FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2025-26

Programme : Master of Pharmacy (Pharmaceutical Analysis)

Semester : II

Course Code : 108310201

Course Title : Advanced Instrumental Analysis

Course Objectives:

Upon completion of this course the student should be able to

1. Interpretation of the NMR, Mass and IR spectra of various organic compounds
2. Theoretical and practical skills of the hyphenated instruments
3. Identification of organic compounds

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
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, m 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	12
2	**Bio-chromatography**: 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	12

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

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	**12**
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	**12**
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 13CNMR: Spin – spin and spin – lattice relaxation phenomenon. 13CNMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations	**12**

Reference Books:

1	Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th 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, 3rdedition, 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. Pavia, 5th Edition
9	Introduction to Instrumental Analysis By Robert D Braun, BSP Books Pvt. Limited, 2016
10	Instrumental Methods of Chemical Analysis By Dr. B. K. Sharma, Krishna Prakashan, 1981

Pedagogy:

1. ICT Tools (Power point presentation, video sharing on Projector, Smart board)
2. Traditional teaching methodology (Blackboard)

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
30	30	20	15	5	0	

Note: This specification table shall be treated as a general guideline for students and teachers. Theactual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Explain principles, instrumentation and applications of sophisticated chromatographic techniques	**40**
CO-2	Describe principle and applications of capillary electrophoresis	**10**
CO-3	Explain principle, instrumentation and applications of mass spectrometry	**25**
CO-4	Explain principles, instrumentation and applications of NMR techniques	**25**

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2020
Last Reviewed on (Month-Year):	April 2025
Next Review on (Month-Year):	April 2030

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

FACULTY OF PHARMACEUTICAL SCIENCE

Effective from Academic Batch: 2025-26

Programme : **MASTER OF PHARMACY (PHARMACEUTICAL ANALYSIS)**

Semester : **II**

Course Code : **108310202**

Course Title : **Modern Bio-analytical Technique**

Course Objectives: Upon completion of the course the student shall be able to

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

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
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, Solid phase extraction and other novel sample preparation approach. **Bioanalytical method validation**: USFDA and EMEA guidelines	12
2	**Biopharmaceutical Consideration**: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In-Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Bio-pharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods	12
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

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

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**
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.	**12**

Reference Books:

1	Analysis of drugs in Biological fluids - Joseph Chamberlain, 2ndEdition. CRC Press, New York, 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– Inter-science 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, 2 nd 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 L Bertholf, 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	Enzymes by Trevor Palmer
12	Identification and Quantification of Drugs, Metabolites, Drug Metabolizing Enzymes, and Transporters Concepts, Methods and Translational Sciences - Shuguang Ma, Swapan Chowdhury, Elsevier Science, 2nd Edition, 2020.

Pedagogy:
Power point presentation, Smart board

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
10	15	25	25	25	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Explain various extraction techniques to isolate drugs and metabolites from biological matrices, bioanalytical method validation as per regulatory guidelines.	**20**
CO-2	Describe the impact of biopharmaceutical consideration on drug bioavailability, and experimental methods for dissolution, solubility and permeability studies.	**20**
CO-3	Explain pharmacokinetic and toxicokinetic studies to assess drug interactions, metabolism, and safety using analytical tools.	**20**
CO-4	Describe in depth cell culture techniques and viability assays for drug screening and toxicity evaluation.	**20**
CO-5	Explain drug metabolite identification approaches and regulatory guidelines to design and interpret bioequivalence studies.	**20**

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2020
Last Reviewed on (Month-Year):	April 2025
Next Review on (Month-Year):	April 2030

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

FACULTY OF PHARMACEUTICAL SCIENCE

Effective from Academic Batch: 2025-26

Programme : **MASTER OF PHARMACY (PHARMACEUTICAL ANALYSIS)**

Semester : **II**

Course Code : **108310203**

Course Title : **Quality Control and Quality Assurance**

Course Objectives: Upon completion of the course the student shall be able to

1. The cGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to pharmaceutical industries
4. To understand the responsibilities of QA & QC Departments

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	Concept and Evaluation 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 nonclinical testing, control on animal house, report preparation and documentation	12
2	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**	12

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

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, parenteral, ophthalmic, and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials	**12**
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**
5	**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	**12**

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, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6	Good laboratory Practice regulations– Allen F. Hirsch, Vol. 38, Marcel Dekker Series, 1989.
7	ICH guidelines
8	ISO 9000 and total quality management
9	The drugs and cosmetics act 1940– Desh Pande, 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, 6th edition, Vol. 1 - With Checklists and Software Package. Taylor & Francis; 2003.
13	Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14	Continuous Manufacturing of Pharmaceuticals - Johannes Khinast, Jukka Rantanen, Peter Kleinebudde, Wiley, 2017.

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

Pedagogy:
1. ICT tools (LCD projector, Laptop, Smart board)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
40	50	5	5	0	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr. No.	Course Outcome Statements	%weightage
CO-1	Describe the concept of quality assurance, quality control, GLP and cGMP in Pharmacy.	**30**
CO-2	Explain CPCSEA guideline.	**10**
CO-3	Explain quality control test for raw materials, finished products, packaging materials for Pharmaceuticals.	**20**
CO-4	Describe documentation in pharmaceutical industry.	**20**
CO-5	Describe pharmaceutical manufacturing operations and controls.	**20**

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2020
Last Reviewed on (Month-Year):	April 2025
Next Review on (Month-Year):	April 2030

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2025-26

Programme : **Master of Pharmacy (Pharmaceutical Analysis)**

Semester : **II**

Course Code : **108310204**

Course Title : **Herbal and Cosmetic Analysis**

Course Objectives: Upon completion of the course the student shall be able to

1. Determine of herbal remedies and regulations
2. Analyze of natural products and monographs
3. Understand of Herbal drug-drug interaction
4. Learn the principles of performance evaluation of cosmetic products

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	**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	12
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, photo – toxin 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	12

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

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 Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs	**12**
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 interaction with suitable examples. Challenges in monitoring the safety of herbal medicines	**12**
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, lipsticks. Hair products and skin creams by the Bureau Indian Standards	**12**

Reference Books:

1	Pharmacognosy by Trease and Evans
2	Pharmacognosy by Kokate, Purohit and Gokhale
3	Quality Control Method for Medicinal Plant, WHO, Geneva
4	Pharmacognosy & Pharmaco – biotechnology by Ashutosh Kar
5	Essential of Pharmacognosy by Dr. S. H. Ansari
6	Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt .Ltd., Delhi
7	Indian Standard Specification, for raw materials, BIS, New Delhi.
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, 7th edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12	Hilda Butler, 10th edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology
13	Quality Control and Evaluation of Herbal Drugs Evaluating Natural Products and Traditional Medicine By Pulok K. Mukherjee, Elsevier Science, 2019.

Pedagogy:

1. Use of Traditional method of teaching (Blackboard) for pedagogy
2. Use ICT tools: Power point presentation (Laptop and projector, Smart Board)

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
30	30	10	10	-	-	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr.	Course Outcome Statements	% Weightage
CO-1	Explain herbal remedies-toxicity and regulation, herbal drug standardization.	**20**
CO-2	Explain adulteration and deterioration of herbal drugs and regulatory requirement for herbal drug industry.	**20**
CO-3	Describe monographs of herbal drugs, testing of natural products and drug.	**20**
CO-4	Explain herb-drug, herb-food interactions, and safety monitoring as per WHO and AYUSH guidelines.	**20**
CO-5	Explain various method of analysis for cosmetic raw materials and finished products as per Bureau of Indian Standards.	**20**

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2020
Last Reviewed on (Month-Year):	April 2025
Next Review on (Month-Year):	April 2030

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2025-26

Programme : **Master of Pharmacy (Pharmaceutical Analysis)**

Semester : **II**

Course Code : **108310205**

Course Title : **Pharmaceutical Analysis Practical-II**

Course Objectives: Upon completion of the course the student shall be able to

1. Understand the concept of interpretation and identification of organic compounds by MS, NMR, FT-IR spectra
2. Learn protocol preparation and performance of analytical and bio analytical method validation
3. Perform quality control test for evaluation of raw materials, finished pharmaceutical products, cosmetics and packaging materials
4. Isolate and estimate drugs from biological fluids
5. Learn preparation of batch manufacturing and master formula records

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
-	-	12	6	-	-	50/20	100/40	150/75

* **J**: Jury; **V**: Viva; **P**: Practical

List of Practicals:

1	Comparison of absorption spectra by UV and Wood ward– Fissure 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/Bio analytical 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, parenteral and creams
13	Quality control tests for Primary and secondary packing materials
14	Assay of raw materials as per official monographs

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

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 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

Course Outcomes (CO):

Sr.	Course Outcome Statements	% Weightage
CO-1	Interpret and identify organic compounds using spectroscopic techniques including UV, FT-IR, NMR, and Mass spectrometry	**25**
CO-2	Apply various analytical techniques for separation, isolation and quantification of biomolecules and drugs from biological fluids	**20**
CO-3	Evaluate pharmaceutical products through in-process and finished product quality control testing according to official guidelines	**20**
CO-4	Design and implement analytical/bioanalytical method validation protocols and procedures for BA/BE studies	**15**
CO-5	Analyze cosmetic products and packaging materials for quality parameters using appropriate analytical methods	**20**

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2020
Last Reviewed on (Month-Year):	April 2025
Next Review on (Month-Year):	April 2030

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in

FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2025-26

Programme: **Master of Pharmacy (Pharmaceutical Analysis)**

Semester: **II**

Course Code: **108310206**

Course Title: **Seminar/Assignment**

Course Objectives:
At completion of this course student shall be able to
1. Develop skills to collect and organize data
2. Acquire knowledge on the current topic in field pharmaceutical science
3. Perform effective presentation and communication skill

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
-	-	8	4	-	-	100/40	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Guidelines
Seminar will be given on the current topic in the field of pharmaceutical science. Student will gather information, compile data in the form of report and give presentation on the topic given.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Develop skills to collect and organize information for the given topic	25
CO-2	Compile data and develop write-up skill on the topic given for seminar presentation	25
CO-3	Develop communication and presentation skills	25
CO-4	Effectively respond to the queries and questions raised	25

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2020
Last Reviewed on (Month-Year):	April 2025
Next Review on (Month-Year):	April 2030

Opp. Shastri Maidan, Beside BVM College, Vallabh Vidyanagar, Dist: Anand, Gujarat - 388120
(O): 02692-238001 | Email: adminoffice@cvmu.edu.in | www.cvmu.edu.in