# M.PHARMACY PROGRAMME

# PHARMACEUTICS (MPH)

# INDUSTRIAL PHARMACY (MIP)

| M.PHARMACY PROGRAMME – PHARMACEUTICS (MPH) /INDUSTRIAL PHARMACY (MIP) | |
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| **PROGRAMME OUTCOMES (PO's)** | |
| **PO 1** | **Scientific knowledge**: To apply the scientific and technological principles to design, develop effective pharmaceutical dosage forms and drug delivery systems for better therapeutic results. |
| **PO 2** | **Technological applications**: To utilize technical knowledge and identify any factors affecting the quality of pharmaceutical production. |
| **PO 3** | **Modern tool usage:** Learn, select, apply appropriate methods, procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations. |
| **PO 4** | **Entrepreneurship:** To understand the basics of establishing and management of pharmaceutical enterprise. |
| **PO 5** | **Practical skills:** To gain practical expertise in formulating and evaluating various novel drug release systems for minor ailments to major diseases. |
| **PO6** | **Applied science:** To employ contemporary scientific knowledge viz., pharmacology, biotechnology for designing disease-centric pharmaceuticals. |
| **PO 7** | **Computational and statistical methodologies:** Applying and utilizing the statistical tools with the aid of computer software to optimize the formulations. |
| **PO 8** | **Pharmaceutical ethics:** To respect personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural, 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. |
| **PO 9** | **Environment and sustainability:** To understand, protect and cooperate environmental concerns for sustaining biodiversity. |
| **PO10** | **Life-long learning:** To develop the habit of updating knowledge from time to time to meet industrial demands and social needs for having a fruitful career. |

| M. PHARMACY PROGRAMME<br>PHARMACEUTICS (MPH) / INDUSTRIAL PHARMACY (MIP) | |
|---|---|
| **PROGRAMME EDUCATIONAL OBJECTIVES (PEO's)** | |
| **PEO 1** | To impart sound pharmaceutical knowledge, scientific principles to make them ever-ready for producing quality, safety and effective pharmaceutical formulations. |
| **PEO 2** | To develop creative thinking, innovative strategies to overcome therapeutic challenges with customized medicines time to time for society. |
| **PEO 3** | To produce skilled pharmaceutical professionals, leaders, policy makers and entrepreneurs for building healthy nation. |

| M. PHARMACY PROGRAMME<br>PHARMACEUTICS (MPH) / INDUSTRIAL PHARMACY (MIP) | |
|---|---|
| **PROGRAMME SPECIFIC OUTCOMES (PSO's)** | |
| **PSO 1** | **Formulation strategies:** To impart practical knowledge, expertise to develop, design disease-centric formulations, targeting approaches using current, advanced scientific principles for better patient care and compliance. |
| **PSO 2** | **Emerging science:** To introduce knowledge about emerging cutting-edge technologies and their application in pharmaceutical field with better formulations for effective treatments. |
| **PSO 3** | **Computational literacy:** To demonstrate the use of artificial intelligence, computer programs or software applications useful in screening formulations, interpretation of experimental data and their validation. |
| **PSO 4** | **Pharmaceutical regulations:** To understand the objectives, roles, functions of various pharmaceutical regulatory bodies governing quality, safety and efficacy of pharmaceuticals from manufacturing to patient door. |

## COURSE OUTCOMES OF M.PHARMACY PROGRAMME

**Programme** : I/II M.Pharmacy

**Semester/Year of Study:** 1st Semester

**Branch** : **Pharmaceutics**

**Course Name** : Modern Pharmaceutical Analytical Techniques

**Course code** : MPH 101 T (Theory)

| | |
|---|---|
| C101.1 | To recall selected instrumental analytical techniques (spectroscopic, chromatographic, electrochemical methods) and relate with volumetric analysis. |
| C101.2 | To gain knowledge on interaction of EMR with matter, affinity of matter with stationary phase and mobile phase, physical and chemical changes of matter on heating, potential differences in different aqueous and organic solution. |
| C101.3 | To build the analytical understanding in the level of ion, atom, group and molecular structure of organic and inorganic compounds with different functional groups and their applications in pharmacy. |
| C101.4 | To categorize different organic and inorganic compounds using suitable spectroscopy, chromatography, electrophoresis, thermal and immuno assay. |
| C101.5 | To elaborate principle, theory and instruments employed for the analysis of drugs. |
| C101.6 | To maximize knowledge of electrophoresis, immunological, thermal and X-Ray crystallographic techniques. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutics**

**Course Name** : Drug Deleivery System

**Course code** : MPH 102 T (Theory)

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|---|---|
| C102.1 | To recall the basic concepts of sustained release, controlled release, polymer science and personalized medicine. |
| C102.2 | To explain (impart) the principles and fundamentals of controlled drug delivery systems, protein-peptide drug delivery and vaccine drug delivery systems. |
| C102.3 | To (train) develop the formulations of gastro retentive, ocular, transdermal, protein-peptide and vaccine drug delivery systems. |
| C102.4 | To analyze the formulations of gastro retentive and ocular drug delivery systems. |
| C102.5 | To assess the transdermal and protein-peptide drug delivery systems. |
| C102.6 | To evaluate the formulated vaccine drug delivery systems. |

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| **Programme** | **:** | I/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 1st Semester |
| **Branch** | **:** | **Pharmaceutics** |
| **Course Name** | **:** | Modern Pharmaceutics |
| **Course code** | **:** | MPH 103 T (Theory) |

| | |
|---|---|
| C103.1 | To recall the concepts of preformulation and relate them to formulation development. |
| C103.2 | To illustrate the parameters of optimization and its applications in formulation development. |
| C103.3 | To develop validation and calibration master plan as per regulatory guidelines. |
| C103.4 | To categorize the policies of cGMP, layout of buildings, equipment and management of production. |
| C103.5 | To explain the principles of tablet compression and compaction. |
| C103.6 | To compile the consolidation parameters to determine the stability of a dosage form. |

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| **Programme** | **:** | I/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 1st Semester |
| **Branch** | **:** | **Pharmaceutics** |
| **Course Name** | **:** | Regulatory Affair |
| **Course code** | **:** | MPH 104 T (Theory) |

| | |
|---|---|
| C104.1 | To recall the concepts of drug product development, innovator and generic products, their drug master file. |
| C104.2 | To outline the scale up post approval changes, post marketing surveillance and outsourcing of bioavailability studies to CRO. |
| C104.3 | To apply the regulatory agencies like USFDA, EU, MHRA, TGA and ROW countries for product approval. |
| C104.4 | To contrast CTD and eCTD format for combination products and medical devices. |
| C104.5 | To compare the submission process of IND, NDA, ANDA and preparation of Medicinal Products Dossier. |
| C104.6 | To build the ability to develop clinical trial protocol, pharmacovigilance and safety monitoring in clinical trials. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutics**

**Course Name** : Pharmaceutics Practical-I

**Course code** : MPH 105 P (Practical)

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|---|---|
| C105.1 | To recall the basic principles of analytical techniques and their instrumentation used for drug analysis. |
| C105.2 | To summarize the preformulation studies and basic excipients used for various controlled/sustained drug delivery systems |
| C105.3 | To make use of various analytical instruments for estimation of drugs in various formulations. |
| C105.4 | To simplify the formulation techniques, prepare matrix tablets, floating tablets and cosmetics. |
| C105.5 | To assess the drug release from sustained and controlled drug delivery systems. |
| C105.6 | To evaluate the dosage forms, construct kinetic plots and determine similarity factor. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutics**

**Course Name** : Molecular Pharmaceutics (Nano Tech and Targeted DDS)

**Course code** : MPH 201 T (Theory)

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|---|---|
| C201.1 | To define the concepts involved in targeting drug delivery specific to tumor and brain. |
| C201.2 | To outline the formulation, optimization and evaluation of nanoparticles, liposomes and multiparticulate drug carrier systems. |
| C201.3 | To develop nanoparticles, liposomes and multiparticulate and other drug delivery systems for drug delivery. |
| C201.4 | To simplify the formulation of pulmonary drug delivery systems and their evaluation. |
| C201.5 | To perceive the concepts of gene therapy and liposomal gene delivery. |
| C201.6 | To discuss the concepts of therapeutic antisense molecules. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutics**

**Course Name** : Advanced Biopharmaceutics & Pharmacokinetics

**Course code** : MPH 202 T (Theory)

| | |
|---|---|
| C202.1 | To recall the basic concepts of absorption, distribution, metabolism and excretion of drugs. |
| C202.2 | To understand the mechanisms, interpret various factors affecting drug absorption, distribution, metabolism and excretion of drugs. |
| C202.3 | To apply the pharmacokinetic models for the determination of pharmacokinetic parameters. |
| C202.4 | To analyze the drug product performance by *in-vitro*, *in-vivo* and *in-situ* models. |
| C202.5 | To determine the bioavailability testing protocol of a drug and compare the bioequivalence among marketed products. |
| C202.6 | To predict pharmacokinetic and pharmacodynamic drug interactions. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutics**

**Course Name** : Computer Aided Drug Delivery System

**Course code** : MPH 203 T (Theory)

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|---|---|
| C203.1 | To recall the basics of computers in pharmaceutical research and development. |
| C203.2 | To illustrate the computational modeling of drug disposition. |
| C203.3 | To utilize the concepts for computer-aided formulation development. |
| C203.4 | To simplify the pharmacokinetic and pharmacodynamic characteristics of drugs by simulations. |
| C203.5 | To assess the applications of computers in clinical data management. |
| C203.6 | To discuss the impact of artificial intelligence, robotics and computational fluid dynamics. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutics**

**Course Name** : Cosmetic and Cosmeceuticals

**Course code** : MPH 204 T (Theory)

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|---|---|
| C204.1 | To remember Indian regulatory requirements for manufacture, sale, import and labeling of cosmetics. |
| C204.2 | To outline the biological aspects of cosmetics, basic structure, functions, common problems associated with skin, hair and oral cavity. |
| C204.3 | To apply the principles of formulation building blocks for different cosmetic / cosmeceutical products. |
| C204.4 | To simplify the controversial ingredients used in the formulation of cosmetics. |
| C204.5 | To justify the cosmeceutical products for solving problems related to skin, hair and oral cavity. |
| C204.6 | To elaborate the regulatory guidelines forherbal cosmetics, herbal ingredients used in hair care, skin care and oral care. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutics**

**Course Name** : Pharmaceutics Practical-II

**Course code** : MPH 205 P (Practical)

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|---|---|
| C205.1 | To recall the basic techniques for preparation of microspheres, liposomes, niosomes and solid dispersions. |
| C205.2 | To compare the dissolution studies of various marketed products. |
| C205.3 | To develop various novel drug delivery systems. |
| C205.4 | To test for drug binding characteristics, cell permeation and bioavailability of the formulations. |
| C205.5 | To evaluate the novel drug delivery systems. |
| C205.6 | To design formulations by QbD concept, use simulations for estimation of pharmacokinetics and pharmacodynamics. |

**Programme** : I/II M.Pharmacy
**Semester/Year of Study** : 1st Semester
**Branch** : **Industrial Pharmacy**
**Course Name** : Modern Pharmaceutical Analytical Techniques
**Course code** : MIP 101 T (Theory)

| | |
|---|---|
| C101.1 | To recall selected instrumental analytical techniques (spectroscopic, chromatographic, electrochemical methods) and relate with volumetric analysis. |
| C101.2 | To gain knowledge on interaction of EMR with matter, affinity of matter with stationary phase and mobile phase, physical and chemical changes of matter on heating, potential differences in different aqueous and organic solution. |
| C101.3 | To build the analytical understanding in the level of ion, atom, group and molecular structure of organic and inorganic compounds with different functional groups and their applications in pharmacy. |
| C101.4 | To categorize different organic and inorganic compounds using suitable spectroscopy, chromatography, electrophoresis, thermal and immuno assay. |
| C101.5 | To elaborate principle, theory and instruments employed for the analysis of drugs. |
| C101.6 | To maximize knowledge of electrophoresis, immunological, thermal and X-Ray crystallographic techniques. |

**Programme** : I/II M.Pharmacy
**Semester/Year of Study** : 1st Semester
**Branch** : **Industrial Pharmacy**
**Course Name** : Pharmaceutical Formulation Development
**Course code** : MIP 102 T (Theory)

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|---|---|
| C102.1 | To recall the significance of preformulation studies in the pharmaceutical formulation development. |
| C102.2 | To illustrate various formulation additives and understand the factors influencing their incorporation, new developments in excipient science. |
| C102.3 | To outline the importance of solubility studies and determine the solubility of drugs in various solvents. |
| C102.4 | To examine different techniques to improve the solubility of poorly aqueous soluble drugs. |
| C102.5 | To perceive the theories, mechanism of dissolution, *in vitro* dissolution testing models, factors influencing dissolution *in-vitro* and *in-vivo* correlation. |
| C102.6 | To elaborate the drug degradation mechanisms, factors influencing drug stability, stability testing of drugs and pharmaceuticals as per ICH guidelines. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Industrial Pharmacy**

**Course Name** : Novel Drug Delivery Systems

**Course code** : MIP 103 T (Theory)

| | |
|---|---|
| C103.1 | To define, list rate controlled drug delivery systems and various polymers used. |
| C103.2 | To explain the basic concepts in the formulation and evaluation of various drug delivery systems. |
| C103.3 | To develop the formulation and evaluation parameters for transdermal drug delivery system and topical delivery systems. |
| C103.4 | To categorize the formulation and evaluation concepts of cosmetics for skin, hair, nail and eye. |
| C103.5 | To appraise the events involved in drug targeting. |
| C103.6 | To elaborate the concepts of protein, peptide drug delivery, recombinant DNA technology and new trends in personalized medicine. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Industrial Pharmacy**

**Course Name** : Intellectual Property Rights

**Course code** : MIP 104 T (Theory)

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|---|---|
| C104.1 | To define the patent, its types, different parts, essential elements and filling process. |
| C104.2 | To understand the role of GATT, TRIPS and WIPO in patenting. |
| C104.3 | To identify the major bodies regulating Indian pharmaceutical sector, IPR's and their types. |
| C104.4 | To classify the organisation and functions of CDSCO, WHO and USFDA. |
| C104.5 | To compare the functions and regulations of EMEA, TGA, MHRA, MCC and ANVISA. |
| C104.6 | To discuss the regulatory requirements for contract research organization and regulations of Biosimilars. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Industrial Pharmacy**

**Course Name** : Industrial Pharmacy Practical-I

**Course code** : MIP 105 P (Practical)

| | |
|---|---|
| C105.1 | To recall the basic principles of analytical techniques and their instrumentation used for drug analysis. |
| C105.2 | To understand the characteristic futures of basic excipients used for various sustained, controlled drug delivery systems and cosmetics. |
| C105.3 | To make use of various analytical instruments for estimation of drugs in various formulations. |
| C105.4 | To examine the formulation techniques, prepare various sustained/controlled drug delivery systems and cosmetic preparations. |
| C105.5 | To evaluate the drug and excipients compatibility and drug release from various formulations. |
| C105.6 | To test the prepared modified drug delivery systems and assess the stability. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Industrial Pharmacy**

**Course Name** : Advanced Biopharmaceutics and Pharmacokinetics

**Course code** : MIP 201 T (Theory)

| | |
|---|---|
| C201.1 | To recall the basic concepts of absorption, distribution, metabolism and excretion of drugs. |
| C201.2 | To understand the mechanisms, interpret various factors affecting drug absorption, distribution, metabolism and excretion of drugs. |
| C201.3 | To apply the pharmacokinetic models for the determination of pharmacokinetic parameters. |
| C201.4 | To examine the drug product performance in *in-vitro*, *in-vivo* and *in-situ* models. |
| C201.5 | To determine the bioavailability testing protocol of a drug and compare the bioequivalence among marketed products. |
| C201.6 | To predict pharmacokinetics for determination of pharmacokinetic and pharmacodynamic drug interactions. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Industrial Pharmacy**

**Course Name** : Scale up and Technology Transfer

**Course code** : MIP 202 T (Theory)

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|---|---|
| C202.1 | To define the pilot plant and scale up processes in pharmaceutical industry. |
| C202.2 | To outline the general concepts of validation, analytical validation, cleaning validation and vendor qualification. |
| C202.3 | To apply the equipment qualification concepts. |
| C202.4 | To analyze the pharmaceutical process validation. |
| C202.5 | To assess the industrial hazards, safety monitoring and prevention systems. |
| C202.6 | To discuss the industrial effluent treatments, testing and forecasting environmental pollution. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Industrial Pharmacy**

**Course Name** : Pharmaceutical Production Technology

**Course code** : MIP 203 T (Theory)

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|---|---|
| C203.1 | To recall the tablet production process, selection of equipment and problems encountered with coating. |
| C203.2 | To explain the production of parenterals, controls and maintenance of aseptic area. |
| C203.3 | To utilize the process of freeze drying and spray drying dosage form development. |
| C203.4 | To assess the production process of capsules and dispersed systems. |
| C203.5 | To justify use of various packaging materials for different dosage forms. |
| C203.6 | To elaborate air handling systems and processing of water for Pharmaceutical use. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Industrial Pharmacy**

**Course Name** : Entrepreneurship Management

**Course code** : MIP 204 T (Theory)

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|---|---|
| C204.1 | To define enterprise, types of enterprises, government policies and schemes for enterprise development. |
| C204.2 | To outline the process entrepreneurship development, interpersonal skills, creativity and factors affecting entrepreneur. |
| C204.3 | To plan for launching an enterprise, its organization and SWOT analysis. |
| C204.4 | To analyze the resources, raw materials, manpower, market and quality control of an enterprises. |
| C204.5 | To appraise the performance, assessment of growth, networking and profitability of an enterprise. |
| C204.6 | To plan for stat new enterprise, project proposal, resources and implementation |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Industrial Pharmacy**

**Course Name** : Industrial Pharmacy Practical-II

**Course code** : MIP 205 P (Practical)

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|---|---|
| C205.1 | To recall the basics of dissolution rate testing. |
| C205.2 | To compare the dissolution profiles of two marketed products. |
| C205.3 | To develop various tablets, capsules, injections, suspensions, emulsions, enteric coated tablets, freeze dried formulations and spray dried formulations. |
| C205.4 | To analyze the pharmacokinetics and IVIVC data by software like WinNonlin® software. |
| C205.5 | To evaluate the prepared tablets, capsules, injections, suspensions, emulsions, enteric coated tablets, freeze dried and spray dried formulations. |
| C205.6 | To predict the *in-vitro* drug permeability, metabolism and *in-vivo* bioavailability. |

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| **Programme** | **:** | II/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 3rd Semester |
| **Branch** | **:** | **Common for All Specializations** |
| **Course Name** | **:** | Research methodology & Biostatistics |
| **Course code** | **:** | MIP 301 T (Theory) |

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|---|---|
| C301.1 | To recall the concepts of research methodology which includes study design, type of studies, stratifies and different design techniques. |
| C301.2 | To infer the data using biostatistics technique like “t” test, ANOVA and chi square tests as well as recognize the importance of samples size and its significances. |
| C301.3 | To learn the history of medical research for understanding the values of clinical ethics as well as its importance in communication and sociological relationships. |
| C301.4 | To explain the CPCSEA guidelines for laboratory animal facilities which include handling, maintenance, record keeping and transportation of lab animals. |
| C301.5 | To discuss the history and basic principles of Declaration of Helsinki for medical research. |

| Course Name: ASSIGNMENTS<br>Year of Study: 1st M.Pharmacy 1st and 2nd Semester | |
|---|---|
| C.1 | To recall the fundamentals of proposed topic and carry out literature review. |
| C.2 | To classify / compare, interpret the various methods and techniques. |
| C.3 | To organize the collected data in chronological order and develop writing skills. |
| C.4 | To analyze the data and interpret the relationships. |
| C.5 | To evaluate and conclude the given topic. |
| C.6 | To propose, design research in given concept and improve presentation skills. |

| Course Name: SEMINARS<br>Year of Study: 1st M.Pharmacy 1st and 2nd Semester | |
|---|---|
| C.1 | To recall the fundamentals of proposed topic and carry out literature review. |
| C.2 | To classify / compare, interpret the various methods and techniques. |
| C.3 | To organize the collected data in chronological order and develop writing skills. |
| C.4 | To analyze the data and interpret the relationships. |
| C.5 | To evaluate and conclude the given topic. |
| C.6 | To propose, design research in given concept and improve presentation skills. |

| Course Name: Journal club<br>Year of Study: 2nd M.Pharmacy 3rd Semester | |
|---|---|
| C.1 | To select the scientific concept based on literature and define the objectives of research. |
| C.2 | To outline the hypothesis and summarize the concept for presentation. |
| C.3 | To plan for a meeting, discuss SOWT analysis, the design and methods used in concept. |
| C.4 | To analyze the variables and their inter relationships. |
| C.5 | To conclude the results and to discuss its significance. |
| C.6 | To appraise the concept for societal needs, acknowledge and improve presentation skills. |

| Course Name: PROJECT WORK<br>Year of Study: 2nd M.Pharmacy 4th Semester | |
|---|---|
| C.1 | To recall the fundamentals, carry out literature review on proposed research topic and identify research problem. |
| C.2 | To outline the requirements toper form the proposed research. |
| C.3 | To construct the research hypothesis. |
| C.4 | To take part in research experiments meticulously and documentation as per format. |
| C.5 | To evaluate and conclude the results using statistical analysis. |
| C.6 | To appraise societal application and appreciation. |

# M.PHARMACY PROGRAMME

# PHARMACEUTICAL ANALYSIS

# (MPA)

## M.PHARMACY PROGRAMME – PHARMACEUTICAL ANALYSIS (MPA)

| PROGRAMME OUTCOMES (PO's) | |
|---|---|
| **PO 1** | **Analytical Knowledge:** Acquire knowledge on various chromatographic and spectroscopic techniques and differentiate with volumetric analysis. |
| **PO 2** | **Analytical Reasoning:** To categorize assumptions and disclose the data according to guidelines. |
| **PO 3** | **Problem Solving:** To utilize the principles of analytical techniques with clear and critical thinking, while solving problems and making decisions. Find, analyze, evaluate and apply information systematically and shall make defensible decisions. |
| **PO 4** | **Modern Techniques:** To learn, choose and apply appropriate hyphenated methods and procedures and related computing tools with thoughtfulness of their applications. |
| **PO 5** | **Experimental Ethics:** To believe and follow ethics and guidelines specified by the regulatory authorities of various countries and Government of India for good laboratory practice. |
| **PO 6** | **Interdisciplinary Commitment:** To acquire skill oriented practical ability and utilize the needs of pharmacy in all other programmes to emerge as potent researcher. |
| **PO 7** | **Professional Identity:** To be committed and responsible person to play a proactive role with loyalty to community and to empower society. |
| **PO 8** | **Statistical Skills:** To apply and evaluate quantitative metrics to gain safety data on dosage and also to compare the effectiveness among different marketed formulations. |
| **PO 9** | **Rational Flexibility:** To engage in critical and logical thinking and to gain an overall knowledge in developing newer methods, impurity profiling and validation protocols those are useful in routine and laboratory purpose. |
| **PO 10** | **Environment and Sustainability:** To understand the level of biohazardous solvents and chemicals in relation to environmental contexts and sustainable development. |
| **PO 11** | **Lifelong Learning:** Understand and apply the concepts in day to day life activities for the benefit of self and for the welfare of society. |

## M.PHARMACY PROGRAMME – PHARMACEUTICAL ANALYSIS-MPA

| PROGRAMME EDUCATIONAL OBJECTIVES (PEO's) | |
|---|---|
| **PEO1** | **Erudition:** Program encompasses the students with profound functional knowledge in core subjects of pharmaceutical Analysis. This enables students to understand the basics of analytical methods to test the drug molecules. This will also enable students to learn the basic theory of analytical tools. |
| **PEO2** | **Substantive skills:** To provide students with a strong foundation of analytical aspects such as handling of instruments, principles, method development, method validation, testing of samples and report the results accurately. |
| **PEO3** | **Breadth:** To train students to understand different hyphenated techniques and apply them practically. To train the students to understand different bio-analytical methods and analyze the bio-analytical samples. |
| **PEO4** | **Analytical skills:** Implementation of innovative teaching learning methodologies with visual aids/ computer aided tools empowers the students in understanding the concepts with clarity and transparency. Students are trained in handling of software's to report the results in a transparent manner. |
| **PEO5** | **Personal Attribute:** To inculcate in students professional and ethical attitude, effective communication skills, teamwork skills, multidisciplinary approach and an ability to relate Pharmaceutical and Health care issues to broader social context. |

## M.PHARMACY PROGRAMME – PHARMACEUTICAL ANALYSIS (MPA)

| PROGRAMME SPECIFIC OUTCOMES (PSO's) | |
|---|---|
| **PSO1** | To deal with various hyphenated instrumental techniques for identification, characterization and quantification of drugs. |
| **PSO2** | To provide studies on drug bioavailability, pharmacodynamics, cell culture techniques and ensure the efficacy and safety use of herbal medicine according to AYUSH guidelines. |
| **PSO3** | To understand calibration, validation methodologies and their applications in industry. |
| **PSO4** | To determine the assay of drugs by spectroscopical and chromatographical methods and preservatives in food and food products. |
| **PSO5** | To understand quality assurance aspects of pharmaceutical industries such as cGMP, documentation, certification, GLP and other regulatory guidelines. |
| **PSO6** | To create a talent pool by involving students in research projects under the guidance of faculty and for publishing their research work. |
| **PSO7** | To impart knowledge about extraction and separation of drugs from biological samples by different analytical techniques. |
| **PSO8** | To deal with detection of impurities in pharmaceutical formulations and development of protocol for stability testing of products. |

**Programme** : I/II M.Pharmacy
**Semester/Year of Study** : 1st Semester
**Branch** : **Pharmaceutical Analysis**
**Course Name** : Modern Pharmaceutical Analytical Techniques
**Course code** : MPA 101 T (Theory)

| | |
|---|---|
| C101.1 | To recall selected instrumental analytical techniques (spectroscopic, chromatographic, electrochemical methods) and relate with volumetric analysis. |
| C101.2 | To gain knowledge on interaction of EMR with matter, affinity of matter with stationary phase and mobile phase, physical and chemical changes of matter on heating, potential differences in different aqueous and organic solution. |
| C101.3 | To build the analytical understanding in the level of ion, atom, group and molecular structure of organic and inorganic compounds with different functional groups and their applications in pharmacy. |
| C101.4 | To categorize different organic and inorganic compounds using suitable spectroscopy, chromatography, electrophoresis, thermal and immuno assay. |
| C101.5 | To elaborate principle, theory and instruments employed for the analysis of drugs. |
| C101.6 | To maximize knowledge of electrophoresis, immunological, thermal and X-Ray crystallographic techniques. |

**Programme** : I/II M.Pharmacy
**Semester/Year of Study** : 1st Semester
**Branch** : **Pharmaceutical Analysis**
**Course Name** : Advanced Pharmaceutical Analysis
**Course code** : MPA 102 T (Theory)

| | |
|---|---|
| C102.1 | To learn the impurity and stability studies in API'S and new drug products. |
| C102.2 | To understand the classification and quantification procedures as ICH. |
| C102.3 | To illustrate the identification of elemental impurities, analytical procedures, instrumentation, C, H, N & S analysis and stability testing protocols as per ICH. |
| C102.4 | To explain impurity profiling, degradant characterization as per ICH and WHO and also stability guidelines for biological products as per ICH. |
| C102.5 | To evaluate the testing of phytopharmaceuticals as per regulatory requirements including finger printing interactions. |
| C102.6 | To design the biological test and assays of vaccines as per IP and immunoassays. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutical Analysis**

**Course Name** : Pharmaceutical Validation

**Course code** : MPA 103 T (Theory)

| | |
|---|---|
| C103.1 | To remember the validation, qualification, concepts and understand the qualification parameters. |
| C103.2 | To understand and apply the qualification of analytical instruments. |
| C103.3 | To demonstrate the water systems in pharmaceutical industry. |
| C103.4 | To explain the validation parameters according to ICH and USP. |
| C103.5 | To evaluate the cleaning of equipment's as per ICH cleaning validation protocol. |
| C103.6 | To formulate the IPR concepts as per present industry scenario |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutical Analysis**

**Course Name** : Food Analysis

**Course code** : MPA 104 T (Theory)

| | |
|---|---|
| C104.1 | To recall the knowledge on analysis of primary metabolites |
| C104.2 | To discuss skill oriented approach on analytical techniques in the determination of food additives |
| C104.3 | To produce awareness on natural products and its applications |
| C104.4 | To analyze the traces of pesticides in various products |
| C104.5 | To explain legislation and regulations of analysis of food products |
| C104.6 | To get aware of analytical procedures of milk products and fermentation products |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutical Analysis**

**Course Name** : Pharmaceutical Analysis Practical-1

**Course code** : MPA 105 P (Practical)

| | |
|---|---|
| C105.1 | To choose the spectroscopic techniques for analysis of pharmacopoeial compounds |
| C105.2 | To understand the impurity profile concept of various drugs. |
| C105.3 | To learn and perform the assay analysis of various drugs by using different titrations |
| C105.4 | To explain the calibration of different analytical instruments for their compliance |
| C105.5 | To analyze the various constituents in food products |
| C105.6 | To estimate the purity of food products by using various methods |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutical Analysis**

**Course Name** : Advanced Instrumental Analysis

**Course code** : MPA 201 T (Theory)

| | |
|---|---|
| C201.1 | To recall selected instrumental analytical techniques and immobilized polysaccharide chiral stationary phases |
| C201.2 | To gain knowledge on affinity of matter with stationary phase and mobile phase in different chromatographic techniques and capillary electrophoresis |
| C201.3 | To explain the instrumentation of mass and NMR and their hyphenated techniques with applications |
| C201.4 | To illustrate principle, theory and instruments employed for the analysis of drugs |
| C201.5 | To evaluate the drugs using conventional and hyphenated instrumental techniques |
| C201.6 | To maximize the knowledge on interpretation of spectra for structural analysis |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutical Analysis**

**Course Name** : Modern Bio-Analytical Techniques

**Course code** : MPA 202 T (Theory)

| | |
|---|---|
| C202.1 | To list out the various extraction procedures and bioavailability studies. |
| C202.2 | To explain various extraction principle and procedures involved in bioanalytical method, its validation according to USFDA and EMEA guidelines and biopharmaceutical considerations. |
| C202.3 | To illustrate biopharmaceutics classification system, pharmaco-kinetics and toxicokinetics studies. |
| C202.4 | To explain different cell culture and metabolite identification techniques and regulatory perspectives in assay of drugs. |
| C202.5 | To elucidate drug product performance, *in-vivo* bioavailability and bioequivalence studies and their clinical significance. |
| C202.6 | To create the knowledge on bioavailability and bioequivalence studies in accordance to regulatory guidelines. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutical Analysis**

**Course Name** : Quality Control and Quality Assurance

**Course code** : MPA 203 T (Theory)

| | |
|---|---|
| C203.1 | To remember the quality assurance, quality management concepts and quality control tests. |
| C203.2 | To create the document maintenance in industry with required regulatory body guidelines, to analyze the complaints and documents maintenance in industry. |
| C203.3 | To understand the good laboratory practice and GMP concepts as per ICH |
| C203.4 | To analyze the raw materials, finished product, packaging materials as per IP, USP, BP and to check for the compliance |
| C203.5 | To evaluate the organization and personal responsibilities as per USFDA and WHO |
| C203.6 | To discuss the manufacturing operations and controls of pharmaceutical products and documentation |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutical Analysis**

**Course Name** : Herbal and Cosmetic Analysis

**Course code** : MPA 204 T (Theory)

| | |
|---|---|
| C204.1 | To recall the efficacy, validation, pharmacodynamics and pharmacokinetic concerned with herbal medicine products. |
| C204.2 | To develop the skills for the detection of adulteration in herbal drugs and identification of drugs |
| C204.3 | To choose WHO and AYUSH guidelines in quality assessment of herbal drugs |
| C204.4 | To analyze the natural products and drugs using modern analytical instruments and study their monographs in pharmacopoeias |
| C204.5 | To explain the safety monitoring of herbal medicine and reporting bio-drug adverse reactions |
| C204.6 | To evaluate and analyze the herbal cosmetic products including the raw materials and finished products |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutical Analysis**

**Course Name** : Pharmaceutical Analysis Practical-II

**Course code** : MPA 205 P (Practical)

| | |
|---|---|
| C205.1 | To learn the structural identification rules of drug molecules. |
| C205.2 | To understand the interpretation rules of different spectroscopic techniques. |
| C205.3 | To remember the quality control tests for various pharmaceuticals. |
| C205.4 | To interpret quantitative methods herbal drug products |
| C205.5 | To understand the protocol preparation of analytical or bioanalytical validation. |
| C205.6 | To analyze the raw materials, finished product, packaging materials as per IP, USP, British pharmacopoeias and create the specifications. |

| | | |
|---|---|---|
| **Programme** | **:** | II/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 3rd Semester |
| **Branch** | **:** | **Common for All Specializations** |
| **Course Name** | **:** | Research methodology & Biostatistics |
| **Course code** | **:** | MPA 301 T (Theory) |

| | |
|---|---|
| C301.1 | To recall the concepts of research methodology which includes study design, type of studies, stratifies and different design techniques. |
| C301.2 | To infer the data using biostatistics technique like “t” test, ANOVA and chi square tests as well as recognize the importance of samples size and its significances. |
| C301.3 | To learn the history of medical research for understanding the values of clinical ethics as well as its importance in communication and sociological relationships. |
| C301.4 | To explain the CPCSEA guidelines for laboratory animal facilities which include handling, maintenance, record keeping and transportation of lab animals. |
| C301.5 | To discuss the history and basic principles of Declaration of Helsinki for medical research. |

| Course Name: ASSIGNMENTS<br>Year of Study: 1st M.Pharmacy 1st and 2nd Semester | |
|---|---|
| C.1 | To recall the fundamentals of proposed topic and carry out literature review. |
| C.2 | To classify / compare, interpret the various methods and techniques. |
| C.3 | To organize the collected data in chronological order and develop writing skills. |
| C.4 | To analyze the data and interpret the relationships. |
| C.5 | To evaluate and conclude the given topic. |
| C.6 | To propose, design research in given concept and improve presentation skills. |

| Course Name: SEMINARS<br>Year of Study: 1st M.Pharmacy 1st and 2nd Semester | |
|---|---|
| C.1 | To recall the fundamentals of proposed topic and carry out literature review. |
| C.2 | To classify / compare, interpret the various methods and techniques. |
| C.3 | To organize the collected data in chronological order and develop writing skills. |
| C.4 | To analyze the data and interpret the relationships. |
| C.5 | To evaluate and conclude the given topic. |
| C.6 | To propose, design research in given concept and improve presentation skills. |

| Course Name: Journal club<br>Year of Study: 2nd M.Pharmacy 3rd Semester | |
|---|---|
| C.1 | To select the scientific concept based on literature and define the objectives of research. |
| C.2 | To outline the hypothesis and summarize the concept for presentation. |
| C.3 | To plan for a meeting, discuss SOWT analysis, the design and methods used in concept. |
| C.4 | To analyze the variables and their inter relationships. |
| C.5 | To conclude the results and to discuss its significance. |
| C.6 | To appraise the concept for societal needs, acknowledge and improve presentation skills. |

| Course Name: PROJECT WORK<br>Year of Study: 2nd M.Pharmacy 4th Semester | |
|---|---|
| C.1 | To recall the fundamentals, carry out literature review on proposed research topic and identify research problem. |
| C.2 | To outline the requirements toper form the proposed research. |
| C.3 | To construct the research hypothesis. |
| C.4 | To take part in research experiments meticulously and documentation as per format. |
| C.5 | To evaluate and conclude the results using statistical analysis. |
| C.6 | To appraise societal application and appreciation. |

# M.PHARMACY PROGRAMME

# PHARMACOLOGY

# (MPL)

| M. PHARMACY PROGRAMME – PHARMACOLOGY ( MPL) | |
|---|---|
| **PROGRAMME OUTCOMES (PO's)** | |
| **PO 1** | **Drug Expertise :** Acquire knowledge on various classes of drugs and their mode of actions to unveil the remedies for many ailments. |
| **PO 2** | **Analytical Reasoning:** Identify assumptions and reveal the evidence based reason for the disease or disorder take place, to select the type of relevant treatment. |
| **PO 3** | **Experimental Ethics :** Consider and follow ethics and guidelines specified by the authorities of various agencies and Government of India for animal congenial laboratory practice. |
| **PO 4** | **Interdisciplinary engagement :** Obtain skill oriented practical proficiency by exposing and utilizing the needs of pharmacy in all disciplines to emerge as potent researcher. |
| **PO 5** | **Professional Identity :** Be committed and responsible person to play a proactive role with fidelity to community and empower society. |
| **PO 6** | **Statistical Skills :** Apply and analyze quantitative metrics to gain safety data on dosage, also to compare the effectiveness among experimental groups. |
| **PO 7** | **Intellectual Flexibility :** Engage in critical thinking and gain insight to identify, design and formulate pharmaceutical products that are in need of current aspects by using material from natural sources. |
| **PO 8** | **Lifelong learning :** Understand and apply the concepts in day to day life activities for the benefit of self and for the welfare of society and its concerns. |

| M. PHARMACY PROGRAMME – PHARMACOLOGY ( MPL) | |
|---|---|
| **PROGRAMME EDUCATIONAL OBJECTIVES (PEOs)** | |
| **PEO 1** | **Innovation Culture :** Devise research strategies for empowering and promoting culture of innovation among students for the industrial needs. Also encourage and excel the students to perform their skills in the areas of interest to promote the potency and zeal towards research. |
| **PEO 2** | **Professional Interaction :** Develop comprehensive skills by identifying time to time life situations and keep updating the knowledge professionally for community up-liftment. Also acquire higher order thinking skills and become professionally competent to take up careers in academics, health care and service industry. |
| **PEO 3** | **Global Health Care :** Integrate and apply techniques to advance the research scenario for the welfare of Global health care. Also acquire knowledge on diagnostic, therapeutic, rehabilitative and preventive health care for qualitative skills. |
| **PEO 4** | **Entrepreneurial Spirit :** Build capacities and develop practical awareness which results in smooth transition from education to self-employment and finally to entrepreneurship. Also relocate the gained knowledge, skills and training to their own personal interests for socio economic empowerment. o promote the potency and zeal towards research. |

| M.PHARMACY PROGRAMME – PHARMACOLOGY ( MPL) | |
|---|---|
| **PROGRAMME SPECIFIC OUTCOMES (PSOs)** | |
| **PSO 1** | **Integrative and Applied Learning :** An Approach where learning through connections and relativity to the concepts of theoretical aspect with preclinical experimentation. Apply knowledge and skills developed in traditional classroom learning to hands-on and real-world settings. |
| **PSO 2** | **Biological Research :** Demonstrate an understanding of the action of drugs, and test samples with isolated organs or non invasive methods by in-vitro and in-vivo techniques. Biological research leads to analyze and compare the safety and toxicity of products at initiation. |
| **PSO 3** | **Technical Advancements :** Exhibit the usage of various advanced equipment to analyze and assess the potency of drug by using the animals. Creates innovative screening methods and best practices to identify and evaluate parameters for various pharmacological activities. |
| **PSO 4** | **Ethical Reasoning :** Apply ethical principles to validate the pre clinical experiments. Plan, implement and evaluate the procedures as per the CPCSEA guidelines. Enhance the functional skills and transparency by record keeping. |
| **PSO 5** | **Employability:** Acquire in depth knowledge on life sciences and exhibit critical thinking, problem solving and decision making to enhance employability. Apply skill based knowledge in various sectors and relate the principles of scientific advancement. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmacology**

**Course Name** : Modern Pharmaceutical Analytical Techniques

**Course code** : MPL 101 T (Theory)

| | |
|---|---|
| C101.1 | To recall selected instrumental analytical techniques (spectroscopic, chromatographic, electrochemical methods) and relate with volumetric analysis. |
| C101.2 | To gain knowledge on interaction of EMR with matter, affinity of matter with stationary phase and mobile phase, physical and chemical changes of matter on heating, potential differences in different aqueous and organic solution. |
| C101.3 | To build the analytical understanding in the level of ion, atom, group and molecular structure of organic and inorganic compounds with different functional groups and their applications in pharmacy. |
| C101.4 | To categorize different organic and inorganic compounds using suitable spectroscopy, chromatography, electrophoresis, thermal and immuno assay. |
| C101.5 | To elaborate principle, theory and instruments employed for the analysis of drugs. |
| C101.6 | To maximize knowledge of electrophoresis, immunological, thermal and X-Ray crystallographic techniques. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmacology**

**Course Name** : Advanced Pharmacology – I

**Course code** : MPL 102 T (Theory)

| | |
|---|---|
| CM102.1 | To learn basic principles of pharmacokinetic and pharmacodynamic parameters of drugs. |
| CM102.2 | To understand various biogenesis pathways involved in synthesis of Neurotansmitters and their physiology and to Illustrate pharmacology of Drugs acting on peripheral nervous system. |
| CM102.3 | To construct the pharmacology of drugs acting on central nervous system |
| CM102.4 | To contrast the relative pros and cons in the use of drugs for various cardiac complications. |
| CM102.5 | To assess the drugs acting on hematopoietic system |
| CM102.6 | To compile the role of autocoids and related drugs. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmacology**

**Course Name** : Pharmacological and Toxicological Screening Methods – I

**Course code** : MPL 103 T (Theory)

| | |
|---|---|
| CM103.1 | To gain basic knowledge on regulations and ethical requirement for the maintenance and breeding of laboratory animals and the role of transgenic animals in preclinical research |
| CM103.2 | To outline General principles of *invivo, in vitro*,screening techniques for drugs acting on CNS and ANS |
| CM103.3 | To identify the newer screening methods for drug acting on respiratory, reproductive and gastrointestinal system. |
| CM103.4 | To distinguish the screening methods for new substances acting on cardiovascular system |
| CM103.5 | To appraise the screening methods of the newer drugs for metabolic disorders |
| CM103.6 | To predict the *invivo, in vitro* screening models for immunomodulators , to discuss General principles of immunoassay and extrapolation of in vitro/preclinical data to human |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmacology**

**Course Name** : Cellular and Molecular Pharmacology

**Course code** : MPL 104 T (Theory)

| | |
|---|---|
| CM104.1 | To learn basic structure and function of genome in the living organism and the importance of siRNA and micro RNA |
| CM104.2 | To summarize various phases of cell cycle,apoptosis ,necrosis and autophagy |
| CM104.3 | To construct the role of receptors and secondary messengers in cellsignaling pathways |
| CM104.4 | To analyse the principles and applications of genomic and proteomic tools DNA eclctrphorsosis,PCR, SDS page, ELISA ,western blotting ,Recombinant DNA technology and gene therapy |
| CM104.5 | To evaluate significance of Pharmacogenomics and immunotherapeutics |
| CM104.6 | Toconstruct the various cell culture techniques, Principles and applications of cell viability/ glucose uptake/Calcium influx assays , flow cytometry and biosmilars |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmacology**

**Course Name** : Pharmacology Practical – I

**Course code** : MPL 105 P (Practical)

| | |
|---|---|
| CM105.1 | To recall handling of laboratory animals, various routes of drug administrations, blood collection, anaesthesia and euthanasia techniques. |
| CM105.2 | To demonstrate the CNS stimulant, depressant, anxiogenics , anxiolytic, anticonvulsant, analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activities using animal models. |
| CM105.3 | To Identify the concentration test compounds using HPLC,UV,GC, fluorimetry and flame photometry |
| CM105.4 | To examine diuretic, antiulcer activities and to analyse Oral glucose tolerance test. |
| CM105.5 | To interpret the isolation of DNA/RNA and to assess PCR, Western Blotting, gel electrophoresis techniques and Enzyme based in-vitro/Cell viability assays |
| CM105.6 | To predict Comet assay and to elaborate the pharmacokinetics parameters of drugs by using biological samples and software |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmacology**

**Course Name** : Advanced Pharmacology – II

**Course code** : MPL 201 T (Theory)

| | |
|---|---|
| CM201.1 | To relate functions of hormones and to list out drugs acting on endocrine system. |
| CM201.2 | To outline the principles of chemotherapy and illustrate the mechanism of action of antibiotics, Antifungal, antiviral, and anti-TB drugs |
| CM201.3 | To identify the chemotherapeutic agents for Protozoal Helimenthetic infections and cancer. |
| CM201.4 | To categorize the inflammatory mediators, allergic /hypersensitivity reactions and simplify pharmacotherapy of asthma and COPD. |
| CM201.5 | To assess the mechanism of drugs acting on GIT and applications of chronopharmacology to treat disorders. |
| CM201.6 | To elaborate the role of free radicals in etiopathology of various diseases and adapt the recent Advances in treatment of various diseases. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmacology**

**Course Name** : Pharmacological and Toxicological Screening Methods – II

**Course code** : MPL 202 T (Theory)

| | |
|---|---|
| CM202.1 | To recall types of toxicology, to list out the regulatory guide lines for conducting toxicity studies and its importance in drug development |
| CM202.2 | To Illustrate Acute, sub-acute and chronic- oral, dermal and inhalational toxicity studies as per OECD guidelines. |
| CM202.3 | To construct reproductive toxicology, tearatogenicity, Genotoxicity and In vivo carcinogenicity studies. |
| CM202.4 | To categorize IND enabling studies |
| CM202.5 | To appraise and importance of safety pharmacological studies(Tier-1 and 2) |
| CM202.6 | To compile the Importance and applications of toxicokinetic Studies and Alternative methods to animal toxicity testing. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmacology**

**Course Name** : Principles of Drug Discovery

**Course code** : MPL 203 T (Theory)

| | |
|---|---|
| CM203.1 | To recall the modern drug discovery process, target Discovery and validation and role of transgenic animalsin target validation. |
| CM203.2 | To relate the concepts of combinatorial chemistry , high throughput screening and in silico lead discovery techniques |
| CM203.3 | To identify the prediction of protein structure and the NMR and X-ray crystallography in protein structure prediction |
| CM203.4 | To contrast the Rational Drug Design Methods and Virtual Screening techniques |
| CM203.5 | To interpret the various molecular Docking studies and to assess the importance of QSAR and SAR studies |
| CM203.6 | To elaborate the Statistical methods used in QSAR and compile the Prodrug design process |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmacology**

**Course Name** : Clinical Research and Pharmacovigilance

**Course code** : MPL 204 T (Theory)

| | |
|---|---|
| CM204.1 | To label various regulatory requirements for clinical trials. |
| CM204.2 | To demonstrate the types and designs of clinical trial and to infer roles and responsibilities of Clinical Trial Personnel |
| CM204.3 | To construct the documentation process of clinical trials and to identify Adverse Drug Reactions |
| CM204.4 | To contrast the roles and responsibilities of Pharmacovigilance |
| CM204.5 | To appraise various methods of ADR reporting and tools used inPharmacovigilance |
| CM204.6 | To predict principles and concepts of Pharmacoepidemiology, Pharmacoeconomics and safety pharmacology |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmacology**

**Course Name** : Pharmacology Practical-II

**Course code** : MPL 205 P (Practical)

| | |
|---|---|
| CM205.1 | To understand the dose response relationship, effect of drugs on DRC and $PD_2$ value |
| CM205.2 | To outline the acute, sub acute and chronictoxicity studies as per OECD guidelines |
| CM205.3 | To identify the effects of various drugs on isolated heart preparations, and to Illustratethe rat BP, heart rate and ECG. |
| CM205.4 | To evaluate the drug concentrations by various bioassay methods using isolated tissue preparations |
| CM205.5 | To prioritize the Repeated dose toxicity studies and evaluate Drug mutagenicity study using mice bone-marrow chromosomal aberration. |
| CM205.6 | To elaborate Protocol for clinical trial, ADR monitoring. In-silico docking studies/pharmacophore based screening/QSAR studies and ADR reporting |

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|---|---|---|
| **Programme** | **:** | II/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 3rd Semester |
| **Branch** | **:** | **Common for All Specializations** |
| **Course Name** | **:** | Research methodology & Biostatistics |
| **Course code** | **:** | MPL 301 T (Theory) |

| | |
|---|---|
| C301.1 | To recall the concepts of research methodology which includes study design, type of studies, stratifies and different design techniques. |
| C301.2 | To infer the data using biostatistics technique like “t” test, ANOVA and chi square tests as well as recognize the importance of samples size and its significances. |
| C301.3 | To learn the history of medical research for understanding the values of clinical ethics as well as its importance in communication and sociological relationships. |
| C301.4 | To explain the CPCSEA guidelines for laboratory animal facilities which include handling, maintenance, record keeping and transportation of lab animals. |
| C301.5 | To discuss the history and basic principles of Declaration of Helsinki for medical research. |

| Course Name: ASSIGNMENTS<br>Year of Study: 1st M.Pharmacy 1st and 2nd Semester | |
|---|---|
| C.1 | To recall the fundamentals of proposed topic and carry out literature review. |
| C.2 | To classify / compare, interpret the various methods and techniques. |
| C.3 | To organize the collected data in chronological order and develop writing skills. |
| C.4 | To analyze the data and interpret the relationships. |
| C.5 | To evaluate and conclude the given topic. |
| C.6 | To propose, design research in given concept and improve presentation skills. |

| Course Name: SEMINARS<br>Year of Study: 1st M.Pharmacy 1st and 2nd Semester | |
|---|---|
| C.1 | To recall the fundamentals of proposed topic and carry out literature review. |
| C.2 | To classify / compare, interpret the various methods and techniques. |
| C.3 | To organize the collected data in chronological order and develop writing skills. |
| C.4 | To analyze the data and interpret the relationships. |
| C.5 | To evaluate and conclude the given topic. |
| C.6 | To propose, design research in given concept and improve presentation skills. |

| Course Name: Journal club<br>Year of Study: 2nd M.Pharmacy 3rd Semester | |
|---|---|
| C.1 | To select the scientific concept based on literature and define the objectives of research. |
| C.2 | To outline the hypothesis and summarize the concept for presentation. |
| C.3 | To plan for a meeting, discuss SOWT analysis, the design and methods used in concept. |
| C.4 | To analyze the variables and their inter relationships. |
| C.5 | To conclude the results and to discuss its significance. |
| C.6 | To appraise the concept for societal needs, acknowledge and improve presentation skills. |

| Course Name: PROJECT WORK<br>Year of Study: 2nd M.Pharmacy 4th Semester | |
|---|---|
| C.1 | To recall the fundamentals, carry out literature review on proposed research topic and identify research problem. |
| C.2 | To outline the requirements toper form the proposed research. |
| C.3 | To construct the research hypothesis. |
| C.4 | To take part in research experiments meticulously and documentation as per format. |
| C.5 | To evaluate and conclude the results using statistical analysis. |
| C.6 | To appraise societal application and appreciation. |

# M.PHARMACY PROGRAMME

# PHARMACEUTICAL REGULATORY AFFAIRS

# (MRA)

| PHARMACEUTICAL REGULATORY AFFAIRS (MRA) | |
|---|---|
| **PROGRAMME OUTCOMES (PO's)** | |
| **PO1** | **Regulatory Knowledge:** Possess knowledge, comprehension of the core and basic knowledge associated with the profession of Pharmaceutical Regulatory Sciences, including drug development process, dossier preparation, good manufacturing practices, clinical trials and human research. |
| **PO2** | **Planning Abilities:** Demonstrate effective planning abilities and elements that are necessary to accumulate the regulatory submissions including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines. |
| **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 while reviewing and submission of dossiers to regulatory markets. |
| **PO4** | **Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources and modern regulatory-related computing tools with an understanding of their limitations. |
| **PO5** | **Collaboration and Team Work:** Understand and consider the human reaction to change, motivation, issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities which also includes interpersonal skills, knowledge sharing and strategy in between members of a virtual team. |
| **PO6** | **Ethics:** Use ethical frameworks, apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions in clinical research and clinical investigations. |
| **PO7** | **Regulatory Professional:** Understand, analyze and communicate the value of their professional roles in society and business development and be reliable with critical thinking and regulatory writing skills. |

| | |
|---|---|
| **PO8** | **Cross Cultural Communication:** Appreciation of and ability to learn from and work with people from diverse linguistic and cultural backgrounds. It should emphasize how regulatory strategy increases a products chance of entering a market and staying there. Once cross-functional teams understand regulatory strategy and its importance in product development and inter-team communication. |
| **PO9** | **Initiative and Entrepreneurialism:** Individual's ability to turn ideas into practice. Like finding new opportunities to share information and concepts. Generating options and solutions to cope with changes. It involves imagination, novelty and risk-taking, as well as the ability to plan and manage projects in order to achieve objectives. |
| **PO10** | **Creativity and Innovation:** Function of knowledge, curiosity, imagination, and evaluation. The greater individual knowledge base and level of curiosity, the more ideas, patterns, and combinations will achieve, which then correlates to creating new and innovative products and services. |
| **PO11** | **Lifelong 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- access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis. |

| PHARMACEUTICAL REGULATORY AFFAIRS (MRA) | |
|---|---|
| **PROGRAMME EDUCATIONAL OBJECTIVES (PEO's)** | |
| **PEO1** | **Cognition:** Program encompasses the students with profound functional knowledge in core subjects of pharmaceutical regulatory sciences. This enables students to understand the basics of regulatory compilation, create and assemble the regulation submission as per the requirements of regulatory agencies and be competent enough and apply these tools in pharmaceutical and health care industries, research, clinical laboratories, hospitals and community pharmacies for overall maintenance of public health. |
| **PEO2** | **Core competence:** To provide students with a strong foundation of regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices as well as prepare for the readiness and conduct of audits and inspections. |
| **PEO3** | **Amplitude:** To train students for understanding different acts and guidelines that regulate Drugs & Cosmetics, Medical devices, Biologicals, Herbals and Food & Nutraceuticals industries as well as comprehend the approval process and regulatory requirements for pharmaceutical products in different regulatory markets. |
| **PEO4** | **Technicality:** Implementation of innovative teaching learning methodologies with visual aids/ computer aided tools to empower the students in understanding the concepts with clarity and transparency. Students are trained in handling regulatory software's like e-CTD and in their troubleshooting procedures, problem-based learning which makes them to apply the learned theoretical concepts to real time applications and meet the current pharmaceutical industrial demand in regulatory market. |
| **PEO5** | **Adroitness:** To inculcate in students professional and ethical attitude, effective communication skills, teamwork skills, multidisciplinary approach and an ability to relate Pharmaceutical, Health care issues to broader social context. |

## PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

| PROGRAM SPECIFIC OUTCOMES (PSO's) | |
|---|---|
| **PSO1** | Gain the respective background information, regulatory framework and necessary resources to understand how pharmaceutical products are regulated in different countries and how regulatory affairs professionals can help organizations navigate through regulatory obstacles. |
| **PSO2** | Apply the relevant regulations, policies, guidance documents as well as important initiatives with respect to pharmaceuticals, biologicals, natural health products and various other therapeutic products. |
| **PSO3** | The course also helps students to discuss on how regulatory affairs professionals add value to various organizations and opportunities available within the industry. |
| **PSO4** | Students able to develop and enhance communication skills, including verbal, nonverbal and written which is essential in professional environments of regulatory affairs. Students learn proper writing, editing and comprehension strategies. |
| **PSO5** | Students gain knowledge of project management processes and their application to regulatory submissions. This course equips students with skills necessary for global regulatory submissions, from selection of submission type to planning and preparing such submissions for review by respective regulatory agencies. |
| **PSO6** | Students become familiar with the legislative framework and regulations that guide the selection and designation of medical products globally. Case studies are used to provide practical experience in applying international regulations and legislations, including EU and US. Students are also introduced to softwares commonly used in the regulatory affairs field. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutical Regulatory Affairs**

**Course Name** : Good Regulatory Practices

**Course code** : MRA 101 T (Theory)

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| C101.1 | To recall the concepts of current Good Manufacturing Practices (cGMP) and Global Harmonization Task Force (GHTF) official guidelines for medical devices. |
| C101.2 | To Illustrate the concepts of Good Laboratory Practices and its regulations including ISO and QCI standards. |
| C101.3 | To make use of the Good Automated Laboratory Practices and its requirements as per US FDA and other regulatory guidelines like ISO and QCI. |
| C101.4 | To explain the Good Distribution Practices which involves personnel, self-inspection, document handling and following its relevant guidelines as per WHO, ISO and CDSCO. |
| C101.5 | To summarize the concepts and process of Quality Management System and its guidelines provided by ICH, ISO and CDSCO. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutical Regulatory Affairs**

**Course Name** : Documentation and Regulatory writing

**Course code** : MRA 102 T (Theory)

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| C102.1 | To recall the documentation in pharmaceutical industries and its plan to product development and to learn preparing documents like SMF and DMF. |
| C102.2 | To outline the process and preparation of regulatory dossier and its online submission by following ICH e-CTD guidelines and other guidelines like ACTD etc. |
| C102.3 | To utilize the concepts of audits and its different types, preparing the reports and maintaining the audit timelines as well as referring the ISO and GHTF guidance documents. |
| C102.4 | To evaluate the reports of Regulatory Inspections and understanding the concepts of Root cause analysis and CAPA. |
| C102.5 | To adapt the product life cycle management and other concepts like PAS, SUPAC, CBE-30 and EIR including ISO risk management standards. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutical Regulatory Affairs**

**Course Name** : Clinical Research Regulations

**Course code** : MRA 103 T (Theory)

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| C103.1 | To define the concepts of clinical drug development process and to plan the clinical investigation and its evaluation process for Medical devices. |
| C103.2 | To outline the concepts related to Ethics in clinical research and understand the role of Sponsors and Investigators including functions of CROs. |
| C103.3 | To apply the regulations governing the clinical trials in INDIA, US and EU by following its official research guidelines towards clinical trials and its registration process. |
| C103.4 | To compare the different clinical research related guidelines by following ICH GCP, ICMR and GHTF guidance documents. |
| C103.5 | To discuss the USA and EU guidelines for clinical investigations and its reports including pharmacovigilance studies and FDA Med watch. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 1st Semester

**Branch** : **Pharmaceutical Regulatory Affairs**

**Course Name** : Regulations and legislation for Drugs & Cosmetics

**Course code** : MRA 104 T (Theory)

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| C104.1 | To recall the acts and rules related to drugs, biologicals, herbals and nutraceuticals. |
| C104.2 | To explain the guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals |
| C104.3 | To compare the Indian Pharmacopoeial, BIS, ISO and other relevant standards |
| C104.4 | To interpret the Bioavailability & Bioequivalence data, Guidelines for Drug testing in animals, humans and ICMR-DBT Guidelines for Stem Cell Research |
| C104.5 | To discuss the concepts of intellectual property rights and comparing IPR vs Regulatory affairs |

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| **Programme** | **:** | I/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 1st Semester |
| **Branch** | **:** | **Pharmaceutical Regulatory Affairs** |
| **Course Name** | **:** | Regulatory Affairs, Practical – I |
| **Course code** | **:** | MRA 105 P (Practical) |

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|---|---|
| C105.1 | To select the case studies of Good Manufacturing Practices and documentation for in-process finished products and their QC tests. |
| C105.2 | To outline the SOP's, documentation record, protocols and analytical reports for BMR, MFR and DR for stability and validation process. |
| C105.3 | To identify the regulatory requirements, registration process and submission guidelines for different pharmaceutical products. |
| C105.4 | To compare the regulatory requirement checklists and documents for registration and submission to different regulatory bodies. |
| C105.5 | To elaborate regulatory requirements checklists for conducting clinical trials in different countries. |

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| **Programme** | **:** | I/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 2nd Semester |
| **Branch** | **:** | **Pharmaceutical Regulatory Affairs** |
| **Course Name** | **:** | Regulatory Aspects of Drugs & Cosmetics |
| **Course code** | **:** | MRA 201 T (Theory) |

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|---|---|
| C201.1 | To recall the regulatory drug approval process and marketing in US and CANADA by following its official guidelines provided by regulatory bodies like USFDA and Health Canada. |
| C201.2 | To show the regulatory drug approval process and marketing in EU and AUSTRALIA by following its official guidelines provided by regulatory bodies like EMA and TGA. |
| C201.3 | To plan the regulatory drug approval process and marketing in JAPAN by following its official guidelines provided by regulatory bodies like PMDA. |
| C201.4 | To compare the regulatory drug approval process and marketing in Emerging Markets like ASEAN, APEC, EAC, GCC, PANDRH and SADC etc. |
| C201.5 | To discuss the regulatory drug approval process and marketing in Brazil, CIS and UAE as well as to understand its post approval requirements. |

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| **Programme** | **:** | I/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 2nd Semester |
| **Branch** | **:** | **Pharmaceutical Regulatory Affairs** |
| **Course Name** | **:** | Regulatory Aspects of Herbal & Biologicals |
| **Course code** | **:** | MRA 202 T (Theory) |

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|---|---|
| C202.1 | To recall the knowledge of regulations, guidelines, market authorization and post market data of similar biologics in India. |
| C202.2 | To compare the generic drug & biosimilars and to study the laws, regulations, guidance and packaging of biologics as per USA. |
| C202.3 | To make use of the scientific guidelines, development pre-clinical and clinical development considerations; stability, safety, advertising, labeling, packing and regulatory approval of biologics in European Union (EU). |
| C202.4 | To take part in the marketing authorisation, clinical evaluation, licensing, quality assessment and pharmacovigilance of vaccines in India. |
| C202.5 | To discuss the quality, safety and legislation for herbal products in India, USA and European Union (EU). |

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| **Programme** | **:** | I/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 2nd Semester |
| **Branch** | **:** | **Pharmaceutical Regulatory Affairs** |
| **Course Name** | **:** | Regulatory Aspects of Medical advices |
| **Course code** | **:** | MRA 203 T (Theory) |

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| C203.1 | To relate the Medical Devices and its risk-based classification along with history of MD and guidance documents of IMDRF like STED and GMDN. |
| C203.2 | To recall the ethics in clinical investigations of medical Devices and its quality related guidelines by ISO. |
| C203.3 | To identify the regulatory approval process and marketing of medical devices in US by following US FDA official guidance documents. |
| C203.4 | To discuss the regulatory approval process and marketing of medical devices in EU by following EMA official guidance documents. |
| C203.5 | To compare the regulatory approval process and marketing of medical devices in ASEAN countries like china & Japan by following their own countries guidance documents. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutical Regulatory Affairs**

**Course Name** : Regulatory Aspects of Food & Nutraceuticals

**Course code** : MRA 204 T (Theory)

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| C204.1 | To define the concepts related to Nutraceuticals and its opportunities in Nutraceutical market. |
| C204.2 | To illustrate the global aspects of Nutraceuticals and its guidelines provided by WHO and NSF Internationals. |
| C204.3 | To identify the regulatory approval process of Nutraceuticals and its market regulations in INDIA with reference to RDA. |
| C204.4 | To explain the regulatory approval process of Nutraceuticals and its market regulations in USA with reference to RDA. |
| C204.5 | To acquire the regulatory approval process of Nutraceuticals and its market regulations in EU with reference to RDA. |

**Programme** : I/II M.Pharmacy

**Semester/Year of Study** : 2nd Semester

**Branch** : **Pharmaceutical Regulatory Affairs**

**Course Name** : Regulatory Affairs Practical – II

**Course code** : MRA 205 P (Practical)

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| C205.1 | To find case studies of change controls, deviations and CAPA in pharmaceutical industries. |
| C205.2 | To Illustrate the preparation of submission through eCTD software for FDA, EMA and MHRA. |
| C205.3 | To compare the drug registration requirements procedures for different regulatory and emerging market countries for marketing authorization. |
| C205.4 | To assess the checklist for different pharmaceutical products for regulatory submissions. |
| C205.5 | To design applications and clinical investigation plans for Medical devices and its facilities. |

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| **Programme** | **:** | II/II M.Pharmacy |
| **Semester/Year of Study** | **:** | 3rd Semester |
| **Branch** | **:** | **Common for All Specializations** |
| **Course Name** | **:** | Research methodology & Biostatistics |
| **Course code** | **:** | MRA 301 T (Theory) |

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|---|---|
| C301.1 | To recall the concepts of research methodology which includes study design, type of studies, stratifies and different design techniques. |
| C301.2 | To infer the data using biostatistics technique like “t” test, ANOVA and chi square tests as well as recognize the importance of samples size and its significances. |
| C301.3 | To learn the history of medical research for understanding the values of clinical ethics as well as its importance in communication and sociological relationships. |
| C301.4 | To explain the CPCSEA guidelines for laboratory animal facilities which include handling, maintenance, record keeping and transportation of lab animals. |
| C301.5 | To discuss the history and basic principles of Declaration of Helsinki for medical research. |

| Course Name: ASSIGNMENTS<br>Year of Study: 1st M.Pharmacy 1st and 2nd Semester | |
|---|---|
| C.1 | To recall the fundamentals of proposed topic and carry out literature review. |
| C.2 | To classify / compare, interpret the various methods and techniques. |
| C.3 | To organize the collected data in chronological order and develop writing skills. |
| C.4 | To analyze the data and interpret the relationships. |
| C.5 | To evaluate and conclude the given topic. |
| C.6 | To propose, design research in given concept and improve presentation skills. |

| Course Name: SEMINARS<br>Year of Study: 1st M.Pharmacy 1st and 2nd Semester | |
|---|---|
| C.1 | To recall the fundamentals of proposed topic and carry out literature review. |
| C.2 | To classify / compare, interpret the various methods and techniques. |
| C.3 | To organize the collected data in chronological order and develop writing skills. |
| C.4 | To analyze the data and interpret the relationships. |
| C.5 | To evaluate and conclude the given topic. |
| C.6 | To propose, design research in given concept and improve presentation skills. |

| Course Name: Journal club<br>Year of Study: 2nd M.Pharmacy 3rd Semester | |
|---|---|
| C.1 | To select the scientific concept based on literature and define the objectives of research. |
| C.2 | To outline the hypothesis and summarize the concept for presentation. |
| C.3 | To plan for a meeting, discuss SOWT analysis, the design and methods used in concept. |
| C.4 | To analyze the variables and their inter relationships. |
| C.5 | To conclude the results and to discuss its significance. |
| C.6 | To appraise the concept for societal needs, acknowledge and improve presentation skills. |

| Course Name: PROJECT WORK<br>Year of Study: 2nd M.Pharmacy 4th Semester | |
|---|---|
| C.1 | To recall the fundamentals, carry out literature review on proposed research topic and identify research problem. |
| C.2 | To outline the requirements toperform the proposed research. |
| C.3 | To construct the research hypothesis. |
| C.4 | To take part in research experiments meticulously and documentation as per format. |
| C.5 | To evaluate and conclude the results using statistical analysis. |
| C.6 | To appraise societal application and appreciation. |