M.S. (Pharm.) Pharmaceutical Analysis

Course No.	Course Name	Credits
Semester-I		
PA-510	Topics in Pharmaceutical Analysis	2
MC-511	Spectral Analysis	2
MC-530	Separation Techniques	1
PE-510	Pharmaceutical Preformulation-I	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-511	Seminar	1
LG-510	General Lab Experience	3
	TOTAL CREDITS	***14***
Semester-II		
PA-610	Pharmacopoeial Methods of Analysis	2
PA-620	Modern Instrumental Techniques for Evaluation of APIs and Drug Products	2
PA-630	Stability Testing	1
PA-640	Quality Control and Quality Assurance	2
PA-650	Structure Elucidation	2
PC-611	Pharmacological Screening and Assays	1
PE-630	Pharmaceutical Product Development-I	1
PE-660	Solid State Pharmaceutics	1
GE-611	Seminar	1
LS-610	General Lab Experience	3
	TOTAL CREDITS	**16**
Semester-III		
Project (22 weeks)		
TH-598	Synopsis	5
TH-599	Presentation	3
	TOTAL CREDITS	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defense of Thesis	3
	TOTAL CREDITS	**12**
GRAND TOTAL CREDITS (I to IV Semesters)		**50**

M.S. (Pharm.) Pharmaceutical Analysis

SEMESTER - I

PA-510 :- Topics in Pharmaceutical Analysis (2 Credits)	
1.	**Introduction to pharmaceutical analysis and techniques**: Scope and range of modern pharmaceutical analysis. Listing of various techniques, with a broad discussion on their applications.
2.	**Material and product specifications:** Definition of specifications, the study of ICH Q6 guidelines, and understanding of specifications through the study of pharmacopeia monographs on drug substances and products.
3.	**Reference standards**: Types (primary, secondary, working, and test standards), preparation, containers, labeling, storage, and use. Quality control tests for certified reference materials along with case studies.
4.	**Documentation-STPs, certificate of analysis, laboratory books**: Typical documents used in a GLP laboratory including standard test protocols, COA, and laboratory notebooks. Electronic records & signatures (21CFR Part-11 requirement).
5.	**Introduction to method development:** Method development concepts, steps involved, intricacies at each step.
6.	**Method validation**: Definition and methodology, discussion on each parameter with examples, special considerations for related substance method validation, and bioanalytical method validation.
7.	**Calibration and qualification of equipment**: Definition of qualification process involving URS [user requirement specification], DQ, IQ, OQ, CQ, and PQ. Difference of definitions, calibration standards, calibration frequency, examples of calibration of pH meter, FTIR, UV spectrophotometer, and HPLC.
8.	**Quality risk management in the analytical laboratory**: Definition of quality risk management in ICH Q9 guideline. Its importance and application to the analytical laboratory with examples. Analytical quality by design.
9.	**Impurity profiling**: Types of impurities in drug substances and products. Method development for impurity analysis, techniques, identification, and quantitation.
10.	Automation and computer-aided analysis, LIMS: The concept of autosamplers and high-throughput analysis, computer-controlled instrumentation, and networked laboratory. Peculiarities of laboratory information management systems (LIMS) and electronic lab notebooks.
11.	Management of analytical laboratories: Organization of laboratories based on their types, staffing, skill development and training, budgeting and financing, purchase of costly equipment, qualities of laboratory manager and management styles.
12.	Laboratory inspections and audit: Internal inspection, external audit, concepts, preparing for inspections and audits.
Recommended Books/Literature:	

1. Chemical Analysis: Modern Instrumentation Methods and Techniques by Francis Rouessac and Annick, Rouessac.
2. Principles of Analytical Chemistry by Miguel Valcarcer.
3. Analytical Method Development and Validation by Michael E. Swartz, Ira S. Krull.
4. Good Laboratory Practices by Jurg P. Seiler.
5. Principles of Instrumental Analysis by Douglas A. Skoog, F. James Holler, Timothy. A. Nineman.
6. Handbook of Modern Pharmaceutical Analysis by Satinder Ahuja, Stephen Scypinski.
7. Principles and Practice of Bioanalysis by Richard F. Venn.

MC 511 :- Spectral Analysis (2 Credits)

1.	**Ultraviolet (UV) and visible spectroscopy**:	
	(a)	Energy levels and selection rules: Definitions, molecular orbital approach for energy absorption, various modes of transitions.
	(b)	Correlation of structural variation with UV absorption: Factors influencing the position and intensity of absorptions, Inductive and resonance effects, effect of ring size, influence of stereochemical factors.
	(c)	Predicting UV absorption: Woodward-Fieser, Fieser-Kuhn and Nelson rules;
	(d)	Other factors: Non-conjugative effect, solvent effect, S-Cis band.
2.	**Infrared (IR) spectroscopy:**	
	(a)	Characteristic regions of the spectrum: Various modes of vibrations, Energy levels
	(b)	Correlation of structure with IR spectra: Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency
	(c)	Applications: Determination of stereochemistry. Spectral interpretation with examples.
3.	**Nuclear Magnetic Resonance (NMR) spectroscopy:**	
	(a)	Fundamentals: Physical basis, magnetic nuclei, resonance, relaxation processes, signal-sensitivity.
	(b)	Instrumentation: Continuous-Wave (CW) instrument, Pulsed Fourier Transform (FT) instrument, Functions, Relation with sensitivity, Sampling.
	(c)	^{1}H NMR, correlation of structure with spectra: Chemical environment and shielding, chemical shift and origin of its concept, reference compound, local diamagnetic shielding and magnetic anisotropy, relation with chemical shift, chemical and magnetic non-equivalence, spin-spin splitting and its origin, Pascal's triangle, coupling constant, mechanism of coupling, integral, NMR solvents and their residual peaks, protons on heteroatoms, quadrupole broadening and decoupling, effect of conformations and stereochemistry on the spectrum, Karplus relationship, diastereomeric protons, Heteronuclear coupling to ^{19}F and ^{31}P, virtual coupling, long range coupling-epi, peri, bay effects. Shift reagents-mechanism of action, spin decoupling and double resonance. Explanation of spectra of some compounds and drugs.
	(d)	^{13}C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled ^{13}C Spectra, Proton-decoupled ^{13}C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarization Transfer (DEFT), Heteronuclear coupling for carbon to

	deuterium, carbon to ^{19}F, carbon to ^{31}P.Explanation of spectra of some compounds and drugs.
4.	**Mass spectrometry (MS):** Molecular ion and metastable peak, fragmentation patterns, nitrogen and ring rules, McLafferty rearrangement, electron and chemical ionization modes, applications

Recommended Books/Literature:

1. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan
2. Organic spectroscopy by William Kemp
3. Spectroscopic Methods in Organic Chemistry by Dudley H. Williams & Ian Fleming
4. Spectrometric Identification of Organic Compounds by Robert M. Silverstein, Francis X. Webster& David J. Kiemie
5. Applications of Absorption Spectroscopy of Organic Compounds by Dyer
6. Fundamentals of Molecular Spectroscopy by Colin N. Banwell & Elaine M. McCash
7. Instrumental Methods of Analysis, Seventh Edition Hobart H. Willard, Lynne L. Merrit, John A. Dean and Frank A. Settle CBS Publishers
8. Edmond de Hoffmann, Vincent Stroobant: Mass Spectrometry, Principles and applications, 3rd Edition, Wiley, 2007.
9. Principles-of-Instrumental-Analysis-7th-edition-Skoog

MC 530 :- Separation Techniques (1 Credit)

1.	**Separation Techniques:** Need for learning separation techniques, separation techniques in natural product research and drug discovery, extraction techniques.
2.	**Chromatography:** General principles and separation mechanisms, classification of chromatographic techniques, normal and reverse phase, bonded phase chromatography, stationary phases, stationary phases, Elutropic series.
3.	**Column Chromatography:** Column packing, sample loading, column development, detection
4.	**Flash Chromatography and Vacuum Liquid Chromatography:** Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.
5.	**High Performance Liquid Chromatography:** Principles, instrumentation, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, gradient HPLC, HPLC solvents, sample preparation, method development, problems and trouble shooting.
6.	**Planar Chromatography - TLC/HPTLC/OPLC:** Basic principles, sample application, development of plates, visualization of plates, 2D TLC, densitometry, Over pressure layer chromatography.
7.	**Counter Current Chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.
8.	**Gas Chromatography:** Principles, instrumentation, split-splitless injector, head space sampling, columns for GC, detectors, quantification
9.	**Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases
10.	**Hyphenated Techniques:** Introduction to GC-MS and LC-MS techniques and their applications in natural products.

Recommended Books/Literature:

1. Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
2. Methods in Biotechnology, Natural Product Isolation by Richard Canell
3. Various Reviews and Research Papers.

PE 510 :- Pharmaceutical Preformulation - I (1 Credit)

1.	**Preformulation studies:** Preformulation studies of drug substances, proteins and peptides. Fundamental and derived properties in preformulation profiling. Preformulation work-sheet.
2.	**Role of pre-formulation in drug discovery:** material properties in lead selection, 'drugability' of new chemical entities, *in silico* and high throughput pre-formulation studies
3.	**Role of preformulation in drug development:** Preformulation as a support for formulation development, identification of 'developmental challenges' during pharmaceutical development, dosage form specific studies.
4.	**Salt selection:** Role of salt selection in drug discovery and development, theoretical concepts for selection of counter ions for salt formation, 'pKa rule' for salt formation, decision tree for salt selection, appropriate case studies.
5.	**Solubilization:** Solubility and solubilization of non-electrolyte, drug solubilization in surfactant systems, use of co-solvents for development of liquid formulations, solid-state manipulations including use of metastable solid forms like amorphous state.

BT-510:-Biotechnology in Pharmaceutical Sciences (1 Credit)

1.	Biotechnology in pharmaceutical Sciences perspective: Biology in drug discovery; Traditional drug discovery vs rational drug discovery; rational drug discovery pipeline; concept of target based drug design and target discovery; role of plant biotechnology in edible vaccine development**.**
2.	**Genomics in target discovery:** Concept of genome, genes and gene expression; genome sequencing and sequence comparison methods (microarray); comparative genomics and expression genomics for target discovery of communicable disease and lifestyle disease.
3.	**Systems and methods of molecular biology:** Isolation and validation of targets; PCR, RT-PCR nucleic acid isolation; cloning vectors (some examples), enzymes used in molecular cloning methods (some examples); cloning and characterization of biopharmaceuticals.
4.	**Protein expression systems:** Gene expression in bacteria, yeast, insect and mammalian cells.
5.	**Enzyme purification and assay:** Various protein purification methods; enzyme based assay for small molecule screening.
6.	**Bioprocess technology:** Upstream process: Introduction to microbial growth, media formulation; sterilization, inoculum preparation.
7.	**Bioprocess technology:** Fermentation: Fermentation process design, operation and characteristics of fermentation processes; batch, fed-batch and continuous culture systems, instrumentation and bioprocess control.
8.	**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.
9.	**Biotechnology in pharmaceutical industry:** Major areas of biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF and therapeutic proteins etc.); commercial aspects, priorities for future biotechnological research.
10.	**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.

Recommended Books/Literature:

1. Analysis of Genes and Genomes by Richard J Reece. John Wiley & Sons.
2. Molecular Biotechnology by Principles and Applications of Recombinant DNA by Bernard R. Glick, Jack J. Pasternak and Cheryl L. Patten, ASM Press.
3. Principles of Fermentation Technology by P F Stanbury, A. Whitaker, S. J. Hall. Butterworth-Heinemann.

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.

Recommended Books/Literature:

1. Fundamentals of Biostatistics by Bernard Rosner
2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon
3. Statistical Misconceptions by Huck

GE-520: 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 IPin 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 Organization), WIPO (World Intellectual Property

	Organization) 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 infrigment- 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 information-internet sites, brouchers, 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; Trademarks 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/commercialisation 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-commercialisation and commercialisation-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, POSTWTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPS; Related registration and marketing issues; Case studies antiretroviral drugs 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. 49 60 Courses of Study 2015.
Recommended Books:	

1. Law Relating to Intellectual Property by B. L. Wadhera.
2. IPR Handbook for Pharma Students and Researchers by P. Bansal.
3. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012).
4. Patent Agent Examination by Sheetal Chopra and Akash Taneja.
5. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan.
6. Making Breakthrough Innovation Happen by Porus Munshi.
7. Innovation X- Why a Company's Toughest Problems are its Greatest Advantage by Adam Richardson.
8. Legal Drafting for the Layman by Nabhi Kumar Jain.
9. How to Write and Publish a Scientific Paper by Rober A Day.
10. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V. Chandrachud.
11. Biomedical Research- From Ideation to Publication by G. Jagadeesh and others.

GE-511:- Seminar (1 Credit)

1. Introduction, Information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation, and references.
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 (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.
3.	**Pharmacology (25 hours):** Animal handling, route of administration of drugs, dose response relationship, acute toxicity testing of drugs, analgesic activity of a compound, estimation of protein and haematological parameters.
4.	**Biotechnology in 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 the common glassware (volumetric flask, burette, and pipette) found in an analytical laboratory.

	b) Calibration of pH meter, UV spectrophotometer, and FT-IR-ATR c) Calibration of HPLC and multicomponent analysis by UV spectrophotometer d) To determine Water content in the given sample by Karl Fischer reagent along with moisture content in the given sample using infrared moisture balance. e) To construct a calibration curve for a drug by UV spectrophotometer. f) Determination of pKa of a given sample by spectrophotometric method. g) FT-IR-ATR analysis of a given drug sample. h) To construct a calibration curve for a drug by HPLC. i) To demonstrate chiral separation of a racemic mixture by HPLC.

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SEMESTER - II

PA-610:- Pharmacopoeial Methods of Analysis (2 Credits)

1. Detailing of ICH Q3 and correlation with Pharmacopeia.
2. Detailing of ICH Q4
   a) Pharmacopoeial Harmonization
   b) Evaluation and recommendation of Pharmacopoeial texts for use in the ICH regions.
3. Study of various pharmacopeias - IP, BP, EP, and USP
4. Pharmacopoeia General notices and their usage.
5. Pharmacopeia General Chapters: Chromatography, Spectroscopy, Elemental Impurities, Packaging, Residual solvents, Water determination, LOD.
6. CDSCO guideline for phytopharmaceutical, Ayurvedic Pharmacopoeia of India.
7. Detailing of dietary supplementary-general chapters.
8. Introduction to the pharmacopoeia forum
9. Microbiological tests and assays as per Pharmacopeia: Antimicrobial (preservative) effectiveness testing, microbial limit tests, sterility test, vitamins assay (zone of exhibition), antibiotics assays, bacterial endotoxin test. Pharmacopeia General Chapters of microbiology.
10. Reference standards: Regulatory and pharmaceutical perspectives along standardization procedures.

Recommended Books/Literature:

1. The Indian Pharmacopoeia, Indian Pharmacopoeia Commission, Ghaziabad.
2. The British Pharmacopoeia, Stationary Office British Pharmacopoeia Commission, London
3. The United States Pharmacopeia-National Formulary, Board of Trustees, Rockville
4. The European Pharmacopoeia, Directorate for Quality of Medicines of the Council of Europe.

PA-620 :- Modern Instrumental Techniques for Evaluation of APIs and Drug Products (2 Credits)

1. **Non-destructive analysis and pharmaceutical visualization:** Terahertz Pulse Spectroscopy, X-Ray Diffraction (XRD), FT-NIR, CD, and fluorescence spectroscopy
2. **Thermal techniques: DSC:** Principle, thermal transitions, instrumentation (heat flux and power-compensation designs), modulated DSC, hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, pharmaceutical applications. **TGA and DTA:** Principle, instrumentation, factors affecting results, pharmaceutical applications.
3. **Particle sizing:** Static & dynamic laser light scattering. Pharmaceutical applications along with Analytical quality by design applications.
4. **Analysis of trace components:** Techniques employed for the qualitative and quantitative evaluation of impurities, elemental impurities, residual solvents.
5. ICP-MS: Theory, Instrumentation, and applications.
6. **LC-MS/MS, GC-MS, GC-MS/MS, and LC-HRMS: Application in Omics and bioinformatics.**
7. **LC-NMR:** Nature of interfaces, qualitative and quantitative applications.
8. Microscopy Optical Microscopy, Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM) – Basic Principles and applications, Application to API and Drug product characterization.

Recommended Books/Literature:

1. Principles of Instrumental Analysis by Dougla A. Skoog, F. James Holler, Timothy A. Nieman.
2. Instrumental Method of Analysis by Hobart H. Willard, Lynne L. Merrit, John A. Dean, Frank A. Settle 3. Fundamentals of Fourier Transform Infrared Spectroscopy by Brian C. Smith.
3. Modern Raman Spectroscopy: A Practical Approach by Ewen Smith, Geoffery Dent.
4. Chemical Analysis: Modern Instrumental Methods and Techniques by Franscis Rouessac and Annick Rouessac.
5. Handbook of Pharmaceutical Analysis by Lena Ohannesian, Antony J. Streeter.
6. HPLC for Pharmaceutical Scientists, Edited by Yuri Kazakevich and Rosario LoBrutto.
7. Introduction to Thermal Analysis Techniques and Applications by Michael E. Brown.
8. Modern Methods of Particle Size Analysis, Edited by Howard G. Barth.
9. Electrophoresis: The Basics by David M. Hawcroft.

PA-630:- Stability Testing (1 Credit)

1. **Drug development cycles and stability testing:** Role and types of stability studies during different stages of drug and product development.
2. **Drug stability testing guidelines:** International, Regional, and National drug stability guidelines.
3. **WHO vs. ICH drug stability testing guidelines:** Comparison of different aspects in WHO guideline, and critical comparison with ICH parent guideline Q1A (R2).
4. **Specific discussion on following ICH guidelines:** Q1B, Q1C, Q1D, Q1E and Q5C.
5. **Stress testing and stability-indicating method development:** Role, regulatory aspects, protocols/approaches, practical considerations.
6. **Stability testing of phytopharmaceuticals and Herbal products:** Regulatory requirements including EMA for herbal products.
7. **Stability test equipment:** Types of stability chambers (walk-in, stand-alone), design

considerations, qualification and other critical issues**.**

8. **Stability testing for Shipping & Distribution:** Stability testing during transport.
9. Stability testing of drug delivery systems.

Recommended Books/Literature:

1. ICH (www.ich.org) and WHO (www.who.int) guidelines
2. Pharmaceutical Stress Testing (Predicting Drug Degradation) by Steven Baertschi a. and Karen Alsante
3. Drug Stability (Principles and Practices) by S. James, Jens ThurØCarstensen
4. Stability-indicating HPLC Methods for Drug Analysis by Quanyun A. Xu, Lawrence A. Trissel
5. Stability of Drugs and Dosage Forms by Sumic Yoshioka, Valentino Stella
6. Physical Pharmacy and Pharmaceutical Sciences by Patrick Sinko, Alfred Martin
7. New Drug Approval Process (Chapter 7) by Richard Guarino
8. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices by Kim Huynh-Ba
9. Stability and Characterization of Protein & Peptide of Drugs by Y. John Wang
10. Peptide and Protein Drug Analysis by Ronald Reid

PA-640:- Quality Control and Quality Assurance (2 Credits)

1. Good manufacturing practices [Schedule M] and Good laboratory practices [Schedule L-I]: Their applications to the pharmaceutical industry.
2. **Basic principles and concepts of quality management:** Quality control, quality assurance, quality auditing, ISO system, electronic quality management system (eQMS).
3. Control of raw & packaging material and labelling, sampling, testing, release and distribution of finished products.
4. **Document control:** Preparation, review, approval, issuance, storage and retrieval (e.g., master manufacturing and packaging records, site master file, etc.), electronic document management system (e-DMS).
5. **Standard operating procedures:** SOP on SOPs, Change control procedure, annual product review/product quality review, handling of deviations & non-conformity, corrective & preventive actions (CAPA), handling of laboratory incidents and OOS and OTT test results.
6. **Qualification of facility and utilities:** Concepts of facility validation, qualification of HVAC and water systems.
7. Process validation, product change over, basic requirements of cleaning and its validation.
8. Technology transfer from R&D to manufacturing, including product life-cycle approach.
9. Handling of market complaints, recalls and returned goods.
10. Quality risk management in production area, data integrity management.
11. Introduction to concepts of QbD, PAT and continuous manufacturing.

Recommended Books/Literature:

1. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials, Volume 1.
2. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials, Volume 2.
3. Q.A. Manual by D. H. Shah.
4. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by John Sharp.
5. WHO Expert Committee on Specifications for Pharmaceutical Preparations.
6. Handbook of Pharmaceutical Quality Assurance by Dr. Premnath Shenoy.

PA-650:- Structure Elucidation (2 Credits)

1. **Structure elucidation**: General strategies for structure elucidation of API / Peptides / natural products with few examples.
2. **Chemical methods**: Determination of carbon skeleton, dehydrogenation, oxidative methods in structure elucidation, reductive methods in structure elucidation.
3. **Chemical methods**: General methods for structure elucidation of steroids, terpenoids, alkaloids with few examples.
4. **Ultraviolet spectroscopy**: Basic principles, rules to calculate max, applications in structure elucidation with examples.
5. **Infra-red spectroscopy**: Basic principles, various factors affecting frequency, functional group identification, applications in structure elucidation with examples.
6. **Mass Spectrometry**: Basic principles, various ionization modes EI, CI, FAB etc. fragmentation patterns, HRMS, applications in structure elucidation with examples such as peptide analysis.
7. Shift, prediction of chemical shifts, coupling constants, Karplus curve, advanced 1D NMR experiments such as NOE, DEPT etc.
8. **Conformational Analysis of Biomolecules**: Circular Dichroism based analysis of peptides and other related biomolecules, Biomolecular studies with alkaloids, flavonoids, sterols, etc..
9. **^{1}H and ^{13}C NMR Spectroscopy**: Basic principles, chemical shift, factors affecting chemical.
10. **2D NMR**: H- H COSY, HSQC, HMBC, NOESY experiments: Their use in structure elucidation
11. **Structure elucidation** - Examples from Small molecules/API, coumarins, triterpenes, and xanthones.

Recommended Books/Literature:

1. Spectroscopy by Pavia, Lampman, Kriz, Vyvyan
2. Spectrometric Identification of Organic Compounds by RM Silverstein
3. Organic Spectroscopy by William Kemp 4. Spectral Data for Structure Elucidation

PC-611:- Pharmacological Screening and Assays (1 Credit)

1. Role of pharmacology in drug discovery.
2. General principles of pharmacological screening.
3. Animal ethics, regulations for conducting animal experimentation.
4. 3 R's concept, alternatives to animal experimentations, Organs-on-chips.
5. Pharmacological screening models.
6. Correlations between various animal models and human situations.
7. Correlation between in-vitro and in-vivo screens.
8. Cell- based assay, CaCo-2 cell permeability assay. Single cell gel electrophoresis assay (COMET) assay.
9. Zebrafish model to screen pharmaceutical molecules.
10. Biochemical assays.
11. Introduction to cell culture, role of genomic and proteomic techniques in the process of target identification in drug discovery, MALDITof., microarray.
12. High throughput screening and high content screening, transgenic animal model for drug screening.
13. Specific use of reference drugs.
14. Interpretation of results.
15. Pharmacogenomics and Personal medicine.

Recommended Books/Literature:

1. Drug Discovery and Evaluation: Pharmacological Assays by Vogel & Vogel.
2. CPCSEA guidelines (http://cpcsea.nic.in)
3. Scientific journals in the area of pharmacology.

PE-630:- Pharmaceutical Product Development – I (1 Credit)

1. **Development of dosage forms:** Four stage development including preformulation, prototype development, scale up studies and commercialization.
2. **Design of materials and product specifications:** Creation and optimization of material and product specifications. In-process, product release and regulatory specifications.
3. **Quality by design (QbD):** Fundamentals of pharmaceutical quality by design, identification of critical quality attributes, critical material attributes, critical process parameters and quality risk management.
4. **Methods of optimization** – OVAT and Design of experiments (DOE). Experimental designs, screening designs, factorial designs, composite designs, mixture designs, response surface methodology. Applications of systematic optimization techniques.
5. **Process analytical technology (PAT)** and other control strategies for QbD.
6. **Pharmaceutical Packaging:** Pack types for different dosage forms, packaging materials like glass and plastic, selection of proper material, labeling, preformulation screening of package components; barrier, child resistant and tamper evident packaging systems; regulatory perspectives.
7. **Testing of packaging materials** – equipment used, extractable and leachable.
8. **Documentation protocols:** Forms and maintenance of records in product development department including clinical batches.
9. **Case studies or regulatory guidelines** related to above topics shall be discussed after each topic.

PE 660 - Solid State Pharmaceutics (1 Credit)

1. **Levels of solid-state properties:** Molecular / particle / bulk level properties, interdependence of various levels on each other, role of different levels during pharmaceutical development and process development
2. **Molecular level:** Crystalline form, definition, concept of long-range order, supramolecular arrangements, building blocks of crystals, unit cell, basic types of unit cells, demonstration of unit cells using crystal visualization softwares.
3. **Polymorphism**: Definition, significance of polymorphism in drug product performance, packing/ conformational polymorphism, thermodynamics of polymorphs, enantiotropy / monotropy, concept of transition temperature, Burger and Ramberger rule
4. **Crystallization process**: Molecular aggregation events in crystallization, energetic of crystallization, enthalpy entropy balance, types of nucleation, Ostwald's step rule, experimental protocols for polymorph screening
5. **Implications of polymorphism in pharmaceutical development**: Regulatory concerns related to polymorphism, introduction to latest regulatory position on polymorphism
6. **Amorphous state**: Definition, long range order versus short range order, disorder in the amorphous state, concept of glass transition temperature (Tg), thermodynamic necessity for Tg, entropy crisis.
7. **Role of amorphous state in drug delivery**: Solubility advantage, spring parachute effect during solubility studies, physical instability of the amorphous form, techniques for stabilization of amorphous form, amorphous solid dispersions.
8. **Co-crystals:** Introduction, synthons used for formation of co-crystals and applications in drug delivery.

9. **Particulate level properties:** Crystal habit, generation of different crystal habits, implications of crystal habit on product performance and processing.
10. **Bulk level**: Bulk density, compressibility, flow properties, cohesivity, electrostatics, aggregation, agglomeration, role in formulation development and processing

Recommended Books/Literature:

1. Polymorphism in Pharmaceutical Solids Edited by Harry Brittain
2. Solid State Characterization of Pharmaceuticals Edited by Angeline and Mark Zarkrzewski
3. Crystal Engineering: A textbook, Edited by G. R. Desiraju, J. J. Vittal and A. Ramanan

GE 611 - Seminar (1 Credit)

Students are required to submit written record and present details of the project to be pursued in semester-III & IV 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 (3 Credits)

Practicals in lab:

1. Analysis of a drug sample by a pharmacopoeial method and preparation of its certificate of analysis.

2. Estimation of the given drug in urine and blood samples using HPLC and identification of metabolites.

3. Plotting and interpretation of pharmacokinetics data and calculation of various pharmacokinetic parameter (Dry Lab).

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/Semipreparative HPLC.

6. Establishment of drug loading, entrapment efficiency and dissolution characteristics of a given controlled release preparation using dissolution apparatus/dialysis bag method.

7. Particle size, PDI and zeta potential analysis using an automated Malvern Zetasizer.

8. Determination of tapped and bulk density, study of different packaging materials and their evaluation using bursting strength tester.

9. Optimization of the mass parameters by LC-MS/MS.

10. Accurate mass measurements by HRMS.

11. Inorganic elemental analysis by ICP-MS.

12. Volatile analysis by GC-MS.

Practicals in Central Instrumentation Facility (CIF)

1. Sample analysis using DSC and its interpretation.
2. Sample analysis using TGA and its interpretation.
3. Spectrofluorimetric analysis of a given sample.
4. Freeze drying of a sample using Lyophilizer.
5. Study of given sample on Polarimeter.

6. Analysis of racemic mixture/isomers using CD spectroscopy.
7. Analysis of crystal samples using XRD.
8. Analysis of samples using Electron microscopy such as SEM, AFM, TEM, etc.
9. Analysis of samples using FT-NMR (^{1}H, ^{13}C and 2D).