



ANAND PHARMACY COLLEGE, ANAND
(An Autonomous College under UGC Regulations 2023)
Managed by Shri Ramkrishna Seva Mandal
 (Approved by PCI, NAAC Accredited – A+ Grade, 3.38 CGPA)
 Awarding University: Gujarat Technological University, Ahmedabad



Name of Program: M. Pharm

Branch: – A08

Semester: I

Course Code: M000001TT

Course Name: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Course Type: Core

Year of Implementation: 2025 – 26

Teaching and Examination Scheme:

Number of hours/Week			Number of Credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
4	0	0	4	0	0	4	10	15	25	0	0	0	75	0	100

Scope:

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):

Upon completion of the course student shall be able to

CO1	Understand different chromatographic principles, instrumentation and techniques
CO2	Understand principles and instrumentation for electrophoresis, X-ray crystallography, potentiometry, and thermal analysis
CO3	Understand and apply principles, instrumentation, and techniques of various spectroscopic methods
CO4	Apply principles of spectroscopic techniques to identify and quantify various drugs

Detailed Syllabus:

Total Teaching hours: 60 hours

Unit 1	UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible Spectroscopy, Simultaneous equation method, Derivative spectroscopic method, Difference spectroscopic method	04 Hours
	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, Data interpretation	04 Hours
	Spectro fluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence Spectrophotometer	02 Hours





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	Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications	02 Hours
Unit 2	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 and ¹³ C NMR. Applications of NMR spectroscopy	11 Hours
Unit 3	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	10 Hours
Unit 4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a. Paper chromatography b. Thin Layer chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Affinity chromatography h. Ultra-High Performance Liquid chromatography	03 hours 03 hours 02 hours 03 hours
Unit 5	Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a. Paper electrophoresis b. Gel electrophoresis c. Capillary electrophoresis d. Zone electrophoresis e. Moving boundary electrophoresis f. Iso electric focusing	06 Hours
	X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.	03 Hours
Unit 6	Potentiometry: Principle, thermal transitions, and instrumentation (heat flux and power compensation and designs) working, Ion selective Electrodes and Application of potentiometry.	04 Hours
	Thermal Analysis: Polymer behavior, factors affecting and instrumentation and working, application of TGA	03 Hours

Recommended Books^: (Latest Editions)

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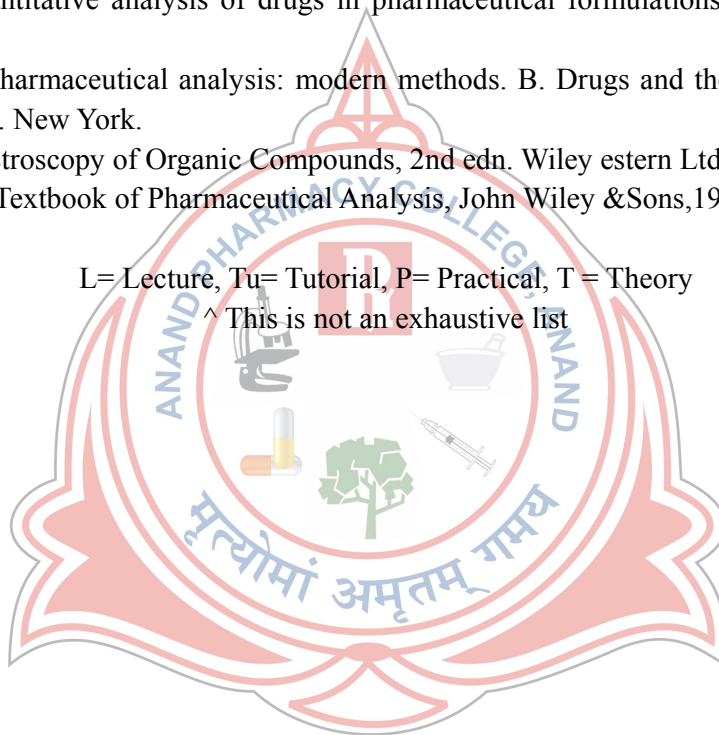
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1. Silverstein RM, Bassler GC. Spectrometric identification of organic compounds. John Wiley & Sons. New York
2. Doglas A Skoog, F. James Holler, Timothy A. Nieman. Principles of Instrumental Analysis Eastern press. Bangalore.
3. Willard H, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis. CBS publisher and distributors. New Delhi. India
4. Beckett AH and Stenlake JB. Practical Pharmaceutical Chemistry. CBS Publishers. New Delhi. India
5. Kemp W. Organic Spectroscopy. ELBS. Macmillan
6. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers. New Delhi. India.
7. Munson JW. Pharmaceutical analysis: modern methods. B. Drugs and the pharmaceutical sciences. Marcel Dekker. New York.
8. P.S/Kalsi, Spectroscopy of Organic Compounds, 2nd edn. Wiley estern Ltd., Delhi.
9. KA. Connors, Textbook of Pharmaceutical Analysis, John Wiley & Sons, 1982.

L= Lecture, Tu= Tutorial, P= Practical, T = Theory

^ This is not an exhaustive list



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Name of Program: M. Pharm

Branch: – A08

Semester: I

Course Code: M080102TT

Course Name: ADVANCED PHARMACEUTICAL ANALYSIS

Course Type: Core

Year of Implementation: 2025 – 26

Teaching and Examination Scheme:

Number of hours/ Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
4	0	0	4	0	0	4	10	15	25	0	0	0	75	0	100

Scope:

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, 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):

Upon completion of the course student shall be able to

CO1	Understand and apply the concepts of impurity profiling in the bulk drugs and various formulations,
CO2	Gain appropriate knowledge related to regulations of impurities, related substances, degradants, residual solvents, elemental impurities
CO3	Understand the fundamentals and apply stability testing principles in different dosage forms as per guidance.
CO4	Apply principles of biological tests, assays and immunoassays

Detailed Syllabus:

Total Teaching hours: 60 hours

Unit 1	Impurity and stability studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines	4 Hours
	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	3 Hours
	Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents	3 Hours
Unit 2	Elemental impurities: Element classification, control of elemental impurities,	4 Hours

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	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.	6 Hours
Unit 3	Impurity profiling and degradant 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 degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products	10 Hours
Unit 4	Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity	10 Hours
Unit 5	Biological tests and assays of the following: a. 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)	10 Hours
Unit 6	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.	10 Hours

Recommended Books^: (Latest Editions)

1. Jeffery J Bassett, J. Mendham, R. C. Denney, Vogel's textbook of quantitative chemical analysis, ELBS, 1991.
2. Beckett and Stenlake, Practical Pharmaceutical Chemistry, Vol II, CBS publishers, New Delhi, 1997.
3. K A Connors, Textbook of Pharmaceutical Analysis, John Wiley & Sons, 1982.
4. Higuchi, Brochmman and Hassen, Pharmaceutical Analysis- Wiley- Inter science Publication, 1961.
5. P D Sethi, Quantitative Analysis of Drugs in Pharmaceutical formulation, CBS Publishers New Delhi, 1997.
6. J W Munson – Pharmaceutical Analysis- Modern methods - Part B, Volume 11, Marcel Dekker Series.
7. D C Carratt, The Quantitative analysis of Drugs, CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.

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9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Snyder, Kirkland, Glajch, Practical HPLC method development, John Wiley & Sons.
11. Klaus Florey, Analytical Profiles of drug substances – Volume 1– 20, Elsevier, 2005
12. Harry G Brittan, Analytical Profiles of drug substances and Excipients – Volume 21– 30, Elsevier, 2005.
13. Joseph Chamberlain, The analysis of drugs in biological fluids, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies

L= Lecture, Tu= Tutorial, P= Practical, T = Theory

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Name of Program: M. Pharm

Branch: – A08

Semester: I

Course Code: M080103TT

Course Name: PHARMACEUTICAL VALIDATION

Course Type: Core

Year of Implementation: 2025 – 26

Teaching and Examination Scheme:

Number of hours/ Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
4	0	0	4	0	0	4	10	15	25	0	0	0	75	0	100

Scope:

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):

Upon completion of the course student shall be able to

CO1	Understand and apply basic concepts of calibration, qualification, and validation in pharmaceutical industry.
CO2	Develop and apply skills for qualification and validation of different equipment as per guidelines.
CO3	Apply the key concepts and documentation for utilities, cleaning, analytical method and computer system validation as per guidelines.
CO4	Understand the role of intellectual property and patent filing procedure in pharmaceutical industry.

Detailed Syllabus:

Total Teaching hours: 60 hours

Unit 1	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.	4 Hours 8 Hours
Unit 2	Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.	12 Hours





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Unit 3	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).	6 Hours 6 Hours
Unit 4	Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.	6 Hours 6 Hours
Unit 5	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 application; 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.	12 Hours

Recommended Books^: (Latest Editions)

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

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Name of Program: M. Pharm

Branch: – A08

Semester: I

Course Code: M080104TT

Course Name: FOOD ANALYSIS

Course Type: Core

Year of Implementation: 2025 – 26

Teaching and Examination Scheme:

Number of hours/Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
4	0	0	4	0	0	4	10	15	25	0	0	0	75	0	100

Scope:

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):

Upon completion of the course student shall be able to

CO1	Understand and apply fundamentals of carbohydrates, proteins, lipids along with their determination by analytical techniques.
CO2	Apply various analytical techniques in the determination of food additives.
CO3	Apply various analytical techniques in the determination of finished food products and pesticides.
CO4	Utilize legal regulations for food products as per guidance related to food analysis.

Detailed Syllabus:

Total Teaching hours: 60 hours

Unit 1	Carbohydrates: classification and properties food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates	7 Hours
	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, Digestion, absorption and metabolism of proteins.	5 Hours
Unit 2	Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.	6 Hours
	Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of	6 Hours

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	microbial assay of vitamins of B-series.	
Unit 3	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.	12 Hours
Unit 4	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.	12 Hours
Unit 5	Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, organophosphorus pesticide cycle, and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.	8 Hours 4 Hours

Recommended Books^: (Latest Editions)

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

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Name of Program: M. Pharm

Branch: – A08

Semester: I

Course Code: M080105PP

Course Name: PHARMACEUTICAL ANALYSIS PRACTICALS- I

Course Type: Core

Year of Implementation: 2025 – 26

Teaching and Examination Scheme:

Number of hours/Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
0	0	12	0	0	6	6	0	0	0	20	30	50	0	100	150

Course Outcomes (CO):

Upon completion of the course student shall be able to

CO1	Recall basic principles of analytical techniques for identification and quantification
CO2	Demonstrate analytical skills for determination of drugs, formulations, impurities and food along with calibration and validation experiments

List of Practicals:

Total Teaching hours: 120 hours

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment



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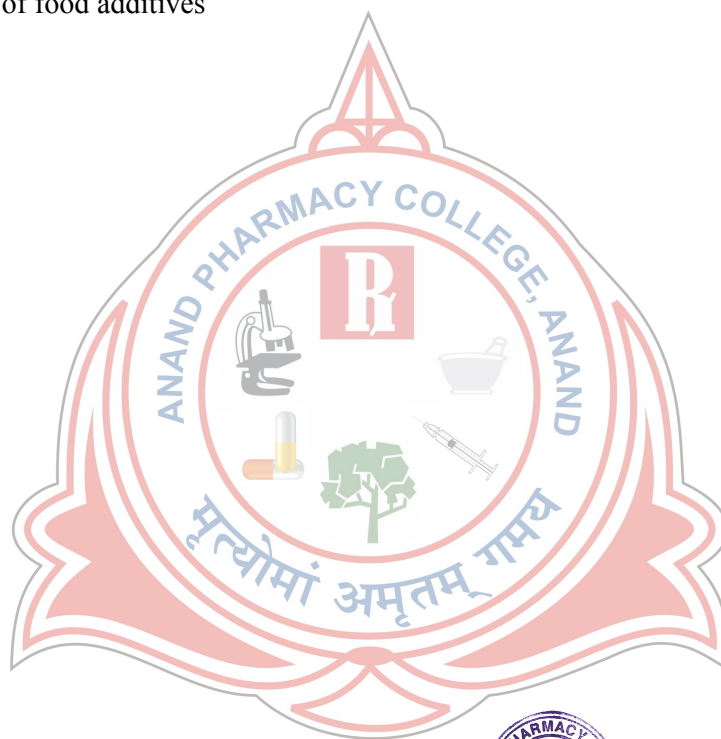
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20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives



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Number of hours/ Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
4	0	0	4	0	0	4	10	15	25	0	0	0	75	0	100

Scope:

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):

Upon completion of the course student shall be able to

CO1	Understand the fundamentals, instrumentation and techniques of chromatography, electrophoresis the detailed interpretation pattern for the organic substances
CO2	Illustrate the principles, instrumentation of hyphenated techniques and its applications
CO3	Interpret and apply knowledge for identification and characterization of organic compounds
CO4	Demonstrate knowledge for selection of appropriate analytical techniques for identification, characterization, quantification along with applying analytical troubleshooting

Detailed Syllabus:**Total Teaching hours:** 60 hours

Unit 1	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	4 Hours
	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	8 Hours

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	approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.	
Unit 2	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. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.	6 Hours 6 Hours
Unit 3	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.	4 Hours 8 Hours
Unit 4	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 (Quadrupole, 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.	4 Hours 8 Hours
Unit 5	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 ¹³ CNMR: Spin spin and spin lattice relaxation phenomenon. ¹³ C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.	5 Hours 7 Hours

Recommended Books^: (Latest Editions)

1. Robert M Silverstein, Spectrometric Identification of Organic compounds- Sixth edition, John Wiley & Sons, 2004.
2. Douglas A Skoog, F. James Holler, Timothy A. Nieman, Principles of Instrumental Analysis- 5th edition, Eastern press, Bangalore, 1998.
3. Willards, Instrumental methods of analysis– 7th edition, CBS publishers.
4. William Kemp, Organic Spectroscopy- 3rd edition, ELBS, 1991.
5. P D Sethi, Quantitative analysis of pharmaceutical formulations by HPTLC- CBS Publishers, New Delhi.

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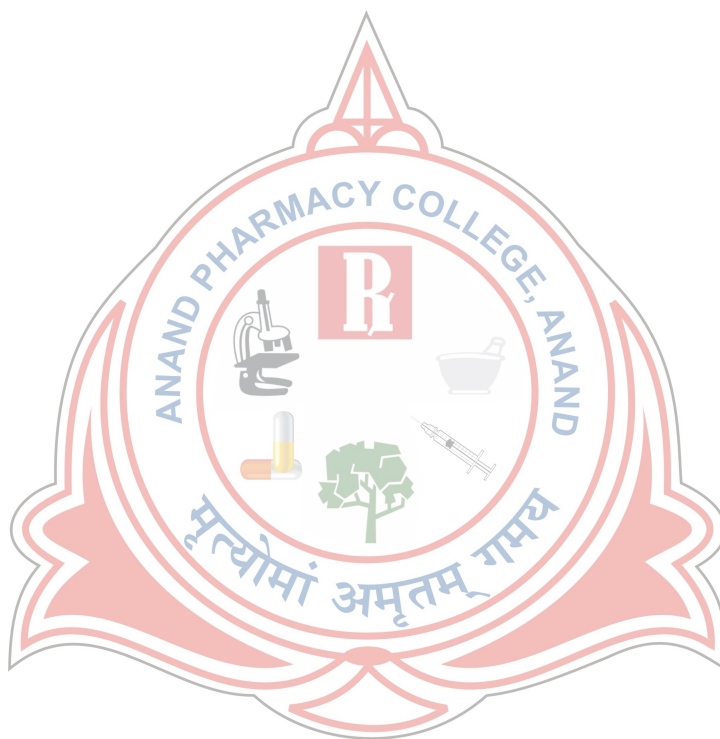
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6. P D Sethi, Quantitative Analysis of Drugs in Pharmaceutical formulation - 3rd Edition, CBS Publishers, New Delhi, 1997
7. J W Munson, Pharmaceutical Analysis- Modern methods– Part B- Volume 11, Marcel Dekker Series.
8. Donald L. Paviya, Organic Spectroscopy, 5th Edition

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Number of hours/ Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
4	0	0	4	0	0	4	10	15	25	0	0	0	75	0	100

Scope:

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

Course Outcomes (CO):

Upon completion of the course student shall be able to

CO1	Understand and apply principles of bioanalysis for analysis of drugs and metabolites with its regulatory requirements
CO2	Illustrate the fundamentals of biopharmaceutics, pharmacokinetics and toxicokinetics
CO3	Apply knowledge to conduct bioequivalence study for formulations by utilizing the regulatory guidelines
CO4	Summarize principles and interpretation of cell culture techniques

Detailed Syllabus:**Total Teaching hours:** 60 hours

Unit 1	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.	12 Hours
Unit 2	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.	12 Hours

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Unit 3	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.	12 Hours
Unit 4	Cell culture techniques: Basic equipments used in cell culture lab. Cell culture media, various types of 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.	12 Hours
Unit 5	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.	4 Hours 8 Hours

Recommended Books^: (Latest Editions)

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

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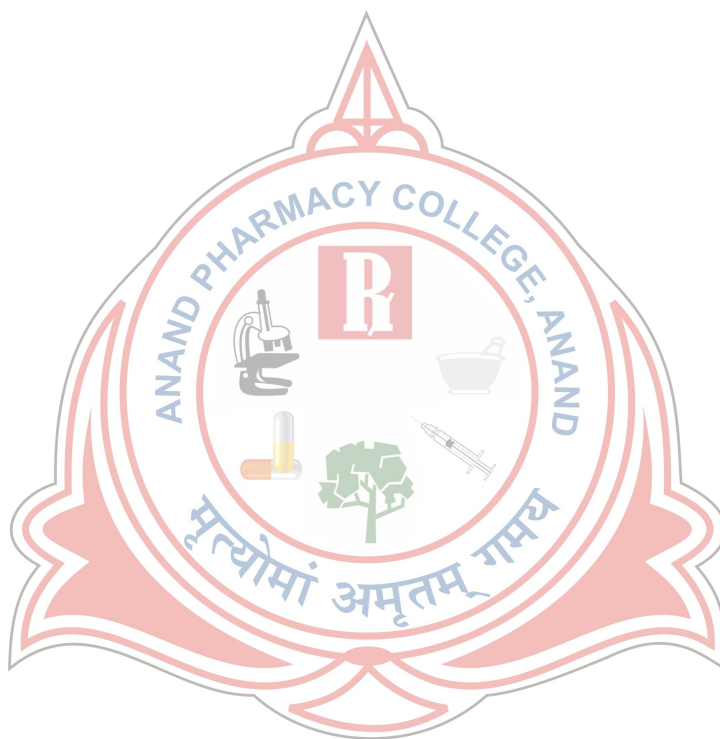


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Number of hours/ Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
4	0	0	4	0	0	4	10	15	25	0	0	0	75	0	100

Scope:

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):

Upon completion of the course student shall be able to

CO1	Understand the evolution and scope of Quality Control and Quality Assurance in the pharmaceutical industry
CO2	Recognize and apply principles of Good Laboratory Practices, CCSEA guidelines, and cGMP guidelines for pharmaceutical industries
CO3	Implement good documentation practices in pharma industry
CO4	Illustrate fundamentals to analyze raw materials, finished products, packaging material and IPQC for ensuring compliance with Pharmacopoeial standards

Detailed Syllabus:**Total Teaching hours:** 60 hours

Unit 1	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.	6 Hours
	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.	6 Hours
Unit 2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and	12 Hours

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	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 3	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.	5 Hours 5 Hours 2 Hours
Unit 4	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.	12 Hours
Unit 5	Manufacturing operations and controls: Sanitation of manufacturing premises, processing mix-ups and cross contamination, 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.	12 Hours

Recommended Books^: (Latest Editions)

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Sandy Weinberg Good Laboratory Practice Regulations, 2nd Edition, 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. P P Sharma, How to Practice GMP's- Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia- vol I, II, III, IV & V- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Allen F. Hirsch, Good laboratory Practice Regulations- Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines

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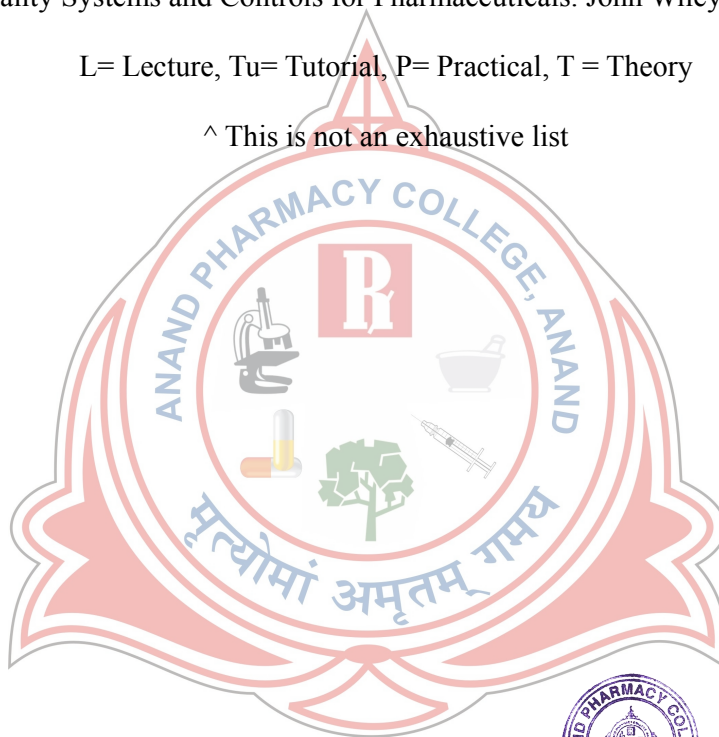
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8. ISO 9000 and total quality management
9. Deshpande, Nilesh Gandhi, The drugs and cosmetics act 1940– 4th edition, Susmit Publishers, 2006.
10. D.H. Shah, QA Manual– 1st edition, Business Horizons, 2000.
11. Sidney H.Willig, Good Manufacturing Practices for Pharmaceuticals a plan for total quality control– 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.

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Number of hours/ Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
4	0	0	4	0	0	4	10	15	25	0	0	0	75	0	100

Scope:

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

Course Outcomes (CO):

Upon completion of the course student shall be able to

CO1	Understand and apply regulatory requirements as per herbal and cosmetic regulations
CO2	Apply analytical techniques for determination of herbal products and study of monographs as per standards
CO3	Recognize herbal adulteration and herbal drug drug interactions for safety of herbal products
CO4	Utilize various performance evaluation techniques for cosmetic products

Detailed Syllabus:**Total Teaching hours:** 60 hours

Unit 1	Herbal remedies- Toxicity and Regulations: Herbals vs of Conventional drugs, Efficacy of herbal medicine products, Validation Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.	12 Hours
Unit 2	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.	12 Hours

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	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 3	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.	8 Hours 4 Hours
Unit 4	Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.	12 Hours
Unit 5	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.	12 Hours

Recommended Books[^]: (Latest Editions)

1. Trease and Evans, Pharmacognosy.
2. Purohit and Gokhale, Pharmacognosy by Kokate.
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Ashutosh Kar, Pharmacognosy & Pharmacobiotechnology.
5. Dr.S.H.Ansari, Essential of Pharmacognosy.
6. P.P. Sharma, Cosmetics– Formulation, Manufacturing and Quality Control, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, NewDelhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, Handbook of Cosmetic Science and Technology, 3rd Edition, 10th Edition, Kluwer Academic Publishers.

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Name of Program: M. Pharm

Branch: – A08

Semester: II

Course Code: M080205PP

Course Name: PHARMACEUTICAL ANALYSIS PRACTICALS- II

Course Type: Core

Year of Implementation: 2025 – 26

Teaching and Examination Scheme:

Number of hours/ Week			Number of credits			Total credits	Evaluation Scheme (Marks)								Total Marks
							Sessional Exams						Term End Assessment		
							Theory			Practical					
L	Tu	P	L	Tu	P		CIE	E	T	CIE	E	T	T	P	
0	0	12	0	0	6	6	0	0	0	20	30	50	0	100	150

Course Outcomes (CO):

Upon completion of the course student shall be able to

CO1	Recall basic principles related to identification, interpretation, analytical, bio-analytical techniques along with QAQC practices
CO2	Demonstrate skills for interpretation, analysis of drugs, dosage forms, cosmetics and bio-analysis along with QAQC related experiments

List of Practicals:

Total Teaching hours: 120 hours

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 Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and 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/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
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

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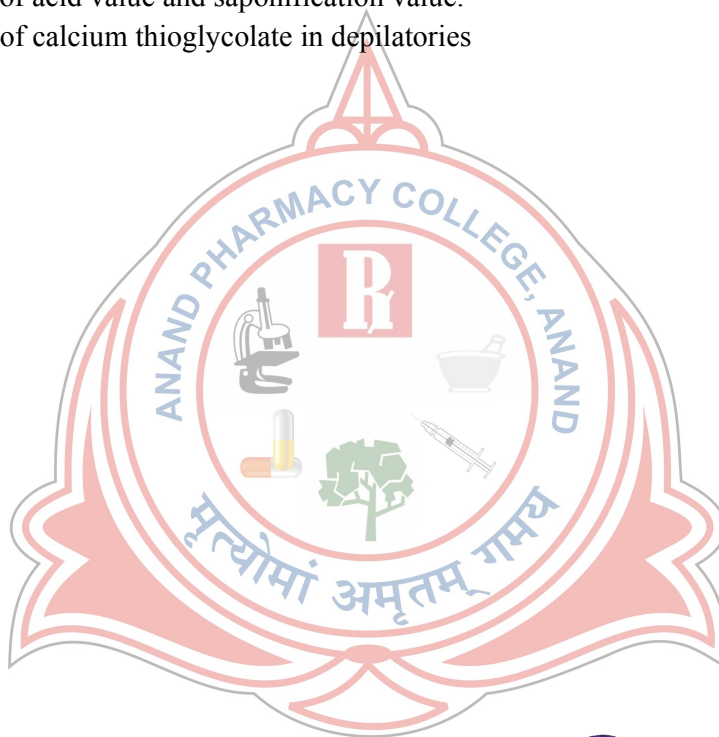
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15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories




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