SYLLABUS FOR MRFT

PHARMACY

UNIT 1. Modern Pharmaceutical Analytical Techniques:

Theory, Principle and Applications of UV-Visible spectroscopy, IR spectroscopy, Spectro-flourimetry, Flame emission spectroscopy and atomic absorption spectroscopy, NMR spectroscopy, Mass Spectroscopy;
Chromatography: Paper Chromatography, Thin Layer Chromatography, Ion Exchange Chromatography, Column chromatography, Gas Chromatography, HPLC, and
Electrophoresis: Paper Electrophoresis, Gel Electrophoresis, Capillary Electrophoresis and Zone Electrophoresis,
X-ray Crystallography; Immunological Assay: RIA, ELISA

UNIT 2. Regulatory Affairs

Documentation in Pharmaceutical industry, Regulatory requirement for product approval, Post approval regulatory affairs, non-Clinical drug development, Clinical trials;
Role of quality systems and audits in pharmaceutical manufacturing environment; Auditing of vendors and Production Department, Auditing of Microbiological Laboratory; Auditing of Quality Assurance and Engineering Department

UNIT 3. Drug Delivery System

Sustained Release (SR) and Controlled Release (CR) formulations: Rate Controlled Drug Delivery Systems: Gastro-Retentive Drug Delivery Systems, Ocular Drug Delivery Systems: Transdermal Drug Delivery Systems, Protein and Peptide Delivery, Vaccine delivery systems

UNIT 4. Modern Pharmaceutics: -

Pre formulation Studies, Drug Stability, Validation, cGMP & Industrial Management,
Study of consolidation parameters**:** Diffusion parameters, Dissolution parameters and pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

UNIT 5. Advanced Pharmaceutical Analysis

Impurity and stability studies, Elemental impurities, Impurity profiling and degradent characterization, Stability testing of phyto-pharmaceuticals,
Biological tests and assays of the following: a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)
Immunoassays (IA): Basic principles, Production of antibodies, Separation of bound and

unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

UNIT 6: Quality Control and Quality Assurance

Concept and Evolution of Quality Control and Quality Assurance: Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house,

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA ; Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), Documentation in pharmaceutical industry, Manufacturing operations and controls:

UNIT 7. Molecular Pharmaceutics (NanoTech and Targeted DDS): Targeted Drug Delivery Systems, Targeting Methods, Micro Capsules/Micro Spheres, Pulmonary Drug Delivery Systems;Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non-viral gene transfer), Liposomal gene delivery systems.

UNIT 8: Advanced Bio pharmaceutics and Pharmacokinetics

Drug Absorption from the Gastrointestinal Tract: Bio-pharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Pharmacokinetics, Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

Application of Pharmacokinetics: Modified release drug products, Targeted drug delivery system.Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics and Chronotherapeutics.

UNIT 9. Advanced Pharmaceutical Technology:

Formulation Development, Validation, Aspectic processing operation and parenteral dosage form development, Scale-up techniques, Process validation: Concept,Process and documentation, validation of various formulation USFDA guidelines on Process Validation, Analytical Method of validation, Cleaning validation, Computerized Systemof Validation, General Principles of Intellectual Property, Patents

UNIT 10: Cosmetics and Cosmeceuticals:

Cosmetics-Regulatory and Biological aspects, Formulation Building Blocks, Design of cosmeceutical products, Herbal Cosmetics**:** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics,

UNIT 11: Indian Systems of medicines

Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine,

Different dosage forms of the ISM.

Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality.

Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

Naturopathy, Yoga and Aromatherapy practices

a) Naturopathy - Introduction, basic principles and treatment, modalities.
b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils. Formulation development of various systems of medicine Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations. Schedule T – Good Manufacturing Practice of Indian systems of medicine Hrs Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records. Quality assurance in ISM formulation industry -GAP, GMP and GLP. Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias. 5 TKDL, Geographical indication Bill, Government bills in AYUSH, 12 ISM, CCRAS, CCRS, CCRH, CCRU

Course: Audits and Regulatory Compliance	Course Code. PHQA C203	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: cGMP regulations, auditing of different departments.		
Course outcome: To understand the importance of auditing and understand the methodology of auditing. Preparation of auditing report.		

Unit	Contents	Hours
1	**Introduction:** Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	**Role of quality systems and audits in pharmaceutical manufacturing environment:** cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.	12
3	**Auditing of vendors and production department:** Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12
4	**Auditing of Microbiological laboratory:** Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12
5	**Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12
Total		60

Course:	Course Code. PHQA C204	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: Knowledge of Pharmaceutical industry development, concept of quality by design.		

Course outcome:

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

Unit	Contents	Hours
1	**Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing. **Plant layout:** Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. **Production planning:** General principles, production systems, calculation of standard cost, process planning, routing, dispatching of records, production control.	12
2	**Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). **Advanced sterile product manufacturing technology:** Area planning & environmental control, wall and floor treatment, fixtures and machineries, personnel flow, utilities & utilities equipment location, engineering and maintenance. **Process Automation in Pharmaceutical Industry:** With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP) Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.	12

3	**Non-sterile manufacturing process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). **Advance non-sterile solid product manufacturing technology:** Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.	12
4	**Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material	12
5	**Quality by design (QbD) and process analytical technology (PAT):** Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.	12
Total		60