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

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
5	23S01105	Modern Pharmaceutical Analytical Techniques Practical	C	6P	**3**	20P+20CA	60
6	23S07104	Food Analysis Practical	C	6P	3	20P+20CA	60
7	23S07105	Seminar/Assignment	C	1T+6P	4	100	-
8	23DAC101a	a. Spirituality & Value Education	CBS	3L+1T	0	50	-
9	23DAC101b	b. Disaster management					
10	23DAC101c	c. Basic Research Skills					
Total				15L+06T +18P	26	390	360

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
5	23S07205	Advanced Instrumental Analysis Practical	C	6P	**3**	20P+20CA	60
6	23S07206	Herbal and Cosmetic Analysis Practical	C	6P	3	20P+20CA	60
7	23S07207	Seminar/Assignment	C	1T+6P	4	100	-
8 9 10	23DAC701a 23DAC701b 23DAC701c	1. Advanced Quality Assurance Techniques 2. Quality Management Systems 3. Stability of Pharmaceuticals	CBS	3L+1T	0	50	-
Total				15L+06T +18P	26	390	360

III SEMESTER

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23DRM101	Research Methodology andBiostatistics	C	3L+1T	4	30S+10Obj	60
2	23S07301	Teaching Assignment	C	4P	2	100	-
3	23S07302	Comprehensive viva voce	C	-	2	-	100
4	23S07303	Research Work-I	C	24P	12	100	-
5	23SPE301	**Professional Elective** Publication ethics in Research	C	2L+1T	3	30S+10Obj	60
6	23SOE101	1. Professional Business Skills	CBS	2L+1T	3	50 IL	-
7	23SOE101	2. IPR and Patents	CBS				-
8	23SOE101	3. Scientific Writing	CBS				-
Total				7L+3T+28P	**26**	330	220

IV SEMESTER

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S07401	Journal Club	C	2L	2	-	-
2	23S07402	Research work-II	C	30P	18	100	100
3	23S07403	Co-Curricular Activities	C	-	2	-	-
Total				2L+30P	22	100	100

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, 4th Edition, 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, 2nd edition, 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, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

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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

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C
23S01105		0	0	6	3
Semester		I			

List of Experiments

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Quantitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography

Course Code	FOOD ANALYSIS PRACTICAL-I	L	T	P	C
23S07104		0	0	6	3
Semester		I			

List of Experiments

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of food additives
11. Determination of Aspartame in soft drinks
12. Determination of 4- imidazole in caramel
13. Determination of benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
14. UV Spectrophotometric methods for determination of sorbic acid in dairy products
15. Determination of nitrite and nitrate in food products

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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.

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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

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COURSE STRUCTURE & SYLLABI

Course Code	QUALITY CONTROL AND QUALITY ASSURANCE	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, 4th edition, 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.

Course Code	ADVANCED INSTRUMENTAL ANALYSIS PRACTICAL-II	L	T	P	C
23S07205		0	0	6	3
	Semester	II			

List of Experiments

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Massspectra
7. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalyticalmethodvalidation.
11. Protocol preparation for the conduct of BA/BE studies according toguidelines.
12. In process and finished product quality control tests for tablets, capsules,parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.

Course Code	HERBAL AND COSMETIC ANALYSIS PRACTICAL-III	L	T	P	C
23S07206		0	0	6	3
	Semester	II			

List of Experiments

1. Quantitative analysis of rancidity in lipsticks and hair oil
2. Determination of aryl amine content and Developer in hair dye
3. Determination of foam height and SLS content of Shampoo.
4. Determination of total fatty matter in creams (Soap, skin and hair creams)
5. Determination of acid value and saponification value.
6. Determination of calcium thioglycolate in depilatories
7. Determination of tannins
8. Determination of microorganisms in herbal products
9. Specifications for adsorbents used in TLC
10. Determination of total phenol content
11. Determination of aflatoxins
12. Determination of swelling index and foaming index
13. Quality control methods for herbal materials/ Medicinal plant materials

AUDIT COURSE-I

Course Code	PEDAGOGY STUDIES	L	T	P	C
23DAC101a		2	0	0	0
Semester		I			

Course Objectives: This course will enable students:

- Reviewexistingevidenceonthereviewtopictoinformprogrammedesignandpolicy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes (CO): Student will be able to

Students will be able to understand:

- Whatpedagogicalpracticesarebeingusedbyteachersinformalandinformalclassrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation (curriculumandpracticum) andtheschoolcurriculumand guidancematerials best support effective pedagogy?

UNIT - I

Introduction and Methodology: Aims and rationale, Policy back ground, Conceptual frame work and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions**.** Overview of methodology and Searching.

UNIT - II

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT - III

Evidence on the effectiveness of pedagogical practices, Methodology for the in-depth stage: quality assessment tof included studies. How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT - IV

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class
sizes

UNIT - V

Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher education**,** Curriculum and assessment**,** Dissemination and research impact.

Suggested Reading

1. AckersJ, HardmanF (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
3. AgrawalM (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
4. AkyeampongK (2003) Teacher training in Ghana - does it count? Multi-site teacher

educationresearch project (MUSTER) country report 1. London: DFID.
5. Akyeampong K, LussierK, PryorJ, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
6. Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
Chavan M (2003)Read India: A mass scale, rapid, 'learning to read'campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

Course Code	SOFT SKILLS AND VALUE EDUCATION	L	T	P	C
23DAC101b		2	0	0	0
Semester		I			

Course Objectives: This course will enable students to learn

- Soft skills like Microsoft word, excel and powerpoint
- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course Outcomes (CO): Student will be able to

Students will be able to

- Learn soft skills
- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

UNIT - I

Introduction to Soft skills, Communication Skills, Presentation Skills, Time Management Skills, Body Language & Etiquettes, Group Discussion & Interview Skills, Preparation of CV, Computer Fundamentals, Operating System & Management Information System, MS-OFFICE & Internet Applications.

UNIT - II

Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT - III

Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity anddiscipline, Punctuality, Love and Kindness.

UNIT - IV

Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT - V

Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message.Mind your Mind, Self-control. Honesty, Studying effectively

Suggested Reading

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford University Press, New Delhi

Course Code	PERSONALITY DEVELOPMENT & STRESS MANAGEMENT BY YOGA	L	T	P	C
23DAC101c		2	0	0	0
Semester		I			

Course Objectives: This course will enable students to learn

- To achieve overall health of body and mind
- To overcome stress
- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes (CO): Student will be able to

Students will be able to

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency
- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetisatakam will help in developing versatile personality of students

UNIT - I

Neetisatakam-Holistic development of personality

- Verses- 19,20,23,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)
- Verses- 52,53,59 (dont's)
- Verses- 71,73,75,78 (do's)

UNIT - II

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 23, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT - III

Do`s and Donts' in life.

- Ahinsa, satya, astheya, bramhacharya and aparigraha
- Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT - IV

Definitions of Eight parts of yoga. (Ashtanga), Yam, Niyam, Asan and Pranayam.

UNIT - V		
i) Various yoga poses and their benefits for mind & body ii) Regularization of breathing techniques and its effects-Types of pranayam		
Suggested Reading		
1. Yogic Asanas for Group Tarining-Part-I": Janardan Swami Yogabhyasi Mandal, Nagpur 2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata		

Course Code	ADVANCED QUALITY ASSURANCE TECHNIQUES	L	T	P	C
23DAC701a		2	0	0	0
Semester		II			

Course Objectives: This course will enable students:

- Exposure to industry can increase their confidence level and carrier opportunity in industry.

Course Outcomes (CO):

- Students can acquire knowledge and skills in Industrial training and manufacturing of pharmaceuticals.

UNIT - I

Designing of the following key documents:
1. Site master file
2. SOP on SOP
3. MPCR/BPCR (for sterile and non sterile products)
4. Change control format
5. Product complaint document
6. Internal audit document
7. Product recall document
8. I.P.Q.C document
9. Warehousing documents
10. System suitability test document

UNIT - II

I. Materials:
1. Purchasing
2. RM/PM/Int./Bulk and Finishing Products
3. Reference and working standards.
4. Miscellaneous and waste materials.

II. Outsourcing:
1. Outsourcing of manufacturing operations.
2. Outsourcing of analytical services.
3. Outsourcing of other services.

UNIT - III

I. Quality Management:
1. Concepts of QA/QC/cGMP.
2. Key activities in quality management function as per cGMP guidelines.

II. Post Operational Activities:
1. Distribution:
2. Recalled, Returned Rejected and Recovered Products
3. Product Complaints.

III. Inspection: WHO guidelines on inspection of Pharma MFG. Facilities.

UNIT - IV

I. Manufacturing Operations and Control:
1. Sanitation of Manufacturing Premises.
2. Control of Mix-ups and Cross Contamination.
3. Processing of in process and bulk products.
4. Packaging and labeling operations

5. I.P.Q.C. activities
6. Release of finished products.
7. Process Deviations.
8. Charge in of components.
9. Time Limitation on production.
10. Drug Product Inspections.
11. Expiration dating.
12. Calculation of yields.

UNIT - V

I. Sterile Pharmaceutical Activities:
Manufacturing and Q.A. aspects of sterile Pharmaceutical Products.
II. CGMP guidelines for biological products:
Manufacturing and Q.A. aspects of Biological Products.

RECOMMENDED BOOKS:

1. Pharmaceutical Quality Assurance by M.A. Potdar Nirali Prakashan, Pune
2. Current Good Manufacturing Practices for Pharmaceuticals by Prof. M.A. Potdar B.S. Publications Hydrabad.
3. Good Manufacturing Practices by S.H. Wills and J.R. Stoker Marcker and Dekker Incorporations.
4. Selected International, GMP guidelines of various countries like UK, USA, Australia, South Africa. WHO. India. & ICH guide lines.

Course Code	QUALITY MANAGEMENT SYSTEMS	L	T	P	C
23DAC701**b**		**2**	**0**	**0**	**0**
Semester		**II**			

Course Objectives: This course will enable students:

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Course Outcomes (CO):

At completion of this course it is expected that students will be able to understand-
The importance of quality Statistical approaches for quality

- Stability testing of drug and drug substances
- Quality evaluation of pharmaceuticals
- Analysis of issues in quality
- Tools for quality improvement
- ISO management systems

UNIT - I

Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, preventing cost of quality.

UNIT - II

Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

UNIT - III

Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

UNIT - IV

Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

UNIT - V

Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

Suggested Reading

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley.
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge.
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman, George Benson, Jossey-Bass.
4. Corporate Culture and the Quality Organization by James W. Fairfield- Sonn, Quorum Books.
5. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge.
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications.
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, ASQ Publications.

Course Code	STABILITY OF PHARMACEUTICALS	L	T	P	C
23DAC701**c**		**3**	**0**	**0**	**3**
	Semester	**III**			

Course Objectives:

These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcomes (CO):

The students should describe the evaluation of stability of solutions, solids, and formulations against adverse conditions.

The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT – I

Role of Decomposition on Drug Stability:

Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.

Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation

Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT – II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

UNIT – III

Physical stability testing of dosage forms:

Solids – tablets, capsules, powder and granules, Disperse systems, Microbial decomposition Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT – IV

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT – V

Stability studies: Concept of stability studies.

cGMP& ICH guidelines for Accelerated stability Testing, Interaction of containers & closure Compatibility Testing.

Reference Books:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.

2. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition.

3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.

4. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II – 2010.

5. J. B. Wilkinson and R. J. Moore: Herry's Cosmeticology; Longman Scientific and Technical

Publishers, Singapore.
6. P. D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition – 1997,
7. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
8. Drug stability: Principles and practices by Jens T. Carstensen
9. Stability Testing of Drug Products by W. Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.
1.

Course Code	RESEARCH METHODOLOGY AND INTELLECTUAL PROPERTY RIGHTS	L	T	P	C
23DRM101		4	0	0	4
	Semester	III			

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes (CO): Student will be able to

At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn
  brings about, economic growth and social benefits.

UNIT - I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT - II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT - III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT - IV		
CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals		
UNIT - V		
Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.		
Reference Books:		
1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science &engineering students'" 2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"		

Course Code	PUBLICATION ETHICS IN RESEARCH	L	T	P	C
21S0E1302		2	0	0	2
	Semester	III			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Understand the significance of writing skills and the level of readability
- Analyze and write title, abstract, different sections in research paper
- Develop the skills needed while writing a research paper

UNIT - I		Lecture Hrs:10

Ethics: definition, moral philosophy, nature of moral judgements and reaction

UNIT - II		Lecture Hrs:10

Ethics with respect to science and research 2. Intellectual honesty and research integrity 3. Scientific misconducts: Falsification, Fabrication, and Plagiarism(FFP) 4. Redundant publications: duplicate and overlapping publications, salami slicing 5. Selective reporting and misrepresentation of data.

UNIT - III		Lecture Hrs:10

Publication ethics: definition, introduction and importance 2. Best practices /Standards setting initiatives and guidelines: COPE. WAME, etc., 3. Conflicts of interest 4. Publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types 5. Violation of publication ethics, authorship and contributorship 6. Identification of publication misconduct, complaints and appeals 7. Predatory publishers and journals

UNIT - IV		Lecture Hrs:9

Group Discussions 1. Subject specific ethical issues, FFP, authorship 2. Conflicts of interest 3. Complaints and appeals: examples and fraud from India and abroad B. Software tools Use of plagiarism software like Turnitin, Urkund and other open source software tools

UNIT - V		Lecture Hrs:9

Databases 1. Indexing databases 2. Citation databases: Web of Science, Scopus, etc. B. Research Metrics 1. Impact Factor of Journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score 2. Metrics: h-index, g index, i10 index, altmetrics

Suggested Reading

1. Bird, A.(2006). Philosophy of Science.Routledge
2. Maclntyre, Alasdair (1967) A Short History of Ethics. London
3. P.Chaddah, (2018) Ethics in Competitive Research: Do not get Scooped; do not get Plagiarized, ISBN :978-9387480865
4. National Academy of Sciences, National Academy of Engineering and Institute of Medicine. (2009). On Being a Scientist: A Guide to responsible conduct in

Research: Third Edition, National Academies Press.
5. Resnik, D.B.(2011) What is ethics in research & why is it important. National institute of Environmental Health Science, 1-10 Retrieved from https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm
6. Beall, J: (2012) Predatory publishers are corrupting open access. Nature, 489(7415), 179-179. https://doi.org/10.1038/489179a
7. Indian National Science Academy (INSA), Ethics in Science Education, Research and Governance (2019), ISBN:978-81-939482-1-7. htt://www.insaindia.res.in/pdf/Ethics_Book.pdf.Heidelberg London, 2011

Course Code	PROFESSIONAL BUSINESS SKILLS	L	T	P	C
21DAC301a	(Audit Course)	3	0	0	0
	Semester	III			

Course Objectives:

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes (CO): Student will be able to

On completion of this course it is expected that students will be able to:

To update and expand basic Informatics skills of the students

To equip the students to effectively utilize the digital knowledge resources for their study

UNIT - I

Professionalism: Meaning -Definition – Characteristics – Traits and Qualities of a good professional – Professionalism in business – Professional Skills: important soft skills for business success- Professionalism in Communication: Verbal Communication: Professional Presentation – Different Presentation Postures- Written Communication: Email–Significance of Email in business – Email etiquette: format – rules – dos and don‘ts – Technical

UNIT - II

E-Learning :Introduction of electronic learning – benefits and drawbacks of e-Learning – Online education – Digital age learners – Knowledge resources on internet – E-books, Audio,

Video and other means for e-learning- Introduction to e-content development and tools – Online libraries – MOOCs – The e-Learning as a service Industry – major technologies used

in e-earning- different approaches for e-Learning delivery – E-learning in India

UNIT - III

Business Data Analysis : Features of New Generation Computers – Concept of data analysis

– Business Data Analysis – Data Analyst – Types of analysts – organisation and source of data, importance of data quality, dealing with missing or incomplete data- Social Networking

Analysis – Big Data Analysis – Role of Data Scientist in Business & Society – Role of Artificial Intelligence and Intelligent Agents in e-business – Ethical and Legal considerations

in Business Analytics

UNIT - IV

Budget planning and Implementation, barriers in budgeting, types of budget

UNIT - V

Digital Marketing : Introduction to Digital marketing Environment –meaning & Concept Need for digital marketing – Advantages and disadvantages of digital marketing -Trends in

digital marketing- Types of digital marketing – Business models in digital marketing

Reference Books:

1. Professional Business Skills – Lee Pelitz 2nd Edition
2. Peter Norton, Introduction to Computers, Tata McGraw Hill Private Limited, New Delhi,
   2009.
3. Alan Evans, ITL ESL, Leslie Lamport, Dolores Etter, Darren George,
   Kenneth C Laoudon, Gary Rogers, Rainer Handel, INFORMATICS -Technology in Action,
   Pearson Education, Delhi, 2009.
4. V.Rajaraman, Introduction To Information Technology, PHI Learning Private Limited,New
   Delhi, 2009.

Course Code	IPR and Patents	L	T	P	C
21DAC301b	(Audit Course)	3	0	0	0
	Semester	III			

Course Objectives: Designed to

1. To know the importance of Intellectual property rights, which plays a vital role in advanced Technical and Scientific disciplines
2. Imparting IPR protections and regulations for further advancement, so that the students can familiarize with the latest developments

Course Outcomes (CO):

At the end of this course, students will be able to

1. IPR Laws and patents pave the way for innovative ideas which are instrumental for inventions to seek Patents
2. Student get an insight on Copyrights, Patents and Software patents which are instrumental for further advancements

UNIT - I

Introduction to Intellectual Property Rights (IPR): Concept of Property – Introduction to IPR – International Instruments and IPR – WIPO – TRIPS – WTO -Laws Relating to IPR – IPR Tool Kit – Protection and Regulation – Copyrights and Neighboring Rights – Industrial Property – Patents – Agencies for IPR Registration – Traditional Knowledge – Emerging Areas of IPR – Layout Designs and Integrated Circuits – Use and Misuse of Intellectual Property Rights.

UNIT - II

Copyrights and Neighboring Rights: Introduction to Copyrights – Principles of Copyright Protection – Law Relating to Copyrights – Subject Matters of Copyright – Copyright Ownership – Transfer and Duration – Right to Prepare Derivative Works –Rights of Distribution – Rights of Performers – Copyright Registration – Limitations – Infringement of Copyright – Relief and Remedy – Case Law – Semiconductor Chip Protection Act.

UNIT - III

Patents: Introduction to Patents – Laws Relating to Patents in India – Patent Requirements – Product Patent and Process Patent – Patent Search – Patent Registration and Granting of Patent – Exclusive Rights – Limitations – Ownership and Transfer — Revocation of Patent – Patent Appellate Board – Infringement of Patent – Compulsory Licensing — Patent Cooperation Treaty – New developments in Patents – Software Protection and Computer related Innovations

UNIT - IV

Trademarks: Introduction to Trademarks – Laws Relating to Trademarks – Functions of Trademark – Distinction between Trademark and Property Mark – Marks Covered under Trademark Law – Trade Mark Registration – Trade Mark Maintenance – Transfer of rights – Deceptive Similarities Likelihood of Confusion – Dilution of Ownership – Trademarks Claims and Infringement – Remedies – Passing Off Action.

UNIT - V

rade Secrets & Cyber Law and Cyber Crime: Introduction to Trade Secrets – General Principles – Laws Relating to Trade Secrets – Maintaining Trade Secret – Physical Security – Employee Access Limitation – Employee Confidentiality Agreements – Breach of Contract – Law of Unfair Competition – Trade Secret Litigation – Applying State Law.

Cyber Law – Information Technology Act 2000 – Protection of Online and Computer Transactions –

E-commerce – Data Security – Authentication and Confidentiality – Privacy – Digital Signatures – Certifying Authorities – Cyber Crimes – Prevention and Punishment – Liability of Network Providers.

Reference Books:

Intellectual Property Rights (Patents & Cyber Law), Dr. A. Srinivas. Oxford University Press, New Delhi.

2) Deborah E.Bouchoux: Intellectual Property, Cengage Learning, New Delhi. 3) PrabhuddhaGanguli: Intellectual Property Rights, Tata Mc-Graw –Hill, New Delhi 4) Richard Stim: Intellectual Property, Cengage Learning, New Delhi.

5) Kompal Bansal &Parishit Bansal Fundamentals of IPR for Engineers, B. S. Publications (Press).

6) Cyber Law – Texts & Cases, South-Western's Special Topics Collections.

7) R.Radha Krishnan, S.Balasubramanian: Intellectual Property Rights, Excel Books. New Delhi.

8) M.Ashok Kumar and MohdIqbal Ali: Intellectual Property Rights, Serials Pub.