytoconstituents.
			BP609P3	Evaluate and standardize herbal formulation.
			BP609P4	Acquire primary knowledge about structural elucidation by analyzing and studying of drug monographs from natural origin.
7	Biopharmaceutics and Pharmacokinetics (2019 Pattern)	BP604T	BP604T1	Understand the basic concepts in biopharmaceutics and pharmacokinetics and their Significance.
			BP604T2	Use plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, climination.
			BP604T3	Understand the concepts of bioavailability and bioequivalence of drug products and their Significance.
			BP604T4	Understand the concept of dissolution and application of in vitro in vivo correlation in drug product development.
8	Pharmaceutical Biotechnology (2019 Pattern)	BP605T	BP605T1	Explain Brief introduction of Biotechnology, Enzyme Biotechnology, Biosensor, Protein Engineering, Basic principles of genetic engineering.
			BP605T2	Tell Cloning vectors, Recombinant DNA technology, Application of genetic engineering and r DNA technology, PCR139.
			BP605T3	Describe Types of immunity, Structure Immunoglobulins and MHC, Preparation methods of vaccines, antitoxins, serum, Hybridoma technology, Storage condition and stability of official vaccines.

			BP605T4	Explain Immuno blotting techniques- ELISA, Western blotting, Southern blotting, Microbial genetics Transformation, transduction, conjugation, plasmid, transposons. Types of Mutation/mutants.
			BP605T5	Describe Fermentation methods and general requirements, large scale fermenter design and various controls, Study of production of Penicillin, Vit.B12, Glutamic acid. Blood products.
9	Quality Assurance (2019 Pattern)	BP606T	BP606T1	Understand The CGMP Aspects in the Pharmaceutical Industry.
			BP606T2	Appreciate The Importance of Documentation.
			BP606T3	Understand The Scope of Quality Certifications Applicable to Pharmaceutical Industries.
			BP606T4	Understand The Responsibilities of QA and QC Departments.
			BP606T5	Understand The CGMP Aspects in Pharmaceutical Industry.

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Course Outcomes Final Y. B. Pharm (Semester-VII)
Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course, student will be able to
1	Instrumental Methods of Analysis (2019 Pattern)	BP701T	BP701T1	Illustrate the basic principle, instrumentation and applications of UV Visible Spectroscopy, Fluorimetry.
			BP701T2	Demonstrate understanding of principles, instrumentation and application of Infra-red spectroscopy, FTIR, Flame Photometry, Atomic Absorption Spectroscopy, Nepheloturbidimetry.
			BP701T3	Understand principle, theory, instrumentation and applications of Adsorption and Partition Column Chromatography, Paper Chromatography, Thin Layer Chromatography, High Performance Thin Layer Chromatography, Ion Exchange Chromatography, Gel Chromatography.
			BP701T4	Differentiate between principles, theory, instrumentation and applications of Gas Chromatography and High Performance Liquid Chromatography.
2	Instrumental Methods of Analysis (2019 Pattern)	BP705 P	BP705P1	Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
			BP705P2	Understand the chromatographic separation and analysis of drugs.
			BP705P3	Perform quantitative & qualitative analysis of drugs/API using various analytical instruments.
			BP705P4	Take appropriate safety measures while handling instruments, chemicals and apparatus.
3	Industrial Pharmacy-II (2019 Pattern)	BP702T	BP702T1	Know the process of pilot plant and scale up of pharmaceutical dosage forms.
			BP702T2	Classify the process of technology transfer from lab scale to commercial batch.
			BP702T3	Explain different Laws and Acts that regulate pharmaceutical industry.
			BP702T4	Understand the approval process and regulatory requirements for drug products.
4	Pharmacy Practice (2019 Pattern)	BP703T	BP703T1	Demonstrate knowledge of and ability to use principles of therapeutics, quality improvement, communication, economics, health behaviour, social and administrative

				aspects, health policy and legal issues in the practice of pharmacy.
			BP703T2	Use knowledge of drug distribution methods in hospital and apply it in the practice of pharmacy.
			BP703T3	Apply principles of drug store management and inventory control to medication use.
			BP703T4	Provide patient-centered care to diverse patients using the best available evidence and monitor drug therapy of patient through medication chart review, obtain medication history interview and counsel the patients, identify drug related problems.
			BP703T5	Engage in innovative activities by making use of the knowledge of clinical trials.
			BP703T6	Exhibit professional ethics by producing safe and appropriate medication use throughout society.
5	Novel Drug Delivery System (2019 Pattern)	BP704T	BP704T1	Explain the principles and technology used in the design of sustained release and controlled release drug delivery systems.
			BP704T2	Learn the criteria for selection of a drugs and polymers for the development of Novel drug delivery systems.
			BP704T3	Learn the various approaches for development of novel drug delivery systems.
			BP704T4	Explain the formulation and characterization of Microencapsulation, Implementable and Mucosal Drug Delivery system.
			BP704T5	Explain the formulation and characterization of transdermal drug Delivery systems.
			BP704T6	Learn the formulation and evaluation of Gastroretentive and Nasopulmonary drug delivery systems.
			BP704T7	Discuss various approaches for the development of targeted drug Delivery systems.
			BP704T8	Explain development of ocular formulations and intra uterine devices (IUDs) and it's applications.
6	Practice School (2019 Pattern)	BP706PS	BP706T1	Recognize the significance of practical training through experience in a variety of fields, including formulation development and evaluation, analytical method development and validation, clinical research, pharmacovigilance and isolation and characterization of natural product phytoconstituents.
			BP706T2	Advance technical and planning skills through hands-on training in a chosen field.
			BP706T3	Assess the issues encountered during practical training and to suggest theoretical knowledge to address those issues.
			BP706T4	Utilize the knowledge they gained through hands-on training while working in various fields.

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Course Outcomes Final Y. B. Pharm (Semester-VIII)
Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course student will be able to
1	Biostatistics and Research Methodology (2019 Pattern)	BP801T	BP801T1	Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment).
			BP801T2	Know the various statistical techniques to solve statistical problems.
			BP801T3	Understand meaning and applications of correlation regression, probability, parametric and non-parametric tests, blocking and confounding.
2	Social and Preventive Pharmacy (2019 Pattern)	BP802T	BP802T1	Understand the concept of Health and prevention and control of disease, social causes of diseases, impact of urbanization on health and disease, Poverty and health, Personal hygiene and health care
			BP802T2	Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
			BP802T3	Develop a critical way of thinking based on current healthcare development.
			BP802T4	Know about National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program.
			BP802T5	Evaluate alternative ways of solving problems related to health and pharmaceutical issues.
3	Pharmacovigilance (2019 Pattern)	BP805ET	BP805T1	Understand history and development of pharmacovigilance.
			BP805T2	Understand Dictionaries, coding and

				terminologies used in pharmacovigilance.
			BP805T3	Acquire knowledge of detection of new adverse drug reactions and their assessment.
			BP805T4	Know adverse drug reaction reporting systems and communication in pharmacovigilance.
			BP805T5	Know Pharmacovigilance Program of India, requirement for ADR reporting in India.
			BP806T6	Understand ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning.
4	Cosmetic Science (2019 Pattern)	BP809ET	BP809ET1	Understand the concepts of cosmetics, anatomy of skin and hair.
			BP809ET2	Explain the concept of cosmeceuticals, history, difference between cosmetics and cosmeceutical agents.
			BP809ET3	Know different Laws and Acts that regulate pharmaceutical industry
			BP809ET4	Understand the approval process and regulatory requirements for drug products.
5	Project Work (2019 Pattern)	BP812PW	BP812PW1	Determine their areas of interest and acquire literature survey skills.
			BP812PW2	Plan and execute necessary experimental procedures.
			BP812PW3	Communicate and defend their findings in the form of thesis and seminar.

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Course Outcomes

F. Y. M. Pharm (Semester-I)

Pharmaceutics

Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course, student will be able to
1	Modern Pharmaceutical Analytical Techniques (2019 Pattern)	MPAT101T	MPAT101T1	Understand the basic principle, theory and applications of various analytical techniques and the fundamentals on conventional analytical methods of drug analysis used in laboratories.
			MPAT101T2	Acquire knowledge about instrumentation and sufficient skills in handling of equipments or procedures for estimation of pharmaceuticals.
			MPAT101T3	Comprehend analytical techniques for identification, characterization and quantification of drugs.
			MPAT101T4	Utilize/Develop new technology and method for qualitative and quantitative analysis of pharmaceutical compound from organic, inorganic and herbal origin with cost effective approach.
			MPAT101T5	Elucidate structure of organic compounds using spectroscopic tools.
2	Drug Delivery System (2019 Pattern)	MPH102T	MPH102T1	Understand the various approaches for development of novel drug delivery systems.
			MPH102T2	Acquire knowledge of criteria for selection of drugs and polymers for the development of delivering system.
			MPH102T3	Understand the formulation and evaluation of Novel drug delivery systems.
3	Modern Pharmaceutics (2019 Pattern)	MPH103T	MPH103T1	Understand the elements of preformulation studies.
			MPH103T2	Understand the Active Pharmaceutical Ingredients and Generic Drug Product development.
			MPH103T3	Know Industrial Management and GMP Considerations.
			MPH103T4	Learn Optimization Techniques & Pilot Plant Scale Up Techniques
			MPH103T5	Perform Stability Testing, sterilization process & packaging of dosage forms.
4	Regulatory Affair	MPH104T	MPH104T1	Understand the Concepts of innovator and generic drugs, drug development process.

	(2019 Pattern)		MPH104T2	Understand The Regulatory guidance's and guidelines for filing and approval process.
			MPH104T3	Understand Preparation of Dossiers and their submission to regulatory agencies in different countries.
			MPH104T4	Recognize the Post approval regulatory requirements for actives and drug products and submission of global documents in CTD/ eCTD formats.
			MPH104T5	Know the Submission of global documents in CTD/ eCTD formats. And clinical trials requirements for approvals for conducting clinical trials.
5	Pharmaceutics Practical I (2019 Pattern)	MPH105P	MPH105P1	Analyze various drugs in single and combination dosage forms for development of theoretical and practical skills of the analytical instruments.
			MPH105P2	Understand various approaches for development and evaluation of novel drug delivery systems.
			MPH105P3	Know the criteria for selection of drugs and polymers for the development of drug delivering system.
			MPH105P4	Investigate and apply micromeritic in pharmaceutical dosage forms.

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Course Outcomes

F. Y. M. Pharm (Semester-II)

Pharmaceutics

Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course, student will be able to
1	Molecular Pharmaceutics (Nano Tech and Targeted DDS) (2019 Pattern)	MPH201T	MPH201T1	The various approaches for development of novel drug delivery systems.
			MPH201T2	The criteria for selection of drugs and polymers for the development of NTDS.
			MPH201T3	The formulation and evaluation of novel drug delivery systems.
2	Advanced Biopharmaceutics & Pharmacokinetics (2019 Pattern)	MPH202T	MPH202T1	Explain mechanism of drug absorption &various factors affecting drug absorption.
			MPH202T2	Learn various biopharmaceutic factors affecting drug bioavailability.
			MPH202T3	Understand basic considerations of pharmacokinetic models.
			MPH202T4	Explain the design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
			MPH202T5	Learn different types of drug interactions which alter the pharmacokinetics of such as drug-protein /drug-tissue binding interactions
3	Computer Aided Drug Delivery System	MPH203T	MPH203T1	Explain Computers in Pharmaceutical Research and Development.
			MPH203T2	Understand and operate Computers in Preclinical Development, Clinical Development and Market Analysis.
			MPH203T3	Create Optimization Techniques in Pharmaceutical Formulation.
			MPH203T4	Understand and apply artificial intelligence (AI) and robotics computational fluid dynamics (CFD) in pharmaceutical preparation.
4	Cosmetic and Cosmeceuticals (2019 Pattern)	MPH204T	MPH204T1	Acquire knowledge about key ingredients used in cosmetics and cosmeceuticals.
			MPH204T2	Acquire knowledge about key building blocks for various formulations.

			MPH204T3	Learn current technologies in the market.
			MPH204T4	Understand use of various key ingredients and basic science to develop cosmetics and cosmeceuticals.
			MPH204T5	Acquire scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability, and efficacy.
5	Pharmaceutics Practical II (2019 Pattern)	MPH205P	MPH205P1	Acquire scientific knowledge to develop and evaluate the various cosmetics and cosmeceuticals formulations with desired safety, stability, and efficacy.
			MPH205P2	Perform formulation and evaluation of various novel drug delivery system with desired safety, stability, and efficacy.
			MPH205P3	Understand various case studies of bioavailability, pharmacokinetic, in vitro cell studies, computer simulations in pharmacokinetics and pharmacodynamics, sensitivity analysis, population modeling and computational modeling of drug disposition.
			MPH205P4	Understand the concept of dissolution kinetics, improvement of dissolution by solid dispersion technique, comparison of dissolution of two different marketed products & protein binding studies.
			MPH205P5	Acquire scientific knowledge of design of experiment for any formulation using and formulation data analysis using design expert® software and use of quality-by-design in pharmaceutical development.

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Course Outcomes

F. Y. M. Pharm (Semester-I)

Pharmaceutical Quality Assurance

Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome Number	Course Outcome
				Upon completion of the course, student will be able to
1	Modern Pharmaceutical Analytical Techniques (2019 Pattern)	MQA101 T	MPAT101T1	Understand the basic principle, theory and applications of various analytical techniques and the fundamentals on conventional analytical methods of drug analysis used in laboratories.
			MPAT101T2	Acquire knowledge about instrumentation and sufficient skills in handling of equipments or procedures for estimation of pharmaceuticals.
			MPAT101T3	Comprehend analytical techniques for identification, characterization and quantification of drugs.
			MPAT101T4	Utilize/Develop new technology and method for qualitative and quantitative analysis of pharmaceutical compound from organic, inorganic and herbal origin with cost effective approach.
			MPAT101T5	Elucidate structure of organic compounds using spectroscopic tools.
2	Quality Management System (2019 Pattern)	MQA102 T	MQA 102T1	Understand the importance of quality.
			MQA 102T2	Explain ISO management system.
			MQA 102T3	Know tools for quality improvement.
			MQA 102T4	Understand analysis of issues in quality.
			MQA 102T5	Discuss quality evaluation of pharmaceuticals.
			MQA 102T6	Understand stability testing of drug and drug substances.
			MQA 102T7	Understand statistical approaches for quality.
3	Quality Control and Quality Assurance (2019 Pattern)	MQA103 T	MQA103 T1	Understand the cGMP aspects in a pharmaceutical industry.
			MQA103 T2	Understand GLP and regulatory Affairs.
			MQA103 T3	Appreciate the importance of documentation.
			MQA103 T4	Understand the responsibilities of QA and QC departments.
			MQA103 T5	Appreciate the importance of documentation.

4	Product Development and Technology Transfer (2019 Pattern)	MQA104 T	MQA 104T1	Acquire knowledge about new product development process, Development and informational content for INDA, NDA, ANDA, SNDA, SUPAC and BACPAC, Product registration guidelines – CDSCO, USFDA.
			MQA 104T2	Acquire knowledge about preformulation study, solubility & methods to improve solubility of drugs.
			MQA 104T3	Understand concept, significance, design, layout of pilot plant, scale up study, large scale manufacturing techniques and different types of pharmaceutical packaging materials available along with quality control tests for the same.
			MQA 104T4	Understand Development of technology by R & D, Technology transfer from R & D to production and documentation involved in technology transfer.
5	Pharmaceutical Quality Assurance Practical I (2019 Pattern)	MQA105P	MQA105P1	Understand principles, instrumentation, working of UV-VIS Spectrophotometry, Fluorimetry, Atomic absorption Spectrophotometry, Flame Photometry, their applications for analysis of pharmaceutical compounds, raw materials, related and foreign substances in drugs and will have practical skills of instrument handling.
			MQA105P2	Acquire knowledge of safety measures while handling instruments, chemicals and apparatus.
			MQA105P3	Comprehend Six Sigma, Total Quality management etc. after performing case studies.
			MQA105P4	Perform preformulation study for tablets, parenterals as per regulatory requirements and in process and finished product quality control tests for various pharmaceutical dosage forms and their packaging materials.
			MQA 105P5	Understand stability study protocol, accelerated stability studies, factors affecting solubility and problem solving skills related to solubility, determination of pKa and Log P values of drugs.

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Course Outcomes

F. Y. M. Pharm (Semester-II)

Pharmaceutical Quality Assurance

Academic Year 2023-24

Sr. No.	Course	Course Code	Course Outcome No.	Course Outcome
				Upon completion of the course student will be able to
1	Hazards and Safety Management (2019 Pattern)	MQA201T	MQA 201T1	Understand basic knowledge about the environment and its allied problems and also develop an attitude of concern for the industry environment.
			MQA 201T2	Demonstrate safety standards in pharmaceutical industry and knowledge on the safety management.
			MQA 201T3	Understand the knowledge of mechanism and management in different kinds of hazards like Air based hazards, chemical based hazards, Fire & explosion etc.
			MQA 201T4	Illustrate ICH guidelines on risk assessment and risk management methods and Tools, safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Effluent treatment procedure.
2	Pharmaceutical Validation (2019 Pattern)	MQA202T	MQA 202T1	Explain the concept of Calibration, Qualification and Validation.
			MQA 202T2	Apply the qualification concepts for various equipments and instruments.
			MQA 202T3	Examine the process validation of different dosage forms.
			MQA 202T4	Demonstrate the validation of analytical methods for estimation of drugs.
			MQA 202T5	Describe the cleaning validation of equipments employed in the manufacture of pharmaceuticals and general principles of Intellectual Property.

3	Audits and Regulatory Compliance (2019 Pattern)	MQA203T	MQA203T1	Understand the importance of auditing in pharmaceuticals.
			MQA203T2	Understand the methodology of auditing for pharmaceutical industry.
			MQA203T3	Prepare the check list for auditing.
			MQA203T4	Carry out the audit process.
4	Pharmaceutical Manufacturing Technology (2019 Pattern)	MQA204T	MQA204T1	Understand the common practice in the pharmaceutical industry developments, plant layout and production planning.
			MQA204T2	Be familiar with the principles and practices of aseptic process technology, advanced sterile and nonsterile manufacturing process technology.
			MQA204T3	Comprehend the practices of packaging technology.
			MQA204T4	Acquire knowledge of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.
5	Pharmaceutical Quality Assurance Practical II (2019 Pattern)	MQA205P	MQA205P1	Analyse contaminant residue, poisonous gas, chemical weapon (disinfectant) in work environment using analytical instrument and will have gained the knowledge of safety measures while handling instruments, chemicals and apparatus.
			MQA205P2	Validate/Qualify various pharmaceutical testing and analytical equipments.
			MQA205P3	Design plant layout and perform validation of processing area, process validation of pharmaceutical dosage form and cleaning validation of equipment.
			MQA205P4	Qualify bulk pharmaceutical vendors, tableting production, sterile production area and water for injection.
			MQA205P5	Comprehend applications of QbD and PAT after performing case studies.

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C. SPPU, Pune Course Structure
B. Pharm and M. Pharm Programmes
Pattern- 2019

SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

RULES & SYLLABUS

FIRST YEAR BACHELOR OF PHARMACY (B. Pharm.) COURSE – 2019 pattern (EFFECTIVE FROM ACADEMIC YEAR 2019-2020)

CHAPTER- I: REGULATIONS

1. Short Title and Commencement These regulations shall be called as "The Revised Regulations for the B. Pharm. Degree Program (CBCS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

2.1 First year B. Pharm: Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Association of Indian Universities (AIU) with English as one of the subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B / P.C.M.B.) as optional subjects individually. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

2.2. B. Pharm lateral entry (to third semester): A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Duration of the program The course of study for B.Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations Medium of instruction and examination shall be in English.

5. Working days in each semester Each semester shall consist of not less than 90 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

6. Attendance and progress A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits.

The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

7.2. Minimum credit requirements The minimum credit points required for award of a B. Pharm. degree is 208. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Project over the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus. The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

8. Academic work A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

9. Course of study The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

Table-I: Course of study for semester I

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3/45	1	4
BP102T	Pharmaceutical Analysis I – Theory	3/45	1	4
BP103T	Pharmaceutics I – Theory	3/45	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3/45	1	4
BP105T	Communication skills – Theory *	2/30	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2/30	-	D
BP107P	Human Anatomy and Physiology – Practical	4/60	-	2
BP108P	Pharmaceutical Analysis I – Practical	4/60	-	2
BP109P	Pharmaceutics I – Practical	4/60	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4/60	-	2
BP111P	Communication skills – Practical*	2/30	-	1
BP112RBP	Remedial Biology – Practical*	2/30	-	D
	Total	**32/34$^{\$}$/36$^{\#}$/480/510$^{\$}$/540$^{\#}$**	**4**	**27**

#Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course. However for Remedial biology and Mathematics no credits to be allotted only 50 % passing i.e D grade will be prerequisite.

$Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course.

* Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3/45	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3/45	1	4
BP203T	Biochemistry – Theory	3/45	1	4
BP204T	Pathophysiology – Theory	3/45	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3/45	-	3
BP206T	Environmental sciences – Theory *	3/45	-	3
BP207P	Human Anatomy and Physiology II – Practical	4/60	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4/60	-	2
BP209P	Biochemistry – Practical	4/60	-	2
BP210P	Computer Applications in Pharmacy – Practical*	4/60	-	1
	Total	**32/480**	**4**	**29**

*Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3/45	1	4
BP302T	Physical Pharmaceutics I – Theory	3/45	1	4
BP303T	Pharmaceutical Microbiology – Theory	3/45	1	4
BP304T	Pharmaceutical Engineering – Theory	3/45	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4/60	-	2
BP306P	Physical Pharmaceutics I – Practical	4/60	-	2
BP307P	Pharmaceutical Microbiology – Practical	4/60	-	2
BP 308P	Pharmaceutical Engineering –Practical	4/60	-	2
	Total	**28/420**	**4**	**24**

Table-IV: Course of study for semester IV

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3/45	1	4
BP402T	Medicinal Chemistry I – Theory	3/45	1	4
BP403T	Physical Pharmaceutics II – Theory	3/45	1	4
BP404T	Pharmacology I – Theory	3/45	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3/45	1	4
BP406P	Medicinal Chemistry I – Practical	4/60	-	2
BP407P	Physical Pharmaceutics II – Practical	4/60		2
BP408P	Pharmacology I – Practical	4/60	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4/60	-	2
	Total	**31/465**	**5**	**28**

Table-V: Course of study for semester V

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3/45	1	4
BP502T	Formulative Pharmacy– Theory	3/45	1	4
BP503T	Pharmacology II – Theory	3/45	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3/45	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3/45	1	4
BP506P	Formulative Pharmacy – Practical	4/60	-	2
BP507P	Pharmacology II – Practical	4/60	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4/60	-	2
	Total	**27/405**	**5**	**26**

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3/45	1	4
BP602T	Pharmacology III – Theory	3/45	1	4
BP603T	Herbal Drug Technology – Theory	3/45	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3/45	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3/45	1	4
BP606T	Quality Assurance –Theory	3/45	1	4
BP607P	Medicinal chemistry III – Practical	4/60	-	2
BP608P	Pharmacology III – Practical	4/60	-	2
BP609P	Herbal Drug Technology – Practical	4/60	-	2
	Total	**30/450**	**6**	**30**

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3/45	1	4
BP702T	Industrial Pharmacy – Theory	3/45	1	4
BP703T	Pharmacy Practice – Theory	3/45	1	4
BP704T	Novel Drug Delivery System – Theory	3/45	1	4
BP705P	Instrumental Methods of Analysis – Practical	4/60	-	2
BP706PS	Practice School*	12/180	-	6
Total		**28/420**	**5**	**24**

***** Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3/45	1	4
BP802T	Social and Preventive Pharmacy	3/45	1	4
BP803ET	Pharmaceutical Marketing	3 + 3 = 6/90	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardizations of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812PW	Project Work	12/180	-	6
	Total	**24/360**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	**27**
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	**209**

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course**.**

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course**.**

1. Program Committee

1. The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Program Committee shall be as follows:

   A senior teacher shall be the Chairperson; One Teacher from each department handling B.Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.

3. Duties of the Program Committee:

   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessionalexam (Internal Assessment) and before the end semester exam.

2. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table – X.

2.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to VIII shall beconducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables-X: Schemes for internal assessments and end semester examinations semester wise

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP101T	Human Anatomy and Physiology I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP103T	Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP105T	Communication skills – Theory *	5	10	1 Hr	15	35	1.5 Hrs	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP109P	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP111P	Communication skills – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
BP112RBP	Remedial Biology – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**70/75$/80#**	**115/125$/130#**	**23/24$/26# Hrs**	**185/200$/210#**	**490/525$/ 540#**	**31.5/33$/ 35# Hrs**	**675/725$/ 750#**

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

* Non University Examination (NUE)

Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP201T	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP203T	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP204T	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP205T	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP206T	Environmental sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP209P	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP210P	Computer Applications in Pharmacy – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
Total		**80**	**125**	**20 Hrs**	**205**	**520**	**30 Hrs**	**725**

***** The subject experts at college level shall conduct examinations

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP302T	PhysicalPharmaceuticsI –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP307P	Pharmaceutical Microbiology – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP308P	Pharmaceutical Engineering – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**60**	**100**	**20**	**160**	**440**	**28Hrs**	**600**

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP401T	Pharmaceutical Organic Chemistry III– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP402T	Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP404T	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP405T	Pharmacognosy I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP406P	Medicinal Chemistry I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP407P	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP408P	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP409P	Pharmacognosy I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**70**	**115**	**21 Hrs**	**185**	**515**	**31 Hrs**	**700**

Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Formulative Pharmacy– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Formulative Pharmacy – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**

Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

Semester VII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP701T	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705 P	Instrumental Methods of Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP706 PS	Practice School*	25	-	-	25	125	5 Hrs	150
Total		**70**	**70**	**8Hrs**	**140**	**460**	**21 Hrs**	**600**

***** The subject experts at college level shall conduct examinations

Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardizations of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150
	Total	**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

11.2 Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table-XI: Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	**Maximum Marks**	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 2 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	4	03
Student – Teacher interaction	2	
Total	**10**	**5**
Practical		
Attendance (Refer Table – XII)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	**5**	

Table- XII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

11.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks. The duration for the conduct of the exam is as below

Exam Type	Marks allotted	Duration
Theory	30	1.5 Hr
Practical	40	04 Hr

Question paper pattern for theory Sessional

For subjects having University exams

I. Objective Type Questions (Answer 05 out of 7)	=5 x 2 = 10
II. Long Answers (Answer 1 out of 2)	=1 x 10 = 10
III. Short Answers (Answer 2 out of 3)	=2 x 5 = 10
Total	**30 marks**

For subjects having Non University Examination

I. Long Answers (Answer 1 out of 2)	=1 x 10 = 10
II.Short Answers (Answer 4 out of 6)	=4 x 5 = 20
Total	**30 marks**

Question paper pattern for practical sessional examinations

I. Synopsis	= 10
II. Experiments	= 25
III. Viva voce	= 05
Total	**40 marks**

12 . Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of B.Pharm.program if he/she secures at least 50% marks in that particular course including internal assessment. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12,then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance in the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Reexamination ofend semester examinationshall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

Table-XIII: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

Question paper pattern for end semester theory examinations

For 75 marks paper

I. Objective Type Questions (Answer 5 out of 7)	=5x 3= 15
II. Long Answers (Answer 2 out of 4)	= 2 x 10 = 20
III. Short Answers (Answer 8 out of 10)	= 8 x 5 = 40
Total	**= 75marks**

For 50 marks paper

I. Long Answers (Answer 2 out of 3)	= 2 x 10 = 20
II. Short Answers (Answer 6 out of 8)	= 6 x 5 = 30
Total	**= 50 marks**

For 35 marks paper

I. Long Answers (Answer 1out of 2)	= 1 x 10 = 10
II. Short Answers (Answer 5 out of 7)	= 5 x 5 = 25
Total	**= 35 marks**

Question paper pattern for end semester practical examinations

I. Synopsis	= 05
II. Experiments	= 25
III. Viva voce	= 05
Total	**= 35marks**

16. Academic Progression:

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.

A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms

specified in 26.

Any student who has given more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.

Note: Grade AB should be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Rules for Carry Forward:

The curriculum (including regulations, structure and syllabi) is in force from academic year 2018-19 and onwards for First Year B. Pharm, for academic year 2019- 20 onwards for Second Year B. Pharm., for academic year 2020-21 and onwards for Third Year B. Pharm., and for academic year 2021-22 and onwards for Final Year B. Pharm.

The learners who were admitted to First Year B. Pharm. of 2015 pattern during the academic year 2017-18 or before & failed in the First Year B.Pharm. of 2015 pattern examination will have to take admission to Semester-III of Second Year B. Pharm. of

2018 pattern in academic year 2019-20 or onwards, provided that

a. Their result of F. Y. B. Pharm of 2015 pattern is either pass or fails with A. T. K. T. The said students will have to take up additional remedial courses as follows.

b) The learners who were admitted to S.Y B. Pharm. of 2015 pattern during the academic year 2018-19 or before and fail in the S.Y B.Pharm. of 2015 pattern examination will have to take admission to Semester-V of Third Year B. Pharm. of 2018 pattern in academic year 2020-21 or onwards, provided that Their result of S. Y. B. Pharm of 2015 pattern is either pass or fails with A. T. K. T. The said students will have to take up additional remedial course as follows.

Sr. No	**Remedial courses for admission to S.Y.B.Pharm in Academic Year 2019-20 (Cleared F.Y. B. Pharm as per 2015 Pattern)**		
	(Non University Examination)	**Semester**	**Passing Criteria**
1.	Biochemistry – Theory/Practicals	Semester III	Minimum 50% marks with D grade
2.	Pathophysiology- Theory		Minimum 50% marks with D grade
3.	Computer Applications in	Semester IV	Minimum 50% marks with D

	Pharmacy – Theory/Practicals		grade
4.	Environmental sciences – Theory		Minimum 50% marks with D grade

Sr. No	Remedial courses for admission to T.Y. B.Pharm in Academic Year 2020-21 (Cleared S. Y.B. Pharm as per 2015 Pattern)		
	(Non University Examination with 50% passing.)	**Semester**	**Passing Criteria**
1.	Medicinal Chemistry I – Theory/ Practical	Semester V	Minimum 50% marks with D grade

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – XII.

Table – XII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of ABand a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester

Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses(Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5 and the student's grade points in these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C1 + C2 + C3 + C4 + C5}$$

The SGPA is calculated to two decimal points.It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4 * ZERO + C5G5}{C1 + C2 + C3 + C4 + C5}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s),till the course(s) is/are passed. When the course(s)is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4 + C5S5 + C6S6 + C7S7 + C8S8}{C1 + C2 + C3 + C4 + C5 + C6 + C7 + C8}$$

where $C_1, C_2, C_3, \ldots$ is the total number of credits for semester I,II,III,…. and $S_1, S_2, S_3, \ldots$ is the SGPA of semester I,II,III,…. .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows

First Class with Distinction	= CGPA of. 7.50 and above
First Class	= CGPA of. 6.00 to 7.49
Second Class	= CGPA of. 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below

Evaluation of Dissertation Book:

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks
Total	**75 Marks**

Evaluation of Presentation:

Presentation of work	25 Marks
Communication skills	20 Marks
Question and answer skills	30 Marks
Total	**75 Marks**

Explanation: The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

22. Industrial training (Desirable)

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

AND/OR

Every candidate shall be required to undergo any one of the Skill development modules mentioned below**(Duration – Min. 04 weeks)**

a) Hands on Training (Central instrumentation lab/Machine room etc)

b) UGC/AICTE recognized online courses (SWAYAM/NPTEL etc)

After the successful completion of the module the candidate shall submit satisfactory report and certificate duly signed by the authority of training organization/Head of the institute

23. Practice School

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

24. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

25. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

26. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

27. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of break up period and he/she has to rejoin the program by paying the required fees.

Chapter-II: Syllabus

Semester-I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory) **45 Hours**

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Course Content:

Unit-I **10 hours**

a) Introduction to human body 3 hours

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

b) Cellular level of organization 3 hours

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signalling pathway activation by extracellular signal

molecule, Forms of intracellular signalling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

c) Tissue level of organization 4 hours

Classification of tissues, structure, location and functions of epithelial,

muscular and nervous and connective tissues.

Unit -II **10 hours**

a) Integumentary system 4 hours

Structure and functions of skin

b) Skeletal system 4 hours

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction.

c) Joints 2 hours

Structural and functional classification, types of joints movements and its articulation

Unit-III **10 hours**

a) Body fluids and blood 7 hours

Body fluids, composition and functions of blood, blood cells, hemopoeisis, formation of hemoglobin, anaemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.

b) Lymphatic system 3hours

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system.

Unit-IV **08 hours**

a) Peripheral nervous system: 3 Hours

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves.

b) Special senses 5 Hours

Structure and functions of eye, ear, nose, tongue, and their disorders.

Unit-V **07 hours**

Cardiovascular system

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

Recommended Books:

1. Chatterjee, C.C., Human Physiology. Medical Allied Agency, Kolkata.
2. Ganong, W.F., Review of Medical Physiology. Prentice-Hall International, London.
3. Guyton, A.C., Textbook of Medical Physiology. W. B. Saunders Co., Philadelphia, USA.
4. Tortora, G.J. and Grabowski, S.R., 2005. Principals of Anatomy and Physiology. Harper Collins College Publishers, New York.
5. Vander, A.J., Sherman, J.H. and Luciano, D.S., Human Physiology. McGraw-Hill Publishing Co., USA.
6. Waugh, A. and Grant, A., Ross and Wilson's Anatomy and Physiology in Health and Illness. Churchill-Livingstone, London.
7. West, J.B., Best and Taylor's Physiological Basis of Medical Practice. Williams and Wilkins,Baltimore, USA.
8. Warwick, R. and Williams, P., Gray's Anatomy. Longman, London.
9. Chaudhari S K. Concise Medical Physiology. New Central Book Agency (P) Ltd., Calcutta.
10. Godkar P.B and Godkar D.P., Textbook of Medical Laboratory Technology. Bhalani Publishing House, Mumbai.
11. Joshi V.D. Practical Physiology. Vora Medical Publications, Mumbai.
12. DiFiore-Mariano S.H., Atlas of Human Histology. Lea and Febiger, Philadelphia.
13. Garg K., Bahel I. and Kaul M., A Textbook of Histology. CBS Publishers and Distributors, New Delhi.
14. Goyal, R.K., Patel, N.M. and Shah, S.A., Practical Anatomy, Physiology and Biochemistry. B. S. Shah Prakashan, Ahmedabad.
15. Ranade, V.G., Joshi, P.N. and Pradhan, S., Textbook of Practical Physiology. Pune Vidyarthi Griha Prakashan, Pune.
16. Singh, I., BD., Chaurasia's Human Anatomy. CBS Publisher and Distributors, New Delhi.
17. Singh, I., Textbook of Human Histology. Jaypee brothers Medical Publishers, New Delhi.
18. Mukherjee, K.L., Medical Laboratory Technology. Tata McGraw Hill Publishing Company Ltd. New Delhi.
19. Beck, W.S., Human Desigh: Molecular, Cellular and Systemic Physiology. Harcourt Brace Jovanovich Inc. New York.
20. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee Brothers medical publishers, New Delhi.
21. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
22. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
23. Textbook of Human Histology by Inderbir Singh, Jaypee brother’s medical publishers, New Delhi.
24. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother’s medical publishers, New Delhi.

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. Study of compound microscope.

2. Microscopic study of epithelial and connective tissue

3. Microscopic study of muscular and nervous tissue

4. Identification of axial bones

5. Identification of appendicular bones

6. Introduction to haemocytometer.

7. Enumeration of white blood cell (WBC) count

8. Enumeration of total red blood corpuscles (RBC) count

9. Determination of bleeding time

10. Determination of clotting time

11. Estimation of haemoglobin content

12. Determination of blood group.

13. Determination of erythrocyte sedimentation rate (ESR).

14. Determination of heart rate and pulse rate.

15. Recording of blood pressure.

16. Visit to Blood bank.

Recommended Books:

1. Godkar P.B and Godkar D.P., Textbook of Medical Laboratory Technology. Bhalani Publishing House, Mumbai.
2. Joshi V.D. Practical Physiology. Vora Medical Publications, Mumbai.
3. DiFiore-Mariano S.H., Atlas of Human Histology. Lea and Febiger, Philadelphia.

4. Mukherjee, K.L., Medical Laboratory Technology. Tata McGraw Hill Publishing Company Ltd. New Delhi.
5. Beck, W.S., Human Desigh: Molecular, Cellular and Systemic Physiology. Harcourt Brace Jovanovich Inc. New York.
6. Chatterjee, C.C., Human Physiology. Medical Allied Agency, Kolkata.
7. Ganong, W.F., Review of Medical Physiology. Prentice-Hall International, London.
8. Guyton, A.C., Textbook of Medical Physiology. W. B. Saunders Co., Philadelphia, USA.
9. Tortora, G.J. and Grabowski, S.R., 2005.
10. Principals of Anatomy and Physiology. Harper Collins College Publishers, New York.
11. Vander, A.J., Sherman, J.H. and Luciano, D.S., Human Physiology. McGraw-Hill Publishing Co., USA.
12. Garg K., Bahel I. and Kaul M., A Textbook of Histology. CBS Publishers and Distributors, New Delhi.
13. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee Brother's medical publishers, New Delhi.

BP102T. PHARMACEUTICAL ANALYSIS (Theory) 45 hours

Scope

This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs.

Objectives

Upon completion of the course a student shall be able to understand -

- The principles of volumetric and electrochemical analysis.
- Carry out various volumetric and electrochemical titrations.
- Develop analytical skills.

COURSE CONTENT

UNIT-1

a) **Pharmaceutical analysis -** Definition and scope
   i. Different techniques of analysis
   ii. Methods of expressing concentration **05 hours**
   iii. Primary and Secondary standards.

b) **Errors :** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

UNIT-II

a) Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves. Preparation and standardization of sodium hydroxide, hydrochloric acid, sulphuric acid, Estimation of ammonium chloride **10 hours**

b) Non aqueous titration: Solvents, acidimetry and alkalimetry titrations, and estimation of sodium benzoate.

UNIT-III

a) Precipitation titrations: Mohr's method, Volhard's method, Modified Volhard's method, Fajans method, and estimation of Sodium Chloride I.P.

b) Complexometric titration: Classification, metal ion indicators, masking and demasking reagents, and estimation of Calcium gluconate I.P. **12 hours**

c) Gravimetry: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, and estimation of Barium sulphate I. P.

UNIT-IV

Redox titrations

i. Concepts of oxidation and reduction
ii. Preparation and standardization of Potassium Permanganate I. P., Ceric Ammonium Sulphate I. P./B. P. and Sodium Thiosulphate I. P./B. P. **08 Hours**
iii. Types of redox titrations (Principles and applications) : Permaganometry,

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titrations with Potassium Iodate I. P.

UNIT-V

a) Electrochemical methods of analysis

i. **Conductometry** - Introduction, Conductivity cell, Conductometric titrations, applications.

ii. **Potentiometry** - Electrochemical cell, construction and working of reference (Standard Hydrogen Electrode, Silver Chloride Electrode and Calomel Electrode) and Indicator Eectrodes (Metal electrodes and Glass Electrode), methods to determine end point of potentiometric titration and applications.

iii. **Polarography** - Principle and llkovik Equation.

b) Refractometry - Introduction, refractive index, specific and molar refraction, measurement of RI, Abbe's refractometer and applications.

10 hours

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours/week

I. Preparation and standardization of

(1) Aq. Sodium Hydroxide I. P.

(2) Aq. Sulphuric Acid I. P./ Aq. Hydrochloric Acid I. P.

(3) Aq. Sodium Thiosulfate I. P.

(4) Aq. Potassium Permanganate I. P.

(5) Aq. Ceric Ammonium Sulphate I. P.

3 turns

II. Assay of the following compounds along with Standardization of Titrant

(1) Ammonium chloride by acid-base titration

(2) Sodium benzoate I. P. by non-aqueous titration

(3) Sodium chloride I. P. by precipitation titration

(4) Calcium gluconate I. P. by complexometry

(5) Hydrogen peroxide I. P./B. P. by Permanganometry

(6) Ferrous sulphate I. P. by cerimetry

(7) Copper sulphate I. P. by iodometry

8 turns

III. Determination of Normality by electro-analytical methods

(1) Conductometric titrations of strong acid against strong base

(2) Conductometric titration of strong acid and weak acid against strong base

(3) Potentiometric titration of strong acid against strong base (Using Sigmoidal and First order derivative plot)

3 turns

IV. Measurement of refractive index of some samples

(Glycerol, Water, Rectified Spirit, Castor Oil I. P.)

1 turn

Recommended Books

1. Indian Pharmacopoeia, Ministry of Health and Family Welfare, Controller of Publications Edition, New Delhi.
2. British Pharmacopoeia, British Pharmacopoeia Commission, London, 2015.
3. Beckett, A.H. and Stenlake J. B., Practical Pharmaceutical Chemistry, Vol I, Stahlome Press, University of London.
4. Vogel, A. I., A Textbook of Quantitative Chemical Analysis, Thames Polytechnic, London, Longman Group, UK Ltd.
5. Connors K. A., A Textbook of Pharmaceutical Analysis, Third Edition, John Wiley and Sons.
6. Christian G. D., Analytical Chemistry, 6/Ed, John Wiley & Sons.
7. Mahadik K. R., Wadodkar S.G., More H. N, Pharmaceutical Analysis, Vol. I and II, Nirali Prakashan.
8. Kar Ashutosh, Pharmaceutical Drug Analysis, Minerva Press, New Delhi.
9. Day R. A. & Underwood A. L. Quantitative Analysis. 5/Ed., Prentice Hall of India Pvt.Ltd. New Delhi.
10. Skoog, A. D. West, D. M. et al. Fundamentals of Analytical Chemistry. 8/ Ed. Thomson Brookslcole.
11. Willard Merit. Dean Settle, Instrumental Methods of Analysis, 7/Ed, CBS Publisher & Distributor.
12. Sharma, B. K. Instrumental Methods of Chemical Analysis, Goel Publishing House.

BP103T. PHARMACEUTICS- I (Theory) 45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:

UNIT – I 10 Hours

- **Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II 10 Hours

- **Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages,Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III **10 Hours**

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
  Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

  Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV **08 Hours**

- **Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V **07 Hours**

- **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

BP109P. PHARMACEUTICS I (Practical)

4 Hours / week

1 . Syrups

a) Syrup IP'66

b) Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs a) Piperazine citrate elixir

b) Paracetamol pediatric elixir

3.Linctus a) Terpin Hydrate Linctus IP'66

b) Iodine Throat Paint (Mandles Paint)

4. Solutions

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) LugOL'S SOLUTion

5. Suspensions (Any two experiments)

a) Calamine lotion

b) Magnesium Hydroxide mixture

c) Aluminimum Hydroxide gel

6. Emulsions a) Turpentine Liniment

b) Liquid paraffin emulsion

7. Powders and Granules (Any three experiments)

a) ORS powder (WHO)

b) Effervescent granules

c) Dusting powder

d) Divided powders

8. Suppositories (Any two experiments)

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

8. Semisolids (Any two experiments)

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopol gel

9. Gargles and Mouthwashes

a) Iodine gargle

b) Chlorhexidine mouthwash

Recommended Books:

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory) 45 Hours

Scope

This subject deals with the concepts and monographs of inorganic drugs and pharmaceuticals.

Objectives

Upon completion of course student shall be able to

- Know the sources of impurities and methods to determine the impurities in drugs and pharmaceuticals
- Understand the medicinal and pharmaceutical importance of inorganic compounds

COURSE CONTENT

UNIT I

a) **Impurities in pharmaceutical substances**: History of pharmacopoeia, sources and types of impurities, principle, reaction and procedure involved in the limit test for chloride, sulphate, iron, arsenic, lead and heavy metals, modified limit test for chloride and sulphate. **10 hours**

b) **Water:** Different official waters and official control test for water.

General methods of preparation and assay for compounds superscripted with asterisk (*). Properties and Medicinal uses of Inorganic Compounds belonging to the following classes

UNIT II

a) **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.

b) **Major extra and intracellular electrolytes:** Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance. **10 hours**

c) **Dental products:** Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III

a) **Gastrointestinal agents**
   i. **Acidifiers:** Ammonium chloride* and Dil. HCl
   ii. **Antacid:** Ideal properties of antacids, combinations of antacids, Sodium
   iii. Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture **10 hours**
   iv. **Cathartics:** Magnesium sulphate, Sodium orthophosphate,

b) **Protectives and Adsorbents**: Kaolin and Bentonite

c) **Antimicrobials:** Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV

Miscellaneous Compounds

08 hours

a) **Expectorants**: Potassium iodide, Ammonium chloride
b) **Emetics**: Copper sulphate* , Sodium potassium tartarate
c) **Haematinics**: Ferrous sulphate*, Ferrous gluconate
d) **Poison and Antidote**: Sodium thiosulphate*, Activated charcoal, Sodium nitrite
e) **Astringents:** Zinc Sulphate, Potash Alum

UNIT V

07 hours

Radiopharmaceuticals: Radio activity, measurement of radioactivity, properties of α, β, γ radiations, half-life, radio isotopes and study of radio isotopes - Sodium iodide^{131} , · Indium^{111}, Calcium^{47} , Chromium ^{51}, Erbium^{169}, Gallium^{68}, Technetium^{99m} , Storage conditions, precautions & pharmaceutical applications of radioactive substances.

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)
4 Hours/Week

I.	**Limit Test of the following:** (1) Chloride (2) Sulphate (3) Iron (4) Arsenic (5) Lead (6) Heavy metals	**6 turns**
II.	**Identification test** (1) Magnesium hydroxide (2) Ferrous sulphate (3) Sodium bicarbonate (4) Calcium gluconate (5) Copper sulphate	**3 turns**
III.	**Test for purity** (1) Swelling power of Bentonite (2) Neutralizing capacity of Aluminum hydroxide gel (3) Determination of Potassium iodate and iodine in Potassium Iodide	**3 turns**
IV.	**Preparation of Inorganic Pharmaceuticals** (1) Boric acid (2) Potash alum (3) Ferrous sulphate	**3 turns**

Recommended Books

1. Beckett, A.H. and Stenlake, J. B. 1970, Practical Pharmaceutical Chemistry, Vol I & II, 4th edn, Stahlone Press of University of London.
2. Jeffery, G. H., Bassett, J., Mendham, J. and Cdenney, R., Vogel's Textbook of Quantitative Chemical Analysis, 5th edn, Thames Polytechnic, Longman Group, UK Ltd, London.
3. Gundu Rao, P. 2008, Pharmaceutical and Medicinal Inorganic Chemistry, Vallabh Prakashan.
4. Bentley, A.O., Driver, J.E. and Atherden, L.M. 1969, Bentley and Driver's Textbook of Pharmaceutical Chemistry, Oxford University Press, London.
5. Anand, S.K. and Chatwal, G.R. 2017, Inorganic Pharmaceutical Chemistry, Himalaya Publishing House Pvt Ltd.
6. Block, J.H., Roche, E.B., Soine, T.O and Wilson, C.O. 1974, Inorganic Medicinal and Pharmaceutical Chemistry, Philadelphia, PA.
7. Indian Pharmacopoeia, Ministry of Health and Family Welfare, Controller of Publications Edition, New Delhi.

BP105T.COMMUNICATION SKILLS (Theory) 30hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business**.**

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation

2. Communicate effectively (Verbal and Non Verbal)
3. Effectivelymanage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

COURSE CONTENT

UNIT – I

- **Communication Skills:** Introduction, Definition, The Importance of Communication,
The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological
Barriers, Emotional barriers **07 Hours**
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other
factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT – II

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of
Voice, Body Language (Non-verbal communication), Verbal Communication, Physical
Communication **07 Hours**
- **Communication Styles:** Introduction, The Communication Styles Matrix with example
for each -Direct Communication Style, Spirited Communication Style, Systematic
c) Communication Style, Considerate Communication Style

UNIT – III

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an
Active Listener, Listening in Difficult Situations **07 Hours**
- **Effective Written Communication:** Introduction, When and When Not to Use

Written
Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of
Meaning, Formal Communication

- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience,

d) Organization of the Message

UNIT – IV

- **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your

iv. Presentation, Delivering Your Presentation, Techniques of Delivery

05 Hours

UNIT – V

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and

c) Dont's of group discussion.

04 Hours

BP111P.COMMUNICATION SKILLS (Practical)
2 Hours / week

The following learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011

2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011

3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013

4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011

5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013

6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010

7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals –PHI, 2011

8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011

9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011

10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011

11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009

12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

BP 106RBT.REMEDIAL BIOLOGY (Theory) **30 hours**

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

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

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

COURSE CONTENT

UNIT I

Living world:

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus, **07 Hours**

Morphology of Flowering plants

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidons.

UNIT II

Body fluids and circulation

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

Digestion and Absorption **07 Hours**

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

Breathing and respiration

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

UNIT III

Excretory products and their elimination **07 Hours**

- Modes of excretion

- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

Human reproduction

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

UNIT IV

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation **05 Hours**

Photosynthesis

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis

UNIT V

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators **04 Hours**

Cell - The unit of life

- Structure and functions of cell and cell organelles.Cell division

Tissues

Definition, types of tissues, location and functions.

Text Books

1. Text book of Biology by S. B. Gokhale
2. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

1. A Text book of Biology by B.V. Sreenivasa Naidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C.Dutta.
4. Outlines of Zoology byM. Ekambaranatha ayyer and T. N. Ananthakrishnan.
5. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112RBP.REMEDIAL BIOLOGY (Practical)
2 Hours/week

1. Introduction to experiments in biology

a) Study of Microscope

b) Section cutting techniques

c) Mounting and staining

d) Permanent slide preparation

2. Study of cell and its inclusions

3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications

4. Detailed study of frog by using computer models

5. Microscopic study and identification of tissues pertinent to Stem, Root

Leaf, seed, fruit and flower

6. Identification of bones

7. Determination of blood group

8. Determination of blood pressure

9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

BP 106 RMT.REMEDIAL MATHEMATICS (Theory) 30 hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

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

1. Know the theory and their application in Pharmacy

2. Solve the different types of problems by applying theory

3. Appreciate the important application of mathematics in Pharmacy

COURSE CONTENT

UNIT – I

Partial fraction

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction , Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics.

Logarithms

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems. **06 Hours**

Function*:*

Real Valued function, Classification of real valued functions

Limits and continuity :

Introduction , Limit of a function, Definition of limit of a function ($\in$ - δ $_{nn}$ definition) ,

$$\lim \frac{x^n - a^n}{} = na^{n-1} , \qquad \lim \frac{\sin\theta}{\theta} = 1,$$

UNIT –II

Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices,Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants , Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem,Applicationof Matrices in solving Pharmacokinetic equationsRespiratory volumes **06 Hours**

UNIT – III

Calculus

Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions **06 Hours**

(Quotient formula) – **Without Proof**, Derivative of *xn w.r.t*x,where *n* is any rational number, Derivative of *ex,*, Derivative of loge *x* , Derivative of *ax* ,Derivative of trigonometric functions from first principles **(without Proof)**, Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

UNIT – IV

Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula, **Straight Line** : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line **06 Hours**

Integration:

Introduction, Definition, Standard formulae, Rules of integration , Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

UNIT-V

Differential Equations : Some basic definitions, Order and degree, Equations in separable form , Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**

Laplace Transform : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations** **06 Hours**

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

Semester- II

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory) **45 Hours**

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc. and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

Unit-I **Nervous system** **10 hours**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fiber, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

Unit -II **Digestive system** **08hours**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

Energetics: Formation and role of ATP, Creatinine Phosphate and BMR.

Unit-III **10 hours**

Respiratory system **6 hours**

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration Lung Volumes

and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

Urinary system **4 hours**

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit-IV **08 hours**

Endocrine system

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

Unit-V **09 hours**

Reproductive system **07 Hours**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

Introduction to genetics **02 hours**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

Recommended Books

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview,MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

9. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
10. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
11. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. To study the integumentary and special senses using specimen, models, etc.,
2. To determine the Platelet count.
3. To perform the differential leukocyte count (DLC).
4. To determine the Arneth index.
5. Determination of osmotic fragility of RBCs.
6. To study the nervous system using specimen, models, etc.,
7. To study the endocrine system using specimen, models, etc
8. To demonstrate the general neurological examination
9. To demonstrate the function of olfactory nerve
10. To examine the different types of taste.
11. To demonstrate the visual acuity
12. To demonstrate the reflex activity
13. Recording of body temperature
14. To demonstrate positive and negative feedback mechanism.
15. Determination of tidal volume and vital capacity.
16. Study of Digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
17. Recording of basal mass index.
18. Study of familyplanning devices and pregnancy diagnosis test.

19. Demonstration of total blood count by cell analyzer.
20. Permanent slides of vital organs and gonads.
21. Visit to Hospital/ Pathology Laboratory.

Recommended Books:

1. Godkar P.B and Godkar D.P., Textbook of Medical Laboratory Technology. Bhalani Publishing House, Mumbai.
2. Joshi V.D. Practical Physiology. Vora Medical Publications, Mumbai.
3. DiFiore-Mariano S.H., Atlas of Human Histology. Lea and Febiger, Philadelphia.
4. Mukherjee, K.L., Medical Laboratory Technology. Tata McGraw Hill Publishing Company Ltd. New Delhi.
5. Beck, W.S., Human Desigh: Molecular, Cellular and Systemic Physiology. Harcourt Brace Jovanovich Inc. New York.
6. Chatterjee, C.C., Human Physiology. Medical Allied Agency, Kolkata.
7. Ganong, W.F., Review of Medical Physiology. Prentice-Hall International, London.
8. Guyton, A.C., Textbook of Medical Physiology. W. B. Saunders Co., Philadelphia, USA.
9. Tortora, G.J. and Grabowski, S.R., 2005.
10. Principals of Anatomy and Physiology. Harper Collins College Publishers, New York.
11. Vander, A.J., Sherman, J.H. and Luciano, D.S., Human Physiology. McGraw-Hill Publishing Co., USA.
12. Garg K., Bahel I. and Kaul M., A Textbook of Histology. CBS Publishers and Distributors, New Delhi.
13. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee Brother's medical publishers, New Delhi.

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY – I (Theory) 45 hours

Scope

This subject deals with classification and nomenclature of simple organic compounds, isomerism, intermediates formed in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds
- Identify/confirm the identification of organic compounds

COURSE CONTENT

Note:

1. **General methods of preparation (any 05) and reactions of class of compounds superscripted with asterisk (*) to be explained.**
2. **To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences.**

UNIT 1

Basic Principles of Organic Chemistry

Hybridization of atomic orbitals of carbon, nitrogen and oxygen to form molecular orbitals. Types of bonds, bond fission, intermolecular forces, inductive effect, steric effect, electromeric, mesomeric effect and resonance, hyperconjugation, concept of tautomerism. **04 hours**

UNIT II

Classification, Nomenclature and Isomerism

a) Classification of organic compounds

i. Compounds containing carbon and hydrogen atoms only : hydrocarbons (alkanes, alkenes alkynes, aromatic hydrocarbons, polynuclear aromatic hydrocarbons, aryl-alkyl hydrocarbons, alicyclic hydrocarbons)
ii. Compounds containing carbon, hydrogen and oxygen atoms only (alcohols, phenols, ethers and epoxides, carbonyl compounds, carboxylic acids, esters, anhydrides)
iii. Compounds containing carbon, hydrogen and nitrogen atoms only
iv. (amines and imine, nitriles, hydrazines, nitro compounds)
v. Compounds containing carbon, hydrogen, and halogens with oxygen (alkyl halides, aryl halides, acyl halides)
vi. Compounds containing carbon, hydrogen, oxygen and nitrogen atoms only (amides , imides, aldoxime and ketoxime)
vii. Compounds containing carbon, hydrogen and sulphur with/without nitrogen, oxygen and halogen. Sulphonic acids, sulphonylhalides.
(At least five mono-functional examples of each class including aromatic

08 hours

and aliphatic compounds should be covered with their common names.)

b) Common and IUPAC systems of nomenclature of organic compounds
IUPAC nomenclature of all classes of compounds: nomenclature of mono-substituted and poly-substituted compounds should be covered.

c) Structural isomerism in organic compounds

UNIT-II

Alkanes*, Alkenes* and Conjugated dienes*

i. Halogenation of alkanes, uses of paraffins.
ii. Stabilities of alkenes, E1 and E2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeff's orientation, Hofmann orientation and evidences. Factors affecting E1 and E2 reactions.
iii. Chemical Reactions: Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation
iv. Stability of conjugated dienes, Diel's-Alder, 1,2 and 1,4- electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement names.

10 hours

UNIT-III

a) Alkyl halides*

i. S_N1 and S_N2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations. S_N1 versus S_N2 reactions, factors affecting S_N1 and S_N2 reactions.
ii. b.Structure and uses of ethylchloride, chloroform, trichloroethylene, dichloromethane, tetrachloromethane and iodoform.

08 hours

b) Alcohols* - Qualitative tests, structure and uses of ethyl alcohol, chlorobutanol, cetosteryl alcohol, benzyl alcohol, glycerol, and propylene glycol.

UNIT-IV

Carbonyl compounds* (Aldehydes and ketones)

i. Nucleophilic addition, Electromeric effect, Aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, and Perkin condensation.
ii. Qualitative tests, structure and uses of formaldehyde, paraldehyde, acetone, chloral hydrate, benzaldehyde, vanillin, and cinnamaldehyde.

08 Hours

UNIT V

a) Carboxylic acids*

i. Acidity of carboxylic acids, effect of substituent/s on acidity, qualitative tests for carboxylic acids, amide and ester. Reactions of interconversion of carboxylic acids, amides and esters.
ii. Structure and uses of acetic acid, lactic acid, tartaric acid/s, citric acid, succinic acid, oxalic acid, salicylic acid, benzoic acid, benzyl benzoate, dimethyl phthalate, methyl salicylate and acetyl salicylic acid.

07 Hours

b) Aliphatic amines* - Basicity, effect of substituent on basicity, qualitative test, structure and uses of ethanolamine, ethylenediamine

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY – I (Practical)

4 Hours/Week

I. Safety measures in an organic laboratory. **1 turn**

II. Introduction to laboratory techniques: Calibration of thermometer, melting point, boiling point, distillation, and crystallization. **3 turns**

III. Systematic qualitative analysis of unknown organic compounds (min 05) **8 turns**

1. Preliminary test: color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
2. Detection of elements like nitrogen, sulphur and halogen by Lassaigne's test.
3. Solubility test
4. Functional group test like phenols, amides, carbohydrates, amines, carboxylic acids, aldehydes and ketones, alcohols, esters, aromatic and halogenated hydrocarbons, nitro compounds and anilides.
5. Melting point/Boiling point of organic compounds.
6. Identification of the unknown compound from the literature using melting point/ boiling point.

IV. Preparation of suitable solid derivatives from organic compounds **2 turns**

V. Building of molecular models of structures containing various functional groups **1 turns**

Recommended Books

1. Morrison, R. T. & Boyd, R. D., Textbook of Organic Chemistry, VI (ed.) ELBS, London, 1996
2. Pine, S. H, Organic Chemistry, V, Tata McGraw Hill, New Delhi, 2007
3. Finar, I. L., Organic Chemistry Vol. I, V (ed.), ELBS, Pearson Education, New Delhi, 2003
4. Finar, I. L., Organic Chemistry Vol. II, V (ed.), ELBS, Pearson Education, New Delhi, 2003
5. Eliel, E. L., "Stereochemistry of Carbon Compounds", Wiley-Interscience, 1994.

BP203 T. BIOCHEMISTRY (Theory) 45 hours

Scope

Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is to provide biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It also emphasizes on genetic organization of mammalian genome, hetero and autocatalytic functions of DNA.

Objectives

Upon completion of course the students shall able to

- Understand the catalytic role of enzymes and importance of enzyme in biochemical process.
- Understand the metabolism of nutrient molecules in physiological and pathological conditions.
- Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

COURSE CONTENT

UNIT –I

a) Biomolecules

Introduction, classification, chemical nature and biological role of carbohydrates, lipids, nucleic acids, amino acids and proteins.

b) Carbohydrate metabolism

i. Glycolysis – Pathway, energetics and significance.
ii. Citric acid cycle- Pathway, energetics and significance. **10 hours**
iii. HMP shunt and its significance; Glucose-6-Phosphate ehydrogenase (G6PD) deficiency.
iv. Glycogen metabolism Pathways and glycogen storage diseases (GSD).
v. Gluconeogenesis- Pathway and its significance.
vi. Hormonal regulation of blood glucose level and Diabetes mellitus.

UNIT-1I

a) Biological oxidation

i. Electron transport chain (ETC) and its mechanism.
ii. Oxidative phosphorylation & its mechanism and substrate level. Phosphorylation Inhibitor
iii. ETC and oxidative phosphorylation / uncouplers. **08 hours**

b) Bioenergetics

i. Concept of free energy, endergonic and exergonic reaction, relationship between free energy, enthalpy and entropy.
ii. Energy rich compounds; classification; biological significances of ATP and cyclic AMP.

UNIT-III **10 hours**

a) Lipid metabolism

i. β-Oxidation of saturated fatty acid (Palmitic acid).
ii. Formation and utilization of ketone bodies; ketoacidosis.
iii. *De novo* synthesis of fatty acids (Palmitic acid).

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D.

Disorders of lipid metabolism: hypercholesterolemia, atherosclerosis, fatty liver and obesity.

b) Amino acid metabolism

i. General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders.
ii. Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, alkaptonuria, tyrosinemia)
iii. Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline
iv. Catabolism of heme; hyperbilirubinemia

UNIT-IV

Nucleic acid metabolism and genetic information transfer

i. Biosynthesis of purine and pyrimidine nucleotides.
ii. Catabolism of purine nucleotides and hyperuricemia and gout disease.
iii. Organization of mammalian genome. **10 hours**
iv. Structure of DNA and RNA and their functions.
v. DNA replication (semi conservative model)
vi. Transcription or RNA synthesis.
vii. Genetic code, Translation or Protein synthesis and inhibitors.

UNIT-V

Enzymes

i. Introduction, properties, nomenclature and IUB classification of enzymes.
ii. Enzyme kinetics (Michaelis plot, Line Weaver Burke plot).
iii. Enzyme inhibitors with examples. **07 hours**
iv. Regulation of enzymes: enzyme induction and repression, allosteric enzyme-regulation.
v. Therapeutic and diagnostic applications of enzymes and isoenzymes.
vi. Coenzymes–Structure and biochemical functions; Co-factors.

BP 209 P. BIOCHEMISTRY (Practical)
4 Hours / week

1.	Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and Starch)	**3 turns**
2.	Identification tests for amino acids (any one aromatic and one aliphatic)	**1 turn**
3.	Identification tests for proteins (albumin and casein)	**1 turn**
4.	Qualitative analysis of urine for abnormal constituents (at least four abnormal constituents)	**2 turns**
5.	Determination of blood creatinine	**1 turn**
6.	Determination of blood sugar by Folin-Wu method/Glucose-oxidase method	**1 turn**
7.	Determination of serum total cholesterol.	**1 turn**
8.	Preparation of buffer solution and measurement of pH (any two).	**1 turn**
9.	Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method).	**1 turn**
10.	Determination of salivary amylase activity.	**1 turn**
11.	Study the effect of temperature on salivary amylase activity.	**1 turn**
12.	Study the effect of substrate concentration on salivary amylase activity.	**1 turn**

Recommended Books

1. David Nelson and Cox M. M., Lehninger's Principles of Biochemistry, 4/Ed., Palgrave Macmillon.
2. Robert K. Murry, Daryl K., Granner and Victor W. Rodwell, Harper's Biochemistry, 27/Ed, McGraw Hill.
3. Lubert Stryer, W.H., Freeman & Company, Biochemistry, New York
4. U. Satyanarayana & U. Chakrapani, Biochemistry, 3/Ed., Books & Allied (P) Ltd.
5. Rao, A. V. S. S. Rama Rao, Textbook of Biochemistry, first edition, UBS Publishers' Distributors Pvt. Ltd.
6. Deb, A. C. Viva & Practical Biochemistry, 3/Ed., New Central Book Agency (P) Ltd.
7. Conn Eric. E. and Stumpf, Paul K. et al., Outlines of Biochemistry, Wiley student edition.
8. Gupta R. C. and Bhargavan, S. Practical Biochemistry, 5/Ed, CBS publishers and distributors.
9. David T. Plummer, Introduction of Practical Biochemistry. 3/Ed, Tata McGraw-Hill Education Pvt. Ltd.
10. Rajagopal and Ramakrishna, Practical Biochemistry for Medical students, Orient BlackSwan (1983)
11. Harold Varley, Varley's Practical Clinical Biochemistry, 6/Ed., CBS Publishers, New Delhi.
12. David T. Plummer, Introduction to Practical Biochemistry, III (ed.), McGraw-Hill Publishing Co., New York, 1987.
13. Alan H. Gowenlock, Varley's Practical Clinical Biochemistry, VI (ed.), Butterworth-Heinemann Ltd., UK & CBS Publication, New Delhi, 2002.

BP 204T. PATHOPHYSIOLOGY (THEORY) 45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes.This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively. Pharmacotherapy of drugs is particularly not to be considered as a part of this subject from examination point of view as the subject deals with pathophysiological aspects of the diseases.

Objectives: Upon completion of the subject, student shall be able to –

1. Describe the etiology and pathogenesis of the selected diseasestates;
2. Name the signs and symptoms of the diseases

Unit-I **Basic principles of Cell injury and Adaptation** **10 Hrs**

Introduction& definitions

Causes of cellular injury**,**Pathogenesis (Cellmembrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage)**,**

Morphology of cell injury – Adaptive changes(Atrophy, Hypertrophy, Hyperplasia, Metaplasia, Dysplasia)**,**Cellswelling, Intracellular accumulation, Calcification, Enzyme leakageand cell death, acidosis and alkalosis, Electrolyte imbalance

Basic mechanism involved in the process of inflammation andrepair

Introduction, Clinical signs of inflammation, Different types of Inflammation,Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's,Mediators of inflammation,Basic principles of wound healing in the skin

Unit -II. **CardiovascularSystem:** **10 Hrs**

Hypertension, Congestive heart failure, Ischemic heart diseases (angina,myocardial infarction, atherosclerosis and arteriosclerosis)

Respiratory system:

Asthma, Chronic obstructive airwaysdiseases

Renal system:

Acute and chronicrenalfailure

Unit-III **HaematologicalDiseases:** **12 Hrs**

Iron deficiencyanaemia, Megaloblasticanaemia (Vit B12 and folic acid), Sickle cell anemia, Thalassemia, Hereditary acquired anemia, Hemophilia

Endocrine system:

Diabetes, Thyroid diseases(Hypothyroidism, hyperthyroidism, Goitre)Disorders of sexhormones(Amenorrhoea, polycystic ovarian syndrome, hypogonadism)

Nervous system:

Epilepsy, Parkinson's disease, Stroke, Psychiatricdisorders: Depression, Schizophrenia and Alzheimer'sdisease

Gastrointestinal system:

PepticUlcer, Inflammatory Bowel Diseases, Jaundice, Hepatitis (A,B,C,D,E,F), Alcoholicliver disease

Unit-IV **Diseases of bones and joints** **06 Hrs**

Rheumatoid Arthritis,Osteoporosis,Gout

Cancer: Classification, etiology and pathogenesis ofcancer

Unit-V **Infectiousdiseases** **07 Hrs**

Tuberculosis, Leprosy, Malaria, Dengue, Meningitis,Typhoid, Urinary tractinfections

Sexually transmitted diseases

AIDS, Syphilis,Gonorrhea

REFERENCES:

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier;2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications;2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill;2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; unitedstates.
5. William and Wilkins, Baltimore;1991 [1990printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson's Principles andPractice of Medicine; 21st edition; London; ELBS/Churchill Livingstone;2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company;2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company;1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication;2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896(Online)
2. The American Journal of Pathology. ISSN:0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology.ISSN-0377-4929.

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory) 30 Hrs

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

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

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

COURSE CONTENT

UNIT – I

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binary division **06 hours**

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II

Web technologies:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database **06 hours**

UNIT – III

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System **06 hours**

UNIT – IV

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery. **06 hours**

UNIT-V

Computers as data analysis in Preclinical development: Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS) **06 hours**

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3 Retrieve the information of a drug and its adverse effects using online tools
4 Creating mailing labels Using Label Wizard , generating label in MS WORD
5 Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books :

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002

BP 206 T. ENVIRONMENTAL SCIENCES (Theory) 30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

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

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

COURSE CONTENT

Unit-I

The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources:

10hours

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources

Unit-II

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.

10hours

- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III

10 hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

RULES & SYLLABUS

FIRST YEAR MASTER OF PHARMACY (M. Pharm.) COURSE
(EFFECTIVE FROM ACADEMIC YEAR 2019-2020)

TABLE OF CONTENTS

CHAPTER - I : REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program – Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016–17. The regulations framed are subject to modifications from time to time by the authorities of theuniversity.

2. Minimum qualification for admission

A. Pass in the following examinations -

a) Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program / Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra– curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week / per activity.

7.1 Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours.Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co–curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co–Curricular activities over the duration of four semesters. The credits are distributed semester–wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester–wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar and Assignment and Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

Sr. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table - 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table - 2 to 11.

Table - 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Development	4	4	4	100
MPH204T	Cosmetic & Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 3: Course of study for M. Pharm. (Industrial Pharmacy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP102T	Pharmaceutical Formulation Development	4	4	4	100
MIP103T	Novel drug delivery systems	4	4	4	100
MIP104T	Intellectual Property Rights	4	4	4	100
MIP105P	Industrial Pharmacy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202T	Scale up and Technology Transfer	4	4	4	100
MIP203T	Pharmaceutical Production Technology	4	4	4	100
MIP204T	Entrepreneurship Management	4	4	4	100
MIP205P	Industrial Pharmacy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 4: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC1012T	Advanced Organic Chemistry – I	4	4	4	100
MPC103T	Advanced Medicinal Chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar / Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry –II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar / Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 5: Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio–Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 6: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 7: Course of study for M. Pharm. (Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
SEMESTER I					
MRA101T	Good Regulatory Practices	4	4	4	100
MRA102T	Documentation and Regulatory Writing	4	4	4	100
MRA103T	Clinical Research Regulations	4	4	4	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
MRA105P	Regulatory Affairs Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA205P	Regulatory Affairs Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 8: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB 102T	Microbial And Cellular Biology	4	4	4	100
MPB 103T	Bioprocess Engineering and Technology	4	4	4	100
MPB 104T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB 105P	Pharmaceutical Biotechnology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPB 201T	Proteins and protein Formulation	4	4	4	100
MPB 202T	Immunotechnology	4	4	4	100
MPB 203T	Bioinformaticsand Computer Technology	4	4	4	100
MPB 204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB 205P	Pharmaceutical Biotechnology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 9: Course of study for M. Pharm. (Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPP 101T	Clinical Pharmacy Practice	4	4	4	100
MPP 102T	Pharmacotherapeutics–I	4	4	4	100
MPP 103T	Hospital & Community Pharmacy	4	4	4	100
MPP 104T	Clinical Research	4	4	4	100
MPP 105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar / Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPP 201T	Principles of Quality Use of Medicines	4	4	4	100
MPP 102T	Pharmacotherapeutics II	4	4	4	100
MPP 203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP 205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 10: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology - I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods–I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods–II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 11: Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy–1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	Advanced Pharmacognosy – II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 12: Course of study for M. Pharm. III Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
	Total	**35**	**21**

** Non University Exam*

Table - 13: Course of study for M. Pharm. IV Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
	Total	**35**	**20**

Table - 14: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

**Credit Points for Co–curricular Activities*

Table – 15 : Guidelines for Awarding Credit Points for Co-curricualr Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India
International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co–curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from eachM.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table - 16.

11.1 End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Question paper pattern for end semester theory examination

I.	Long answer questions (solve 1 out of 2)	1 X 15=15
II.	Medium Length answers (Solve 2 out of 4)	2 X 7.5=15
III.	Short answer questions (solve 3 out of 5)	3 X 5=15
IV.	Long answer questions (solve 1 out of 2)	1 X 15=15
V.	Short notes (Solve 3 out of 5)	3 X5= 15
		Total Marks= 75

Question paper pattern for end semester practical examination

I.	Synopsis	15
II.	Experiment(s)	70
III.	Viva voce	15
		Total Marks = 100

Tables - 16 : Schemes for internal assessments and end semester (Pharmaceutics - MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPH 201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & PharmacoKinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Development	10	15	1 Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables - 17 : Schemes for internal assessments and end semester (Industrial Pharmacy–MIP)

Course Code	Course	Internal Assessment				End Se. Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs	100
MIP102T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3Hrs	100
MIP103T	Novel drug delivery systems	10	15	1 Hr	25	75	3Hrs	100
MIP104T	Intellectual Property Rights	10	15	1 Hr	25	75	3Hrs	100
MIP105P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MIP201T	Advanced Biopharmaceu ticsand Pharmacokine tics	10	15	1 Hr	25	75	3Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3Hrs	100
MIP203T	Pharmaceutic al Production Technology	10	15	1 Hr	25	75	3Hrs	100
MIP204T	Entrepreneurs hip Management	10	15	1 Hr	25	75	3Hrs	100
MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables - 18 : Schemes for internal assessments and end semester (Pharmaceutical Chemistry–MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Mark
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs	100
MPC102T	Advanced Organic Chemistry –I	10	15	1 Hr	25	75	3Hrs	100
MPC103T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3Hrs	100
MPC104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3Hrs	100
MPC105P	Pharmaceutic al Chemistry Practical I	20	30	6 Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry –II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer AidedDrug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutic alProcess Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutic alChemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables - 19: Schemes for internal assessments and end semester examinations (Pharmaceutical Analysis–MPA)

Course Code	Course	Internal Assessment				End Semester Exams			Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Dura tion		
			Marks	Duration					
SEMESTER I									
MPAT101T	Modern Pharmaceuti cal Analysis Techniques	10	15	1 Hr	25	75	3 Hrs		100
MPA102T	Advanced Pharmaceuti cal Analysis	10	15	1 Hr	25	75	3 Hrs		100
MPA103T	Pharmaceuti cal Validation	10	15	1 Hr	25	75	3 Hrs		100
MPA104T	Food Analysis	10	15	1 Hr	25	75	3 Hrs		100
MPA105P	Pharmaceuti cal Analysis Practical–I	20	30	6 Hrs	50	100	6 Hrs		150
-	Seminar /Assignment	-	-	-	-	-	-		100
								Total	**650**
SEMESTER II									
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs		100
MPA202T	Modern Bio–Analytical Techniques	10	15	1 Hr	25	75	3 Hrs		100
MPA203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs		100
MPA204T	Herbal and Cosmetic analysis	10	15	1 Hr	25	75	3 Hrs		100
MPA205P	Pharmaceuti cal Analysis Practical– II	20	30	6 Hrs	50	100	6 Hrs		150
-	Seminar /Assignment	-	-	-	-	-	-		100
								Total	**650**

Tables - 20: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance–MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous	Sessional Exams		Total	Marks	Duration	
		Mode	Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA102T	Quality Management System	10	15	1 Hr	25	75	3 Hrs	100
MQA103T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA1 04T	Product Developmentand Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA1 05P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MQA201T	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MQA2 03T	Auditsand Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
MQA2 04T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
MQA2 05P	Pharmaceutical QualityAssurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables - 21: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs–MRA)

Course Code	Course	Internal Assessment				End Semester Exams		
		Continuo Sessional Exams			Total	Marks	Duration	Total Marks
		Continuous Mode	Marks	Duration				
SEMESTER I								
MRA10 1T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
MRA10 2T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
MRA10 3T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA10 4T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In Indiaand ntellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MRA10 5T	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	–	–	–	–	–	–	100
							Total	**650**
SEMESTER II								
MRA20 1T	Regulatory Aspects of Drugs & Cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MRA20 2T	Regulatory Aspects of Herbal & Biologicals	10	15	1 Hr	25	75	3 Hrs	100
MRA20 3T	Regulatory Aspects of Medical Devices	10	15	1 Hr	25	75	3 Hrs	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	10	15	1 Hr	25	75	3 Hrs	100
MRA20 5P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables - 22: Schemes for internal assessments and end semester examinations (Pharmaceutical Biotechnology–MPB)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPB102T	Microbial And Cellular Biology	10	15	1 Hr	25	75	3 Hrs	100
MPB10 3T	Bioprocess Engineering and Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB10 4T	Advanced Pharmaceutical Biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB10 5P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPB20 1T	Proteins and protein Formulation	10	15	1 Hr	25	75	3 Hrs	100
MPB202T	Immunotechnolo gy	10	15	1 Hr	25	75	3 Hrs	100
MPB20 3T	Bioinformatics And Computer Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB20 4T	Biological Evaluation of Drug Therapy	10	15	1 Hr	25	75	3 Hrs	10
MPB20 5P	Pharmaceutical Biotechnology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables - 23: Schemes for internal assessments and end semester examinations (Pharmacy Practice–MPP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP10 1T	Clinical Pharmacy Practice	10	15	1 Hr	25	75	3 Hrs	100
MPP10 2T	Pharmacotherapeutics–I	10	15	1 Hr	25	75	3 Hrs	100
MPP10 3T	Hospital Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MPP10 4T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100
MPP10 5P	PharmacyPractice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPP20 1T	Principles of Quality Use of Medicines	10	15	1 Hr	25	75	3 Hrs	100
MPP10 2T	Pharmacotherapeutics II	10	15	1 Hr	25	75	3 Hrs	100
MPP20 3T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP20 4T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP20 5P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables - 24: Schemes for internal assessments and end semester examinations (Pharmacology–MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Session Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs	100
MPL102T	Advanced Pharmacology–I	10	15	1 Hr	25	75	3Hrs	100
MPL10 3T	Pharmacological and Toxicological Screening Methods–I	10	15	1 Hr	25	75	3Hrs	100
MPL10 4T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3Hrs	100
MPL105P	Experimental Pharmacology – I	20	30	6 Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods–II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Clinical research and pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Experimental Pharmacology- II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables - 25: Schemes for internal assessments and end semester examinations (Pharmacognosy–MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognosy–1	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Phytochemistr y	10	15	1 Hr	25	75	3 Hrs	100
MPG104T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG105P	Pharmacognos y Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPG20 1T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognosy–II	10	15	1 Hr	25	75	3 Hrs	100
MPG203T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognos y Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Seminar/Assignment

1. **Seminar:** The evaluation of seminar for semester I & II shall be carried out as per following scheme.
   a. Reference work and scientific contents --------- 10 marks
   b. Communication skill --------- 05 marks
   c. Discussion/defense --------- 05 marks
   d. Presentation --------- 30 marks
   Total --------- **50 marks**

2. **Assignment:** one assignment related to any topic from the specialization shall be conducted in semester I and II.
   Evaluation criteria for assignment are as follows:

   a. Structure, organization and content --------- 20 marks
   b. Creativity and originality --------- 05 marks
   c. Compilation of information --------- 10 marks
   d. Literature resources --------- 10 marks
   e. Reference style --------- 05 marks
   Total --------- **50 marks**

Tables - 26: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM30 1T	Research methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	–	–	–	25	–	–	25
-	Discussion / Presentation (Proposal Presentation)	–	–	–	50	–	–	50
-	Research work*	–	–	–	–	350	1 Hr	350
							Total	**525**
SEMESTER IV								
-	Journal club	–	–	–	25	–	–	25
-	Discussion / Presentation (Proposal Presentation)	–	–	–	75	–	–	75
-	Research work and Colloquium	–	–	–	–	400	1 Hr	400
							Total	**500**

*Non University Examination

11.2 Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table - 27: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	**10**
Practical	
Attendance (Refer Table – 28	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

Table - 28: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The sessional exam will be conducted for 30 marks and computed for 15 marks. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Scheme for theory Sessional examination

I. Objective Type questions (solve 5 out of 7) 5 X 2=10
II. Short answer questions (solve 2 out of 3) 2 X 5=10
III. Long answer questions (solve 1 out of 2) 1 X 10=10

Total Marks= 30

Scheme for Practical Sessional examination

I. Synopsis 05
II. Experiment(s) 20
III. Viva voce 05

Total Marks= 30

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance in each semester sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of end semester theory examinations.

15. Re examination of end semester examinations

Re examination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table - 29: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table - 30.

Table – 30: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester.
For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO}}{C_1 + C_2 + C_3 + C_4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,.... is the total number of credits for semester I,II,III,…. and S_1,S_2, S_3,....is the SGPA of semester I,II,III,….

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of. 7.50 And above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).The internal and external exainer appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

- Objective(s) of the work done 50 Marks
- Methodology adopted 150 Marks
- Results and Discussions 250 Marks
- Conclusions and Outcomes 50 Marks

Total 500 Marks

Evaluation of Presentation:

- Presentation of work 100 Marks
- Communication skills 50 Marks
- Question and answer skills 100 Marks

Total 250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation and retotaling of answer papers

There is provision for re-totaling and revaluation of the answer papers in any examination. The candidates can apply for revaluation/ re-totaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re–admission to the program after break of study has to get the approval from the university by paying a condonation fee.

Common subjects for all specializations except for Pharmaceutical Regulatory Affairs (MRA) and Pharmacy Practice (MPP)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory) (MPAT101T) **60 hours**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs.

Instruments dealt are UV, IR, NMR, Mass spectrometer, HPLC, GC etc.

Simple structure elucidation problems may be included based on UV-IR-NMR data.

Objectives

Upon completion of the course the student shall be able to

- Analytical techniques for identification, characterization and quantification of drugs
- Theoretical and practical skills of instrument handling and use.
- Structural Elucidation of organic compounds using spectroscopic tools

UNIT-1

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

b) **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **10 hrs**

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

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

UNIT-II

- **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 hrs**

UNIT-III

- **Mass Spectrometry:** Principle, Theory, Instrumentation of Mass Spectrometry, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectrometry **12 hrs**
- **Simple structure elucidation problems based on UV, IR, NMR and Mass data.**

UNIT-IV

Chromatography: Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **10 hrs**

a) High Performance Liquid chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography

d) Gas chromatography
e) Ultra High Performance Liquid chromatography
f) Affinity chromatography
g) Gel Chromatography

UNIT-V

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

10 hrs

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

UNIT - VI

Thermal Techniques:

a) **Thermogravimetric analysis (TGA):** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.
b) **Differential scanning calorimetry (DSC):** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.
c) **Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

08 hrs

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part A and B - J W Munson, Volume 11, Marcel Dekker Series
8. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.
9. Solving spectroscopy problems: A basic approach by Nazma Inamdar (Career publications).

PHARMACEUTICS (MPH)
DRUG DELIVERY SYSTEM (MPH 102T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

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

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

		THEORY 60 Hrs
1.	Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages / disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, and Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	**10 Hrs**
2	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	**10 Hrs**
3.	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	**10 Hrs**
4.	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers	**06 Hrs**
5.	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	**10 Hrs**
6.	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	**08 Hrs**
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	**06 Hrs**

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor– Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery – concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel &Decker) desirable

MODERN PHARMACEUTICS
(MPH 103T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

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

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

THEORY **60 HRS**

1. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability. Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. **12 Hrs**

2. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation . **10 Hrs**

3. Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, ICH & WHO guidelines for validation of equipments, Validation of cone blender, mixer granulator and tablet compression machine, URS, DQ, IQ, OQ & P.Q. of facilities, Types of process validation. Process validation of any one dosage form. Technology transfer from R & D to pilot plant to plant scale. **12 Hrs**

4. GMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. **10 Hrs**

5. Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles, Study of consolidation parameters, Heckel plots. **10 Hrs**

6. Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Similarity factors – f2 and f1, Disolution models including Higuchi, Peppas plot, zero order, first order and Hixson Crowell. **06 Hrs**

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS
(MPH 104T)

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

OBJECTIVES

Upon completion of the course, it is expected that the students will be able to understand

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

THEORY **60 Hrs**

1. a) Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch– Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in–vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. **12 Hrs**

   b) Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. **12 Hrs**

2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. **12 Hrs**

3. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). **12 Hrs**

4. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA – new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. **12 Hrs**

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga–basics

PHARMACEUTICS PRACTICALS – I
(MPH 105P)

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

MOLECULAR PHARMACEUTICS
(NANO TECHNOLOGY & TARGETED DDS) (NTDS)
(MPH 201T)

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.

THEORY **60 Hrs**

1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. **12 Hrs**

2. Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation **12 Hrs**

3. Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. **12 Hrs**

4. Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. **12 Hrs**

5. Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex–vivo & in–vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. **12 Hrs**

6. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. **12 Hrs**

REFERENCES

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, VallabhPrakashan, New Delhi, First edition 2002.

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MPH 202T)

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 this course it is expected that students will be able 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 biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY **60 Hrs**

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability–Solubility–Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight–Junction Complex. **12 Hrs**
2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate–limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, 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 testingperformance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product. **12 Hrs**
3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model– IV bolus, IV infusion, extra–vascular. Multi compartment model:two compartment – model in brief, non–linear pharmacokinetics: cause of non–linearity, Michaelis - Menten equation, estimation of k_{max} and v_{max}. 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. **12 Hrs**

4. Drug Product Performance, In Vivo: Bioavailabilityand 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. **12 Hrs**
5. Application of Pharmacokinetics: 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. **12 Hrs**

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 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, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande 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,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development– Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT

(MPH 203T)

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 this course it is expected that students will 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)

THEORY **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
   b) Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD – examples of application. **12 Hrs**
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 Hrs**
3. Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis **12 Hrs**
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 Hrs**

5. Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

12 Hrs

REFERENCES

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.

COSMETICS AND COSMECEUTICALS
(MPH 204T)

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, the students 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.

THEORY **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 Hrs**

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 Hrs**

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. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formal - ehyde liberators, dioxane. **12 Hrs**

4. Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun–protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. **12 Hrs**

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 Hrs**

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics – Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II
(MPH 205P)

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/microparticles
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. Case studies of Bioavailability studies of Paracetamol in animals.
10. Case studies of Pharmacokinetic and IVIVC data analysis
11. Case studies of In vitro cell studies for permeability and metabolism
12. Design of Experiment for any formulation using Design Expert® Software (Only formulation DOE is expected)
13. Formulation data analysis Using Design Expert® Software (Data analysis and interpretation of the previous experiment is expected)
14. Quality-by-Design in Pharmaceutical Development
15. Case studies of Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Case studies of Computational Modeling of Drug Disposition
17. Case studies of Developing Clinical Data Collection manual
18. Case studies of 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 to address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

INDUSTRIALPHARMACY (MIP)

PHARMACEUTICAL FORMULATION DEVELOPMENT

(MIP 102T)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

OBJECTIVES

On completion of this course it is expected that students will be able to understand-

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry. The significance of dissolution and product stability

THEORY 60 Hrs

1. Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug–excipient compatibility studies, methods of determination. **12 Hrs**
2. Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments - factorial design for product and process development. **12 Hrs**
3. Solubility: Importance, experimental determination, phase– solubility analysis, pH–solubility profile, solubility techniques to improve solubility and utilization of analytical methods - cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. **12 Hrs**
4. Dissolution: Theories, mechanisms of dissolution, in–vitro dissolution testing models - sink and non–sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus - designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in–vitro and in–vivo correlations, levels of correlations. **12 Hrs**
5. Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing–media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines. **12 Hrs**

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. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol–12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3 CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York, 2005.
11. W. Grimm – Stability testing of drug products.
12. Mazzo DJ. Internationalstability testing. Eastern Press Pvt. Ltd.,Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed 2004.CBS Publishers & distributors, New Delhi,
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I- III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

NOVEL DRUG DELIVERY SYSTEMS
(MIP 103T)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

OBJECTIVE

On completion of this course, it is expected that students will be able to understand,

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

THEORY **60 Hrs**

1. Carriers for Drug Delivery:Polymers / co–polymers–introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers. **12 Hrs**
2. Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems **12 Hrs**
3. Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. **08 Hrs**
4. Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects. **04 Hrs**
5. Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting - nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions - multiple emulsions, micro–emulsions. **12 Hrs**
6. Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.
7. Biotechnology in Drug Delivery Systems: Brief review of major areas – recombinant DNA technology, monoclonal antibodies, gene therapy. **06 Hrs**
8. New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics and Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. **06 Hrs**

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.

7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

INTELLECTUAL PROPERTY RIGHTS
(MIP 104T)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY **60 Hrs**

1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non–obviousness in Patent. **12 Hrs**

2. Role of GATT, TRIPS, and WIPO **12 Hrs**

3. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector. **12 Hrs**

4. Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA **12 Hrs**

5. Regulatory requirements for contract research organization. Regulations for Biosimilars. **12 Hrs**

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management by Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000–Norms and explanations
5. GMP for pharmaceuticals– Willing S.H. Marcel and Dekker

INDUSTRIAL PHARMACY PRACTICAL – I
(MIP 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation.
9. Stability studies of drugs in dosage forms at 25 RH. ^{o}C, 60% RH and 40^{o}C, 75%
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet / oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body– wash, creams, lotions, shampoo, toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MIP 201T)

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.

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY 60 Hrs

1. Drug Absorption from The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH-partition theory, 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. Solubility: Experimental methods. Permeability: In–vitro, in–situ and In–vivo methods. **12 Hrs**

2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate– Limiting Steps in Drug Absorption, Physicochemical Nature of the

   Drug Formulation Factors Affecting Drug Product Performance, 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. **12 Hrs**

3. Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model– IV bolus, IV infusion, Extra–vascular; Multi Compartment model: Two compartment – model in brief, Non–Linear Pharmacokinetics: Cause of non–linearity, Michaelis - Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein–binding interactions, the effect of tissue–binding interactions, Cytochrome P450–based drug interactions, and Drug interactions linked to transporters. **12 Hrs**

4. Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model– IV bolus, IV infusion, Extra–vascular; Multi Compartment model: Two compartment – model in brief, Non–Linear Pharmacokinetics: Cause of non–linearity, Michaelis - Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein–binding interactions, the effect of tissue–binding interactions, Cytochrome P450–based drug interactions, and Drug interactions linked to transporters. **12 Hrs**

5. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution. **12 Hrs**

6. Application of Pharmacokinetics: Modified–Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic-pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. **12 Hrs**

REFERENCES

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.J aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, 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 expande 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,1 st 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.

SCALE UP AND TECHNOLOGY TRANSFER
(MIP 202T)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

OBJECTIVES:

On completion of this course it is expected that students will be able to understand,

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY **60 Hrs**

1. Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

   Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products - stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in–process and finished product specifications, problems encountered during transfer of technology **12 Hrs**

2 Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification. **12 Hrs**

3 Equipment Qualification: Importance, IQ, OQ, PQ for equipments - autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation. **12 Hrs**

4 Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control. **12 Hrs**

5 Industrial safety: Hazards - fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution. **12 Hrs**

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel

Dekker, NY.

8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.

PHARMACEUTICAL PRODUCTION TECHNOLOGY
(MIP 203T)

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

THEORY 60 Hrs

1. Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

   Coating Technology: Process, equipments, particle coating, fluidized bed coating, and application techniques. Problems encountered. **12 Hrs**

2. Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. **12 Hrs**

3. Lyophilization & Spray drying Technology: Principles, process, freeze–drying and spray drying equipments. **12 Hrs**

4. Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered. Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

   Packaging Technology: Types of packaging materials, machinery, labeling, and package printing for different dosage forms. **12 Hrs**

5. Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance - RO, DM, ultra - filtration, WFI. **12 Hrs**

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.

6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation in Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

ENTREPRENEURSHIP MANAGEMENT
(MIP 204T)

SCOPE:

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

OBJECTIVES:

On completion of this course it is expected that students will be able to understand,

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

THEORY **60 Hrs**

1. Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise - Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management. **12 Hrs**

2 Entrepreneur: Entrepreneurial motivation - dynamics of motivation. Entrepreneurial competency -Concepts. Developing Entrepreneurial competencies – requirements and understanding the process of entrepreneurship development, self–awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role. **12 Hrs**

3 Launching and Organising an Enterprise: Environment scanning - Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation – finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation. **12 Hrs**

4 Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth - Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co–ordination and feasibility study. **12 Hrs**

5 Preparing Project Proposal to start on new Enterprise Project work - Feasibility report; Planning, resource mobilisation and implementation. **12 Hrs**

REFERENCES

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

INDUSTRIAL PHARMACY PRACTICAL – II
(MIP 205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
14. Preparation and evaluation of a spray dried formulation.

PHARMACEUTICAL CHEMISTRY (MPC)

ADVANCED ORGANIC CHEMISTRY - I (MPC 102T)	60 Hrs
Scope The subject is designed to provide in–depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery. **Objectives** Upon completion of course, the student shall be to understand • The principles and applications of reterosynthesis • The mechanism & applications of various named reactions • The concept of disconnection to develop synthetic routes for small target molecule. • The various catalysts used in organic reactions • The chemistry of heterocyclic compounds	
UNIT-I **a) Basic Aspects of Organic Chemistry** **1. Organic intermediates:** Carbocations, carbanions, free radicals, carbenes and nitrenes, their method of formation, stability and synthetic applications. **2.** Types of reaction mechanisms and methods of determining them: reactions, mechanisms and their relative reactivity and orientations. **b) Addition reactions** • **Nucleophilic uni– and bimolecular reactions (SN1 and SN2)** • **Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)** • **Rearrangement reactions**	**10 Hrs**
UNIT-II **Study of mechanism and synthetic applications of following name reactions** **1) Important Name reactions:** Ullmann coupling reactions, Dieckmann reaction, Doebner-Miller reaction, Sandmeyer reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack reaction, Sharpless asymmetric epoxidation, Shapiro & Suzuki reaction, Ozonolysis, Michael addition reaction **2) Multi-component synthesis:** Ugi reaction, Biginelli reaction, Hantzsch reaction, Passerini reaction and Strecker synthesis.	**12 Hrs**
UNIT-III **a) Synthetic Reagents & Applications** Aluminiumisopropoxide, N–bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol–1–yloxy) tris (dimethylamino) phosphonium hexafluoro–phosphate (BOP). **b) Protecting groups** i. Role of protection in organic synthesis ii. Protection for the hydroxyl group, including 1,2–and1,3–diols: ethers, esters, carbonates, cyclic acetals & ketals iii. Protection for the Carbonyl Group: Acetals and Ketals iv. Protection for the Carboxyl Group: amides and hydrazides,	**12 Hrs**

esters v. Protection for the Amino Group and Amino acids: carbamates and amides	
UNIT-IV • **Heterocyclic Chemistry** Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus–Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis. • **Synthesis of few representative drugs containing these hetrocyclic nucleus** such as Ketoconazole, Metronidazole, Celecoxib, Metamizole sodium, Antipyrine, Alprazolam, Triamterene, Sulfamerazine, Hydroxychloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Theophylline , Mercaptopurine.	**14 Hrs**
UNIT-V **Synthon approach and retrosynthesis applications** i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA) ii. C-X disconnections; C-C disconnections - alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds iii. Strategies for synthesis of three, four, five and six-membered ring.	**12 Hrs**

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers. Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry - Synthesis and applications - Stephen R Wilson & Anthony W Czarnik, Wiley - Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)	60 Hrs
Scope The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design. **Objectives** At completion of this course it is expected that students will be able to understand • Different stages of drug discovery • Role of medicinal chemistry in drug research • Different techniques for drug discovery • Various strategies to design and develop new drug like molecules for biological targets • Peptidomimetics	
UNIT-I **a) Drug discovery**: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. **b) Biological drug targets**: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonist's vs antagonists, and artificial enzymes.	**12 Hrs**
UNIT-II **Medicinal Chemistry Aspects of following classess of drugs** **Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:** **a)** Anti–hypertensive drugs, psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX-1 & COX-2 inhibitors, Alzheimer's and Parkinson's disease, Antineoplastic and Antiviral agents. **b) Stereochemistry and Drug action**: Stereo selectivity as a pre–requisite for evolution, role of chirality in selective and specific therapeutic agents, Enantio selectivity in drug adsorption, metabolism, distribution and elimination with Case studies.	**16 Hrs**
UNIT-III **Peptidomimetics** Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.	**10 Hrs**
UNIT-IV **Rational Design of Enzyme Inhibitors** Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.	**10 Hrs**
UNIT-V **Prodrug Design and Analog design** **a) Prodrug design**: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and	**12 Hrs**

distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design. **b) Combating drug resistance**: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance. **c) Analog Design**: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.	

REFERENCES

1. Medicinal Chemistry by Burger, Vol I -VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry - Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)	60 Hrs
Scope The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin. **Objectives** At completion of this course it is expected that students will be able to understand – • Different types of natural compounds and their chemistry and medicinal importance • The importance of natural compounds as lead molecules for new drug discovery • The concept of rDNA technology tool for new drug discovery • General methods of structural elucidation of compounds of natural origin • Isolation, Purification and characterization of simple chemical constituents from natural source	
UNIT-I **Study of Natural products as leads for new pharmaceuticals for the following class of drugs** a) Drugs Affecting the Central Nervous System: Morphine Alkaloids b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol d) Neuromuscular Blocking Drugs: Curare alkaloids e) Anti-malarial drugs and Analogues f) Chemistry of macrolide antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β- Lactam antibiotics (Cephalosporins and Carbapenem)	**12 Hrs**
UNIT-II **a) Alkaloids**: General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine. **b) Flavonoids**: Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin. **c) Steroids**: General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone,Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit - D).	**12 Hrs**
UNIT-III **a) Terpenoids**: Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene). **b) Vitamins** : Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.	**12 Hrs**

UNIT-IV **a) Recombinant DNA technology and drug discovery** rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation **b) Active constituent of certain crude drugs used in Indigenous system** **Diabetic therapy**- *Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum;* Liver dysfunction - *Phyllanthus niruri; Antitumor - Curcuma longa Linn.*	**12 Hrs**
UNIT-V **Structural Characterization of natural compounds** Structural characterization of natural compounds using IR, ^{1}H-NMR, ^{13}C-NMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit–D, Quercetin and Digitalis glycosides.	**12 Hrs**

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer - Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV - Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" - Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry - CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro–Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I
(MPC 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen–Schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co–chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

ADVANCED SPECTRAL ANALYSIS (MPC 201T)	60 Hrs
Scope This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC–MS, GC–MS, ATR–IR, DSC etc. **Objectives** At completion of this course it is expected that students will be able to understand - • Interpretation of the NMR, Mass and IR spectra of various organic compounds • Theoretical and practical skills of the hyphenated instruments • Identification of organic compounds	
UNIT-I **UV and IR spectroscopy** • Woodward - Fieser rule for 1,3– butadienes, cyclic dienes and α, β– carbonyl compounds and interpretation compounds of enones. • ATR–IR, Interpretation of IR Spectra of Organic Compound	**12 Hrs**
UNIT-II **NMR spectroscopy** 1–D and 2–D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.	**12 Hrs**
UNIT-III **Mass Spectroscopy** Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks,Interpretation of organic compounds.	**12 Hrs**
UNIT-IV **Chromatography:** Principle, Instrumentation and Applications of the following : a) GC–MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE- MS g) Super critical fluid chromatography h) Flash chromatography i.) LC-MS/MS	**16 Hrs**
UNIT-V **a) Thermal methods of analysis** Interpretation of TGA, DTA and DSC spectras of drug and excipients **b)** Bioassay, ELISA, Radioimmuno assay of digitalisand insulin.	**8 Hrs**

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC – P D Sethi, CBS Publishers, New Delhi.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis– Modern methods - Part B – J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY - II (MPC 202T)	60 Hrs
Scope The subject is designed to provide in–depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery. **Objectives :** Upon completion of course, the student shall able to understand • The principles and applications of Green chemistry • The concept of peptide chemistry. • The various catalysts used in organic reactions • The concept of stereochemistry and asymmetric synthesis.	
UNIT-I **Green Chemistry** **a.** Introduction, principles of green chemistry **b.** Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis **c.** Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid–liquid and liquid–solid reactions, synthetic applications **d.** Continuous flow reactors: Working principle, advantages and synthetic applications. **e.** Ionic liquids, and solvent free reactions	**12 Hrs**
UNIT-II **Stereochemistry & Asymmetric Synthesis** **a)** Basic concepts in stereochemistry - optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis–trans isomerism, E and Z notation. **b)** Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.	**12 Hrs**
UNIT-III **Chemistry of peptides** a) Coupling reactions in peptide synthesis b) Principles of solid phase peptide synthesis, t–BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site–specific chemical modifications of peptides c) Segment and sequential strategies for solution phase peptide synthesis with any two case studies d) Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over– activation and side reactions of individual amino acids.	**12 Hrs**
UNIT-IV	**12 Hrs**

a) **Photochemical Reactions** Basic principles of photochemical reactions. Photo–oxidation, photo–addition and photo–fragmentation. b) **Pericyclic reactions** Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples	
UNIT-V **Catalysis** **a)** Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages **b)** Heterogeneous catalysis - preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. **c)** Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs **d)** Transition–metal and Organo–catalysis in organic synthesis: Metal–catalyzed reactions **e)** Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. **f)** Phase transfer catalysis - theory and applications	**12 Hrs**

REFERENCES

1) "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.

2) "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston,NewYork.

3) "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.

4) "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.

5) Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)

6) Organic synthesis–the disconnection approach, S. Warren, Wily India

7) Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns

8) Organic synthesis– Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.

9) Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN (MPC 203T)	60 Hrs
Scope The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design. **Objectives** At completion of this course it is expected that students will be able to understand • Role of CADD in drug discovery • Different CADD techniques and their applications • Various strategies to design and develop new drug like molecules. • Working with molecular modeling software's to design new drug molecules • The in silico virtual screening protocols	
UNIT-I **Molecular Properties and Drug Design** a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design. b) De novo drug design: Receptor/enzyme–interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design. c) Homology modeling and generation of 3D–structure of protein.	**12 Hrs**
UNIT-II • **Pharmacophore Mapping and Virtual Screening** Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. • In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.	**12 Hrs**
UNIT-III **Molecular Modeling and Docking** **a)** Molecular and Quantum Mechanics in drug design. **b)** Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation **c)** Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra–precision docking. Agents acting on enzymes such as DHFR, HMG–CoA reductase and HIV protease, choline esterase (AchE & BchE)	**12 Hrs**
UNIT-IV • **Introduction to Computer Aided Drug Design (CADD)** History, different techniques and applications. • **Quantitative Structure Activity Relationships**: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi–substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.	**12 Hrs**
UNIT-V • **Quantitative Structure Activity Relationships:**	**12 Hrs**

Applications: Hansch analysis, Free Wilson analysis and relationship between them, • **Advantages and disadvantages**; Deriving 2D-QSAR equations. • 3D–QSAR approaches and contour map analysis. • **Statistical methods** used in QSAR analysis and importance of statistical parameters.	

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry -Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry - Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)	60 Hrs
Scope Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost–effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase. **Objectives** At completion of this course it is expected that students will be able to understand • The strategies of scale up process of apis and intermediates • The various unit operations and various reactions in process chemistry	
UNIT-I **Industrial Safety** **a)** MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) **b)** Fire hazards, types of fire & fire extinguishers Occupational Health & Safety Assessment Series 1800 (OHSAS–1800) and ISO–14001(Environmental Management System), Effluents and its management	**12 Hrs**
UNIT-II **Process chemistry** • Introduction, Synthetic strategy • **Stages of scale up process**: Bench, pilot and large scale process. In–process control and validation of large scale process. • Case studies of some scale up process of APIs. • Impurities in API, types and their sources including genotoxic impurities	**12 Hrs**
UNIT-III **Unit operations** **a. Extraction**: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction. **b. Filtration**: Theory of filtration, pressure and vacuum filtration, centrifugal filtration, **c. Distillation**: azeotropic and steam distillation **d. Evaporation**: Types of evaporators, factors affecting evaporation. **e. Crystallization**: Crystallization from aqueous, non– aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.	**12 Hrs**
UNIT-IV **Unit Processes – I** a) **Nitration**: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration, **b) Halogenation**: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation	**12 Hrs**

process. **c) Oxidation**: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis	
UNIT-V **Unit Processes – II** a) **Reduction**: Catalytic hydrogenation, Heterogeneous and omogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) **Fermentation**: Aerobic and anaerobic fermentation. Production of - i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 iii. Statins: Lovastatin, Simvastatin c) Reaction progress kinetic analysis i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale–up.	**12 Hrs**

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever– Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1–8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale–Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Tech., WEP East–West Press Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
11. Lowenheim & M.K. Moran: Industrial Chemicals
12. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
13. J.K. Stille: Industrial Organic Chemistry (PH)
14. Shreve: Chemical Process, Mc Grawhill.

PHARMACEUTICAL CHEMISTRY PRACTICALS – II (MPC 205P)
1) Synthesis of organic compounds by adapting different approaches involving (3 experiments) • Oxidation • Reduction/hydrogenation • Nitration
2) Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3) Assignments on regulatory requirements in API (2 experiments)
4) Comparison of absorption spectra by UV and Wood ward - Fieser rule
5) Interpretation of organic compounds by FT–IR
6) Interpretation of organic compounds by NMR
7) Interpretation of organic compounds by MS
8) Determination of purity by DSC in pharmaceuticals
9) Identification of organic compounds using FT–IR, NMR, CNMR and Mass spectra
10) To carry out the preparation of following organic compounds
11) Preparation of 4–chlorobenzhydrylpiperazine. (An intermediate for cetirizine HCl).
12) Preparation of 4–iodotolene from p–toluidine.
13) NaBH4 reduction of vanillin to vanillyl alcohol
14) Preparation of umbelliferone by Pechhman reaction
15) Preparation of triphenyl imidazole
16) To perform the Microwave irradiated reactions of synthetic importance (Any two)
17) Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares.
18) Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling
19) 2D–QSAR based experiments
20) 3D–QSAR based experiments
21) Docking study based experiment
22) Virtual screening based experiment

PHARMACEUTICAL ANALYSIS (MPA)

ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

SCOPE

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

OBJECTIVE

After completion of the course students shall able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY **60 Hrs**

1. Impurity and stabilitystudies:Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines Impurities in new drug products:Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products Impurities in residual solvents:General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

   Elemental impurities:Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis **10 Hrs**

2. Stability testing protocols:Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations. **10 Hrs**

3. Impurity profiling and degradent characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products **10 Hrs**

4. Stability testing of phytopharmaceuticals: Regulatory requirements, protocols,

HPTLC/HPLC finger printing, interactions and complexity. **10 Hrs**

5. Biological tests and assays of the following: a.) Adsorbed Tetanus vaccineb.)Adsorbed Diphtheria vaccine c.) Human anti haemophilic vaccine d.) Rabies vaccine e.) Tetanus Anti toxin f.) Tetanus Anti serum g.) Oxytocin h.) Heparin sodium IP i.) Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures) **10 Hrs**

6. Immunoassays (IA) Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA. **10 Hrs**

REFERENCES

1. Vogel‘s textbook of quantitative chemical analysis – Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis – K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis – Higuchi, Brochmman and Hassen, 2nd Edition, Wiley - Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis– Modern methods – J W Munson - Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs – D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I, II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development - Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances - Klaus Florey, Volume 1 - 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients - Harry G Brittan, Volume 21 - 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids – Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION
(MPA 103T)

SCOPE

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

OBJECTIVES

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY **60 Hrs**

1. Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

   Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re – Qualification (Maintaining status – Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments. **12 Hrs**

2. Qualification of analytical instruments: Electronic balance, pH meter, UV–Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette. **12 Hrs**

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

   12 Hrs

4. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance–21 CFR part 11 and GAMP 5. **12 Hrs**

5. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property -patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP

in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications– provisional and non–provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics–positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

12 Hrs

REFERENCES

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. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

FOOD ANALYSIS
(MPA 104T)

SCOPE

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

OBJECTIVES

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY 60 Hrs

1. Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates

   Proteins: Chemistry and classification of amino acids and proteins, Physico–Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins. **12 Hrs**

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

   Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B–series. **12 Hrs**

3. Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

   Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted syntheticyes, Non–permitted synthetic dyes used by industries, Method of detection of natural, permitted and non–permitted dyes. **12 Hrs**

4. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.**12 Hrs**

5. Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US–FDA. **12 Hrs**

REFERENCES

1. The chemical analysis of foods - David Pearson, Seventh edition, Churchill

Livingstone, Edinburgh London, 1976

2. Introduction to the Chemical analysis of foods - S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents - Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICALS – II
(MPA 105P)

1) Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2) Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3) Experiments based on HPLC
4) Experiments based on Gas Chromatography
5) Estimation of riboflavin/quinine sulphate by fluorimetry
6) Estimation of sodium/potassium by flame photometry
7) Assay of official compounds by different titrations
8) Assay of official compounds by instrumental techniques.
9) Quantitative determination of hydroxyl group.
10) Quantitative determination of amino group
11) Colorimetric determination of drugs by using different reagents
12) Imupurity profiling of drugs
13) Calibration of glasswares
14) Calibration of pH meter
15) Calibration of UV–Visible spectrophotometer
16) Calibration of FTIR spectrophotometer
17) Calibration of GC instrument
18) Calibration of HPLC instrument
19) Cleaning validation of any one equipment
20) Determination of total reducing sugar
21) Determination of proteins
22) Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23) Determination of fat content and rancidity in food products
24) Analysis of natural and synthetic colors in food
25) Determination of preservatives in food
26) Determination of pesticide residue in food products
27) Analysis of vitamin content in food products
28) Determination of density and specific gravity of foods
29) Determination of food additives

ADVANCED INSTRUMENTAL ANALYSIS
(MPA 201T)

SCOPE

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC–MS, GC–MS, and hyphenated techniques.

OBJECTIVES

After completion of course student is able to know,

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THOERY **60 Hrs**

1. HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC–role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. **12 Hrs**

2. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
   Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.
   High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications. **12 Hrs**

3. Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.
   Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and methoddevelopment in CE, Crown ethers as buffer additives in capillary electrophoresis. CE–MS hyphenation. **12 Hrs**

4. Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC–MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT–ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF–TOF;Q–IT, Q–TOF, LTQ–FT, LTQ–Orbitrap. **12 Hrs**

5. NMR spectroscopy: Quantum numbers and their role in NMR, Principle,

Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin–Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT–NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13CNMR, 1–D and 2–D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC–NMR hyphenations. **12 Hrs**

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC – P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis– Modern methods - Part B – J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES
(MPA 202T)

SCOPE

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

OBJECTIVES

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY **60 Hrs**

1) Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid – Liquid extraction and Solid phase extraction and other novel sample preparation approach.
Bioanalytical method validation: USFDA and EMEA guidelines. **12 Hrs**

2) Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. **12 Hrs**

3) Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK–PD interactions), the effect of protein–binding interactions, the effect of tissue–binding interactions, Cytochrome P450–based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics–Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC–MS in bioactivity screening and proteomics. **12 Hrs**

4) Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry. **12 Hrs**

5) Metabolite identification: In–vitro / in–vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met -ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.
Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies. **12 Hrs**

REFERENCES

1. Analysis of drugs in Biological fluids – Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis – Higuchi, Brochmman and Hassen, 2ndEdition, Wiley - Interscience Publications, 1961.
4. Pharmaceutical Analysis– Modern methods- Part B – J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development - Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals - John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology - Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2ndEdition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

QUALITY CONTROL AND QUALITY ASSURANCE
(MPA 203T)

SCOPE

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

OBJECTIVES

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

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

THEORY **60 Hrs**

1. Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines – QSEM, with special emphasis on Q–series guidelines.
   Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. **12 Hrs**

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines. **12 Hrs**

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)
   Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials. **12 Hrs**

4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles– How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. **12 Hrs**

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix–ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge–in

of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. **12 Hrs**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals– A compedium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's - P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia - vol I, II, III, IV & V – General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 - Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual - D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control - Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 – With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

HERBAL AND COSMETIC ANALYSIS
(MPA 204T)

SCOPE

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

OBJECTIVES

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug–drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY **60 Hrs**

1. Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines. **12 Hrs**

2. Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, and DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.
   Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol. **12 Hrs**

3. Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.
   Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. **12 Hrs**

4. Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug–drug and bio drug–food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. **12 Hrs**

5. Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of

analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards. **12 Hrs**

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics - Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition

PHARMACEUTICAL ANALYSIS PRACTICALS – I
(MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward - Fiesure rule
2. Interpretation of organic compounds by FT–IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT–IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

QUALITY MANAGEMENT SYSTEMS (MQA 102T)	60 Hrs

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the Pharmaceutical industries.

Objectives

Upon completion of the course the student shall be able to

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

COURSE CONTENT

UNIT-I • **Introduction to Quality: Evolution of Quality** • **Definition of Introduction to Quality**: Evolution of Quality, Definition of Quality, Dimensions of Quality • **Quality as a Strategic Decision**: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers. Case studies. • **Cost of Quality**: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, preventing cost of quality.	**08 Hrs**
UNIT-II • **Pharmaceutical quality Management**: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	**16 Hrs**
UNIT-III • **Six System Inspection model** : Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self inspection. • **Quality systems**: Change Management / Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), • **Complaints** - evaluation and handling, Investigation and determination	**12 Hrs**

of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	
UNIT-IV • **Drug Stability**: ICH guidelines for stability testing of drug substances and drug products. • Study of ICH Q8, Quality by Design and Process development report • **Quality risk management**: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	**12 Hrs**
UNIT-V • **Statistical Process control (SPC)**: Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	**08 Hrs**
UNIT-VI • **Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking**: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	**04 Hrs**

REFERENCES

1. Al Endres, Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, Wiley, 2000.
2. Jiju Antony; David Preece, Routledge, Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, 2002.
3. Edward E. Lawler, Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report, 2001.
4. James W. Fairfield-Sonn, Corporate Culture and the Quality Organization, Quorum Books, 2001.
5. Christine Avery; Diane Zabel, Routledge, the Quality Management Sourcebook: An International Guide to Materials and Resources 1997.
6. Nancy R. Tague, the Quality Toolbox, Second Edition, ASQ Publications.
7. Joseph M. Juran and Joseph A., De Feo, Juran's Quality Handbook, Sixth Edition, ASQ Publications.
8. Duke Okes, Root Cause Analysis, the Core of Problem Solving and Corrective Action, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)	60 Hrs
Scope This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs. **Objectives** **Upon completion of this course the student should be able to** • Understand the cGMP aspects in a pharmaceutical industry • To appreciate the importance of documentation • To understand the scope of quality certifications applicable to Pharmaceutical industries To understand the responsibilities of QA & QC departments.	
UNIT-I • **Introduction**: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	**12 Hrs**
UNIT-II • **cGMP guidelines according to schedule M, USFDA (inclusive ofCDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering**: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	**12 Hrs**
UNIT-III • Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. 126 In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	**12 Hrs**
UNIT-IV • **Documentation in pharmaceutical industry**: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. • Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non	**16 Hrs**

regulated markets.	
UNIT-V • **Manufacturing operations and controls**: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.	**08 Hrs**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Sandy Weinberg, Good Laboratory Practice Regulations, 2nd Edition, Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. Sharma P. P., How to Practice GMP's Vandana Publications, Agra, 1991, 127.
5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Allen F. Hirsch, Good laboratory Practice Regulations, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines.
8. ISO 9000 and total quality management.
9. Deshpande, Nilesh Gandhi, The Drugs and Cosmetics Act 1940, 4th edition, Susmit Publishers, 2006.
10. D.H. Shah, QA Manual, 1st edition, Business Horizons, 2000.
11. Sidney H. Willig, Good Manufacturing Practices for Pharmaceuticals a plan for total quality control, Vol. 52, 3rd edition, Marcel Dekker Series.
9. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
12. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
13. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)	60 Hrs
Scope This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following Candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in Manufacturing places. **Objectives** **Upon completion of this course the student should be able to** • To understand the new product development process • To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D • To elucidate necessary information to transfer technology of existing products between various manufacturing places	
UNIT-I • **Principles of Drug discovery and development**: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.	**12 Hrs**
UNIT-II • **Pre-formulation studies**: Introduction / concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. • **Solubility, Methods to improve solubility of Drugs**: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	**12 Hrs**
UNIT-III • **Pilot plant scale up** : Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	**12 Hrs**
UNIT-IV • **Pharmaceutical packaging**: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. **Quality control test**: Containers, closures and secondary packing materials.	**12 Hrs**
UNIT-V • **Technology transfer**: Development of technology by R & D, Technology transfer from R & D to production, Optimization and	**12 Hrs**

Production, Qualitative and quantitative technology models. • **Documentation in technology transfer**: Development report, technology transfer plan and Exhibit.	

REFERENCES

1. Charles G. Smith, James T and O. Donnell, The process of new drug discovery and development. I and II Edition (2006) CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd E/d Bhalani publishing house Mumbai.
4. Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, Tablets Vol. I, II, III, 2nd E/d. (1989), Marcel Dekker Inc. New York.
5. Milo Gibaldi, Text book of Bio- Pharmaceutics and clinical Pharmacokinetics 3rd E/d Lea & Febriger, Philadelphia.
6. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji, Pharmaceutical product development. CRC Press, Group of Taylor and Francis.
7. Abdou H.M, Dissolution, Bioavailability and Bio-Equivalence, Mack Publishing company, Eastern Pennsylvania.
8. Alfonso & Gennaro, Remingtons Pharmaceutical Sciences, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. D. A Sawant, The Pharmaceutical Sciences; the Pharma Path way Pure and applied Pharmacy, Pragathi Books Pvt. Ltd.
10. D.A. Dean. E.R. Evans, Pharmaceutical Packaging technology, I.H. Hall. 1st E/d (Reprint 2006). Taylor and Francis. London and New York. 130

QUALITY ASSURANCE PRACTICAL - I
(MQA 105P)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet / capsules / semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on –
   - Total Quality Management
   - Six Sigma
   - Change Management/ Change control. Deviations
   - Out of Specifications (OOS)
   - Out of Trend (OOT)
   - Corrective & Preventive Actions (CAPA)
   - Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)	60 Hrs

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 situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- 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 ideas 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.

UNIT-I • Multidisciplinary nature of environmental studies Natural Resources and associated problems, Renewable and non-renewable resources, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources • **Ecosystems**: Concept of an ecosystem, Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	**12 Hrs**
UNIT-II • Air based hazards Sources, Types of Hazards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non sterile area.	**12 Hrs**
UNIT-III • **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, MSDS, Labelling guidelines, Management of over-Exposure to chemicals and TLV concept, Disposal of hazardous material.	**12 Hrs**
UNIT-IV • **Fire and Explosion**: Introduction, Industrial processes and hazards potential, Mechanical, electrical, thermal and process hazards, mechanical and chemical explosion, multiphase reactions. Safety and hazards regulations • **Fire protection system**: Fire prevention, types of fire extinguishers and critical Hazard management system, Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, fire walls, bunds, relief systems - relief valves, flares, scrubbers.	**12 Hrs**

UNIT-V • **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, Preliminary hazard analysis • 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 Hrs**

REFERENCES

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. T.S.S. Dikshith, Hazardous Chemicals: Safety Management and Global Regulations, CRC press
4. M. N. Vyas, Safety and hazard management in chemical industries, Atlantic Publisher
5. Daniel A. Crowl, Joseph F. Louvar, Chemical Process Safety: Fundamentals with Applications, 3rd Edition, Prentice Hall, 2011
6. H. H. Fawcett and W.S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd E/d, John Wiley & Sons, New York 1982.
7. C.S.Rao, Environmental Pollution Control Engineering, New Age international publisher
8. Phillip Carson, Clive Mumford, Butterworth-Heinemann, Hazardous Chemicals Handbook, Second edition, An imprint of Elsevier Science.

PHARMACEUTICAL VALIDATION (MQA 202T)	60 Hrs
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** At completion of this course, it is expected that students will 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	
UNIT-I • **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 Hrs**
UNIT-II • **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, GC, HPLC, HPTLC.	**10 Hrs**
UNIT-III • **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 Hrs**
UNIT-IV • **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.), 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.	**10 Hrs**
UNIT-V	**10 Hrs**

• 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	
UNIT-VI • General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property–patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	**10 Hrs**

REFERENCES

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. Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, The Theory & Practice of Industrial Pharmacy, 3rd edition, Varghese Publishing House, Bombay.
3. Terveeks , Validation Master plan Davis Harwood International publishing.
4. Carleton & Agalloco, Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Syed Imtiaz Haider.Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries,
7. Phillip A. Cloud, Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, , Interpharm Press.
8. Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Validation of Pharmaceutical Processes: Sterile Products, Marcel Dekker.
9. Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Analytical Method validation and Instrument Performance Verification, 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 D. A. Validated Cleaning Technologies for Pharmaceutical Manufacturing, Interpharm Press.

AUDITS AND REGULATORY COMPLIANCE **60 Hrs**
(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 this course the student should be able to

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

UNIT-I

- **INTRODUCTION**: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies **12 Hrs**

UNIT-II

- **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 Hrs**

UNIT-III

- 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 Hrs**

UNIT-IV

- **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 Hrs**

UNIT-V

- **Auditing of Quality Assurance and engineering department**: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. **12 Hrs**

REFERENCES

1. Karen Ginsbury and Gil Bismuth,Compliance auditing for Pharmaceutical Manufacturers. Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Shayne Cox Gad, Pharmaceutical Manufacturing Handbook, Regulations and Quality, Wiley-Interscience, A John Wiley and sons, Inc. Publications.
3. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. Handbook of microbiological Quality control,CRC Press. 2000.
4. C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden, Laboratory auditing for quality and regulatory compliance. Donald Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T) **60 Hrs**

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives

At completion of this course it is expected that students will 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

UNIT-I

- **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. **12 Hrs**
- **Production planning**: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

UNIT-II

- **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. **12 Hrs**
- **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), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.

UNIT-III

- **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). **12 Hrs**
- 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 pelletization equipments, continuous and batch mixing, rapid mixing

granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments.

- **Problems encountered. Coating technology**: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT-IV

- **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 Hrs**

UNIT-V

- **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. **12 Hrs**
- **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.

REFERENCES

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, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial 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.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS
(MQA 205P)

1. Organic contaminants residue analysis by HPLC
2. Identification of antibiotic residue by TLC
3. Estimation of Chlorine in Work Environment.
4. Sampling and analysis of SO_2 using Colorimetric method
5. Qualification of following Pharma equipment
   a) Autoclave b) Hot air oven
   c) Powder Mixer (Dry) d) Tablet Compression Machine
6. Validation of an analytical method for a drug
7. Process validation of any non-sterile or sterile dosage form
8. Validation of a processing area
9. Qualification of at least two analytical instruments
10. Cleaning validation of one equipment
11. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, riability Apparatus, Disintegration Tester)
12. Check list for Bulk Pharmaceutical Chemicals vendors
13. Check list for tableting production.
14. Check list for sterile production area
15. Check list for Water for injection.
16. Design of plant layout: Sterile and non-sterile
17. Case study on application of QbD
18. Case study on application of PAT

PHARMACEUTICALREGULATORY AFFAIRS (MRA)

GOOD REGULATORY PRACTICES (MRA 101T)

Scope

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

OBJECTIVES

At completion of this course it is expected that students will be able to understand,

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

THEORY **60 Hrs**

1. Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211.EC Principlesof GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP–5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs. **12 Hrs**

2. Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards **12 Hrs**

3. Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards. **12 Hrs**

4. Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self–Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards **12 Hrs**

5. Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents. **12 Hrs**

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

SCOPE

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

OBJECTIVES

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

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

THEORY **60 Hrs**

1. Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF). **12 Hrs**

2. Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO. **12 Hrs**

3. Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485. **12 Hrs**

4. Inspections: Pre–approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA). **12 Hrs**
5. Product life cycle management: Prior Approval Supplement (PAS), Post Approval

Changes [SUPAC], Changes Being Effected in 30 Days (CBE–30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard **12 Hrs**

REFERENCES

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. Singer, Raluca–loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey–Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield– Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph

A. De Feo, ASQ Publications

12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS
(MRA 103T)

SCOPE

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

OBJECTIVES

Upon completion of the course, the student shall be able to (know, do and appreciate)

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

TTHOERY **60 Hrs**

1. Clinical Drug Development Process
   - Different types of Clinical Studies
   - Phases of clinical trials, Clinical Trial protocol
   - Phase 0 studies
   - Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug - drug interaction, PK end points
   - Phase II studies (proof of concept or principle studies to establish efficacy)
   - Phase III studies (Multi ethnicity, global clinical trial, registration studies)
   - Phase IV studies (Post Marketing Studies; PSUR)
   - Clinical Investigation and Evaluation of Medical Devices & IVDs
   - Different Types of Studies
   - Key Concepts of Medical Device Clinical Evaluation Key concepts of Clinical Investigation **12 Hrs**

2. Ethics in Clinical Research:
   - Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
   - Origin of International Conference on Harmonization – Good Clinical Practice (ICH–GCP) guidelines.
   - The ethics of randomized clinical trials
   - The role of placebo in clinical trials
   - Ethics of clinical research in special population
   - Institutional Review Board / Independent Ethics Committee / Ethics Committee-composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data

- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation **12 Hrs**

3. Regulations governing Clinical Trials
   - India: Clinical Research regulations in India - Schedule Y & Medical Device Guidance
   - USA: Regulations to conduct drug studies in USA (FDA)
   - NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
   - NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
   - ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
   - FDA Guidance for Industry – Acceptance of Foreign Clinical Studies
   - FDA Clinical Trials Guidance Document: Good Clinical Practice
   - EU: Clinical Research regulations in European Union (EMA) **12 Hrs**

4. Clinical Research Related Guidelines
   - Good Clinical Practice Guidelines (ICH GCP E6)
   - Indian GCP Guidelines
   - ICMR Ethical Guidelines for Biomedical Research
   - CDSCO guidelines
   - GHTF study group 5 guidance documents
   - Regulatory Guidance on Efficacy and Safety ICH Guidance's
   - E4 – Dose Response Information to support Drug Registration
   - E7 - Studies in support of General Population: Geriatrics
   - E8 - General Considerations of Clinical Trials
   - E10 - Choice of Control Groups and Related Issues in Clinical Trials
   - E 11 - Clinical Investigation of Medicinal Products in the Pediatric Population
   - General biostatics principle applied in clinical research **12 Hrs**

5. USA & EU Guidance USA: FDA Guidance
   - CFR 21Part 50: Protection of Human Subjects
   - CFR 21Part 54: Financial Disclosure by Clinical Investigators
   - CFR 21Part 312: IND Application
   - CFR 21Part 314: Application for FDA Approval to Market a New Drug
   - CFR 21Part 320: Bioavailability and bioequivalence requirements
   - CFR 21Part 812: Investigational Device Exemptions
   - CFR 21Part 822: Post–market surveillance
   - FDA Safety Reporting Requirements for INDs and BA/BE Studies
   - FDA Med Watch
   - Guidance for Industry: Good Pharmacovigilance Practices and

Pharmacoepidemiologic Assessment

- European Union: EMA Guidance
- EU Directives 2001
- EudraLex (EMEA) Volume 3- Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR)
- Volume 9A - Pharmacovigilance for Medicinal Products for Human Use
- EU MDD with respect to clinical research
- ISO 14155 **12 Hrs**

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001

   http://www.eortc.be/services/doc/clinical–eudirective–04–april–01.pdf
2. Code of FederalRegulations,FDA:

   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization:

   http://www. ich.org/products/guidelines.html
4. Eudralex Guidelines

   http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application:

   http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm

6. Medicines and Healthcare products Regulatory Agency:
http://www.mhra.gov.uk
7. Central Drugs Standard Control Organization Guidance for Industry:
http://cdsco.nic.in/CDSCO–GuidanceForIndustry.pdf
8. ICMR Ethical Guidelines for Biomedical Research:
http://icmr.nic.in/ethical_guidelines.pdf

REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS
(MRA 104T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):
   a. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
   b. Other relevant provisions (rules schedules and guidelines for approval of Drugs Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

   Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act. **12 Hrs**

2 Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- Format & contents of Regulatory dossier filing Clinical trial / investigations

12 Hrs

3. Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards **12 Hrs**

4. Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study
   Stability requirements: ICH and WHO
   Guidelines for Drug testing in animals/Preclinical Studies
   Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR–DBT Guidelines for Stem Cell Research

12 Hrs

5. Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

12 Hrs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by the Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline - Good Clinical Practice" by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL - I (MRA 105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II
REGULATORY ASPECTS OF DRUGS & COSMETICS
(MRA 201T)

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 countriesIt 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, the student shall be able to know

- 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

THEORY **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 Approval Process 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 Hrs

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 of cosmetics in European Union & Australia.

   12 Hrs

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 Hrs**

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 Hrs**

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, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries. **12 Hrs**

REFERENCES :

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 ByFrederick 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), Instute of South East Asian studies, Singapore

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS
(MRA 202T)

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 the completion of the course the 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 of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

THEORY **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 & GDP. **12 Hrs**
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 Hrs**
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 Hrs**
4. Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorisation, 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 Hrs**
5. Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union. **12 Hrs**

REFERENCES

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; Wei 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 RegulatoryInformation (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES
(MRA 203T)

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, the student shall be able to know

- 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

THEORY **60 Hrs**

1. Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. 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 Hrs**

2. Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device **12 Hrs**

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 Hrs**

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 Hrs**

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 Hrs**

REFERENCES

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.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS
(MRA 204T)

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, the 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.

THEORY **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 Hrs**
2. Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements & Nutraceuticals Industries, NSF Certification, NSF Standards for Food Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.**12 Hrs**
3. India : 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 Hrs
4. USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. 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 **12 Hrs**
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 Hrs

REFERENCES

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/IPOL_STU(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.

REGULATORY AFFAIRS PRACTICAL – II
(MRA 205P)

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

PHARMACEUTICAL BIOTECHNOLOGY (MPB)

MICROBIAL AND CELLULAR BIOLOGY
(MPB 102T)

SCOPE

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

OBJECTIVE

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

THEORY **60 Hrs**

1. Microbiology Introduction - Prokaryotes and Eukaryotes. Bacteria, fungi, actionomycetes and virus – structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms – examples and applications **12 Hrs**

2. Molecular Biology: Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and translation.

   Gene regulation Gene copy number, transcriptional control and translational control.

   RNA processing Modification & aturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids types purification and application. Phage genetics, geneticorganization, phage mutation and lysogeny.

   12 Hrs

3. Cell structure and function Cell organelles, cytoskeleton & cell movements, basic aspectsof cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Celljunctions/adhesion and extra cellular matrix, germ cells and fertilization, histology - thelife and death of cells in tissues.

   Cell Cycle and Cytoskeleton : Cell Division and its Regulation, G–Protein CoupledReceptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, IntermediateFilaments.

   Apoptosis and Oncogenes : Programmed Cell Death, Tumor cells, carcinogens & repair.

Differentiation and Developmental Biology : Fertilization, Events of Fertilization, In vitro Fertilization, Embryonic Germ Cells, Stem Cells & its Application. **12 Hrs**

4. Principles of microbial nutrition: Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.

   Growth of animal cells in culture: General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. In-vitro screening techniques– cytotoxicity, anti–tumor, anti–viral assays. **12 Hrs**

5. Microbial pathology : Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy. **12 Hrs**

REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells - A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore, Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol–I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins– A Waverly Company.

BIOPROCESS ENGINEERING AND TECHNOLOGY
(MPB 103T)

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

OBJECTIVE

At the completion of this subject it is expected that students will be able to,

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

THEORY **60 Hrs**

1. Introduction to fermentation technology
   - Basic principles of fermentation
   - Study of the design and operation of bioreactor
   - Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.
   - Types of bioreactor
   - CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application
   - Computer control of fermentation process
   - System configuration and application **12 Hrs**

2. Mass transfer : Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co– efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

   Rheology : Rheological properties of fermentation system and their importance in bioprocessing. **12 Hrs**

3. Scale up of fermentation process : Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

   Cultivation and immobilized culture system Cultivation system – batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

Introduction to immobilization: Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering. **12 Hrs**

4. Scale down of fermentation process : Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.

   Isolation and screening : Primary and secondary, maintenance of stockculture, strain improvement for increased yield. **12 Hrs**

5. Bioprocessing of the industrially important microbial metabolites

   a) Organic solvents - Alcohol and Glycerol

   b) Organic acids – Citric acids, Lactic acids,

   c) Amino acids – Glutamic acids, Lysine, Cyclic AMP and GMP

   d) Antibiotics – Penicillin, Streptomycin, Griseofulvin,

   e) Vitamins – B12, Riboflavin and Vitamin C

   Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids

   Regulation governing the manufacturing of biological products. **12 Hrs**

REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY
(MPB 104T)

SCOPE

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

OBJECTIVE

At the completion of this subject it is expected that students will be able to

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r–DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug–device combinations.

THEORY **60 Hrs**

1. Enzyme Technology: Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin. **12 Hrs**

2. Genetic Engineering : Techniques of gene manipulation, cloning strategies,procedures, cloning vectors expression vectors, recombinant selection andscreening, expression in E.coli and yeast.

   Site directed mutagenesis, polymerase chain reaction, and analysis of DNAsequences.

   Gene library and cDNA

   Applications of the above technique in the production of,

   - Regulatory proteins - Interferon, Interleukins
   - Blood products - Erythropoietin
   - Vaccines - Hepatitis–B
   - Hormones - Insulin **12 Hrs**

3. Therapeutic peptides: Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

   Transgenic animals: Production of useful proteins in transgenic animals and gene therapy.

   Human Genome: The human genome project–a brief study, Human chromosome - Structure and classification, chromosomal abnormalities - Syndromes **12 Hrs**

4. Signal transduction: Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.

   Oncogenes: Introduction, definition, various oncogenes, their proteins. **12 Hrs**

5. Microbial Biotransformation : Biotransformation for the synthesis of chiral drugs and steroids.

   Microbial Biodegradation : Biodegradation of xenobiotics, chemical and industrial wastes, Production of single–cell protein,

   Applications of microbes in environmental monitoring.

   Biosensors : Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors. **12 Hrs**

REFERENCES

1. Biotechnology The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology:Harvey Lodish, David Baltimore, Arnold Berk, S awence Zipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Gene transfer and expression protocols–methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL – I
(MPB 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV– survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio–autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS - polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

PROTEINS AND PROTEIN FORMULATIONS
(MPB 201T)

SCOPE

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

OBJECTIVE

At the completion of this course it is expected that students will be able to understand,

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

THEORY **60 Hrs**

1. Protein engineering : Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution. **12 Hrs**

2. Peptidomimetics : Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

   12 Hrs

3. Proteomics : Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N– and C–terminal tags.

   2-Dimensional gel electrophoresis : Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments **12 Hrs**

4. Protein formulation : Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre– formulation, Liposomes, Neon–spears, Neon–particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

   12 Hrs

5. Methods of protein sequencing: Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

   12 Hrs

REFERENCES

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company

2. Protein Purification - Hand Book, Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins–Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

IMMUNOTECHNOLOGY
(MPB 202T)

SCOPE

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology – based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

OBJECTIVE

After this course, the students will be able to:–

- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background; Develop approaches for the immune intervention of diseases

THEORY **60 Hrs**

1. Fundamental aspects of immunology : Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.

   Types of immune responses, anatomy of immune response. Overview of innate and adaptive Immunity.

   Humoral Immunity : B - Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

   Cell mediated Immunity : Thymus derived lymphocytes (T cells) - their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis **12 Hrs**

2. Immune Regulation and Tolerance: Complement activation and types and their biological functions, cytokines and their role in immune response.

   Hypersensitivity: Hypersensitivity Types I–IV, Hypersensitivity reactions and treatment Autoimmune diseases **12 Hrs**

3. Vaccine technology : Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.

   Stem cell technology : Technology and applications to immunology **12 Hrs**

4. Hybridoma Technology : Hybridoma techniques - fusion methods for myeloma cells and B–ymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry. **12 Hrs**

5. Immunological Disorder : Autoimmune disorders and types,pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

   Immunodiagnosis : Antigen antibody interaction - Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot

analysis, immune–electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction. **12 Hrs**

REFERENCES

1. J. Kubey, Immunology - an Introduction.
2. S.C. Rastogi, Immunodiagonstics, New Age International.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB 203T)

SCOPE

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

OBJECTIVES

Upon completion of this course it is expected that the students will be able to understand,

- Use of computers in developing a new drugs
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene findingmethods
- Searching the biological databases
- Target searching
- Various methods of drug designing

THEORY 60 Hrs

1. Introduction to Bioinformatics : Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics, Biological Database

   Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics. **12 Hrs**

2 Sequence analysis : Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTALW and CLUSTALX for the multiple sequence alignment. Tools used for sequence analysis. **12 Hrs**

3. Protein informatics : Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S fit of conformers, assigning secondary structures; Sequence alignment–methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

   Protein structure prediction : Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural

profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence– sequence scoring.

Docking : Docking problems, methods for protein– ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results. **12 Hrs**

4. Diversity of Genomes : Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications– Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.

   Completed Genomes

   Bacterium, Nematode, Plant and Human

   Evolution of Genomes

   Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome– General Account

   Phylogenetic analysis

   Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique. **12 Hrs**

5. Target searching and Drug Designing : Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality. **12 Hrs**

REFERENCES

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics– Concepts Skill and Applications, CBS Publishers and Distributors
3. T.E.Creighton, Protein Structure and Molecular Properties, W.H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY
(MPB 204T)

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

OBJECTIVE

At the completion of this subject it is expected that students will be able to,

- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs in vitro and in vivo

TTHEORY **60 Hrs**

1. Biological Standardization : General principles, Scope and limitation of bio–assay, bioassay of some official drugs.

   Preclinical drug evaluation : Preclinical drug evaluation of its biological activity, potency and toxicity–Toxicity test in animals including acute, sub–acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity.

   Guidelines for toxicity studies : Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials. **12 Hrs**

2. Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.

   Microbiological assay: Assay of antibiotics and vitamins.

   Biological evaluation of drugs screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study). **12 Hrs**

3. Biologic Medicines in Development for various diseases - By Therapeutic Category

   - Genetic Disorders
   - Eye related Disorders
   - Digestive Disorders
   - Diabetes/Related Conditions
   - Cardiovascular Disease
   - Cancer/Related Conditions
   - Blood Disorders
   - Autoimmune Disorders
   - Infectious Diseases
   - Neurologic Disorders
   - Skin Diseases
   - Organe Transplantation

Biologic Medicines in Development for various diseases - by Product Category

- Antisense
- Vaccines
- Recombinant Hormones/Proteins
- Monoclonal Antibodies (mAb)
- Interferons
- Growth Factors
- Gene Therapy
- RNA Interference **12 Hrs**

4. Regulatory aspects: drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product.
   Regulatory consideration: Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.
   New Drug Applications for Global Pharmaceutical Product Approvals **12 Hrs**

5. Bioavailability: Objectives and consideration in bio–availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio–availability.
   Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio–availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals.
   Pharmacokinetics: Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals. **12 Hrs**

REFERENCES

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological tandardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I& II), R.A. Turner.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL – II
(MPB 205P)

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCRapplications - Isolation, Purity and Quantification
14. Introduction to PCR - working of PCR, Programming.
15. Introduction to RT–PCR - working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

PHARMACY PRACTICE (MPP)

CLINICAL PHARMACY PRACTICE
(MPP 101T)

SCOPE

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to :

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

THEORY **60 Hrs**

1. Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care
   Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions) **12 Hrs**

2. Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services. **12 Hrs**

3. Patient Data Analysis: Patient Data & Practice Skills: Patient's case history – its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non–verbal communications, its applications in patient care services.
   Lab Data Interpretation : Hematological tests, Renal function tests, Liver function tests. **12 Hrs**

4. Lab Data Interpretation: Tests associated with cardiac disorders, pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests. **12 Hrs**

5. Medicines & Poison Information Services : Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre.

Poison Information Service: Definition, need, organization and functions of poison information centre. **12 Hrs**

REFERENCES

1. A Textbook of Clinical Pharmacy Practice - Essential concepts and skills - Parthasarathi G, Karin Nyfort–Hansen and Milap Nahata
2. Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP 102T)

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 this course it is expected that students shall be able to:

- 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)

THEORY 60 Hrs

1. Etiopathogenesis and pharmacotherapy of diseases associated with following systems

   Cardiovascular system: Hypertension, Congestive cardiac failure, acute coronary eyndrome, Arrhythmias, Hyperlipidemias. **12 Hrs**

2. Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

   Endocrine system: Diabetes, Thyroid diseases **12 Hrs**

3. Gastrointestinal system: Pepticulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis **12 Hrs**

4. Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug–induced liver disease
   Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders. **12 Hrs**

5. Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis
   Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders
   Ophthalmology: Conjunctivitis, Glaucoma **12 Hrs**

REFERENCES

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

HOSPITAL & COMMUNITY PHARMACY
(MPP 103T)

SCOPE

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

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

THEORY **60 Hrs**

1. Introduction toHospitals - Definition,classification, organizational structure

   Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management

   Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

   12 Hrs

2. Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

3. Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter.

   Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.

   Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy. **12 Hrs**

4. Prescription - Legal requirements & interpretation, prescription related problems

   Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,

   OTC medication: Rational use of over the counter medications

Medication counseling and use of patient information leaflets Medication adherence - Definition, factors influencing adherence behavior, strategies to improve medication adherence

Patient referrals to the doctors

ADR monitoring in community pharmacies **12 Hrs**

5. Health Promotion - Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non–communicable diseases, smoking cessation, Child & mother care

   National Health Programs- Role of Community Pharmacist in Malaria and TB control programs

   Home Medicines review program - Definition, objectives, Guidelines, method and outcomes

   Research in community pharmacy Practice **12 Hrs**

REFERENCES

1. Hospital Pharmacy – Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy – Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice - Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH
(MPP 104T)

SCOPE

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

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

THEORY **60 Hrs**

1. Drug development process: Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research - Principles of ethics in biomedical research, Ethical committee [institutional review board] – its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting. **12 Hrs**

2. Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)

   Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, and Contract Research Organization. **12 Hrs**

3. Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards

   Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre–study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission **12 Hrs**

4. Investigational Product: Procurement and Storage of investigation product

   Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up

   Clinical Trial Monitoring and Close out:

Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow–up

Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close–Out visit report.

12 Hrs

5. Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow–up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management. Data Management

   Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival

   Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set–up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data,

   Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing. **12 Hrs**

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices– Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I
(MPP 105P)

SCOPE

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics–I, Hospital & Community Pharmacy and Clinical Research.

LIST OF EXPERIMENTS (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

PRINCIPLES OF QUALITY USE OF MEDICINES
(MPP 201T)

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 this course it is expected that students shall be able to:

- 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

THEORY **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 Hrs**

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 Hrs**

3. QUM in various settings: Hospital settings, Ambulatory care / Residential care, Role of health care professionals in promoting the QUM, 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. **12 Hrs**

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 Hrs**

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 Hrs**

REFERENCES:

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_Red uced.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.

PHARMACOTHERAPEUTICS II
(MPP 202T)

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 this course it is expected that students shall be able to:

- 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)

THEORY **60 Hrs**

1. Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management. **12 Hrs**
2. Psychiatric disorders: Schizophrenia,Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders renal system: Acute renal failure, chronic renal failure, Renal dialysis, Drug induced renal disease **12 Hrs**
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 Hrs**
4. Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections
   Gynecological disorders: Dysmenorrhea, Hormone replacement therapy. **12 Hrs**
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 Hrs**

REFERENCES

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

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP 203T)

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 this course it is expected that students 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 paediatrics 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

THEORY 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 Hrs**

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 Hrs**

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 Hrs**

4. Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics, 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 Hrs**

5. Therapeutic Drug monitoring: Introduction, Individualization of drug dosage regimen (Variability - Genetic, age, weight, disease and Interacting drugs), 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. **12 Hrs**

REFERENCES

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. Iippincott 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

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS
(MPP 204T)

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 this course it is expected that students shall be able to:

- 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.

THEORY **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, defineddaily 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 & relative risk, Time risk relationship & odds ratio

12 Hrs

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 Hrs

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 Hrs**

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 Hrs**

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 Hrs**

REFERENCES

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. GeorgeE Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics 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

PHARMACY PRACTICE PRACTICAL – II
(MPP 205P)

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.

LIST OF EXPERIMENTS (24)

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 analyses for the given data (two)

PHARMACOLOGY (MPL)

ADVANCED PHARMACOLOGY – I
(MPL 102T)

SCOPE

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

OBJECTIVES

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

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

THEORY **60 Hrs**

Unit-I **General Pharmacology** **12 Hrs**

Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non–linear compartment models. Significance of Protein binding.

Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

Unit -II. **Neurotransmission** **12 Hrs**

Neurotransmission

General aspects and steps involved in neurotransmission.

Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters– Adrenaline and Acetyl choline).

Neurohumoral transmission in central nervous system (Detailed study about neurotransmitter histamine, serotonin, dopamine, GABA, glutamate and glycine).

Non adrenergic non cholinergic transmission (NANC). Co– transmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems.

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction.

Unit-III **Central nervous system Pharmacology** **12 Hrs**

General anesthetics

Sedatives and hypnotics, anti-anxiety drugs.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases Parkinsonism and Alzheimer's).
Narcotic and non–narcotic analgesics.

Unit-IV **Cardiovascular Pharmacology** **12 Hrs**

Diuretics, anti-hypertensives, anti-ischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia.
Hematinics, coagulants and anticoagulants, fibrinolytics and anti– platelet drugs.

Unit-V **Autocoid Pharmacology** **12 Hrs**

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.
Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's.
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer–Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung.
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment.
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (MPL 103T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

Unit-I **Laboratory Animals** **12 Hrs**

Common Laboratory animals: Description, handling and applications of different species and strains of animals.
Transgenic animals: Production, maintenance and applications.
CPCSEA Guidelines for experimental animals.
Anesthesia and euthanasia of experimental animals
Maintenance and breeding of laboratory animals.
Good laboratory Practice.

Unit -II **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro* and other possible alternative methods in animals.** **12 Hrs**

CNS Pharmacology:
General principles of preclinical screening, screening of behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics, nootropics, Parkinsonism and Alzheimer's.
Drugs acting on Autonomic nervous system.

Unit-III **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro* and other possible alternative methods in animals.** **12 Hrs**

Respiratory Pharmacology:
Anti-asthmatics, drugs for COPD and anti-allergic.
Reproductive Pharmacology: Aphrodisiacs and ant-fertility agents
Gastrointestinal drugs:

Anti-ulcer, anti-emetic, anti-diarrheal and laxatives
Analgesic, anti-inflammatory and anti-pyretic drugs.

Unit-IV **Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro* and other possible alternative methods in animals.** **12 Hrs**

Cardiovascular Pharmacology:
Anti-hypertensive, anti-arrhythmic, anti-anginals, anti-atherosclerotic, and diuretics.
Drugs for metabolic disorders:
Anti-diabetic, anti-hyperlipidemic and anti-cancer drugs.
Methods for screening of Hepatoprotective drugs.

Unit-V **Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro* and other possible alternative methods in animals.** **12 Hrs**

Immunosuppressant's and immunomodulators
General principles of immunoassay: Theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay system. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin.
Limitation of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans.

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Evaluation of drugs activities by Laurence and Bachrach.
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M. N. Ghosh.
6. Pharmacological experiment on intact preparations by Churchill Livingstone.
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R. K. Goyal.
9. Preclinical evaluation of new drugs by S. K. Gupta.
10. Handbook of Experimental Pharmacology, S. K. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, S. K. Kulkarni, 3rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee.
14. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi , Ajay Prakash.

CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL 104T)

SCOPE

This subject imparts a fundamental knowledge on the structure and functions of cellular components and helps to understand the interaction of these components with drug. This information will further help the student to apply the knowledge in drug discovery.

OBJECTIVES

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

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

THEORY **60 Hrs**

Unit-I **Cell biology** **12 Hrs**

Structure and function of cell and is organelles.
Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing.
Cell cycle and its regulation.
Cell death events, regulators intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

Unit -II **Cell signaling** **12 Hrs**

Intercellular and intracellular signaling pathways.
Classification of receptor family and molecular structure of :
Ligand gated ion channels, G-protein coupled receptors, tyrosine kinase receptor and nuclear receptor.

Secondary messengers :

cyclic AMP , cyclic GMP, calcium ion , inositol 1,4,5-triphosphte (IP_3), NO and diacylglycerol (DAG).

Detailed study of following intracellular signaling pathways:

cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK) / signal transducer and activator of transcription (STAT) signaling pathway.

Unit-III **Principle and application of genomic and proteomic tools:** **12 Hrs**

DNA electrophoresis, PCR (reverse transcriptase and real time), Gene sequencing, microarray technique, SDS page, ELISA and western blotting.

Basic principles of recombinant DNA technology:

Restriction enzymes, various types of vectors. Applications of various recombinant DNA technology.

Gene therapy: various types of gene transfer techniques, clinical

applications and recent advances in gene therapy.

Unit IV **Pharmacogenomics :** **12 Hrs**

Gene mapping and cloning of disease gene.
Gene variation and its role in health / pharmacology.
Polymorphism affecting drug metabolism.
Genetic variation in drug transporters.
Genetic variation in G-protein coupled receptors.

Application of proteomic science :

Genomics, proteomics, metbolomics , functionomics , nutrigenomics.

Immunotherapeutics :

Types of immunotherapeutics, humanisation, antibody therapy, Immunotherapeutics in clinical practice.

Unit V **Cell culture techniques :** **12 Hrs**

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell culture, isolation of cells 'subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays.

Principles and application of flow cytometry.

Introduction and applications of Biosimilars

REFERENCES

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M L. Wong.
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al.
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al.
5. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Miller.
6. Basic Cell Culture (Practical Approach) by J. M. Davis.
7. Animal Cell Culture: A Practical Approach by John R. Masters.
8. Current protocols in molecular biology Vol I to VI edited by Frederick M. Ausuvel et la.

PHARMACOLOGICAL PRACTICAL-I
(MPL 105P)

1. Analysis of pharmacopoeial compounds & their formulations by UV Vis spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry.
3. Experiments based on HPLC.
4. Experiments based on Gas Chromatography.
5. Estimation of riboflavin/quinine sulphate by Fluorimetry.
6. Estimation of sodium/potassium by flame photometry.

LABORATORY ANIMALS EXPERIMENTS

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti–inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, a -amylase, a- glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.

19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares.
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines.
2. Fundamentals of experimental Pharmacology by M. N. Ghosh.
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds – Robert M Silverstein,
6. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman.
7. Vogel's Text book of quantitative chemical analysis –Jeffery, Basset, Mendham, Denney.
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Mille.
9. Basic Cell Culture (Practical Approach) by J. M. Davis.
10. Animal Cell Culture: A Practical Approach by John R. Masters.
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi, Ajay Prakash Jaypee brothers' medical publishers Pvt. Ltd

ADVANCED PHARMACOLOGY-II
(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 the course the student shall be able to:

- 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 the treatment of diseases.

THEORY **60 Hrs**

Unit-I **Endocrine Pharmacology** **12 Hrs**

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormone.

Anti-thyroid drugs, oral hypoglycemic agents, oral contraceptives, corticosteroids and drugs affecting on calcium regulation.

Unit -II **Chemotherapy** **12 Hrs**

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as β-lactams, aminoglycosides, quinolones, Macrolides antibiotics.

Antifungal, antiviral and anti-TB drugs.

Unit-III **Chemotherapy** **12 Hrs**

Drugs used in Protozoal infections, Helminthiasis and cancer.

Cellular and biochemical mediators of inflammation and immune response, allergy or hypersensitivity reactions, Pharmacotherapy of asthma and COPD.

Immunosuppressants and immunomodulators.

Unit-IV **GIT Pharmacology** **12 Hrs**

Anti-ulcer drugs, Prokinetics, anti-emetics, 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.

Unit-V **Free Radical Pharmacology** **12 Hrs**

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 antioxidants such as Vitamin E, Vitamin C, Curcumin, CoQ10, Lipoic acid etc.

Recent advances in the treatment of Alzheimer's disease, Parkinson's disease, cancer and diabetes mellitus.

REFERENCES

1. The Pharmacological basis of therapeutics-Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G-Katzung.
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
9. Robbins and Cortan Pathologic Basis of Disease, 9^{th} 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.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL202T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

Unit-I	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. History, concept and its importance in drug development	**12 Hrs**
Unit -II	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 toxicity studies.	**12 Hrs**
Unit-III	Reproductive toxicity studies, Male reproductive toxicity studies, Female reproductive studies (segment I and III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	**12 Hrs**
Unit-IV	IND enabling studies (IND studies): Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies: origin, concepts and importance of safety pharmacology Tier 1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier 2- GI, renal and other studies.	**12 Hrs**
Unit-V	Toxicokinetics – Toxicokinetic evaluation in preclinical studies, saturation kinetics. Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	**12 Hrs**

REFERENCES

1. Hand book on GLP, Quality practices for regulated non–clinical research and development (http://www.who.int/tdr/publications/documents/glp– handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,2005, ministry of health and family welfare (department of health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals

   (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY
(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, the student shall be able to,

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
- Explain various targets, biomarkers and *in vitro* screening techniques 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.

THEORY **60 Hrs**

Unit-I **An overview of modern drug discovery process:** **12 Hrs**

Target identification, target validation, lead identification and lead His 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 oligonucleotides, Zinc finger proteins Role of transgenic animals in target validation.

Unit -II **Lead Identification** **12 Hrs**

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.

Unit-III **Rational Drug Design** **12 Hrs**

Structure and pharmacophore based approaches, virtual screening technique, rational approaches for reperfusing of existing molecules for new therapeutic target.

Introduction to molecular docking and QSAR statistical method and product concept.

Unit-IV **Classical Targets, Translational Medicine and Biomarkers in Drug Discovery** **12 Hrs**

Enzymes and Enzymes Inhibition, G-Protein-Coupled Receptors (GPCRs), Ion Channels, Membrane Transport Proteins (Transporters), Emerging Targets.

Definition of a Biomarker and Their Classification, Characteristics and Impact of Biomarkers, Biomarkers versus Surrogate End Points, Imaging Technologies, The Practical Application of Biomarkers.

Biomarkers for cancer (breast, lung, skin), diabetes, CVs etc.

Unit-V ***In vitro*** **screening systems** **12 Hrs**

The Language of Screening: Basic Terms, Biochemical versus Cellular Assays, Assay Systems and Methods of Detection, Radioligand Assay Systems (RIA), Enzyme-Linked Immunosorbent Assay (ELISA), Fluorescence-Based Assay Systems, Reporter Gene Assays, Kinetic Fluorescent Measurement Systems, Label-Free Assay Systems, Electrophysiological Patch Clamp, General Consideration for All Screening Methods.

REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markel In. 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 Joachin Bohm. 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.
8. Benjamin Blass. Basic Principles of Drug Discovery and Development.1st Edition, Academic Press.

CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL204T)

SCOPE:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will reach 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, the student shall be able to:

- 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 reaction and their assessment.
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance.

THEORY **60 Hrs**

Unit-I **Regulatory Perspective of Clinical Trials:** **12 Hrs**

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.

Inform Consent Process: Structure and content of an Inform Consent Process Ethical principles governing informed consent process.

Unit -II **Clinical Trials: Types and Design** **12 Hrs**

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

Unit-III **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 **12 Hrs**

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

Unit-IV **Basic aspects, terminologies and establishment of Pharmacovigilance** **12 Hrs**

History and progress of Pharmacovigilance, Significant 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

Unit-V **Methods, ADR reporting and tools used in Pharmacovigilance** **12 Hrs**

International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Arugs, Aris G Pharmacovigilance, Vigiflow, Statistical methods for evaluating medication safety data. Introduction to pharmacoepidemiology and pharmacoeconomics.

REFERENCES

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 Biomediical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical trials by David Machin, Simon Day and Sylvan Green. 2005. John Wiley and Sons.
5. Clinical Data management edited by R. K. Rondels, S A Varley, C F Webbs. Second edition, 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 lgnazio, di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL – II
(MPL 205P)

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

REFERENCES

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.

PHARMACOGNOSY (MPG)

ADVANCED PHARMACOGNOSY – I (MPG 102T) **60 Hrs**

SCOPE

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

- advances in the cultivation and production of drugs
- various phyto-pharmaceuticals and their source, its utilization and
- medicinal value.
- various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

UNIT 1

Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices,Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and Insitu conservation of medicinal plants. **12 Hrs**

UNIT 2

Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. **12 Hrs**

UNIT 3

Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin,Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals,Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following **12 Hrs**

i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii**)** Flax seeds viii) Black cohosh ix) Turmeric.

UNIT 4

Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following. **12 Hrs**

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α – Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids- Ellagic acid
f) Vitamins
g) Tocotrienols and Tocopherols
h) Andrographolide, Glycolipids, Gugulipids, Withanolides,

Vascine, Taxol
i) Miscellaneous

UNIT 5

Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine,Spontaneous reporting schemes for biodrug adverse reactions,bio drug-drug and bio drug-food interactions with suitable examples. **12 Hrs**

REFERENCES (Latest Editions of)

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh,New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman.V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi,1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S.Sreeramu. University Press, 2001
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
16. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

PHYTOCHEMISTRY (MPG 103T) **60 Hrs**

SCOPE

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phytoconstituents

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

- different classes of phytoconstituents, their biosynthetic pathways, their
- properties, extraction and general process of natural product drug
- discovery
- phytochemical fingerprinting and structure elucidation of
- phytoconstituents

UNIT 1

Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:

a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine,Berberine, Taxol, Vinca alkoloids. **12 Hrs**

b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides,Bacosides, Quercitin.

c) Steroids: Hecogenin, guggulosterone and withanolides

d) Coumarin: Umbelliferone.

e) Terpenoids: Cucurbitacins

UNIT 2

Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process,structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. **12 Hrs**

UNIT 3

Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography **12 Hrs**

UNIT 4

Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. **12 Hrs**

UNIT 5

Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) **12 Hrs**

a. Carvone, Citral, Menthol

b. Luteolin, Kaempferol

c. Nicotine, Caffeine iv) Glycyrrhizin.

REFERENCES (LATEST EDITIONS OF)

1. Organic chemistry by I.L. Finar Vol.II

2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 104T)	60 Hrs
SCOPE To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin. **OBJECTIVES** By the end of the course the student shall be able to know, • the requirements for setting up the herbal/natural drug industry. • the guidelines for quality of herbal/natural medicines and regulatory issues. • the patenting/IPR of herbals/natural drugs and trade of raw and finished materials.	
UNIT 1 **Herbal drug industry:** Infrastructure of herbal drug industry Involved in production of standardized extracts and various Dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.	**12 Hrs**
UNIT 2 **Regulatory requirements for setting herbal drug industry:** Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS. Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000.	**12 Hrs**
UNIT 3 **Monographs of herbal drugs:** General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.	**12 Hrs**
UNIT 4 **Testing of natural products and drugs:** Herbal medicines -clinical laboratory testing. Stability testing of natural products, protocols.	**12 Hrs**
UNIT 5 **Patents:** Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.	**12 Hrs**

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.

3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.

4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.

5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.

6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.

7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.

8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.

9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.

10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.

11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,

12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

PHARMACOGNOSY PRACTICAL – I
(MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC- estimation of glycerrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.

REFERENCES (Latest Editions of)

1. Indian Pharmacopoeia, 2017.

2. Florey K., "Analytical Profiles of Drug Substances", Academic press, Harcourt Brace Publishers, New York.
3. Skoog D.A., "Principles of Instrumental Analysis", 5th edition, 1998, Estern Press, Banglore.
4. Wagner H., Baldt S., "Plant Drug Analysis", Springer Publications, Berlin.
5. Deore S.L., Khadbadi S.S., et.al. "Experimental Phytopharmacognosy-A Comprehensive Guide", Nirali Prakashan, Mumbai,
6. Indian Herbal Pharmacopoeia, IDMA, Delhi.
7. Rangari V.D., "Pharmacognosy & Phytochemistry", Vol I &II, 3rd edition, Career Publications, Pune.
8. Kaushik A., et.al. "Formulation and Evaluation of Herbal Cough Syrup", European Journal of Pharmaceutical and Medical Research, Department of Pharmacy/Teerthankar Mahaveer University, Moradabad, India.

MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T) **60 Hrs**

SCOPE

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

OBJECTIVES

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

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

UNIT 1

Introduction to Plant biotechnology: Historical perspectives,prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. **12 Hrs**

Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology**.**

UNIT 2

Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.. **15 Hrs**

UNIT 3

Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.. **15 Hrs**

UNIT 4

Biotransformation and Transgenesis: Biotransformation bioreactors for pilot and large scale cultures of plant cells and Hrs retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis **13 Hrs**

UNIT 5

Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest**.** **05 Hrs**

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.

6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plan tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham

ADVANCED PHARMACOGNOSY- II (MPG 202T)	60 Hrs
SCOPE To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening **OBJECTIVES** **Upon completion of the course, the student shall be able to know** • the validation of herbal remedies • methods of detection of adulteration and evaluation techniques for the herbal drugs • methods of screening of herbals for various biological properties	
UNIT 1 **Herbal remedies –** Toxicity and Regulations: Herbals vs 12 Conventional drugs, Efficacy of Herbal medicine products, Hrs Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues	**12 Hrs**
UNIT 2 **Adulteration and Deterioration :** Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.	**12 Hrs**
UNIT 3 **Ethnobotany and Ethnopharmacology:** Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.	**12 Hrs**
UNIT 4 **Analytical Profiles of herbal drugs:** *Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, and Psoralea corylifolia***.**	**12 Hrs**
UNIT 5 **Biological screening of herbal drugs:** Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluatingNatural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines	**12 Hrs**

REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.

5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal

INDIAN SYSTEMS OF MEDICINE (MPG 203T)	**60 Hrs**
SCOPE To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines. **OBJECTIVES** **After completion of the course, student is able to** -To understand the basic principles of various Indian systems of medicine -To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.	
UNIT 1 Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine Different dosage forms of the ISM. **Ayurveda**: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality. **Siddha**: Gunapadam (Siddha Pharmacology),raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).	**12 Hrs**
UNIT 2 Naturopathy, Yoga and Aromatherapy practices a) Naturopathy - Introduction, basic principles and treatment modalities. b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques. c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.	**12 Hrs**
UNIT 3 Formulation development of various systems of medicine Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations	**12 Hrs**
UNIT 4 Schedule T – Good Manufacturing Practice of Indian systems of medicine. Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area machinery and equipments, standard operating procedures health and hygiene, documentation and records Quality assurance in ISM formulation industry GAP GMP and GLP. Preparation of documents for new drug application and export registration Challenges in monitoring the safety of herbal medicines Regulation , Quality assurance and control National/Regional pharmcopeias	**12 Hrs**
UNIT 5 TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU	**12 Hrs**

REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, the Controller of Publications, Civil Lines, Govt. of India, New Delhi.

2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy: An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, and New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, British Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
12. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG 204T)	60 Hrs
SCOPE This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals. **OBJECTIVES** After completion of the course, student shall be able to, • understand the basic principles of various herbal/natural cosmetic preparations • current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities	
UNIT 1 **Introduction**: Herbal/natural cosmetics, Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics	**12 Hrs**
UNIT 2 **Commonly used herbal cosmetics, raw materials**, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.	**12 Hrs**
UNIT 3 **Herbal Cosmetics :** Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions,Face powders,Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.	**12 Hrs**
UNIT 4 **Cosmeceuticals of herbal and natural origin:** Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Hrs Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.	**12 Hrs**
UNIT 5 Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act.	**12 Hrs**

REFERENCES (Latest Editions of)

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.

7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.

8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

HERBAL COSMETICS PRACTICALS
(MPG 205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.

REFERENCES (Latest Editions of)

1. Dubey R.C., "A Textbook of Biotechnology", 1st edition, 1993, S. Chand Publication, New Delhi.
2. Indian Pharmacopoeia, Vol I & II, 2017
3. Deore S.L., Khadbadi S.S., et.al. "Experimental Phytopharmacognosy-A Comprehensive Guide", 1st edition, Nirali Prakashan, Mumbai, may 2011.
4. Ayurvedic Pharmacopeia of India
5. Worwood A.V., "The complete Book of Essential oil and Aromatherapy", Sept.1991, New World Liabrary, Calofornia.
6. Sharma P.P., "Cosmetics Formulation, Manufacturing & Quality control", 3rd edition, 2005, Vandana Publications, Delhi.
7. Gupta S., "Herbal Cosmetics and Beauty Products with Formulations", Engineers India Research Institute, Delhi.

SEMESTER III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non–parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non–maleficence, double effect, conflicts between autonomy and beneficence/non–maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.