M.PHARM PHARMACY PRACTICE

SEMESTER I

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MPP 101T	Clinical Pharmacy Practice	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.
MPP 102T	Pharmacotherapeutics – I	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.
MPP 103T	Hospital & Community Pharmacy	This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.
MPP 104T	Clinical Research	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.
MPP 105P	Pharmacy Practice Practical – I	Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

SEMESTER II

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MPP 201T	Principles of Quality use of Medicines	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.
MPP 202T	Pharmacotherapeutics II	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.
MPP 203T	Clinical Pharmacokinetics and therapeutic Drug Monitoring	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
MPP 204T	Pharmacoepidemiology& Pharmacoeconomics	This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology.
MPP 205P	Pharmacy Practice Practical II	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.

SEMESTER III

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MRM 301T	Research Methodology and Biostatistics	To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials

SEMESTER IV

The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions.

7/1/22

PRINCIPAL
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M.PHARM PHARMACEUTICS

SEMESTER I

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MPT 101T	Modern Pharmaceutical Analytical Techniques	This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
MPH 102T	Drug Delivery Systems	This course is designed to impart knowledge on the area of advances in novel drug delivery systems. 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.
MPH 103T	Modern Pharmaceutics	Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries. 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.
MPH 104T	Regulatory Affairs	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
MPH 105P	Pharmaceutics Practical I	The practical section deals with the analysis of compounds using different analytical techniques, utilizing various instruments. The practical syllabus is designed in such a manner to cover topics from all the different subjects learned.

SEMESTER II

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MPH 201T	Molecular Pharmaceutics	This course is designed to impart knowledge on the area of advances in novel drug delivery systems. 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
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	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.
MPH 203T	Computer Aided Drug Development	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.
MPH 204T	Cosmetics and Cosmeceuticals	This course is designed to impart knowledge and skills necessary forthefundamental need for cosmetic and cosmeceutical products.
MPH 205P	Pharmaceutics Practical – II	The practical section deals with the analysis of compounds using different analytical techniques, utilizing various instruments. The practical syllabus is designed in such a manner to cover topics from all the different subjects learned.

SEMESTER III

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MRM 301T	Research Methodology and Biostatistics	To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials

SEMESTER IV

The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions.

M.PHARM PHARMACEUTICAL CHEMISTRY

SEMESTER I

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MPT 101T	Modern Pharmaceutical Analytical Techniques	This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
MPC 102T	Advanced Organic Chemistry –I	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.
MPC 103T	Advanced Medicinal Chemistry	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.
MPC 104T	Chemistry of Natural Products	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.
MPC 105P	Pharmaceutical Chemistry Practical – I	The practical section deals with the analysis of compounds using different analytical techniques, utilizing various instruments. The practical syllabus is designed in such a manner to cover topics from all the different subjects learned. It includes synthesis of various compounds, isolation, etc.

SEMESTER II

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MPC 201T	Advanced Spectral Analysis	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.
MPC 202T	Advanced Organic Chemistry –II	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.
MPC 203T	Computer Aided Drug Design	The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.
MPC 204T	Pharmaceutical Process Chemistry	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..
MPC 205P	Pharmaceutical Chemistry Practical – II	The practical section deals with the analysis of compounds using different analytical techniques, utilizing various instruments. The practical syllabus is designed in such a manner to cover topics from all the different subjects learned. It includes synthesis of various compounds, isolation, etc.

SEMESTER III

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MRM 301T	Research Methodology and Biostatistics	To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

SEMESTER IV

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M.PHARM PHARMACEUTICAL ANALYSIS

SEMESTER I

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MPT 101T	Modern Pharmaceutical Analytical Techniques	This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
MPA 102T	Advanced Pharmaceutical Analysis	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
MPA 103T	Pharmaceutical Validation	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
MPA 104T	Food Analysis	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
MPA 105P	Pharmaceutical Analysis Practical - I	The practical section deals with the analysis of compounds using different analytical techniques, utilizing various instruments. The practical syllabus is designed in such a manner to cover topics from all the different subjects learned.

SEMESTER II

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MPA 201T	Advanced Instrumental Analysis	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
MPA 202T	Modern Bio-Analytical Techniques	This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.
MPA 203T	Quality Control and Quality Assurance	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.
MPA 204T	Herbal and Cosmetic Analysis	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.
MPA 205P	Pharmaceutical Analysis Practical – II	The practical section deals with the analysis of compounds using different analytical techniques, utilizing various instruments. The practical syllabus is designed in such a manner to cover topics from all the different subjects learned.

SEMESTER III

SUBJECT CODE	SUBJECT	COURSE OUTCOME
MRM 301T	Research Methodology and Biostatistics	To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

SEMESTER IV

The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions

M PHARM PHARMACEUTICAL QUALITY ASSURANCE (MQA)

Semester I

Subject Code	Subject	Course Outcome
MPT 101T	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
MQA 102T	QUALITY MANAGEMENT SYSTEMS	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.
MQA 103T	QUALITY CONTROL AND QUALITY ASSURANCE	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.
MQA 104T	PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER	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.
MQA 105P	QUALITY ASSURANCE PRACTICAL - I	The practical session deals with Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectro-photometer. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry, Experiments based on HPLC. Experiments based on Gas Chromatography. Estimation of riboflavin/quinine sulphate by fluorimetry. Estimation of sodium/potassium by flame photometry or AAS. 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. Development of Stability study protocol. Estimation of process capability. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms. Assay of raw materials as per official monographs. Testing of related and foreign substances in drugs and raw materials 13. To carry out preformulation study for tablets, parenterals. To study the effect of pH on the solubility of drugs. Quality control tests for Primary and secondary packaging materials. Accelerated stability studies. Improved solubility of drugs using surfactant systems. Improved solubility of drugs using co-solvency method. Determination of pKa and Log p of drugs.

SEMESTER II

Subject Code	Subject	Course Outcome
MQA 201T	HAZARDS AND SAFETY MANAGEMENT	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.
MQA 202T	PHARMACEUTICAL VALIDATION	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.
MQA 203T	AUDITS AND REGULATORY COMPLIANCE	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.
MQA 204T	PHARMACEUTICAL MANUFACTURING TECHNOLOGY	Designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing
MQA 205P	QUALITY ASSURANCE PRACTICAL – II	Deals with Case studies on Organic contaminants residue analysis by HPLC. Estimation of Metallic contaminants by Flame photometer. Identification of antibiotic residue by TLC. Estimation of Hydrogen Sulphide in Air. Estimation of Chlorine in Work Environment. Sampling and analysis of SO2 using Colorimetric method. Qualification of following Pharma equipment Autoclave, Hot air oven, Powder Mixer (Dry) , Tablet Compression Machine. Validation of an analytical method for a drug. Validation of a processing area. Qualification of at least two analytical instruments. Cleaning validation of one equipment. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester). Check list for Bulk Pharmaceutical Chemicals vendors. Check list for tableting production. Check list for sterile production area. Check list for Water for injection. Design of plant layout: Sterile and non-sterile. Case study on application of QbD . Case study on application of PAT

SEMESTER III

Subject Code	Subject	Course Outcome
MRM 301T	Research Methodology and Biostatistics	General Research Methodology: Research, objective, requirements, practical difficulties, typesof research, scientific methods of research, types of studies, study design.

SEMESTER IV

The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes the identification of problem, formulation of hypothesis review of literature, getting acquainted with recent advances, designing of research study, collection of data, critical analysis, and comparison of results and drawing conclusion.

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M PHARM PHARMACOGNOSY

Semester I

Subject Code	Subject	Course Outcome
MPT101T	Modern Pharmaceutical Analytical Techniques	This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
MPG 102T	Advanced Pharmacognosy I	To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various Phytopharmaceutical, nutraceuticals and their medicinal uses and health benefits.
MPG103T	Phytochemistry	Students shall be equipped with the knowledge of natural product drug discovery and will beable to isolate, identify and extract and the phyto-constituents.
MPG 104T	Industrial Pharmacognostical Technology	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 andquality policy for the trade of herbals and drugs of natural origin.
MPG105P	Pharmacognosy Practical – I	The practical session deals with analysis of various herbal constituents by using different analytical instruments. Formulation and evaluation of herbal constituents. Monograph analysis of crude drugs.

Prepared by

DEEPIKA DINESH A

SEMESTER II

Subject Code	Subject	Course Outcome
MPG 201T	Medicinal Plant Biotechnology	To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants
MPG 202T	Advanced Pharmacognosy -II	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
MPG 203T	Indian Systems of Medicine	To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Alsofocusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines
MPG 204T	Herbal Cosmetics	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.
MPG205P	Pharmacognosy Practical II	Isolation and Estimation, Formulation and Standardization of herbal cosmetics.

SEMESTER III

Subject Code	Subject	Course Outcome
MRM 301T	Research Methodology and Biostatistics	General Research Methodology: Research, objective, requirements, practical difficulties, types of research, scientific methods of research, types of studies, study design.

SEMESTER IV

The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes the identification of problem, formulation of hypothesis review of literature, getting acquainted with recent advances, designing of research study, collection of data, critical analysis, and comparison of results and drawing conclusion.

24/4/2025

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M PHARM PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

Semester I

Subject Code	Subject	Course Outcome
MRA 101T	GOOD REGULATORY PRACTICES	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.
MRA 102T	DOCUMENTATION AND REGULATORY WRITING	To impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.
MRA 103T	CLINICAL RESEARCH REGULATIONS	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.
MRA 104T	DRUG REGULATIONS AND INTELLECTUAL PROPERTY RIGHTS	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.
MRA 105P	REGULATORY AFFAIRS PRACTICAL - I	The practical session deals with case studies of each of Good Pharmaceutical Practices. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations. Preparation of SOPs, Analytical reports (Stability and validation), Protocol preparation for documentation of various types of records (BMR, MFR, DR), Labeling comparison between brand & generics. Preparation of clinical trial protocol for registering trial in India, Registration for conducting BA/ BE studies in India, Import of drugs for research and developmental activities, Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM. Registering for different Intellectual Property Rights in India. GMP Audit Requirements as per CDSCO. Preparation and documentation for Indian Patent application. Preparation of checklist for registration of IND as per ICH CTD format. Preparation of checklist for registration of NDA as per ICH CTD format. Preparation of checklist for registration of ANDA as per ICH CTD format. Case studies on response with scientific rationale to USFDA Warning Letter, Preparation of submission checklist of IMPD for EU submission. Comparison study of marketing authorization procedures in EU. Comparative study of DMF system in US, EU and Japan, Preparation of regulatory submission using e CTD software, Preparation of Clinical Trial Application (CTA) for US submission, Preparation of Clinical Trial Application (CTA) for EU submission. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form. Regulatory requirements checklist for conducting clinical trials in India. Regulatory requirements checklist for conducting clinical trials in Europe. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II

Subject Code	Subject	Course Outcome
MRA 201T	REGULATORY ASPECTS OF DRUGS & COSMETICS	Designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.
MRA 202T	REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS	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
MRA 203T	REGULATORY ASPECTS OF MEDICAL DEVICES	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 alongwithWHOregulations.Itpreparesthestudentstolearnindetailonthe harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.
MRA 204T	REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS	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.
MRA 205P	REGULATORY AFFAIRS PRACTICAL - II	Deals with Case studies on Change Management/ Change control. Deviations Corrective & Preventive Actions (CAPA) Documentation of raw materials analysis as per official monographs, Preparation of audit checklist for various agencies. Preparation of submission to FDA using eCTD software. Preparation of submission to EMA using eCTD software. Preparation of submission to MHRA using eCTD software. Preparation of Biologics License Applications (BLA). Preparation of documents required for Vaccine Product Approval. Comparison of clinical trial application requirements of US, EU and India of Biologics. Preparation of Checklist for Registration of Blood and Blood Products. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization. Checklists for 510k and PMA for US market. Checklist for CE marking for various classes of devices for EU. STED Application for Class III Devices. Audit Checklist for Medical Device Facility. Clinical Investigation Plan for Medical Devices

SEMESTER III

Subject Code	Subject	Course Outcome
MRM 301T	Research Methodology and Biostatistics	General Research Methodology: Research, objective, requirements, practical difficulties, typesof research, scientific methods of research, types of studies, study design.

SEMESTER IV

The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes the identification of problem, formulation of hypothesis review of literature, getting acquainted with recent advances, designing of research study, collection of data, critical analysis, and comparison of results and drawing conclusion.

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DEEPIKA DINESH A

M PHARM PHARMACOLOGY (MPL)

Semester I

Subject Code	Subject	Course Outcome
MPT101T	Modern Pharmaceutical Analytical Techniques	This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
MPL 102T	Advanced Pharmacology I	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.
MPL 103T	Pharmacological And Toxicological Screening Methods - I	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
MPL 104T	Cellular And Molecular Pharmacology	To imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process
MPL 105P	Pharmacology Practical – I	The practical session deals with Handling of laboratory animals. Various routes of drug administration,Techniques of blood sampling, anesthesia and euthanasia of experimental animals. Functional observation battery tests (modified Irwin test). Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity. 6. Evaluation of diuretic activity. Evaluation of antiulcer activity by pylorus ligation method. Oral glucose tolerance test. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver). Isolation of RNA from yeast Estimation of proteins by Braford/Lowry's in biological samples. Estimation of RNA/DNA by UV Spectroscopy, Gene amplification by PCR.

SEMESTER II

Subject Code	Subject	Course Outcome
MPL 201T	ADVANCED PHARMACOLOGY – II	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
MPL 202T	PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II	To imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.
MPL 203T	PRINCIPLES OF DRUG DISCOVERY	Desinged to imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process.
MPL 204T	CLINICAL RESEARCH AND PHARMACOVIGILANCE	provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.
MPL 205P	PHARMACOLOGY PRACTICAL – II	To record the DRC of agonist using suitable isolated tissues preparation.To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations. To study the effects of various drugs on isolated heart preparations.Recording of rat BP, heart rate and ECG. Recording of rat ECG. Drug absorption studies by averted rat ileum preparation. Acute oral toxicity studies as per OECD guidelines. Acute dermal toxicity studies as per OECD guidelines. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies. Drug mutagenicity study using mice bone-marrow chromosomal aberration test. Protocol design for clinical trial. Design of ADR monitoring protocol. In-silico docking studies. In-silico pharmacophore-based screening. In-silico QSAR studies. ADR reporting

SEMESTER III

Subject Code	Subject	Course Outcome
MRM 301T	Research Methodology and Biostatistics	General Research Methodology: Research, objective, requirements, practical difficulties, typesof research, scientific methods of research, types of studies, study design.

SEMESTER IV

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