SEVEN HILLS COLLEGE OF PHARMACY
[AUTONOMOUS]
Venkatramapuram, **TIRUPATI** - 517 561, A.P, INDIA
Approved by AICTE & PCI, New Delhi, Govt. of A.P.
Awarding University: JNT University Anantapur – Ananthapuramu
Recognized by UGC Under Sections 2(f) & 12(B) of UGC Act 1956

SHCP R23 Syllabus

M. Pharmacy – Pharmaceutical Analysis
Pre-Ph.D. Course Work

COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2023-2024
(2023 Admitted Batch)

I YEAR - I Semester

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S01101	Modern Pharmaceutical Analytical Techniques	C	3L+1T	4	30S+10Obj	60
2	23S07101	Advanced Pharmaceutical Analysis	C	3L+1T	4	30S+10Obj	60
3	23S07102	Pharmaceutical Validation	C	3L+1T	4	30S+10Obj	60
4	23S07103	Food Analysis	C	3L+1T	4	30S+10Obj	60

I YEAR II Semester

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S07201	Advanced Instrumental Analysis	C	3L+1T	4	30S+10Obj	60
2	23S07202	Modern Bio-Analytical Techniques	C	3L+1T	4	30S+10Obj	60
3	23S07203	Quality Control and Quality Assurance	C	3L+1T	4	30S+10Obj	60
4	23S07204	Herbal and Cosmetic Analysis	C	3L+1T	4	30S+10Obj	60

M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

M.PHARMACY I SEMESTER

(23S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	L	T	P	C
23S01101		4	0	0	4
	Semester	I			

Course Objectives:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Outcomes (CO): Student will be able to

After completion of course student is able to know about chemicals and excipients.

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

UNIT - I	11hrs	
Self-Study-	*Principle, Instrumentation of UV-Visible Spectroscopy*	

a. **UV-Visible spectroscopy:** Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy,Difference/ Derivative spectroscopy, **Woodward's Rule and its application in determination of molecular weight of compounds.**

b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

c. **Spectro flourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.

UNIT - II	11hrs	
Self-Study	*Principle, Instrumentation of NMR*	

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy, **Interpretation of NMR Spectra.**

UNIT - III	11hrs	
Self-Study	*Principle, Theory, Instrumentation of Mass Spectroscopy*	

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy, **Interpretation of MASS Spectra.**

UNIT - IV	12hrs	
Self-Study	*Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation*	

Chromatography- Principle, instrumentation, selection of solvents; chromatographicparameters, factors affecting resolution, applications of the following:

a) Thin Layer chromatography; b) High Performance Thin Layer Chromatography
c) Paper Chromatography; d) Column chromatography
e) Gas chromatography; f) High Performance Liquid chromatography
g) Affinity chromatography; h) Gel Chromatography
UPLC and its applications

UNIT - V	15hrs	

a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:
i) Paper electrophoresis ii) Gel electrophoresis iii) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, Xray powder technique, Types of crystals and applications of X-raydiffraction.

c. Immunological assays: RIA (Radio immuno assay), ELISA, **RT-PCR**, Bioluminescence assays.

Reference Books:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
4. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
5. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
6. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
7. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
8. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
9. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
10. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
11. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley& Sons, 1982.
12. Organic Chemistry by I. L. Finar
13. Quantitative Analysis of Drugs by D. C. Garrett
14. HPTLC by P.D. Seth
15. Indian Pharmacopoeia 2007
16. High Performance thin layer chromatography for the analysis of medicinal plants by Eike
17. Reich, Anne Schibli
18. Introduction to instrumental analysis by Robert. D. Braun

M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED PHARMACEUTICAL ANALYSIS	L	T	P	C
23S07101		4	0	0	4
Semester		I			

Course Objectives:

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Course Outcomes (CO): Student will be able to

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

UNIT - I		
Self-Study	*Introduction to ICH Guidelines, QSEM, quality guidelines*	

Impurity and stability studies

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

UNIT - II		
Self-Study	*Rate of reaction and types of reactions*	

Elemental impurities

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C,H, N and S analysis

Stability testing protocols

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

UNIT – III		

Impurity profiling and degradent characterization

Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photo stability testing guidelines, ICH stability guidelines for biological products

UNIT – IV		

Stability testing of phytopharmaceuticals

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

Biological tests and assays of the following

Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures),

UNIT – V		

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA. **Bacterial Endotoxin test**

Reference Books:

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J.Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thEdition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley& Sons, 1982.102.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia VolI , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2ndedition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 23 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2ndedition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL VALIDATION	L	T	P	C
23S07102		4	0	0	4
	Semester	**II**			

Course Objectives:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application

Course Outcomes (CO): Student will be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

UNIT – I		
Self study	*Definition of Qualification and Validation, Advantage of Validation*	

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification &Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management),Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments, **Difference between calibration and validation.**

UNIT – II		

Qualification of analytical instruments

Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLCQualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT – III		

Validation of Utility systems

Pharmaceutical Water System &pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). **Validation of facilities in sterile and non sterile plant**

UNIT – IV		

Analytical method validation

General principles, Validation of analytical method as per ICH guidelines and USP.

Computerized system validation: Electronic records and digitalsignificance-23 CFR part 11 and GAMP. **Concept of process validation, USFDA guidelines on process validation**

UNIT – V		

General Principles of Intellectual Property

Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP),Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-

positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

Reference Books:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master Plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci.Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	FOOD ANALYSIS	L	T	P	C
23S07103		4	0	0	4
	Semester	**I**			

Course Objectives:

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products

Course Outcomes (CO): Student will be able to

various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

UNIT - I		
Self study	*Classification and properties of food carbohydrates, classification of aminoacids and proteins*	

Carbohydrates

Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, **digestion of carbohydrates, metabolism**.

Proteins

Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, **Importance of carbohydrate analysis, protein content based on nitrogen content and conversion factors.**

UNIT - II		
Self study	*Classification of lipids and vitamins*	

Lipids

Classification, general methods of analysis, refining of fats and oils; **Rancidity of oils**, hydrogenation of vegetable oils,Determination of adulteration in fats and oils. **Importance of fat analysis, fat characterization and its importance**

Vitamins

Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitaminsof B-series, **importance of vitamin analysis**

UNIT – III		

Probiotics

Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT – IV		
Self study	*Introduction to food additives, types of food additives and natural pigments*	

Food additives

Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes

Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes, **pH control agents.**

UNIT – V		
Self study	*Composition of milk, processing of milk and milk products*	

Milk (constituents and milk products)

General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

- Analysis of fermentation products like wine, spirits, beer and vinegar.

- Pesticides Analysis in food like organophosphorus and organochlorine
- And also student shall have knowledge in food regulations and legislations

Textbooks:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International
6. 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

Reference Books:

1. Indian Pharmacopoeia 2012
2. Remington's Pharmaceutical Sciences by Alfonso and Gennaro

M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED INSTRUMENTAL ANALYSIS		L	T	P	C
23S07201			4	0	0	4
Pre-requisite		Semester	II			

Course Objectives:

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Course Outcomes (CO): Student will be able to

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

UNIT - I	*Self study- Instrumentation of HPLC*	

HPLC

Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

UNIT - II	*Self study-GC Instrumentation*	

Biochromatography

Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. **Method development in GC**

High performance Thin Layer chromatography

Principles, instrumentation, pharmaceutical applications.

UNIT – III	*Self study- Principles of CE, methods and modes of CE*	

Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications

Capillary electrophoresis:

Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

UNIT – IV	*Self study*- Ionization techniques *FAB and MALD, APCI, ESI, APPI*	

Mass spectrometry

Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments.

MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap. **GC-MS hyphenation**

UNIT – V		

NMR spectroscopy

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief

outline of principles of FT-NMR with reference to 13CNMR:Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

Reference Books:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	MODERN BIO-ANALYTICAL TECHNIQUES	L	T	P	C
23S07202		4	0	0	4
Semester		II			

Course Objectives:

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Course Outcomes (CO): Student will be able to

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

UNIT – I

Extraction of drugs and metabolites from biological matrices

General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines

UNIT – II

Biopharmaceutical Consideration

Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT – III

Pharmacokinetics and Toxicokinetics:

Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics

UNIT – IV

Cell culture techniques

Cell culture techniques Basic equipment's used in cell culture lab. Cell culture media, various typesof cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

UNIT – V

Metabolite identification

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

Reference Books:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger LBertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38,Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	QUALITY CONTROL AND QUALITYASSURANCE	L	T	P	C
23S07203		4	0	0	4
Semester		I			

Course Objectives:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Outcomes (CO): Student will be able to

- The cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments

UNIT - I

Quality Control and Quality Assurance

Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines -QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices

Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

UNIT - II

cGMP

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

UNIT – III

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

UNIT – IV

Documentation in pharmaceutical industry

Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

UNIT – V

Manufacturing operations and controls:

Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

Reference Books:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4thedition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley& Sons; 2008.

M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	HERBAL AND COSMETIC ANALYSIS	L	T	P	C
23S07204		4	0	0	4
Semester		II			

Course Objectives:

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic productsis included for the better understanding of the equipments used in cosmetic industries for thepurpose.

Course Outcomes (CO): Student will be able to

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

UNIT – I

Herbal remedies- Toxicity and Regulations

Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines

UNIT – II

Adulteration and Deterioration:

Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

UNIT – III

Testing of natural products and drugs

Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British
herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

UNIT – IV

Herbal drug-drug interaction

General principles, Validation of analytical method as per ICH guidelines and USP.
Computerized system validation: Electronic records and digitalsignificance-23 CFR part 11 and GAMP.

UNIT – V

Evaluation of cosmetic products:

Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished

forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards

Reference Books:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master Plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci.Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.