

# Rajasthan University of Health Sciences, Jaipur

## Syllabus

### M.Pharm. (Pharmaceutics)

#### First Semester

M.Ph.111T

Methods in Pharmaceutical Research, Theory

60 Hrs,

**UV- Visible spectroscopy:** Brief review of electromagnetic spectrum, UV-Visible range, energy- wavelength-color relationships. Interaction of electromagnetic radiation (UV-Vis) and matter and its effects, chromophores and their interaction with E.M.R. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs, shifts and their interpretations (including solvent effects); photo-acoustic spectroscopy.

**Infra- Red spectroscopy:** Nature of I.R. radiation, interaction of I.R. radiation with organic molecules and effects on bonds, molecular on infra- red spectra including sample preparation for spectroscopy, qualitative interpretation of I.R. spectra, quantitative methods and recent advances in I.R. spectroscopy including FTIR, ATR, etc.

**Nuclear Magnetic Resonance spectroscopy:** Fundamental principles of NMR (magnetic properties of nuclei: applied field and precession: absorption and transition frequency), chemical shifts concept, factors affecting chemical shift, isotopic nuclei, reference standards; Proton magnetic spectra, their characteristics, presentation, term used in describing spectra and their interpretation (number position and intensity of signal), brief outline of instrumental arrangements and some practical details, signal multiplicity phenomenon in high resolution PMR; Spin –spin coupling, application of signal splitting and coupling constant data to interpretation of spectra, proton exchange reaction, decoupling and shift reagent methods.

**Brief outline of principles of FT-NMR with reference to  $^{13}\text{C}$ -NMR:** Spin- spin and spin- lattice relaxation phenomenon, free induction decay (FID), proton noise decoupling, signal averaging time domain and frequency domain signals, nuclear overhauser enhancement:  $^{13}\text{C}$ -NMR spectra; their presentation, characters tics, interpretation, examples and applications.

Brief indication of application of magnetic resonance spectral data of other nuclei by modern NMR instruments, introduction to 2-D NMR techniques.

**Mass Spectrometry:** Basis principles and brief outline of instrumentation, ion formation and types; molecular ions, meta stable ions, fragmentation, patterns and fragment characteristics in relation to parent structure and functional groups, relative abundances of isotopes and their contribution to characteristics peaks, mass spectrum; its characteristics, presentation and interpretation, chemical ionization mass spectrometry, GC-MS including recent advances in MS, Fast atom bombardment mass spectroscopy; analysis of drugs in biological samples by combined GC-MS.

**Chromatography:** Basis principles, instrumentation, methodological techniques and quantitative analysis of drugs and their metabolites using column chromatography, paper chromatography, TLC, ion exchange chromatography, GC, GLC, HPLC and HPTLC.

**Electrophoresis:** Moving boundary electrophoresis, zone electrophoresis, isotachopheresis, iso-electric focusing and continuous electrophoresis.

**Fluorimetry: and chemiluminescence:** Principle, instrumentation and applications; electro- chemiluminescence resonant ionization and Laser- enhanced ionization.

X-ray crystallography, thermal methods of analysis, DSC, SEM etc.

Experiments based on calibration and validation of analytical instruments.

Qualitative and quantitative analysis of pharmaceutical preparations and dosages having single component or in combination of following categories having single component or in combination of following categories: (biological and microbiological methods excluded).

(i) Alkaloid (ii) Antibiotics (iii) steroidal hormones (iv) Vitamins (v) Barbiturates (vi) Sulfa drugs.

U.V./Visible spectrum scanning of certain organic compounds. Absorption and correlation of structures. comparison e.g., chloramphenicol, analgin, paracetamol, sulphadiazine, ibuprofen etc., effect of pH and solvent on UV spectrum of certain drugs.

Estimation of single drug (raw material/ formulations) by colorimetry involving different reagents.

Determination of UV cut off wavelength for different solvents.

Estimation of single drug (raw material/ formulations) by UV spectrophotometry.

Simultaneous estimation of paracetamol and ibuprofen and other combination formulations by UV spectrophotometry using simultaneous equations/ derivative spectroscopy etc.

Comparison of three different analytical methods for salbutamol or other drugs.

Calibration of IR spectrophotometer using polystyrene film and checking the performance of the instrument.

Recording IR spectra for known drugs and comparing with that of Pharmacopoeia, estimation of drug using IR.

IR spectra of simple molecules and interpretation of the same.

Estimation of drugs by fluorimetry.

Estimation of drugs by flame photometry.

Structural elucidation of at least 5 unknown compounds using UV, IR, NMR, and Mass spectral data.

**Fundamental Aspects of product Development:** Studies of wettability, solubility, dissolution, and absorption, surfactant and hydrocolloids and their role in drug delivery and targeting.

**Designing of oral Pharmaceutical:** Formulation, evaluation, stability Studies and recent advances in dosage form; tablet, capsule, suspension, emulsion; microencapsulation, advances in coating techniques.

**Development of parenterals:** Concepts, formulation, evaluation of large and small volume parenterals, environmental control and quality assurance in manufacturing.

**Ophthalmic Preparation:** Introduction, Physiology of eye, formulation consideration and evaluation of ophthalmic products ( ointments, suspension, eye drops, contact lenses, occuserts etc.), container and closures.

**Pulmonary Preparations:** DPI, Aerosols: Basic Preparation and type of preparation, formulation and evaluation, containers recent developments of pressurized dosages forms.

**Suppositories:** Selection of suppository bases, characteristics of bases, formulation, preparation, evaluation and packaging of suppositories, stability studies and recent development.

**Dermatological Preparations:** Anatomy and physiology of skin, mechanism of absorption through skin including mathematical treatment, formulation and evaluation of ointments, creams, paste, gels including herbal cosmetic creams.

**Stability Studied:** Basic concepts, consideration of physical and chemical stability studies, determination of shelf life, problems encountered during storage of dosages forms.

Validation of dissolution test apparatus.

Determination of molecular weight of the given polymer.

Enhancement of solubility of the given drug by solid dispersion technique.

Performance of powder glass test on different type of glasses.

Performance of water attack on treated soda lime glass container.

Formulation and evaluation of matrix tablet of given drug.

Formulation and characterization of topical gels of some anti-inflammatory drugs.

Comparison of release rate profile of conventional and sustained release tablets.

Preparation of microcapsules by different techniques and their evaluation

Determination of shelf life of aspirin by accelerated stability studies.

Evaluation of spherical crystallization as a particle size enlargement technique for aspirin.

Formulation and evaluation of ophthalmic dosage forms.

Performance of physical stability and dissolution studies of the suspension of given drug.

Formulation and evaluation of suppositories of given drug.

Determination of the effect of process variable on physicochemical characteristics and in-vitro release profile of microcapsule.

**M.PH.114P**

**Advanced Pharmaceutics &  
Biotechnology, Theory**

**60Hrs.**

**Formulation considerations:** preformulation studies in development of solid, oral liquid and parenteral dosage form; solubility, dissolution rate, pka, partition coefficient, stability etc., in- vivo evaluation techniques.

**Production Management And Documentation:** ISO 9000 Series, Intellectual Property Rights, Total Quality Management, GMP And Quality Assurance, Validation For Table And Parenterals, Practice of WHO GMP.

**Pilot Plant Scale up Techniques:** Significance of pilot plant scale up phase, laboratory procedure and Formulations, routine production procedure, Discussion on important parameter such as formulation, equipments etc, pilot study of dosage form such as tablets, capsules and oral liquid.

**Pharmaceutical Packaging Technology:** Selection and evaluation of pharmaceutical packaging materials, containers and closures, problem of container- product interaction pharmacopoeial specifications, test and standards for packaging materials.

**Industrial Safety:** Industrial hazards and their prevention, fire, accidents, mechanical and electrical equipments, industrial effluent testing and treatment.

**Biotechnology:** Introduction, importance and application of pharmaceutical application of enzymes, application of immobilization in design of novel drug delivery systems and drug targeting.

**Tissue Culture:** Introduction, types of culture micropropagation protoplast microinjection plant tissue culture animal cell culture pharmaceutical application of plant and animal tissue culture production of commercially useful compounds by plant cell culture, growth of cell in bioreactor and production of active principles, bioreactor, tissue culture based pharmaceutical industries.

**Recombinant DNA Technology ad Genetics:** Basis concept of DNA, protein synthesis and targeting, genetic recombination, gene transfer methods in prokaryotes and eukaryotes, techniques of genetic engineering, application of recombinant DNA technology in proteins, vaccines, hormones production, genetic disorders and gene therapy.

## Second Semester

**M.121T**

**Advance in Pharmaceutical Science  
Including Biostatistics, Theory**

**60 Hrs**

Biostatistics: The application of the following in pharmacy shall be covered.

Mean, median and mode, standard deviation and coefficient of variation, student-test, one way ANOVA, chi-square test, probability, frequency distribution, regression analysis, bioavailability-cross-over study, Wilcoxon signed rank test, introduction to control charts.

Pharmainformatics: introduction to information resources available on the internet for the various subjects in pharmacy.

Experimental Design: Introduction to full factorial designs. Centrals composite designs, evolution of full and reduced mathematical models in experimental designs, applications of the experimental designs for the subjects mentioned under pharmainformatics, introduction to contour plots.

Patents: Definition, need for patenting, types of patents, conditions to be satisfied by an invention to be patentable, introduction to patent search.

The essential element of parent: Guideline for preparation of laboratory notebook, non obviousness in parent, drafting of parent claims, important patent related web-sites, brief introduction to trademark protection and WTO patents.

Introduction to 'The Patent Act 1970' as amended in 1999, 202 & 2005 and the rule made there under, with special emphasis on the form to be submitted along with a patent application.

Biological evaluation of the following classes of drugs: analgesics, anti-inflammatory agent, tranquilizers, hypoglycemic agents and diuretic agents.

Introduction to various stage in process of drug development. Scope and aims of preclinical and clinical trials for drugs and dosage forms.

Pharmacopoeial methods for evaluation of crude drugs, mono or polyherbal formulation by F.O.M. determination, L.O.D., ash values, extractive value, phytomorphology, microscopical methods, quantitative microscopy, qualitative

analysis, pesticide analysis, microbial content determination and evaluation by other advanced methods like UV, IR, GLC, HPLC, TLC, & HPTLC etc.; automated analysis – Computer aided Analysis.

Drug Stability: Solution stability, solid stability, parameters for physical stability testing, protocol for physical stability testing program, accelerated studies and shelf life assignment.

**M.122P**

**Advances in Pharmaceutical sciences  
Including Biostatistics, Practical**

**90 Hrs**

Animal experiment for determination of activity, potency and toxicity of drug substance and dosage forms.

Parameter studies for physical stability of drug.

Shelf life study of formulations.

Evaluation of crude drugs.

Evaluation /standardization of extract based on WHO guidelines.

Isolation, separation, purification and identification of important phytoconstituents.

Practical exercise based on student 't' test, one –way ANOVA, Chi- square test, first and second order equations. Calculation of RF value, mean, median, mode, standard deviation, Stoke's linear trapezoidal rule.

Cumulative percentage drug release, linear regression, and other simple programs of pharmaceutical interest.

Practical exercise based on biostatistics in clinical research.

Preparing protocol on various validation requirement.

Polymer and their Application in Development of NDDS: Introduction, basis properties of biodegradable and non biodegradable polymers and their uses.

Sustained Release Drug Delivery System: Principle involved, advantages and disadvantages, dose considerations, physical- chemical and biological properties of drugs relevant to sustained release formulation, micro encapsulation, evaluation and stability studies of SRDF.

Oral controlled Drug Delivery System: Principle involved, basis concept , osmotic pressure controlled, membrane permeation controlled, pH independent, ion exchange, controlled gel diffusion, controlled and hydro dynamically balanced systems, evaluation.

Mucosal Drug Delivery System: Introduction, anatomy and physiology of oral mucosal, mechanism of Transmucosal permeation and mucous membrane models, buccal, nasal, pulmonary, rectal, vaginal, drug delivery system, delivery of peptides based pharmaceuticals.

Transdermal Drug Delivery System : Fundamental of transdermal permeation and factors affecting it, permeation enhancers, development of transdermal drug delivery system, evaluation and recent developments.

Targeted Drug Delivery System : Principles of targeting, method of targeting preparation and evaluation of vesicular carrier systems such as liposomes, aquasomes, niosomes, pharmacosomes, dendrimers and particulate carrier systems such as nano particles, micro spheres, modified micro spheres, solid lipid nano particles (SLN), liquid crystals, resealed erythrocytes, monoclonal antibodies, interaction of colloidal delivery system with biological environment, surface modification of colloidal drug delivery systems.

Parenteral Drug Delivery System: Basis concepts and approaches to parenterals, controlled release of drugs, formulation of parenteral controlled release, implants.

Intravaginal and intrauterine Drug Delivery System: Introduction, vaginal contraceptive ring, medicated IUD, copper IUD, hormone releasing IUD.

**M.PH.123T**

**Novel Drug Delivery System, Practical**

**60 Hrs**

Characterization of given polymers such as viscosity, molecular weight and glass transition temperature.

Evaluation of drug free polymeric films.

In-vitro characterization of transdermal patches of given drug.

Development and evaluation of ocular inserts of given drug.

Formulation and evaluation of floating microspheres.

Formulation and evaluation floating tablets.

Preparation and evaluation of buccal film of some cardiovascular drugs.

Taste abatement of some bitter drugs by ion-exchange resins.

Preparation and physico-chemical characterization of microcapsules of given drug.

Development and evaluation of osmotically controlled drug delivery system.

Study of effect of solubility enhancers on diffusion of poorly water soluble drugs.

Preparation and evaluation of muco-adhesive microspheres.

Preparation characterization of wax embedded microspherules of given drugs.

Preparation and characterization of – (a) liposome (b) niosomes (c) nanoparticles

**M.PH.125T**

**Biopharmaceutics and  
Pharmacokinetics, Theory**

**60 Hrs**

**Drug Absorption:** Gastrointestinal absorption of drugs, mechanism of drug absorption, physico-chemical, biological factors influencing absorption, buccal absorption, salivary excretion of drugs.

**Drug Distribution, Biotransformation and Excretion:** Factor affecting drug distribution, volume of biotransformation and factor affecting it, renal and non-renal excretion, concept of clearance and kinetics.

**Bioavailability and Bioequivalence:** Introduction, factor influencing bioavailability methods to determine bioavailability, designing the study for assessment of bioavailability and bioequivalence, in-vitro and in-vivo correlation of bioavailability, methods to enhance bioavailability, statistical concepts.

**Pharmacokinetics:** Basis consideration of one, two and multiple compartment models including IV- bolus, IV infusion and extra vascular administration, kinetics of multiple dosing, dosage regimens (loading and maintenance dosage)

**Clinical Pharmacokinetics:** Concepts, absorption, distribution and renal excretion, hepatic clearance and elimination, disposition and absorption kinetics, therapeutic regimen, therapeutic response and toxicity, dosage regimen, clinical based studies.

**Physiologic Pharmacokinetics Models:** Basis concepts, physiologic Pharmacokinetics model with building, blood flow- limited versus diffusion limited model, application and limitation Pharmacokinetics models, mean residence time (MRT), statistical moment theory (SMT).

**Non- linear Pharmacokinetics:** Recognition of non- linearity, one and two compartment open model with Michael is- Menton Kinetics, determination of  $k_m$ ,  $V_{max}$ , nonlinear tissue building constants.

**Applications of Computer:** Introduction, application of computers in pharmacokinetics and biostatistics.