

# Pt. Ravishankar Shukla University, Raipur (C.G.), India 492010

# **CURRICULUM & Syllabus**

(Based on CBCS & LOCF)

# M. Pharm.- Pharmaceutical Analysis

(Semester System)

**Semester: I-IV** 

Session: 2025-2027

टीप:- सत्र. 20242025 के पाठ्यक्रम को सत्र 20252026.....के लिए यथावत प्रभावशील किया जाता है।

Approved by Board of Studies:

Pharmacy

Dates

16-05-2025

Name of Chairman

Dr. S. J. Daharwal

Name of Member's

Dr. Preeti K. Suresh

Dr. Manju Singh

Dr. Amber Vyas-

Dr. Deependra Singh

# M. Pharm in Pharmaceutical Analysis

#### Program Outcomes (POs)

#### PO-1: Knowledge

Acquire comprehensive knowledge and skills in analytical method development, validation, and application across various pharmaceutical dosage forms. Gain expertise in advanced instrumentation such as HPLC, GC, UV-Vis, IR, NMR, and MS, as well as in regulatory frameworks (ICH, WHO, FDA), quality assurance, stability testing, impurity profiling, and pharmacopoeial standards.

#### PO-2: Critical Thinking and Reasoning

Develop the ability to critically evaluate data, interpret analytical results, and troubleshoot analytical problems. Apply scientific reasoning to ensure accuracy, precision, and reliability of pharmaceutical analyses in alignment with regulatory expectations.

#### **PO-3: Problem Solving**

Identify, analyze, and provide solutions to complex analytical challenges related to drug purity, content uniformity, degradation products, and bioanalytical quantification using a rational and scientific approach.

# PO-4: Advanced Analytical and Computational Skills

Utilize modern analytical technologies and computational tools for data analysis, method optimization, and validation processes. Understand the integration of informatics and automation in pharmaceutical analysis and quality control.

#### **PO-5: Effective Communication**

Communicate effectively and professionally with peers, regulatory bodies, industry personnel, and academic audiences regarding analytical findings, method validation reports, and compliance documentation.

#### PO-6: Social/Interdisciplinary Interaction

Collaborate with experts from interdisciplinary fields such as formulation, pharmacology, toxicology, and regulatory sciences to address analytical requirements throughout the drug development lifecycle and support public health initiatives.

#### PO-7: Self-directed and Life-long Learning

Foster a commitment to continuous learning and professional growth. Stay abreast of advancements in analytical sciences, evolving regulatory guidelines, and emerging instrumentation to maintain relevance and leadership in the field.

#### PO-8: Effective Citizenship: Leadership and Innovation

Demonstrate leadership in laboratory settings and research environments by implementing innovative analytical strategies and ensuring adherence to good laboratory practices (GLP) and ethical standards. Contribute meaningfully to the organization and society.

#### PO-9: Ethics

Adopt a strong sense of professional and scientific ethics in handling data integrity, regulatory documentation, research practices, and industrial operations. Ensure compliance with ethical norms in quality control and regulatory submissions.

# PO-10: Further Education or Employment

Pursue higher studies (Ph.D., post-doctoral research) or build a career in quality control, quality assurance, R&D, regulatory affairs, or academia. Become industry-ready for roles in pharmaceutical companies, CROs, and global regulatory organizations.

1 × 1

#### **PO-11: Global Perspective**

Understand the global implications of pharmaceutical analysis, including harmonization of standards, cross-border regulatory expectations, and international quality benchmarks. Appreciate cultural diversity and global healthcare needs in the analytical domain.

#### **Program Specific Outcomes (PSOs)**

#### **PSO-1: Mastery of Analytical Techniques**

Demonstrate advanced proficiency in the operation, calibration, and troubleshooting of sophisticated analytical instruments such as HPLC, GC, UV-Vis, FTIR, NMR, and MS for qualitative and quantitative analysis of pharmaceutical substances.

#### **PSO-2: Method Development and Validation**

Design, develop, and validate analytical and bioanalytical methods following ICH and other global regulatory guidelines to ensure reliability, accuracy, and reproducibility of test results in both R&D and quality control settings.

#### **PSO-3: Regulatory and Quality Compliance**

Apply comprehensive knowledge of regulatory standards and quality assurance practices to prepare dossiers, audit laboratories, and maintain compliance with cGMP, GLP, and global regulatory frameworks (ICH, WHO, FDA).

#### **PSO-4: Research and Data Interpretation**

Engage in scientific research by employing validated analytical methods, conducting stability studies, impurity profiling, and statistical data analysis using appropriate biostatistical and computational tools to support formulation and product development.

# **PSO-5: Industry Readiness and Ethical Practice**

Demonstrate readiness to take up professional roles in the pharmaceutical industry, CROs, or academia with strong ethical standards, effective communication skills, and a thorough understanding of industry workflows in analytical and regulatory domains.

Art Shart

# M. Pharm in Pharmaceutical Analysis

# Semester-I

Program	Subject	Year		Semester
M. Pharm.	Pharmaceutical Analysis	1		I
Course Code	Course '	Title		Course Type
MPA 102T	MODERN PHARMACEUTI TECHNIQUES	CAL ANALYTICAL	AN INCOME.	Core
Credit		Hours Per Week (L-	Г-Р)	
	L	Ť		P
4	4			
Maximum Marks	CIA			ESE
100	25			75

# Learning Objective (LO):

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

# Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to:	CL
1	Understand the significance of pharmacognosy in the herbal drug industry and explain the principles and practices of cultivation, collection, and conservation of medicinal plants, including regulatory and ethical guidelines.	Ap
2	Describe the techniques for isolation and purification of marine natural products, identify marine toxins, discuss recent advances, and analyze challenges and solutions in marine drug research.	Ap
3	Explain the classification, formulation, standardization, and regulatory guidelines of nutraceuticals; and evaluate the sources, chemical nature, and health benefits of commonly used nutraceutical ingredients.	U
4	Identify and classify important phytopharmaceuticals based on chemical nature, explain their isolation, and evaluate their pharmacological and health-related applications.	An
5	Understand and apply WHO and AYUSH guidelines for safety monitoring of natural medicines, and analyze biodrug interactions and reporting systems with appropriate examples.	Ū

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

A.110 3 X X M

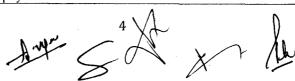
# CO-PO/PSO Mapping for the course:

PO	. A.		i dayan		1.504	POs	and the second		A Section				i de la	PS	О	
co	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	1	2	3	3	2	3	2	2	3	1	2	3	2
CO2	3	3	3	3	1	1	3	1	2	3	2	2	3	2	1	2
CO3	3	3 .	2	3	2	2	2	2	2	3	3	3	3	2	2	3
CO4	3	2	3	3	2	1	3	2	2	3	2	3	3	3	2	2
CO5	3	3	2	1	3	2	3	1	3	2	3	2	2	2	2	3

<sup>&</sup>quot;3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

# Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
	a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 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) Spectroflourimetry: 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.		1
II	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 13C NMR. Applications of NMR spectroscopy.		2
III	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.		3
	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:  a. Thin Layer chromatography  b. Thin Layer Chromatography  c. Ion exchange chromatography  d. Column chromatography  e. Gas chromatography  f. High Performance Liquid chromatography  g. Affinity chromatography		4



V	<ul> <li>a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:</li> <li>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d)</li> <li>Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing</li> </ul>	10hrs	
	b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction		
	Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays		
VI	<b>Potentiometry:</b> Principle, working, Ion selective Electrodes and Application of potentiometry.	10hrs	
	Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.		

#### **Books Recommended:**

- 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, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
- 3. Instrumental methods of analysis Willards, 7th edition, CBS publishers.
- 4. Practical Pharmaceutical Chemistry Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
- 5. Organic Spectroscopy William Kemp, 3rd edition, ELBS, 1991.
- 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, Vol 11, Marcel. Dekker Series
- 8. Spectroscopy of Organic Compounds, 2<sup>nd</sup> edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
- 9. Textbook of Pharmaceutical Analysis, KA.Connors, 3<sup>rd</sup> Edition, John Wiley & Sons, 1982.

And 5 A A

	Subject	Year	Semester		
M. Pharm.	Pharmaceutical Analysis	1	I		
Course Code	Course	Fitle	Course Type		
MPA 102T	Advanced Pharmaceutical Ar	nalysis	Core		
Credit	İ	P)			
	L.	T	Р		
4	4	_			
Maximum Marks	CIA		ESE		
100	25		75		

# Learning Objective (LO):

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.

After completion of the course students shall able to know,

- 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

	Course Outcomes (CO):
CO1	Understand and classify impurities in drugs, their quantification as per ICH guidelines, and regulatory aspects of residual solvents and elemental impurities.
CO2	Explain stability testing protocols, study factors affecting stability, and perform shelf life calculations following ICH and WHO guidelines.
CO3	Develop analytical methods for impurity profiling and degradation characterization; apply accelerated stability testing and photostability testing.
CO4	Describe stability testing of phytopharmaceuticals and use HPTLC/HPLC fingerprinting techniques for analysis.
CO5	Understand biological assays for vaccines and biological products, PCR techniques for gene regulation, and principles/applications of immunoassays.

AND 6 M X M

# CO-PO/PSO Mapping for the course:

POCO				POs									PSO			
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	1	1	1	0	0	0	0	0	l	0	0	1	1	1	0	0
CO2	1	1	1	1	0	0	1	0	1	0	0	0	1	1	1	0
CO3	1	1	1	1	0	0	1	0	1	0	0	1	1	1	1	0
CO4 +	1	0	1	1	0	0	0	0	1	0	0	1	1	1	0	0
CO5	1	1	0	1	1	1	1	0	1	0	1	1	0	0.	1	1

,	Detailed Syllabus:	
1.	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	60 Hrs 10 Hrs
2	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.	10 Hrs
3	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. Photostability testing guidelines, ICH stability guidelines for biological products	10 Hrs
4	Stability testing of phytopharmaceuticals:  Regulatory requirements, protocols, HPTLC/HPLC fingerprinting, interactions and complexity.	10 Hrs

A. Wis S 7 X As Ale

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine	Hrs
h 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)	
Immunoassays (IA)	10
Basic principles, Production of antibodies, Separation of bound and unbound drug,	Hrs
Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification	
and applications of IA.	
	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)  Immunoassays (IA)  Basic principles, Production of antibodies, Separation of bound and unbound drug,  Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification

#### Books Recommended:

- 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.
- 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, NewDelhi, 1964.
- 8. Indian Pharmacopoeia Vol I, 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 21 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.

10 m2 8 1 /m

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Analysis	1	I
Course Code	Course	itle	Course Type
MPA 103T	PHARMACEUTICAL VAL	IDATION	Core
Credit	H	ours Per Week (L-T	(-P)
	L	T	P
4	4		
Maximum Marks	CIA		ESE
100	25		75

# Learning Objective (LO):

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

At completion of this course, it is expected that students will be able to understand

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

# **Course Outcomes (CO):**

CO No.	Expected Course Outcomes	CL
1	At the end of the course, the students will be able to:	A m
1	Understand concepts and processes of qualification and validation including Validation Master Plan and equipment qualification.	Ap
2	Perform qualification of analytical instruments and laboratory glassware following standard procedures.	Ap
3	Explain validation of utility systems (water, HVAC, compressed gases) and cleaning validation in pharmaceutical settings.	U
4	Understand principles of analytical method validation and computerized system validation in compliance with regulatory guidelines.	An
5	Comprehend fundamental concepts of Intellectual Property, types of protection, patent application procedures, and ethical considerations in pharmaceutical industry.	U

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

A. val

# CO-PO/PSO Mapping for the course:

POCO			<u> </u>	THE		POs							7	PSO	18.7	
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
COI	1	1	1	0	0	0	0	1	1	0	0	1	0	1	0	0
CO2	1	1	1	1	0	0	1	1	1	0	0	1	0	1	0	0
CO3	1	1	1	1	0	0	1	1	1	0	0	1	0	1	0	0
CO4	1	1	1	1	0	0	1	1	1	0	0	1	1	1	1	0
CO5	1	0	0	0	1	0	0	0	1	1	1	0	0	0	0	0

<sup>&</sup>quot;3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

# Detailed Syllabus:

Unit No.	Topics	No, of Lectures	CO No
I I	Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.	12hrs	1
	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.		
П	Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC	12hrs	2
	<b>Qualification of Glassware:</b> Volumetric flask, pipette, Measuring cylinder, beakers and burette.		
Ш	Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.	12hrs	3
	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).		
IV	Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.	12hrs	4
	Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.		
V	General Principles of Intellectual Property: Concepts of Intellectual	12hrs	5
	Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of		3 3 3 1

A: 12

10

X A

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.

#### **Books Recommended:**

- 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-Upl, 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.

11 A A M

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Analysis	1	· I
Course Code	Course T	itle	Course Type
MPA 104T	Food Analysis		Core
Credit	H <sub>c</sub>	ours Per Week (L-T-P)	
	L	T	P
04	4	-	
Maximum Marks	CIA		ESE
100	25		75

# Learning Objective (LO):

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

# Course Outcomes (CO):

CO No.	Expected Course Outcomes	CL
	At the end of the course, the students will be able to:	
1	Understand classification, properties, digestion, metabolism, and analysis methods of carbohydrates and proteins in food.	Ap
2	Explain classification, analysis, refining, adulteration detection, and spoilage measurement of lipids and vitamins.	Ap
3	Analyze food additives including preservatives, antioxidants, sweeteners, and synthetic/natural pigments and dyes in food.	U
4	Apply general analytical methods for milk, milk products, and fermentation products including detection of adulterants.	An
5	Understand pesticide usage, analysis of pesticide residues in foods, and food product legislation and regulatory frameworks.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

POCO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	1	1	1	0	0	0	1	0	ì	0	0	1	1	0	0	0
CO2	1	1	1	1	0	0	1	0	1	0	0	1	1	0	0	0
CO3	1	1 .	1	1	0	0	0	0	1	0	0	1	0	0	0	0
CO4	1	1	1	1	0	1	0	0	1	0	0	1	1	0	0	0
CO5	1	0	1	0	1	0	0	0	1	0	1	0	0	1	0	0

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

Avis S

12

X /h

Detailed Syllabus:

Unit	Topics	No. of	CO
No.		Lectures	No.
	Carbohydrates: classification and properties of 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  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.	12hrs	1
Π	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.  Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series		2
Ш .	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.	·	3
IV	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.		4
V	Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus 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		5

## **Books Recommended:**

- 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, 18th edition, 2005.

13 X 1- /L

Program	Subject	Year	Semester							
M. Pharm.	Pharmaceutical Analysis	1	I							
Course Code	Course	Course Title								
MPA 105P	Pharmaceutical Analysis Prac	Core								
Credit	J	lours Per Week (L-T-I	)							
	L	T	P							
6	_	<del></del>	12							
Maximum Marks	CIA		ESE							
150	50		100							

# Learning Objective (LO):

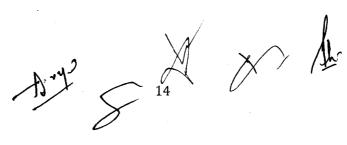
Upon completing this course, the students will be able to:

- 1. Recognize and utilize instrumental methods like UV-Vis, HPLC, GC, Fluorimetry, Flame Photometry for qualitative as well as quantitative analysis.
- 2. Conduct chemical assays and group-specific determinations of drugs and food materials.
- 3. Execute impurity profiling and calibration of analytical equipment.
- 4. Examine and interpret results for food quality characteristics such as preservatives, vitamins, and contaminants.
- 5. Maintain analytical accuracy and regulatory adherence via method validation and equipment calibration.

# Course Outcomes (CO):

CO	Expected Course Outcomes	CL
No.	At the end of the course, the students will be able to:	
1	Perform UV-Vis spectrophotometric analysis for single and multicomponent drug formulations.	Ap
1	Use chromatographic methods (HPLC, GC) for separation and quantitation of pharmaceutical compounds.	Ap
3	Perform fluorimetric and flame photometric estimations of vitamins and electrolytes.	U
4	Perform classical and instrumental titrimetric assays for official drug compounds.	An
1	Perform qualitative and quantitative determination of functional groups (e.g., hydroxyl, amino).	U
1	Perform impurity profiling and interpret analytical data according to pharmacopeial standards.	С
7	Adjust analytical instruments according to standard operating procedures.	

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).



CO-PO/PSO Mapping for the course:

POCO						POs				- 17				PSO		
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	3	3		1		2	2	1	2	3	0	0	0
CO2	3	3	3	3	3		1		2	2	1	2	3	0	0	0
CO3	3	2	2	2	3				2	2		2	3	0	0	0
CO4	3	2	2	2	2				2	2		2	3	0	0	0
CO5	3	3	2	2	2				2	2		2	3	1	0	0

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

#### **Detailed Syllabus:**

# LIST OF PRACTICALS

- 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. Imupurity 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
- 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

AVP S 15 X AT M

# M. Pharm in Pharmaceutical Analysis

# Semester-II

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Analysis	1	П
Course Code	Course	Title .	Course Type
MPA201T	Advanced Instrumental Anal	lysis	Core
Credit	The state of the s	Hours Per Week (L-T-	<b>P</b> )
	L	T	P
4	4		
Maximum Marks	CIA		ESE
100	25		75

# Learning Objective (LO):

After completion of the course students shall able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

	Course Outcomes (CO):
CO1	Understand the principles, instrumentation, method development, and pharmaceutical applications of HPLC, including chiral and preparative HPLC.
CO2	Explain the principles, instrumentation, and applications of biochromatography techniques including SEC, ion exchange, affinity chromatography, gas chromatography, and HPTLC
CO3	Describe the principles, instrumentation, and pharmaceutical applications of supercritical fluid chromatography and capillary electrophoresis.
CO4	Understand mass spectrometry including ionization techniques, mass analyzers, hyphenated techniques like LC-MS, and interpretation of spectra.
CO5	Explain the principles, instrumentation, and applications of NMR spectroscopy including 1D, 2D NMR, and hyphenated LC-NMR techniques

# CO-PO/PSO Mapping for the course:

POCO					PSO											
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	1	1	1	0	0	0	0	0	1	0	0	1	1	l	0	0
CO2	1	1	1	1	0	0	1	0	1	0 -	0	0	1	1	1	0
CO3	1	1	1	1	0	0	1	0	1 .	0	0	1	1	1	1	0
CO4	1	0	1	1	0	0	0	0	1	0	0	1	1	1	0	0
CO5	1	1	0	1	1	1	1	0	1	0	1	1	0	0	1	1

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

13,42

\_16

ys the

# Detailed Syllabus: THEORY

60 Hrs

	IHEUKY	ov mrs
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, 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 Hrs
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.	12 Hrs
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 Hrs
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 (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.	12 Hrs
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. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.	12 Hrs

# Books Recommended:

- 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.

17 A. W.

Program	Subject	Year	Semester								
M. Pharm.	Pharmaceutical Analysis	1	II								
Course Code	Course T	Course Type									
MPA202T	Modern Bio-Analytical Tech	niques	Core								
Credit	Hours Per Week (L-T-P)										
	L L	T	P								
4	4	<del>-</del>	~-								
Maximum Marks	CIA		ESE								
100	25		75								

# Learning Objective (LO):

Upon completion of the course, the student shall be able to understand

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

# **Course Outcomes (CO):**

CO No.	Expected Course Outcomes	Я
	At the end of the course, the students will be able to:	
1	Understand principles and procedures of drug and metabolite extraction from biological matrices and bioanalytical method validation guidelines.	Ap
2	Explain biopharmaceutical considerations including factors affecting drug bioavailability, dissolution testing, solubility, and permeability methods.	Ap
i .	Describe pharmacokinetics, toxicokinetics, drug interactions, and the application of LC-MS in bioactivity and proteomics screening.	U
1	Understand basic cell culture techniques, media, procedures, and applications including cell viability assays and flow cytometry.	An
5	Understand metabolite identification approaches, regulatory perspectives, and concepts of bioavailability and bioequivalence studies including biosimilars	U

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

CO-PO/PSO Mapping for the course:

POCO			σ			POs					40.00			PSO		
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	1	1	1	1	0	0	1	0	1	0	0	1	1	1	0	0
CO2	1	1	1	1	0	0	1	0	1	0	0	0	1	0	0	0
CO3	1	1	1	1	0	0	1	0	1	0	0	1	1	0.	1	0
CO4	1	1	0	0	0	1	1	0	1	0	0	0	0	0	0	0
CO5	1	1	1	1	0	0	1	0	1	0	0	1	1	1	1	0

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

S 18 X M

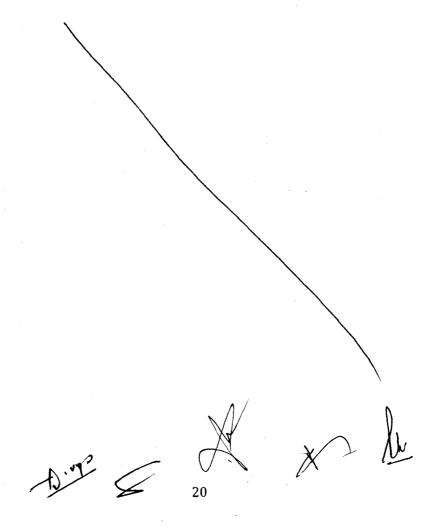
# Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
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		1
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		2
<b>M</b>	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.		3
IV	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		4
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.		5

19 19 A

#### **Books Recommended:**

- 1. Analysis of drugs in Biological fluids Joseph Chamberlain, 2<sup>nd</sup> Edition. CRC Press, Newyork. 1995.
- 2. Principles of Instrumental Analysis Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
- 3. Pharmaceutical Analysis Higuchi, Brochmman and Hassen, 2<sup>nd</sup> 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, 2<sup>nd</sup> Edition, John Wiley & Sons, New Jercy. USA.
- 6. Chromatographic Analysis of Pharmaceuticals John A Adamovics, 2<sup>nd</sup> 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, 2<sup>nd</sup> 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



Program	Subject	Year	Semester								
M. Pharm.	Pharmaceutical Analysis	1	П								
Course Code	Course	Course Type									
MPA203T	Quality Control and Quality	Core									
Credit	Hours Per Week (L-T-P)										
	L	T.	P								
4	4										
Maximum Marks	CIA	1	ESE								
100	25		75								

# Learning Objective (LO):

At the completion of this subject it is expected that the student shall be able to know

- 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

# Course Outcomes (CO):

CO	Expected Course Outcomes	CL
No.	At the end of the course, the students will be able to:	
1	Understand the concepts and evolution of Quality Control, Quality Assurance, Good	Ap
	Laboratory Practices (GLP), and ICH Q-series guidelines.	
2	Explain cGMP guidelines including regulatory frameworks from Schedule M, USFDA,	Ap
	PIC, WHO, EMEA, and CPCSEA for pharmaceutical manufacturing.	
3	Apply quality control principles for analysis of raw materials, finished products, packaging materials, and in-process quality control as per Indian, US, and British pharmacopoeias.	U
4	Understand documentation systems in pharmaceutical industry including SOPs, batch	An
	records, quality audit plans, and electronic data management.	
5	Comprehend manufacturing operations and controls covering sanitation, mix-ups,	U
	packaging, process deviations, aseptic process control, and release procedures.	

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

CO-PO/PSO Mapping for the course:

PO-CO						POs		1.5	- 1 1 - 1					PSC	)	
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	1	1.	1	0	0	0	1	1	1	0	0	0	1	1	0	0
CO2	1	1	1	0	0	0	1	1	1	0	0	0	1	1	0	0
CO3	1	1	1	0	1	0	1	0	1	0	0	1	1	1	0	0
CO4	1	1	0	l	1	0	1	0	1	0	0	0	1	1	0	0
CO5	1	1	1	0	1	0	1	1	1	0	0	1	1	1	0	0

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

- Ami

21

4

# Detailed Syllabus:

Unit No.		No. of Lectures	CO No.
I	Concept and Evolution of Quality Control and Quality A ssurance 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	12	1
П	cGMP guidelines according to schedule M, USFDA (inclusive o.f 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		2
m	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.		3
IV	Documentation in pharmaceutical industry: Three tier d.ocumentation, 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.		4
V	Manufacturing operations and controls: Sanitation of m anufacturing 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	5

#### **Books Recommended:**

- 1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3<sup>rd</sup> revised edition, Volume I & II, Mumbai, 1996.
- 2. Good Laboratory Practice Regulations, 2<sup>nd</sup> 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, 2<sup>nd</sup> 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, 3<sup>rd</sup> 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, 4<sup>th</sup> edition, Susmit Publishers, 2006.
- 10. QA Manual D.H. Shah, 1<sup>st</sup> edition, Business Horizons, 2000.
- 11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control Sidney H. Willig, Vol. 52, 3<sup>rd</sup> 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; 200

AT' 5 23 L

Program	Subject	Year	Semester							
M. Pharm.	Pharmaceutical Analysis	1 .	П							
Course Code	Course Ti	Course Type								
MPA204T	Herbal and Cosmetic Analysis	Core								
Credit	Hours Per Week (L-T-P)									
	L	T	P							
04	4	-	•••							
Maximum Marks	CIA		ESE							
100	25		75							

# Learning Objective (LO):

At completion of this course student shall be able to understand

- 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.

# Course Outcomes (CO):

CO No.	Expected Course Outcomes	CL
	At the end of the course, the students will be able to :	
1	Understand toxicity, efficacy, pharmacokinetics, pharmacodynamics, and regulatory	Ap
	guidelines for herbal remedies including WHO and AYUSH standards.	
2	Identify types, causes, and detection methods of adulteration and deterioration in herbal	Ap
	drugs; understand regulatory requirements and patent laws related to herbal industry.	
3	Apply modern analytical techniques for testing natural products, understand stability testing protocols, and compare monographs of herbal drugs from various pharmacopoeias.	Ü
4	Analyze herbal drug-drug, drug-food interactions and safety monitoring guidelines as per	An
	WHO and AYUSH; understand challenges in herbal medicine safety.	
5	Evaluate cosmetic products through physico-chemical testing methods and understand BIS	U
	standards for raw materials and finished cosmetics.	

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

CO-PO/PSO Mapping for the course:

POCO			-	<u> </u>		POs		300	A. ( 3/1)					PSC	)	
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
COI	. 1	1	1	0	0	0	1	1	1	0.	0	0	1	1	0	0
CO2	. 1	1	1	0	0	0	1	1	1	0	0	0	1	1	0	0
CO3	1	1	1	0	1	0	1	0	1	0	0	1	1	1	0	0
C04	1	1	0	1	1	0	1	0	1	0	0	0	1.	1	0	0
CO5	1	1	1	0	1	0	1	1	1	0	0	1	1	1	0	0

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

D. 44/27

24

 $\mathcal{S}$ 

# Detailed Syllabus:

Unit No.		No. of Lectures	CO No
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.	12	1
П	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.		2
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.		3
	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.		
IV	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		4
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.	12	5
	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		

## **REFERENCES**

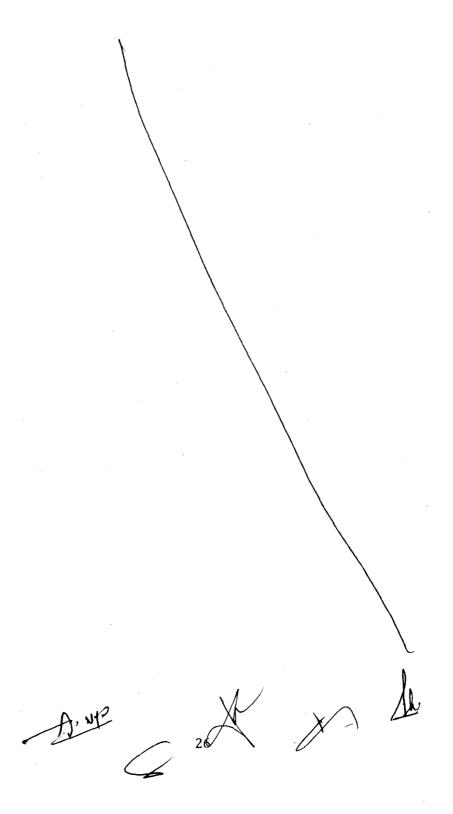
- 1. Pharmacognosy by Trease and Evans
- 2. Pharmacognosy by Kokate, Purohit and Gokhale
- 3. Quality Control Methods for Medicinal Plant, WHO, Geneva
- 4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
- 5. Essential of Pharmacognosy by Dr.S.H.Ansari

Min C

25

4

- 6. Cosmetics Formulation, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> 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, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
- 12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,



Program	Subject	Year	Semester							
M. Pharm.	Pharmaceutical Analysis	1	П							
Course Code	Course	Title	Course Type							
MPA205P	Pharmaceutical Analysis P	Core								
Credit	Hours Per Week (L-T-P)									
	L	r	P							
6	6	-	12							
Maximum Marks	CIA		ESE							
150	50		100							

# Learning Objective (LO):

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

# **Course Outcomes (CO):**

CO No.	Expected Course Outcomes	CL
	At the end of the course, the students will be able to:	
1	Understand and apply spectroscopic techniques (UV, IR, NMR, MS) for structural elucidation of organic compounds.	Ap
2	Perform separation and quantitative analysis of biomolecules using HPLC and electrophoresis techniques	Ap
3	Execute validation protocols for analytical and bioanalytical methods according to regulatory guidelines.	U
4	Conduct quality control tests on pharmaceutical products and packaging materials	An
5	Determine physicochemical properties and active content in cosmetics and personal care formulations	U

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

# CO-PO/PSO Mapping for the course:

PO-CO	POs								PSO							
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	3	2	1	1	1	2	3	2	3	3	3	2	2
CO2	3	2	2	3	3	1	1	2	2	3	2	3	3	3	3	3
CO3	3	3	2	3	3	3	2	1	1	3	2	3	3	3	2	3
CO4	. 3	2	2	2	2	3	1	2	2	3	3	3	3	3	2	3
CO5	· 3	2	2	2	2	2	1	2	2	3	2	3	3	2	1	3

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

1.4.

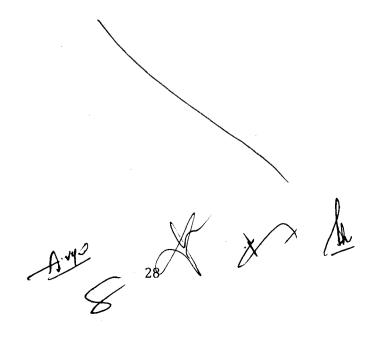
27

Mr

#### **Detailed Syllabus:**

#### LIST OF PRACTICALS

- 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
- 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



Program	Subject	Year	Semester						
M. Pharm.	Pharmaceutical Analysis	1	II						
Course Code	Course	Course Type							
	Seminar /Assignment	Seminar /Assignment							
Credit	F	Iours Per Week (L-T	T-P)						
	L	T	P						
4	_	<del></del>							
Maximum Marks	CIA		ESE						
100			100						

# Learning Objective (LO):

The subject is designed to create an environment where teachers provide the students a critical eye and openness to fortify the presentation and academic writing skills of students in the field of Pharmaceutics and industrial pharmacy.

# Course Outcomes (CO):

CO No.	Expected Course Outcomes	CL						
INO.	At the end of the course, the students will be able to:							
1	Develop skills to gather, organize, deliver information, and defend a given topic in							
	Pharmaceutics and industrial pharmacy.							
2	Learn to organize complex concepts using audio-visual aids.							
3	Acquire communication and presentation skills.	U						
4	Effectively respond to questions raised by peers and stand scientific scrutiny.							
5	Develop a write-up on the subject of seminar presentation and cultivate continuous							
	learning.							

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

# CO-PO/PSO Mapping for the course:

POCO						POs			<del></del>					PSO		
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	2	2	2	3	3	2	2	2	3	2	2	2	2
CO2	3	3	3	2	2	2	2	3	2	2	2	2	2	2	2	2
CO3	3	3	3	3	2	2	2	3	3	3	3	3	2	2	2	2
CO4	3	3	3	3	2	3	3	3	3	3	3	3	3	2	2	2
CO5	3	3	3	2	3	3	2	2	2	2	3	3	3	3	3	2

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

And See A Mr.

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Analysis	2	Ш
Course Code	Course.	Course Type	
MPA301T	Research Methodology and	Core	
Credit		T-P) "	
	Ĺ	Т	P
4	4		
Maximum Marks	CIA		ESE
100	25		75

#### Learning Objective (LO):

- Understand the fundamentals of research methodology including study designs, bias elimination, controls, and randomization techniques.
- Apply biostatistical methods for analyzing data, interpreting statistical tests, and understanding the role of sample size in research.
- Comprehend the ethical principles and dilemmas in medical research, including patient autonomy, informed consent, confidentiality, and conflicts of interest.
- Learn the CPCSEA guidelines for proper laboratory animal care and management in compliance with ethical and regulatory standards.
- Recognize the significance of the Declaration of Helsinki in framing ethical standards for medical research involving human subjects.

## Course Outcomes (CO):

CO No.	Expected Course Outcomes	CL					
	At the end of the course, the students will be able to:						
1	Explain general research methodology, including study designs, bias elimination, controls, randomizat blinding techniques.	Ap ion, and					
2	Apply biostatistical concepts including sample size determination, parametric and non-parametric tests, and interpretation of results.	Ap					
3	Discuss medical ethics principles, including autonomy, beneficence, informed consent, confidentiality, and ethical dilemmas.						
4	Understand and implement CPCSEA guidelines for ethical treatment and management of laboratory animals in research facilities.	An					
5	Describe the history, principles, and applications of the Declaration of Helsinki for ethical medical research.	U					

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

AND

30

#### CO-PO/PSO Mapping for the course:

PO						POs								PSO		
co	1.	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	4	4	-3	3	2	1	3	1	1	2	1	2	2	2	1	2
CO2	4	4	4	5	2	1	4	1	1	2	1	3	4	2	1	3
CO3	3	4	4	2	4	3	3	2	4	3	3	2	2	3	1	2
C04	3	3	3	2	2	2	2	2	4	2	1	4	2	3	5	3
CO5	3	3	3	2	2	2	3	2	5_	2	2	3	3	3	2	3

<sup>&</sup>quot;3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics Topics	No. of Lectures	CO No.
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.	4	1
II	<b>Biostatistics:</b> 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.	4	2
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.	4	3
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.		4
V	<b>Declaration of Helsinki:</b> History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	4	5

#### **Books Recommended:**

- 1. Research Methodology: Methods and Techniques by C.R. Kothari
- 2. Biostatistics: A Foundation for Analysis in the Health Sciences by Wayne W. Daniel and Chad L. Cross
- 3. Statistical Methods for Practice and Research by Ajai S. Gaur and Sanjaya S. Gaur
- 4. Principles of Biomedical Ethics by Tom L. Beauchamp and James F. Childress
- 5. Medical Ethics: Accounts of Ground-Breaking Cases by Gregory Pence
- 6. Ethics and the Practice of Psychology by Gerald P. Koocher and Patricia Keith-Spiegel
- 7. Guide for the Care and Use of Laboratory Animals by Institute for Laboratory Animal Research (ILAR)
- 8. CPCSEA Guidelines on Laboratory Animal Facilities and Ethics
  - 9. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

A 31 X - 1

Program	Subject	Year	Semester				
M. Pharm.	Pharmaceutical Analysis	2	Ш				
Course Code	Course	Course Type					
	JOURNAL CLUB	7	Core				
Credit		Hours Per Week (L-T-P)					
	L	T	P				
1	1						
Maximum Marks	CIA		ESE				
75	25						

#### Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

## Course Outcomes (CO):

CO No.	Expected Course Outcomes	CL
	At the end of the course, the students will be able to:	r Edia
1	Organize and present complex research concepts effectively using audio-visual aids.	Ap
2	Develop strong communication and presentation skills in the context of scientific research.	Ap
3	Critically analyze published research papers and respond effectively to scientific queries and scrutiny	U
4	Understand and apply principles of research methodology, ethics, and biostatistics in research analysis.	An
5	Foster continuous self-learning and knowledge upgradation in advanced research techniques.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

#### CO-PO/PSO Mapping for the course:

PO						POs								PSO	,	
CO	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
COI	3	3	2	2	2	2	3	3	2	2	2	3	2	2	2	2
CO2	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO3	3	3	3	3	2	3	3	3	3	- 3	3	3	3	2	2	2
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	2	3	3	2	2	2	2	3	3	3	3	3	2

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

32

A h

Program	Subject	Year	Semester							
M. Pharm.	Pharmaceutical Analysis	Ш								
Course Code	Course	Title	Course Type							
	DISCUSSION / PRESENT PRESENTATION)	DISCUSSION / PRESENTATION (PROPOSAL PRESENTATION)								
Credit	Hours Per Week	Hours Per Week (L-T-P)								
	L.	Т	P							
2	2	_								
Maximum Marks	CIA		ESE							
50	50									

# Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

#### Course Outcomes (CO):

CO No.	Expected Course Outcomes	CL
Gode a	At the end of the course, the students will be able to:	
1	Understand the significance of clear vision and well-defined objectives in pharmaceutical research	Ap
2	Identify and analyze the key components of vision and objectives statements in research proposals.	Ap
3	Develop a comprehensive and coherent vision and objectives statement for pharmaceutical research projects.	U
4	Enhance scientific communication and presentation skills through proposal and final presentations.	An
5	Critically evaluate peer presentations and provide constructive feedback to improve research quality.	U

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

#### CO-PO/PSO Mapping for the course:

PO						POs								PSO		
CO	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
COI	3	2	2	2	1	2	1	1	1	1	1	3	2	1	2	2
CO2	3	3	2	2	1	2	2	2	1	1	1	3	2	1	2	2
CO3	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO4	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO5	3	3	3	3	2	3	3	3	3	2	2	3	3	3	3	3

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

133 X

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Analysis	2	III
Course Code	Course	Title	Course Type
	RESEARCH WORK		Core
Credit		Hours Per Week (L-T-P	)
	L	T	P
14		_	28
Maximum Marks	CIA		ESE
350			350

# Course Outcomes (CO):

CO No.	Expected Course Outcomes	CL
INO.	At the end of the course, the students will be able to:	
1	Design, conduct, and analyze original pharmaceutical research to contribute to the advancement of knowledge in pharmacy	Ap
2	Apply theoretical and practical knowledge to solve real-world pharmaceutical problems, develop research hypotheses, and critically evaluate scientific literature	Ap
3	Develop research skills including study design, data collection, analysis, interpretation, and prepare scientific manuscripts and presentations	U
4	Demonstrate expertise in a specific pharmacy area and innovate new methodologies or technologies to improve pharmaceutical practice and patient care.	An
5	Effectively communicate and present research findings through scientific writing, posters, and oral presentations to prepare for research and academic careers.	U

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

# CO-PO/PSO Mapping for the course:

PO						POs								PSO		
CO	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
COI	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO2	3	3	3	2	2	3	2	2	2	2	2	3	3	2	3	2
CO3	3	3	3	3	3	3	3	2	2	- 2	2	3	3	3	3	3
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

A: 112 S34 A

#### Semester- IV

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Analysis	2	Ш
Course Code	Course	Title	Course Type
	DISCUSSION / PRESEN PRESENTATION)	Core	
Credit		)	
	L	T	P
2	2	-	•
Maximum Marks	CIA		ESE
75	75		

#### Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

# Course Outcomes (CO):

co	Expected Course Outcomes	CL
No.		
	At the end of the course, the students will be able to:	
1	Understand the significance of clear vision and well-defined objectives in	Ap
	pharmaceutical research	
2	Identify and analyze the key components of vision and objectives statements in	Ap
	research proposals.	_
3	Develop a comprehensive and coherent vision and objectives statement for	U
	pharmaceutical research projects.	
4	Enhance scientific communication and presentation skills through proposal and final	An
l E	presentations.	
5	Critically evaluate peer presentations and provide constructive feedback to improve	U
	research quality.	

CL: Cognitive Levels (R-Remember; U-Understanding; Ap-Apply; An-Analyze; E-Evaluate; C-Create).

#### CO-PO/PSO Mapping for the course:

PO						POs						1		PSO		
CO	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	2	2	1	2	1	1	1	1	1	3	2	1	2	2
CO2	3	3	2	2	1	2	2	2	1	- 1	1	3	2	1	2	2
CO3	3	3	3	3	2	3	2	2 -	2	2	2	3	- 3	2	3	3
CO4	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO5	3	3	3	3	2	3	3	3	3	2	2	3	3	3	3	3

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

1.71°

S

35

## Semester-IV

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Analysis	2	Ш
Course Code	Course	Course Type	
	RESEARCH WORK		Core
Credit		)	
	L. L.	Τ	P
31			16
Maximum Marks	CIA		ESE
400			400

# Course Outcomes (CO):

CO No.	Expected Course Outcomes  At the end of the course, the students will be able to:	CL
1	Design, conduct, and analyze original pharmaceutical research to contribute to the advancement of knowledge in pharmacy	Ap
2	Apply theoretical and practical knowledge to solve real-world pharmaceutical problems, develop research hypotheses, and critically evaluate scientific literature	Ap
3	Develop research skills including study design, data collection, analysis, interpretation, and prepare scientific manuscripts and presentations	U
4	Demonstrate expertise in a specific pharmacy area and innovate new methodologies or technologies to improve pharmaceutical practice and patient care.	An
5	Effectively communicate and present research findings through scientific writing, posters, and oral presentations to prepare for research and academic careers.	U

CL: Cognitive Levels (R-Remember; U-Understanding: Ap-Apply; An-Analyze; E-Evaluate; C-Create).

# CO-PO/PSO Mapping for the course:

PO	100				POs								PSO				
CO	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5	
COI	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3	
CO2	3	3	3	2	2	3	2	2	2	2	2	3	3	2	3	2	
CO3	3	3	3	3	3	3	3	2	2	2	2	3	3	3	3	3	
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
CO5	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3	

"3" - Strong; "2" - Moderate; "1"- Low; "-" No Correlation

13 5 36 X X M

# Semester wise credits distribution

Semester	Credit Points			
	26			
	26			
	21			
IV.	20			
Co-curricular Activities (Attending Conference, Scientific Presentations andOther Scholarly Activities)	Minimum=02 Maximum=07*			
	Minimum=95			
Total Credit Points	Maximum=100*			

<sup>\*</sup>Credit Points for Co-curricular Activities

# Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity			
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01			
Participation in international Level Seminar/ Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02			
Academic Award/Research Award from State Level/National Agencies	01			
Academic Award/Research Award from International Agencies	02			
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01			
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02			

Note: International Conference: Held Outside India International Journal: The Editorial Board Outside India

\*The credit points assigned for extracurricular and or co-curricular activities shallbe given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

1. "M" 37 M