

F.Y.M. Pharm (Pharmaceutics)

Semester I

Subject: Modern Pharmaceutical Analytical Techniques **Subject Code: MPAT101T**

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPAT101T.1** To apply the Spectrometric techniques for identification, characterization, quantification and structural elucidation of drugs by using the knowledge of UV, IR, Mass, NMR, Spectrofluorimetry and Flame emission techniques.
- CMPAT101T.2** To apply the Chromatographic techniques for identification, characterization, quantification and separation of drugs by using the knowledge of HPLC, HPTLC, Ion exchange, Gas, Affinity, Gel, Ultra HPLC
- CMPAT101T.3** To apply the knowledge for research using Electrophoretic and X Ray Crystallography Techniques.
- CMPAT101T.4** To apply the knowledge for research using Thermal Techniques

Subject: Drug Delivery Systems

Subject Code: MPH101T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPH102T.1** The various approaches for development of novel drug delivery systems.
- CMPH102T.2** The criteria for selection of drugs and polymers for the development of delivering system.
- CMPH102T.3** The formulation and evaluation of Novel drug delivery system

Subject: Modern Pharmaceutics

Subject Code: MPH 103T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPH103T.1** The elements of preformulation studies.
- CMPH103T.2** The Active Pharmaceutical Ingredients and Generic drug Product development
- CMPH103T.3** Industrial Management and GMP Considerations.
- CMPH103T.4** Optimization Techniques & Pilot Plant Scale Up Techniques
- CMPH103T.5** Stability Testing, sterilization process & packaging of dosage forms.

Subject: Pharmaceutics (Practical)

Subject Code: MPH 105P

Course learning objectives related to knowledge, skill and attitude: on completion of laboratory experiments, learner should be able to:

- CMPH105P.1** Principles, instrumentation and analysis of drug samples using UV, HPLC, GC, Flame photometry and Fluorimetry.
- CMPH105P.2** Determination of drug release rate of the marketed CR and SR tablets using USP dissolution test apparatus
- CMPH105P.3** To formulate and evaluate SR/ CR, Floating and Osmotically controlled drug delivery system.
- CMPH105P.4** To prepare and evaluate Mucoadhesive tablets and transdermal patches.
- CMPH105P.5** Determine similarity factor in two dosage forms.

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

Subject: Molecular Pharmaceutics

Subject Code: MPH 201T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPH 201T.1** The various approaches for development of novel drug delivery systems.
- CMPH 201T.2** The criteria for selection of drugs and polymers for the development of NTDS
- CMPH 201T.3** The formulation and evaluation of novel drug delivery systems.

Subject: Advanced Biopharmaceutics & Pharmacokinetics

Subject Code: MPH202T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPH202T.1** The basic concepts in biopharmaceutics and pharmacokinetics.
- CMPH202T.2** The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- CMPH202T.3** The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- CMPH202T.4** The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- CMPH202T.5** The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Subject: Computer Aided Drug Development

Subject Code: MPH 203T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPH203T.1** History of Computers in Pharmaceutical Research and Development
- CMPH203T.2** Computational Modeling of Drug Disposition
- CMPH203T.3** Computers in Preclinical Development
- CMPH203T.4** Optimization Techniques in Pharmaceutical Formulation
- CMPH203T.5** Computers in Market Analysis
- CMPH203T.6** Computers in Clinical Development
- CMPH203T.7** Artificial Intelligence (AI) and Robotics
- CMPH203T.8** Computational fluid dynamics (CFD)

Subject: Cosmetics and Cosmeceuticals

Subject Code: MPH 204T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPH 204T.1** Key ingredients used in cosmetics and cosmeceuticals.
- CMPH 204T.2** Key building blocks for various formulations.
- CMPH 204T.3** Current technologies in the market
- CMPH 204T.4** Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- CMPH 204T.5** Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

S. Y. M. Pharm (Pharmaceutics)
Semester III

Subject: Research Methodology & Biostatistics

Subject Code: MRM 301T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMRM 301T.1** Understand & explain research methodology & Biostatistics along with their applications.
- CMRM 301T.2** Discuss basic principles of medical research, importance of communication along with medical care.
- CMRM 301T.3** Elaborate CPCSEA guidelines for laboratory animal facility.

F. Y. M. Pharm (Pharmacognosy)
Semester –I

Subject: Advanced Pharmacognosy – I (Theory)

Subject Code: (MPG 102T)

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPG102T.1** Understand & explain advances in cultivation, collection & production of herbal drugs.
- CMPG102T.2** Elaborate marine natural products & nutraceuticals.
- CMPG102T.3** Discuss phytopharmaceuticals for their occurrence, utility & medicinal significance.
- CMPG102T.4** Discuss importance of pharmacovigilance systems including WHO & AYUSH guidelines in this regard

Subject: Phytochemistry (Theory)

Subject Code: (MPG 103T)

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPG103T.1** Elaborate the phytoconstituents of medicinal utility, their extraction, isolation & characterization including general process of natural product drug discovery.
- CMPG103T.2** Understand & explain biosynthetic pathways & various tracer techniques.
- CMPG103T.3** Discuss phytochemical fingerprinting & structure elucidation of phytoconstituents.

Subject: Industrial Pharmacognostic Technology (Theory)

Subject Code: (MPG 104T)

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPG104T.1** Discuss infrastructural requirements for setting of herbal drug industry involved in production & standardization of herbal products as per official guidelines.
- CMPG104T.2** Elaborate evaluation of herbal products as per official guidelines and patenting of herbal drugs including their trade.

Subject: Pharmacognosy (Practical – I)

Subject Code: MPG 105P

Course learning objectives related to knowledge, skill and attitude: on completion of laboratory experiments, learner should be able to:

CMPG105P.1 Understand & explain standardization of phytopharmaceuticals by various analytical techniques like UV spectroscopy, Gas chromatography, Flame photometry, etc.

CMPG105P.2 Elaborate development of fingerprint of plant extracts of industrial utility.

CMPG105P.3 Prepare & evaluate various herbal dosage forms including monograph analysis of clove & castor oil.

Class: F. Y. M. Pharm. (Pharmacognosy)

Semester -II

Subject: Medicinal Plant Biotechnology

Subject Code: MPG 201T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPG201T.1** Understand and explain the principal and applications of plant biotechnology including molecular biology.
- CMPG201T.2** Discuss different tissue culture & immobilization techniques & their applications for improved production of Secondary Metabolites.
- CMPG201T.3** Discuss various biotechnological techniques like biotransformation, fermentation, transgenesis, etc. for obtaining & improving quality of natural products.

Subject: Advanced Pharmacognosy II

Subject Code: MPG 202T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPG202T.1** Comprehend toxicity, regulations & validation of herbal therapies.
- CMPG202T.2** Explain adulteration & deterioration of herbal drugs along with evaluation techniques for the same.
- CMPG202T.3** Explain adulteration & deterioration of herbal drugs along with evaluation techniques for the same.
- CMPG202T.4** Discuss analytical & biological screening of herbal drugs

Subject: Indian Systems of Medicines (Theory)

Subject Code: (MPG 203T)

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPG203T.1** Understand & explain principle & theory of traditional systems of medicines including naturopathy, Yoga & Aroma practices along with method of preparation of TSM formulations.
- CMPG203T.2** Comprehend current good manufacturing practices of Indian System of Medicines & their formulations.

Subject: Herbal Cosmetics (Theory)

Subject Code: MPG 204T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPG204T.1** Understand the basic principles of various herbal/natural cosmetic preparations and standardization
- CMPG204T.2** Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

Subject: Herbal Cosmetics (Practical)

Subject Code: MPG 205P

Course learning objectives related to knowledge, skill and attitude: on completion of laboratory experiments, learner should be able to:

- CMPG205P.1** Prepare & evaluate Ayurvedic, Siddha, Homeopathy, Unani, Herbal medicinal and cosmetic formulations
- CMPG205P.2** Conduct evaluation of crude drugs by physicochemical parameters.
- CMPG205P.3** Discuss various plant tissue culture techniques.
- CMPG205P.4** Able to handle various equipments as per SOPs & learn various demonstrations (of experiments).

S. Y. M. Pharm. (Pharmacognosy)

Semester -III

Subject: Research methodology & Biostatistics (Theory)

Subject Code: MRM 301T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMRM301T.1** Understand & explain research methodology & Biostatistics along with their applications.
- CMRM301T.2** Discuss basic principles of medical research, importance of communication along with medical care.
- CMRM301T.3** Elaborate CPCSEA guidelines for laboratory animal facility.

F. Y.M. Pharm. (Pharmaceutical Quality Assurance)

Semester-I

Subject: Modern Pharmaceutical Analytical Techniques **Subject Code: MPAT101T**

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPAT101T.1** To apply the Spectrometric techniques for identification, characterization, quantification and structural elucidation of drugs by using the knowledge of UV, IR, Mass, NMR, Spectrofluorimetry and Flame emission techniques.
- CMPAT101T.2** To apply the Chromatographic techniques for identification, characterization, quantification and separation of drugs by using the knowledge of HPLC, HPTLC, Ion exchange, Gas, Affinity, Gel, Ultra HPLC.
- CMPAT101T.3** To apply the knowledge for research using Electrophoretic and X Ray Crystallography Techniques.
- CMPAT101T.4** To apply the knowledge for research using Thermal Techniques.

Subject: Quality Management System (Theory)

Subject Code: MQA102T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMQA102T.1** Understand the importance of quality with ISO management systems.
- CMQA102T.2** Understand the importance of quality with ISO management systems.
- CMQA102T.3** Describe analysis of issues in quality
- CMQA102T.4** Explain Quality evaluation of pharmaceuticals
- CMQA102T.5** Explain Quality evaluation of pharmaceuticals

Subject: Quality Control and Quality Assurance (Theory) Subject Code: MQA103T
Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

CMQA103T.1	Understand the cGMP aspects in a pharmaceutical industry
CMQA103T.2	Appreciate the importance of documentation in Pharmaceutical industries
CMQA103T.3	Understand the scope of quality certifications applicable to Pharmaceutical industries
CMQA103T.4	Understand the responsibilities of QA & QC departments.

Subject: Product Development and Technology Transfer (Theory) Subject Code: QA104T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CQA104T.1** Understand the new product development process
- CQA104T.2** Understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D.
- CQA104T.3** Elucidate necessary information to transfer technology of existing products between various manufacturing places

Pharmaceutical Quality Assurance (Practical I)

Subject Code: MQA105P

Course learning objectives related to knowledge, skill and attitude: on completion of laboratory experiments, learner should be able to:

- CMQA105P.1** Perform analysis of Pharmacopoeial compounds in bulk and in their formulations along with simultaneous estimation of multi-drug component by UV spectrophotometry along with perform experiments based on HPLC, Gas Chromatography
- CMQA105P.2** Perform estimation of compounds by fluorimetry, flame photometry or AAS
- CMQA105P.3** Develop of stability study protocol & estimate process capability and perform In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
- CMQA105P.4** Develop of stability study protocol & estimate process capability and perform In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
- CMQA105P.5** Perform Assay of raw materials as per official monographs & Testing of related and foreign substances in drugs and raw materials
- CMQA105P.6** Carry out pre formulation study for tablets, parenterals & study the effect of pH on the solubility of drugs and to perform Quality control tests for Primary and secondary packaging materials with Accelerated stability studies.

F. Y.M. Pharm. (Pharmaceutical Quality Assurance)

Semester-II

Subject: Hazards and Safety Management (Theory)

Subject Code: MQA201T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMQA201T.1** Understand about environmental problems related to natural resources and ecosystem including environmental hazards
- CMQA201T.2** Study air based hazards and processes for prevention of it.
- CMQA201T.3** Study chemical based hazards and control measures for it, management of combustible gases and over exposure to chemicals
- CMQA201T.4** Get knowledge about fire and explosion hazards and to implement safety standards and management of fires and explosion
- CMQA201T.5** Study the factory acts and rules and processes of risk managements.

Subject: Pharmaceutical Validation (Theory)

Subject Code: MQA 202T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMQA202T.1** Understand concepts of calibration, qualification and validation
- CMQA202T.2** Qualification of various Manufacturing and Laboratory equipment and validation of utility systems
- CMQA202T.3** Study different Concept, Process and documentation of Process Validation, ICH and guidelines regarding analytical method development USFDA guidelines regarding process validation
- CMQA202T.4** Understand the concept of cleaning validation and computerized system validation
- CMQA202T.5** Study the principles of intellectual property consisting of IP, IPP, IPR, copyright and trademark, types of patents, its applications and responsibilities of patentees

Subject: Audits and Regulatory Compliance (Theory)

Subject Code: MPA 203T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMPA203T.1** understand objectives, management, responsibilities, planning and administration of auditing.
- CMPA203T.2** study auditing processes in pharmaceutical manufacturing environment
- CMPA203T.3** auditing of vendors and production department consisting bulk manufacturing, packaging material, storage and warehousing and dry production
- CMPA203T.4** study the microbiological laboratory auditing consisting of manufacturing process, Product and process information, building raw materials and Water, Packaging materials.
- CMPA203T.5** auditing of quality assurance and engineering department consisting of QA department, critical systems of Q. A.

Subject: Pharmaceutical Manufacturing Technology

Subject Code: MQA204T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMQA204T.1** The common practice in the pharmaceutical industry developments, plant layout and production planning
- CMQA204T.2** Understand the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
- CMQA204T.3** Understand the principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in Pharmaceutical manufacturing

Subject: Pharmaceutical Quality Assurance (Practical-II)

Subject code: MQA205P

Course learning objectives related to knowledge, skill and attitude: on completion of laboratory experiments, learner should be able to:

- CMQA205P.1** perform analysis of Organic contaminants residue analysis by HPLC and estimation of Metallic contaminants by Flame photometer
- CMQA205P.2** identify of antibiotic residue by TLC and Estimation of Hydrogen Sulphide in Air as well as Chlorine in Work Environment
- CMQA205P.3** perform Sampling and analysis of SO₂ using Colorimetric method
- CMQA205P.4** perform qualification of Autoclave, Hot air oven, Powder Mixer (Dry) Tablet compression Machine, Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)and two analytical instruments
- CMQA205P.5** perform validation of an analytical method for a drug and processing area and Cleaning validation of one equipment
- CMQA205P.6** design of plant layout: Sterile and non-sterile products and do Check list for Bulk Pharmaceutical Chemicals vendors, tableting production, sterile production area, Water for injection.
- CMQA205P.7** explain Case study on application of QbD and PAT

S. Y. M. Pharm. (Pharmaceutical Quality Assurance)

Semester -III

Subject: Research methodology & Biostatistics (Theory)

Subject Code: MRM 301T

Course learning objectives related to knowledge and cognitive skills: Upon the completion of theory topics, learner should be able to:

- CMRM 301T.1** Understand & explain research methodology & Biostatistics along with their applications.
- CMRM 301T.2** Discuss basic principles of medical research, importance of communication along with medical care.
- CMRM 301T.3** Elaborate CPCSEA guidelines for laboratory animal facility.