Program: M. Pharmacy

Duration: 2 years

Program Specific Outcomes (PSO):

Course: Pharmaceutics:

1. Impart knowledge on the novel drug delivery systems, approaches, criteria for selection of polymers and drugs and their formulation and evaluation.
2. To know various preformulating elements, industrial management and GMP considerations, Pilot Plant Scale Up Techniques, Stability testing, sterilization and packaging of dosage forms.
3. To impart knowledge and skills in generic drug development, various regulatory filings the approval process, and concept of generics across the globe.
4. To impart knowledge and skills for dose calculations, dose adjustments and apply biopharmaceutics theories in practical problem solving. The pharmacokinetic models, bioequivalence and potential clinical pharmacokinetic problem analysis
5. Skill development in Pharmaceutical research, Pharmacoinformatic, in drug development in Computational modeling, Preclinical development, clinical development, Artificial Intelligence and Robotics, and Computational fluid dynamics
6. To impart knowledge and skills necessary for cosmetics and cosmeceuticals, their safety and efficacy and current technologies in cosmetic industry
7. To gain knowledge in use of advanced instrumentation, formulation and evaluation of controlled release formulations, floating drug delivery systems, transdermal drug delivery systems, micromeritics, and mathematical simulations
8. To train the students and develop their technical skill knowledge in computer simulations, population modelings, in vitro and in vivo studies
9. To create a talent pool by involving students in research projects and to make students undertake research projects under faculty guidance for publication
10. To foster ambitious desire among students to undertake higher studies and career growth

Course: Pharmaceutical Analysis

1. Able to perform qualitative and quantitative analysis of drugs in different matrices by various spectroscopic, electro-analytical and chromatographic techniques

2. Able to perform stability studies, impurity profiling and metabolite profiling of drugs by hyphenated analytical techniques

3. Thorough knowledge about quality control, quality assurance of pharmaceuticals and regulatory guidelines

Course: Pharmaceutical Quality Assurance

1. Students are well versed with latest regulatory guidelines, functions of Quality Assurance in pharmaceutical Industry and Good Documentation Practices.

2. Students are acquainted with operation of analytical instruments.

3. Students are able to acquire professional, ethically correct and self esteemed attitude.

COURSE OBJECTIVES & OUTCOMES

SPECIALISATION: PHARMACEUTICS (MPH)

SEMESTER -I

MPH101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

OBJECTIVE: 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.

OUTCOMES:

Upon completion of the course student will be able to

1. Understand the UV-Visible spectroscopy, IR, flame and atomic absorption spectroscopy.
2. Know principles of NMR spectroscopy, instrumentation and applications.
3. Understand the principles of mass spectroscopy, different ionization techniques and applications of mass spectroscopy.
4. Understand the different chromatographic techniques like paper, ion exchange, gas, HPLC, etc
5. Know the principles and procedures of paper and capillary electrophoresis; XRD and its applications.
6. Understand the principles and procedures of immunoassays like radioimmunoassay, ELISA and bioluminescent assays.

MPH102T. DRUG DELIVERY SYSTEMS (Theory)

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

OUTCOMES:

Upon completion of the course student will be able to

1. Understand drug delivery system give a detailed information transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect.
2. Understand approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect with suitable drug delivery.
3. Know methods of manufacture and evaluation of various Sustained Release (SR) and Controlled Release (CR) formulations like Gastroprotective, Baccal, Transdermal and Occular drug delivery systems.
4. Understand recent developments in protein and peptide for parenteral delivery approaches will give new dimension of drug deliver for antibiotics, insulin, etc.

5. Understand vaccine delivery and different mode of application approach for clinical use. They know the different types of Drug carrier used in the process of drug delivery which serves to improve the selectivity, effectiveness, and/or safety of drug administration.
6. Know the latest drug delivery knowledge and think to develop new formulation based on the individual requirement.

MPH103T. MODERN PHARMACEUTICS (Theory)

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

OUTCOMES:

Upon completion of the course student will be able to

1. Learn about the science behind performing a Preformulation study before formulating a novel drug delivery system.
2. Understand the current good manufacturing practices that are implemented in various pharmaceutical industries.
3. Understand various validation protocols that are been followed in the pharmaceutical industries as per various regulatory guidelines.
4. Understand various optimization techniques that are used in prior to formulate any new dosage form.
5. Understand how to run the optimization softwares (For ex: Design expert and Minitab).
6. Understand about the science between compaction and compression of a tablet.
7. Understand about various dissolution parameters that have to be incorporated while performing dissolution studies.

MPH104T. REGULATORY AFFAIRS (Theory)

OBJECTIVE:

1. To understand the drug development process.
2. To know the filing process of IND, NDA and ANDA.
3. To understand the concept of regulations regarding clinical trials.
4. To know the chemistry, manufacturing controls and their importance.

OUTCOMES:

Upon completion of the course student will be able to

1. Identify the concepts of innovator and generic drugs and drug development process.
2. Describe the regulatory guidance and guidelines for filing and approval process.
3. Detail the preparation of dossiers and their submission to regulatory agencies in different countries.
4. Identify the post approval regulatory requirements for actives and drug products.
5. Express the submission of global documents in CTD/eCTD formats.

6. Define the clinical trials for approvals for conducting clinical trials.
7. Describe the Pharmaco Vigilence and process of monitoring in clinical trials.

MPH105PA. PHARMACEUTICS PRACTICAL – I (Practical)

Upon completion of the course student will be able to

1. Know Variability and Operation of commonly used analytical instruments like UV Vis spectrophotometer, HPLC, Gas Chromatography, Fluorimetry and Flame photometry.
2. Perform Analysis of various drugs and their formulation in single and combination dosage forms.
3. Have knowledge as well as hands on training with respect to the principles of formulation science such as Preformulation studies and Micromeritics.
4. Possess the knowledge about effect of compressional force on tablets Properties.

MPH105PB. PHARMACEUTICS PRACTICAL – II (Practical)

Upon completion of the course student will be able to

1. Get knowledge with respect to composition of dosage forms, selection of drugs and polymers for the development of delivering system
2. Formulate and evaluation of various customized, Sustained Release (SR) and Controlled Release (CR) formulations.
3. Formulate and evaluate various novel drug delivery systems: Floating DDS, Muco adhesive tablets and Trans dermal patches

SEMESTER -II

MPH201T. MOLECULAR PHARMACEUTICS (Nano Tech and Targeted DDS) (Theory)

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

OUTCOMES:

Upon completion of the course student will be able to

1. Understand the various approaches for development of novel drug delivery systems like Tumor targeting and Brain specific delivery.
2. Understand the criteria for selection of drugs and polymers for the development of NTDS
3. Know the need, concept, design and evaluation of various targeted drug delivery systems like Nano Particles, Liposomes, Niosomes, Aquasomes, Phytosomes, Electrosomes and Monoclonal Antibodies.
4. Understand gene therapy and different mode of application approach for clinical use.
5. Understand the formulation and evaluation of Aerosols and Intra Nasal Route Delivery systems.

MPH202T. ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (Theory)

OBJECTIVE: 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.

OUTCOMES:

Upon completion of the course student will be able to

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics
2. Understand the use of raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolism and elimination. Describe various pharmacokinetic parameters by using various mathematical models.
3. Know the critical evaluation of biopharmaceutic studies involving drug product equivalency
4. Understand the design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic
6. Understand the basic concepts of BA/BE studies and in-vitro -in-vivo correlations (IVIVC)

MPH203T. COMPUTER AIDED DRUG DELIVERY SYSTEM (Theory)

OBJECTIVE: This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the

principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

OUTCOMES:

Upon completion of the course student will be able to

1. Explain about the role of computers in pharmaceutical research, various modelling approaches and parameters used in modelling.
2. Understand about basics and guidelines of Quality by Design (QbD)
3. Understand about computation modelling techniques of ADME process for a drug
4. Understand about the concept of optimization and they can design a formulation of emulsion and microemulsion using software's like design expert.
5. Understand about legal aspects involved in using computers in pharmaceutical research
6. Understand about using of computer aided designs in in-vitro dissolution studies.
7. Understand about usage of computers in stimulating whole organisms and tissues.
8. Understand the regulations involved in clinical data collection and management.
9. Understand about current status of pharmaceutical automation and its future trends

MPH204T. FORMULATION DEVELOPMENT OF PHARMACEUTICAL AND COSMETIC PRODUCTS (Theory)

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

OUTCOMES:

Upon completion of the course student will be able to

1. Learn about the science behind performing a Preformulation study before formulating a novel drug delivery system.
2. Learn about various pre-formulation parameters that have to be studied before formulating a novel drug delivery system.
3. Learn about basics and recent developments in excipient science.
4. Learn about the importance of solubility for a drug and methods to enhance the solubility.
5. Learn about basics of drug dissolution and various parameters involved in in vitro drug dissolution studies.
6. Know about the standard stability testing procedures for formulated dosage forms using ICH guidelines.
7. Understand about basics and legal aspects of cosmeticology and various formulations like dentifrices, lipsticks, nail polish and baby products etc.

MPH205PA. PHARMACEUTICS PRACTICAL III (Practical)

Upon completion of the course student will be able to

1. Know the effect of temperature, nonsolvent, incompatible polymer addition on preparation of microcapsules.
2. Design and perform in-vitro evaluation studies for various novel drug delivery systems: Alginate beads, gelatin /albumin microspheres, liposomes / niosomes and spherules.
3. Perform in-vitro dissolution of marketed products and interpretation of dissolution data.
4. Calculate the various pharmacokinetic parameters of drugs and pharmaceutical products in animal models / Software.

MPH205PB. PHARMACEUTICS PRACTICAL IV (Practical)

Upon completion of the course student will be able to

1. Learn how to use the Design Expert Software in the formulation design and data analysis.
2. Calculate the various pharmacokinetic and pharmacodynamics parameters using Computer Simulations / Computational Modelling.
3. Formulate and evaluate various cosmetic products and Multi Vitamin Syrup.
4. Know the optimization techniques in Formulation Development of Tablets.

SEMESTER -III

MRM301T. Research Methodology and Biostatistics (Theory)

upon completion of the course student will be able to

1. Identify the concepts of medical research and values in medical ethics.
2. Define the CPCSEA guidelines for laboratory animal facility.
3. Describe the declaration of Helsinki and basic principles for medical research.
4. Understand Basic statistical methods which are used in collecting data study and analyse. Observe Errors relating experimentation
5. Perceive relation between components also measure and study linearly. We can observe one component influence with multiple factors.
6. Know testing of the hypothesis and understand how far population parameter significant based on estimator with the help of parametric tests. Non parametric tests can also observed.
7. Define analysis of variance helps in study total variation
8. Know application of Analysis in field or lab experimental to design and factorial experiments.
9. Apply the knowledge in research objects about reliability and validity experimental study

SEMESTER -IV

Journal club

Upon completion of the course student will be able to

1. Critically appraise the research article of their specialization published in reputed journals. Students are trained for inquiry based learning and critical thinking skills.
2. Access journals by adopting search engines and made to collect relevant data, analyse and comment on the findings with the submission of the document evidence and present on the same for assessment

MRW 403. Project Work

Upon completion of the course student will be able to

1. Generate the topic for the project and Collect the information from the relevant sources
2. Assemble the information into a more realistic draft ethically and conclude the contents.
3. Students prepare the presentation and explain outcome of their project along with further scope for research. This develops their oratory and leadership skills.

Discussion / Final Presentation

Upon completion of the course student will be able to

1. Prepare the presentation based on the results obtained in the research work
2. Explain outcome of their project along with further scope for research. This develops their oratory and leadership.

COURSE: PHARMACEUTICAL ANALYSIS (MPA)

SEMESTER -I

MPA101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

OBJECTIVE: 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.

OUTCOMES:

Upon completion of the course student will be able to

1. Understand the UV-Visible spectroscopy, IR, flame and atomic absorption spectroscopy.
2. Know principles of NMR spectroscopy, instrumentation and applications.
3. Understand the principles of mass spectroscopy, different ionization techniques and applications of mass spectroscopy.
4. Understand the different chromatographic techniques like paper, ion exchange, gas, HPLC, etc
5. Know the principles and procedures of paper and capillary electrophoresis; XRD and its applications.
6. Understand the principles and procedures of potentiometry and thermal analytical techniques like DSC and TGA.

MPA102T. ADVANCED PHARMACEUTICAL ANALYSIS (Theory)

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

OUTCOMES:

Upon completion of the course student will be able to

1. Know about impurities classification, residual solvents classification and limits.
2. Understand the classification of elemental impurities, factors affecting stability and stability commitment
3. Understand accelerated stability studies, stability zones, photostability testing and stability of biological products.
4. Understand the regulatory requirements and HPTLC fingerprinting.
5. Know bioassays of vaccines and PCR instrumentation
6. Understand the principles and procedures of different immunoassays.

MPA103T. PHARMACEUTICAL VALIDATION (Theory)

OBJECTIVE: 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.

OUTCOMES:

Upon completion of the course student will be able to

1. Understand introduction of Qualification and Validation involving Validation Master Plan, DQ, IQ, OQ, PQ, RQ, FAT, SAT.
2. Know qualification of analytical instruments and glassware
3. Know Advanced Validation of Utility Systems (Water, HVAC, Compressed air and Nitrogen) and Cleaning Validation.
4. Know Analytical Method Validation according to USP and ICH guidelines.
5. Understand Rigorous detailing of General principles of Intellectual Property.

MPA104T. FOOD ANALYSIS (Theory)

OBJECTIVE: 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.

OUTCOMES:

Upon completion of the course student will be able to

1. Learn about the flavour studies and to detect spoilage of food.
2. Understand the advanced analytical methods for estimation of concentration of carbohydrates, vitamins, fats, amino acids, proteins in food.
3. Understand the process of determining nutritional quality
4. Know very well about Chromatography techniques like GC-MS, LC- MS, Electrophoresis, HPLC, HPTLC, SFC, HPCPC, RIA, ELISA in analysis of food adulterants.
5. Understand how to select a suitable analytical method for qualitative and quantitative analysis of a pesticide residue in food substance.
6. Know about the use of BIS MARK, AGMARK on food substances.

MPA105PA. PHARMACEUTICAL ANALYSIS PRACTICAL - I (Practical)

Upon completion of the course student will be able to

1. Calibration of glassware and pH meter
2. Calibration of UV-Visible spectrophotometer and FTIR spectrophotometer
3. Calibration of GC and HPLC
4. Cleaning validation of any one equipment and Impurity profiling of drugs
5. Assay of official compounds by different titrations and instrumental techniques
6. Estimation of riboflavin/quinine sulphate by fluorimetry; Estimation of sodium/potassium by

flame photometry

7. Quantitative determination of hydroxyl group and amino group, and Colorimetric determination of drugs by using different reagents

MPA105PB. PHARMACEUTICAL ANALYSIS PRACTICAL - II (Practical)

Upon completion of the course student will be able to

1. Learn about the determination of total reducing sugar, proteins, vitamins content in foods
2. Determine the saponification value, Iodine value, Peroxide value, Acid value of food products.
3. Understand the selection of analytical methods for analysis of synthetic colors in food products
4. Know very well about determination of concentration of preservatives and pesticides residue in food products
5. Understand the selection of various analytical methods for determining food additives
6. Determine density and specific gravity of food substances.

SEMESTER -II

MPA201T. ADVANCED INSTRUMENTAL ANALYSIS (Theory)

OBJECTIVE: The subject is designed to impart basic knowledge about chromatographic and spectroscopic techniques like HPLC, affinity chromatography, SFC and CE; NMR and mass spectroscopic techniques. Develop student's ability to interpret the spectra's.

OUTCOMES:

Upon completion of the course student will be able to

1. Understand the basic principles of HPLC and applications of HPLC.
2. Understand the chromatographic techniques like size exclusion, ion exchange, ion pair, affinity, gas and HPTLC.
3. Know basic concepts about SFC, CE and CE-MS hyphenation.
4. Understand the principles of mass spectroscopy, different ionization techniques, mass analysers and MS/MS systems.
5. Understand the NMR spectroscopy, 2D NMR techniques and LC-NMR hyphenation

MPA202T. MODERN BIO-ANALYTICAL TECHNIQUES (Theory)

OBJECTIVE: The course will impart basic knowledge about extraction of drugs and metabolites from biological matrices, biopharmaceutical factors affecting drug bioavailability, toxicokinetic and PK-PD interactions. It also provides knowledge about cell culture techniques and metabolite profiling studies by using liver microsomes.

OUTCOMES:

Upon completion of the course student will be able to

1. Perform extraction of drugs and metabolites from biological samples and validation of bio-analytical methods
2. Know factors affecting bioavailability, transport models and permeability methods.
3. Understand drug interactions, microsomal assays and toxicokinetic; and applications of LC-MS in bioactivity screening and proteomics.
4. Know cell culture techniques, cell viability assays and flow cytometry.
5. Explain Metabolite identification by microsomal approaches and drug product performance

MPA203T. QUALITY CONTROL AND QUALITY ASSURANCE (Theory)

OBJECTIVE: 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.

OUTCOMES:

Upon completion of the course student will be able to

1. Understand concepts of QC/QA, GLP, ICH Guidelines Q-Series. Purchase specifications, selection of vendors and maintenance of stores
2. Know cGMP guidelines in accordance to USFDA including CDER, CBER, PIC, WHO, EMEA for industrial management and CPCSEA guidelines.
3. Understand detailed analysis of raw materials, IPQC, finished products and developing specifications according to ICH Q6 and Q3.
4. Know characteristic documentation in pharmaceutical industry
5. Understand clear perspective of manufacturing operations and controls.

MPA204T. HERBAL AND COSMETIC ANALYSIS (Theory)

OBJECTIVE: 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 forth purpose.

OUTCOMES:

Upon completion of the course student will be able to

1. Learn about the Quality control of crude drugs
2. Understand the advanced analytical methods for estimation of adulterants and deterioration of herbal drugs
3. Understand the process of detection of herbal drugs and monographs of herbal dugs
4. Know very well about herbal drug- drug interactions
5. Know about the evaluation of cosmetic products

MPA205PA. PHARMACEUTICAL ANALYSIS PRACTICAL III (Practical)

Upon completion of the course student will be able to

1. Know comparison of absorption spectra by UV and Wood ward – Fiesure rule and Interpretation of organic compounds by FT-IR
2. Know Interpretation of organic compounds by NMR and MS
3. Understand determination of purity by DSC in pharmaceuticals and Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
4. Perform bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by gel electrophoresis and HPLC techniques.
5. Perform Isolation of analgesics from biological fluids (Blood serum and urine).

6. Know protocol preparation and performance of analytical / bioanalytical method validation, and protocol preparation for the conduct of BA/BE studies according to guidelines.

MPA205PB. PHARMACEUTICAL ANALYSIS PRACTICAL IV (Practical)

Upon completion of the course student will be able to

1. Perform in process and finished product quality control tests for tablets, capsules, parenterals and creams.
2. Perform quality control tests for primary and secondary packing materials, and assay of raw materials
3. Know testing of related and foreign substances in drugs and raw materials, and preparation of Master Formula Record and Batch Manufacturing Record
4. Perform quantitative analysis of rancidity in lipsticks and hair oil, and determination of aryl amine content and Developer in hair dye
5. Know determination of foam height and SLS content of Shampoo, and determination of total fatty matter in creams
6. Know determination of acid value and saponification value, and determination of calcium thioglycolate in depilatories

SEMESTER -III

MRM301T. Research Methodology and Biostatistics (Theory)

Upon completion of the course student will be able to

1. Identify the concepts of medical research and values in medical ethics.
2. Define the CPCSEA guidelines for laboratory animal facility.
3. Describe the declaration of Helsinki and basic principles for medical research.
4. Understand Basic statistical methods which are used in collecting data study and analyse. Observe Errors relating experimentation
5. Perceive relation between components also measure and study linearly. We can observe one component influence with multiple factors.
6. Know testing of the hypothesis and understand how far population parameter significant based on estimator with the help of parametric tests. Non parametric tests can also observed.
7. Define analysis of variance helps in study total variation
8. Know application of Analysis in field or lab experimental to design and factorial experiments.
9. Apply the knowledge in research objects about reliability and validity experimental study.

SEMESTER -IV

Journal club

Upon completion of the course student will be able to

1. Critically appraise the research article of their specialization published in reputed journals. Students are trained for inquiry based learning and critical thinking skills.
2. Access journals by adopting search engines and made to collect relevant data, analyse and comment on the findings with the submission of the document evidence and present on the same for assessment

MRW 403. Project Work

Upon completion of the course student will be able to

1. Generate the topic for the project and Collect the information from the relevant sources
2. Assemble the information into a more realistic draft ethically and conclude the contents.
3. Students prepare the presentation and explain outcome of their project along with further scope for research. This develops their oratory and leadership skills.

Discussion / Final Presentation

Upon completion of the course student will be able to

1. Prepare the presentation based on the results obtained in the research work
2. Explain outcome of their project along with further scope for research. This develops their oratory and leadership skills.

COURSE: Pharmaceutical Quality Assurance

SEMESTER -I

MQA101T. Modern Pharmaceutical Analytical Techniques (Theory)

OBJECTIVE: 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.

OUTCOMES:

Upon completion of the course student will be able to

1. Understand the UV-Visible spectroscopy, IR, flame and atomic absorption spectroscopy.
2. Know principles of NMR spectroscopy, instrumentation and applications.
3. Understand the principles of mass spectroscopy, different ionization techniques and applications of mass spectroscopy.
4. Understand the different chromatographic techniques like paper, ion exchange, gas, HPLC, etc
5. Know the principles and procedures of paper and capillary electrophoresis; XRD and its applications.
6. Understand the principles and procedures of potentiometry and thermal analytical techniques like DSC and TGA.

MQA102T. QUALITY MANAGEMENT SYSTEMS (Theory)

OBJECTIVE: The importance of quality 1) ISO management systems 2) Tools for quality improvement 3) Analysis of issues in quality 4) Quality evaluation of pharmaceuticals 4) Stability testing of drug and drug substances 5) Statistical approaches for quality

OUTCOMES:

Upon completion of the course student will be able to

1. To build the knowledge of importance of quality in pharmaceutical industry.
2. To outline the guidelines related to maintain quality management in pharmaceutical industry.
3. To select the different tools for quality improvement.
4. To compare the ICH guidelines for determining stability of drug and drug substances.
5. To make use of statistical approaches to maintain quality of drug and drug products.
6. To interpret the regulatory compliance through quality management.

MQA103T. QUALITY CONTROL AND QUALITY ASSURANCE- (Theory)

OBJECTIVE:

1) Understand the CGMP aspects in a pharmaceutical industry 2) To appreciate the importance of documentation 3) To understand the scope of quality certifications applicable to Pharmaceutical industries 4) To understand the responsibilities of QA & QC departments.

OUTCOMES:

Upon completion of the course student will be able to

1. To interpret the GLP aspects in a pharmaceutical industry as per the regulatory guidelines
2. To relate and interprete CGMP guidelines as per regulatory bodies.
3. To apply specifications to analytical tests for various dosage forms as per pharmacopoeias.
4. To make use of department level and plant level documentation.
5. To justify quality guidelines applicable to Pharmaceutical manufacturing operations and infer measures taken to comply.

MQA104T. PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (Theory)

OBJECTIVE:

1) To understand the new product development process 2) To understand the necessary information to transfer technology from R&D 3) To actual manufacturing by sorting out various information obtained during R&D 4) To elucidate necessary information to transfer technology of existing products between various manufacturing places

OUTCOMES:

Upon completion of the course student will be able to

1. To understand the new product development process
2. To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
3. To elucidate necessary information to transfer technology of existing products between various manufacturing places
4. Understand concept of Pilot plant scale up
5. To Know Pharmaceutical packaging

MQA105P QUALITY ASSURANCE PRACTICAL - I (Practical)

Upon completion of the course student will be able to

1. Analyse and interpret Pharmaceutical compounds and formulations by spectrometric techniques
2. Perform and Explain chromatography.
3. Illustrate Quality management principles through case studies, process capability study and stability study
4. Perform analysis of raw materials, in-process materials and finished products as per pharmacopeia
5. Determine physicochemical properties of bulk drugs

SEMESTER –II

MQA201T. HAZARDS AND SAFETY MANAGEMENT (Theory)

OBJECTIVE: This course examines occupational safety and health practices needed to address occupational safety and health issues in the workplace.

OUTCOMES:

Upon completion of the course student will be able to

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

MQA202T. PHARMACEUTICAL VALIDATION (Theory)

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

OUTCOMES:

Upon completion of the course student will be able to

1. The concepts of calibration, qualification and validation
2. The qualification of various equipments and instruments
3. Process validation of different dosage forms
4. Validation of analytical method for estimation of drugs
5. Cleaning validation of equipments employed in the manufacture of pharmaceuticals

MQA203T. AUDITS AND REGULATORY COMPLIANCE (Theory)

OBJECTIVE:

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

OUTCOMES:

Upon completion of the course student will be able to

1. To understand the importance of auditing
2. To understand the methodology of auditing
3. To carry out the audit process
4. To prepare the auditing report
5. To prepare the check list for auditing

MQA204T. PHARMACEUTICAL MANUFACTURING TECHNOLOGY (Theory)

OBJECTIVE:

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

Upon completion of the course student will be able to

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

MQA205PA. QUALITY ASSURANCE PRACTICAL – II (Practical)

Upon completion of the course student will be able to

1. Organic contaminants residue analysis by HPLC.
2. Estimation of Metallic contaminants by Flame photometer
3. Estimation of Hydrogen Sulphide in Air
4. Estimation of Chlorine in Work Environment.
5. Sampling and analysis of SO2 using Colorimetric method
6. Validation of an analytical method for a drug
7. Qualification of at least two analytical instruments.
8. Cleaning validation of one equipment
9. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
10. Qualification of following Pharma equipment a.)Autoclave b).Hot air oven c).Powder Mixer (Dry) d.)Tablet Compression Machine

MASTER OF PHARMACY

SEMESTER -III

MRM301T. Research Methodology and Biostatistics (Theory)

Upon completion of the course student will be able to

1. Identify the concepts of medical research and values in medical ethics.
2. Define the CPCSEA guidelines for laboratory animal facility.
3. Describe the declaration of Helsinki and basic principles for medical research.
4. Understand Basic statistical methods which are used in collecting data study and analyse. Observe Errors relating experimentation
5. Perceive relation between components also measure and study linearly. We can observe one component influence with multiple factors.
6. Know testing of the hypothesis and understand how far population parameter significant based on estimator with the help of parametric tests. Non parametric tests can also observed.
7. Define analysis of variance helps in study total variation
8. Know application of Analysis in field or lab experimental to design and factorial experiments.
9. Apply the knowledge in research objects about reliability and validity experimental study

MASTER OF PHARMACY

SEMESTER -IV

Journal club

Upon completion of the course student will be able to

1. Critically appraise the research article of their specialization published in reputed journals. Students are trained for inquiry based learning and critical thinking skills.
2. Access journals by adopting search engines and made to collect relevant data, analyse and comment on the findings with the submission of the document evidence and present on the same for assessment

MRW 403. Project Work

Upon completion of the course student will be able to

1. Generate the topic for the project and Collect the information from the relevant sources
2. Assemble the information into a more realistic draft ethically and conclude the contents.
3. Students prepare the presentation and explain outcome of their project along with further scope for research. This develops their oratory and leadership skills.

Discussion / Final Presentation

Upon completion of the course student will be able to

1. Prepare the presentation based on the results obtained in the research work
2. Explain outcome of their project along with further scope for research. This develops their oratory and leadership skills