# Pharmaceutical Analysis

**M.S (Pharm.)**

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Total Credits (I to IV semesters) 50
Semester-I

PA-510 Topics in Pharmaceutical Analysis (2 credits)

1. Introduction to pharmaceutical analysis and techniques.
3. Reference standards.
4. Documentation-STPs, certificate of analysis, laboratory books.
5. Introduction to methods development.
8. Impurity profiling.
10. Automation and computer-aided analysis, LIMS.
11. Management of analytical laboratory.
12. Laboratory inspections.

MC-511 Spectral Analysis (2 credits)

1. Ultra violet and visible spectroscopy: Energy levels and selection rules, Woodward-Fieser and Fieser-Kuhn rules. Influence of substituent, ring size and strain on spectral characteristics; Solvent effect; Stereochemical effect; Non-conjugated interactions; Spectral correlation with structure.
3. Nuclear magnetic resonance spectrometry (NMR): Magnetic nuclei, chemical shift and shielding, relaxation processes, chemical and magnetic non-equivalence, local diamagnetic shielding and magnetic anisotropy, spin-spin splitting, Pascal's triangle, coupling constant, mechanism of coupling, quadrupole broadening and decoupling, effect of conformations and stereochemistry on the spectrum, diastereomeric protons, virtual coupling, long range coupling-epi, peri, bay effects. Shift reagents-mechanism of action, spin decoupling, double resonance.
4. Mass spectrometry (MS): Molecular ion and metastable peak, fragmentation patterns, nitrogen and ring rules, McLafferty rearrangement, electron and chemical ionization modes, applications.

NP-510 Separation Techniques (1 credit)

1. Chromatography: General principles, classification of chromatographic techniques, normal and reversed phase, bonded phase, separation mechanisms.
2. Column chromatography: Merits and demerits, short-column chromatography and flash chromatography, vacuum liquid chromatography (VLC), medium pressure liquid chromatography, high pressure liquid chromatography (HPLC).
3. TLC, HPTLC, over pressure layer chromatography (OPLC), centrifugal chromatography.
4. Counter-current chromatography, droplet counter-current chromatography, ion-exchange, affinity, size exclusion and ion-pair chromatography.
5. Gas chromatography, introduction to GC-MS and LC-MS techniques.
**PE-510 Dosage Form Design Parameters (1 credit)**

1. *Physicochemical aspects:*
   a. pKa
   b. Partition Coefficient
   c. Solubility
   d. Solid state characterization and physical behavior of drugs.
   e. Reaction kinetics and mechanisms.

2. *Biological aspects:*
   a. Role of physicochemical parameters on drug absorption and their implications.
   b. Routes of administrations and implications on bioavailability
   c. Physicochemical aspects of drugs and first pass metabolism.

3. *Dissolution:*
   a. Theories of dissolution, release rates and constants.
   b. Mechanisms of conventional release and controlled release.
   c. Dissolution data handling and correction factors.
   d. Dissolution equipments
   e. IVIVC.

**BT-510 Biotechnology in Pharmaceutical Sciences (1 credit)**


2. *Genomics in target discovery:* Concept of genome, genes and gene expression. Genome sequencing and sequence comparison methods (e.g. BLAST), gene expression comparison methods (microarray). Comparative genomics and expression genomics for target discovery of communicable disease and lifestyle disease.


5. *Bioprocess technology:* Introduction to microbial growth, media formulation, fermentation processes, design, operation and characteristics of fermentation processes, instrumentation and bioprocess control.

6. *Downstream process:* Introduction to various downstream process operations in biopharmaceutical manufacturing such as centrifugation, filtration, tangential flow filtration, cell disintegration, solvent-solvent extraction, supercritical fluid extraction etc.

7. *Biotechnology in pharmaceutical industry:* Major areas for biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF & therapeutic proteins etc.); Commercial aspects, priorities for future biotechnological research.

8. *Industrial enzymes in drug development:* Penicillin amidase, lipase, oxidoreductase, nitrilase, protease etc. Use of all these enzymes for enantioselective synthesis of pharmaceutically important drugs/drug intermediates, future directions.
PT-560 Fundamentals of Intellectual Property (IP) and Technology Management (1 credit)

1. Intellectual property: Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property-patents, copyrights, trademark; Factors effecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.

2. Trade related aspects of intellectual property rights: Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology / drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.

3. Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS: Filing of a patent application; Precautions before patenting-disclosures / non-disclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search requests, costs; Patent application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications-provisional, non provisional, PCT and convention patent applications; International patenting-requirement procedures and costs; Financial assistance for patenting-introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attorneys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infringement- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists-University / organizational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related internet sites, broucherls, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Beme convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringements.

4. Technology development / transfer / commercialization related aspects: Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialization and commercialization-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personnel; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory licensing excess to medicine issues; DOHA declaration, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalization of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPS; Related registration and marketing issues; Case studies-antiretrovirals and others.

5. Funding sources for commercialization of technology: Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept-Case studies with respect to IIT, CCMB, IMTECH, NIPER. Documentation and related aspects.

6. Ethics and values in IP: IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social and environmental benefits of modern biotechnology; Voluntary adoption of pollution control strategies.
GE-510 Biostatistics (2 credits)
1. **Statistics**: Introduction, its role and uses. Collection; Organization; Graphics and pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.
2. **Probability**: Basic concepts; Common probability distributions and probability distributions related to normal distribution.
3. **Sampling**: Simple random and other sampling procedures. Distribution of sample mean and proportion.
4. Estimation and hypothesis testing: Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student- t and Chi square tests. Sample size and power.
5. **Experimental design and analysis of variance**: Completely randomized, randomized blocks. Latin square and factorial designs. Post-hoc procedures.
6. **Correlation and regression**: Graphical presentation of two continuous variables; Pearson’s product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.
7. **Non-parametric tests**: Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and Friedman two way ANOVA tests. Spearman rank correlation.
8. Statistical techniques in pharmaceutics: Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

GE-511 Seminar (1 credit)
1. Introduction, information and retrieval systems.
2. Writing term papers and reports.
4. Reading research papers.
5. Skills in oral presentation.

*Each student has to present a seminar before end of the semester.*

LG-510 General Laboratory Experience-15 hours/week (3 credits)
1. **Analytical techniques**: (75 hours)
   a. Spectral analysis workshop (45 hours)
   b. Separation Techniques (30 hours)
2. **Computer and application in pharmaceutical sciences** (100 hours): Introduction to computers, basic unit and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dBase, windows, statistical S/W programs and packages. Steps involved in S/W development, computer languages with emphasis to FORTRAN language and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
4. Biotechnology for pharmaceutical sciences (20 hours)
   Day-1: Preparation for plasmid miniprep.
   Day-2: Plasmid miniprep and restriction digestion.
   Day-3: Gel electrophoresis and molecular weight calculation.
   Day-4: Discussion of result and viva.
5. **Specialization** (50 hours)
   a) To calibrate thermometer
b) To calibrate the common glassware (volumetric flask, burette and pipette) found in an analytical laboratory

c) Calibration of pH meter

d) To determine water content in the given sample by Karl Fischer reagent

e) To determine moisture content in the given sample using infrared moisture balance

f) To construct calibration curve for a drug by UV spectrophotometer

g) To perform dissolution test on the given sample

h) Determination of pKa of given sample by spectrophotometric method.
Semester-II

PA-610 Pharmacopoeial Methods of Analysis (2 credits)
1. Physical tests.
2. Limit tests.
3. Special tests.
4. Microbiological assays.
5. Biological tests.
6. Dissolution tests
7. Miscellaneous tests

PA-620 Modern Instrumental Techniques for Evaluation of APIs and Drug Products (2 credits)
1. Spectroscopic techniques: FT-NIR, ATR, FT-Raman.
2. Thermal techniques: DSC, DTA, TGA
3. Particle sizing: Laser diffraction equipment, photo correlation spectroscopy.
4. Electrophoresis: Capillary electrophoresis.
5. Chromatographic techniques: HPLC
6. Hyphenated techniques: LC-MS

PA-630 Stability Testing (1 credit)
1. Drug development cycle and stability-testing.
2. Stress testing of drug substances.
4. Role of kinetic studies.
5. Stability-testing protocols.
7. Photostability testing.
8. Stability testing of biotechnological products.
10. Post-approval changes.
11. Reduced stability-testing plans.
12. Ongoing and follow-up stability-testing.

PA-640 Quality Control and Quality Assurance (2 credits)
1. Good manufacturing practices and its applications to pharmaceutical industry.
2. Basic principles and concepts of quality management viz. quality control, quality assurance, quality auditing and ISO system etc.
3. Sampling, finished products testing and release, control of packaging materials and labeling, distribution records.
5. Standard operating procedures, change control procedure and annual product review.
6. Basic principles of validation, validation protocols, analytical method validation and process validation.
7. Technology transfer from R & D to manufacturing.
8. Product change over, basic requirements of cleaning and its validation.
9. Market complaint and handling of returned goods.
**NP-640 Structure Elucidation (2 credits)**

Some typical structure elucidation insights for natural products by combination of classical, spectroscopic, synthetic and degradative methods depicting examples

1. Use of spectroscopic techniques such as $^1$H NMR, $^{13}$C NMR, NOE, DEPT, HMQC, HMBC, COSY, NOESY, HRMS and FAB mass for structural elucidation of selected natural products.

2. Structure elucidation of natural products by spectroscopy and degradative methods:

   Examples of natural products from following classes of secondary metabolites
   Alkaloids 2-3 examples; Flavonoids 2-3 examples. Sterols 2-3 examples;
   Coumarins 2-3 examples Triterpenes 2-3 examples; Xanthones 2-3 examples

**PC-611 Pharmacological Screening and Assays (1 credit)**

1. General principles of screening, correlations between various animal models and human situations and animal ethics.

2. Pharmacological screening models for therapeutic areas such as hypertension, heart failure, myocardial ischemia, cerebral ischaemia, pain, epilepsy, depression, Parkinson’s disease, Alzheimer’s disease, diabetic, leishmania etc.

3. Correlation between in-vitro and in-vivo screens; Special emphasis on cell based assay, biochemical assay, radioligand binding assay, high throughput put screening, high through put pharmacokinetic analysis, specific use of reference drugs and interpretation of results.

**PE-630 Pharmaceutical Product Development-I (2 credits)**


2. *Complexation*: Metal and organic molecular complexes, inclusion compounds with reference to cyclodextrins, methods of analysis.


5. *Micromeritics*: Particle size distribution, evaluation and its implications in formulations, measurements, and solid dosage forms.


7. Case studies will be discussed after each topic with current literature.

**PE-660 Solid State Pharmaceutics (1 credit)**

1. *Molecular Level*: Crystallinity, crystal habit, polymorphism, amorphous state, solvates, hydrates, analytical techniques for characterization, molecular modeling in solid state characterization- case studies and regulatory perspective.

2. *Particle level*: Particle size, particle shape, porosity, surface area, compaction, particle engineering in pharmaceuticals and relevance in doses form designing.

3. *Bulk level*: Bulk density, compressibility, flow properties, cohesivity, electrostatistics, aggregation, agglomeration, role in formulation development and processing.

**GE-611 Seminar (1 credit)**

Students are required to submit written record and present details of the project to be pursued in semester-III. This should include the purpose and basis of the project, stating aims, objectives and probable outcomes, be able to supplement these with necessary information, literature review towards it, and process for the project itself.
LS-610 General Laboratory Experience-10 hours/week (2 credits)

Practicals in lab:
1. Analysis of a drug sample by a pharmacopoeial method and preparation of its certificate of analysis.
2. Determination of viscosity of given samples using Ostwald viscometer and rotoviscometer.
3. Estimation of the given drug in urine and blood samples using HPLC and identification of metabolites.
4. Stress study of a drug sample in proposed conditions and establishment of a stability indicating assay using HPLC.
5. Separation of an impurity in a sample on a preparative HPLC.
7. Particle size and shape analysis using of an automated particle size analyzer.
8. Determination of tapped and bulk density.
9. Study of different packaging materials and their evaluation.
10. Determination of osmolality of given solutions.

Practicals in CIL:
1. Determination of instrument calibration, melting behavior and polymorphic behavior of various compounds by DSC.
2. Spectrofluorimetric analysis of a given sample.
3. Study of hydrate forms of ampicillin trihydrate using TGA.
4. Study of the given sample by AAS.
5. Freeze drying of a sample.
6. Separation of impurities of betamethasone velerate on LC-MS using BP method and study the mass values of impurities.
7. Study of a given mixture by GC-MS.
8. Study of given sample on polarimeter.
9. ATR analysis of a given drug sample.
10. Conduct of a titration using an autotitrator.
Ph.D. courses

PA-710 Impurity Profiling (1 Credit)
1. Introduction: Basics of impurity
2. Impurity profiling: Practical approach
3. Regulatory perspectives.
4. Basic of intrumentation techniques: HPLC, LC-MS, LC-NMR, LC-IR

PA-720 Bioanalytical Methods and Metabolite profiling (1 Credit)
1. Role of bio-analysis in drug discovery and development
2. Immuno assays in Pharmacokinetic and Pharmacodynamic bioanalysis
3. The importance of protein binding in drug development and the techniques used for measuring protein binding.
4. Metabolite profiling: practical approach
7. Bio-analytical method development, validation and transfer for high throughput bioanalytical techniques: LC-MS/MS etc.

PA-730 Method Development and troubleshooting - GC and HPLC (2 Credit)
1. Preparation of drug sample for analysis-Introduction, compatibility with the instrumental method, fundamental theories controlling preparation techniques.
2. Specific sample preparation techniques: soxhlet extraction, Liquid-liquid extraction, solid phase extraction, solid phase micro extraction, protein precipitation methods, Ultra filtration, direct injection methods, derivatization methods, residual sample preparation, different sample preparation methods for pharmaceutical dosage forms: tablets, capsules, ointments etc,
3. Gas Chromatography: inlets and injectors, GC column characteristics, GC detectors, GC preventive maintenance and trouble shooting, method development process, method validation and QA Processes
4. HPLC: Detectors- PDA, ELSD, Conductivity, UV, Refractive Index, Fluorescence, Mass, HPLC column selection and mobile phases, mobile phase additives.
5. HPLC Method development by using different stationary phases, mechanism of interactions, HPLC preventive maintenance and troubleshooting, case studies.
6. Calibration methods: external, internal and standard addition methods.
PA-740 CE and SFC in pharmaceutical analysis (2 Credit)

1. Overview of CE in pharmaceutical analysis, Basic configuration, CE characteristics, principles of CE, methods and modes of CE.
2. Improved performance of CE methods- general considerations, method development, CE as orthogonal technique to chromatography. Crown ethers as buffer additives in capillary electrophoresis.
3. SFC Introduction, developing achiral separation methods in pharmaceutical development, preps SFC, some case histories from Pharma.
4. Investigation into the use of atypical organic solvents with immobilized chiral stationary phases in SFC mode.
5. Use of chiroptical and ELSD detection in analytical and prep.SFC.
6. Pharmaceutical analysis applications.

PA-750 Liquid chromatography in Pharmaceutical Analysis (1 Credit)

1. HPLC Method development for biomolecules, monolithic stationary phases-applications, chiral stationary phases, principle of chiral recognition, molecular imprinted polymers as sorbents for separation and extraction.
2. Assay and stability testing by HPLC, application of HPLC for cleaning validation, HPLC in dissolution testing, HPLC in chiral analysis of pharmaceuticals.
4. Preparative HPLC, practical aspects of preparative HPLC: Equipment, sample solubility, effect of sample size: Touching-Band separations, column saturation capacity, gradient elution, heavily overload separations, unusual isothermal behavior and recovery.
5. Examples of preparative method developments: normal, reversed phase and chiral phases, recent advances in preparative HPLC separations.

PA-760 Analytical Chemometrics (1 Credit)

3. Propagation of measurement uncertainties (inaccuracy and imprecision).
5. Analytical validation techniques, Non-linear regression analysis, good manufacturing practice (GMP), Good lab practice (GLP), lab and industrial safety.
PA-770 Mass Spectrometry in Pharmaceutical Analysis (2 Credit)

1. Importance of chromatographic separation, mass analyzers, atmospheric pressure ionization techniques: ESI, APPI, APCI.

2. Interpretation of API mass spectra: Molecular weight determination, typical fragmentation behavior for individual functional groups: (i) phosphorous (ii) sulfur (iii) nitrogen (iv) oxygen (5) halogen substituent’s (6) alkyl and aryl substitution on the aromatic ring, polycyclic aromatic hydrocarbons, alkenes and alkynes.

3. Liquid chromatography - electrospray ionization - mass spectrometry (LC-ESI-MS) to the detection and determination of antibiotics drugs, antidiabetics, antitumour, antiretroviral drugs.

4. EI-MS of small molecular mass of selected drugs - fragmentation information.

MC-740 Advanced Topics in Drug Action and Drug Design (2 credits)

Molecular recognition and supra-molecular chemistry; Molecular associations involving weak interactions; Solvation effects on molecular associations; Metalloenzymes in medicinal chemistry; Metals in medicine- reversible and irreversible enzyme inhibition. Mechanisms of drug activation; Enzyme activation of drugs; Bioprocess prodrugs chemistry of metabolic reactions. Organic chemistry of drug metabolism- conjugation reactions, reductive reactions, oxidative reactions. Molecular interaction fields- Molecular electrostatic potentials in understanding drug action. Drug action on biomembranes- organic chemistry of drug permeability through membranes. Molecular similarity and molecular diversity in drug design.

GE- 711 Seminar (1 Credit)

1. Introduction, information retrieval systems.
2. Writing term papers and reports.
4. Reading research papers.
5. Skill in oral presentation.

*Each student has to present a seminar.*