M.PHARMACY TWO YEAR DEGREE

PROGRAM CURRICULUM-2025

(Applicable for the batches admitted from A.Y 2025-26)

PHARMACEUTICAL ANALYSIS

ADITYA UNIVERSITY

Aditya Nagar, ADB Road, Surampalem - 533 437

ADITYA UNIVERSITY

Vision

- To be a globally recognized university through excellence in Education, Innovation and Sustainable growth.

Mission

Deliver collaborative education to prepare students for global challenges through

- Transformative learning
- Vibrant research ecosystem
- Sustainable and inclusive community

School of Pharmacy

Vision:

To emerge as a center of excellence producing competent, ethical pharmacists and researchers through holistic education and lifelong learning.

Mission:

- Empower future pharmacists through outcome-based learning for global healthcare challenges.
- Promote collaborative research for national and global healthcare impact.
- Ensure integrity, inclusion, and accountability in global healthcare education.

PROGRAMME EDUCATIONAL OBJECTIVES (PEO)

Postgraduates of the Program will:

PEO 1: Apply scientific knowledge and research skills to develop, evaluate, and ensure the quality of pharmaceuticals.

PEO 2: Lead pharmaceutical R&D and academia while developing advanced analytical techniques across domains.

PEO 3: Utilize cutting-edge technologies and contribute to global healthcare through ethical innovation.

PROGRAMME SPECIFIC OUTCOMES (PSO)

After successful completion of the program, the post graduates will be able to

PSO1: Develop and validate analytical methods using modern instruments with regulatory compliance.

PSO2: Perform impurity profiling, stability testing, and bioanalytical method development and ensure industry readiness.

PROGRAMME OUTCOMES (PO)

After successful completion of the program, the post graduates will be able to

PO1: Independently carry out research /investigation and development work to solve practical problems

PO2: Write and present a substantial technical report/document

PO3: Demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program

PO4: Uphold ethical principles and legal standards in pharmaceutical research, testing, and practice while ensuring drug safety.

PO5: Evaluate pharmaceutical activities' impact on health and environment, advocating for sustainable and safe practices.

PO6: Commit to continuous learning by adapting to advancements in pharmaceutical science, technology, and regulations.

School of Pharmacy

M. Pharmacy (Pharmaceutical Analysis) Program Curriculum – 2025

(Applicable for the students admitted from the A.Y 2025-26)

CREDIT DIVISION CATEGORY-WISE

S. NO	CATEGORY OF COURSE	NUMBER OF CREDITS
1	Major Core Courses (MCC)	40
2	Multidisciplinary Courses (MDC)	4
3	Skill Enhancement Courses (SEC)	4
4	Ability Enhancement Courses (AEC)	$14^{\#}$-$19^{\$}$
5	Full Semester Internship (PROJ)	33
Total Credits to be earned for M. Pharmacy Degree		**$95^{\#}$-$100^{\$}$**

$^{\#}$Minimum Credit required in AEC to earn the M. Pharmacy degree.

$^{\$}$Maximum Credit required in AEC to earn the M. Pharmacy degree.

IC- Intermediate Courses
AC- Advanced Courses

CATEGORY WISE COURSES

Major Core Courses (MCC)

Course Code	Sem	Course Name	Level	L	T	P	C	CIE	SEE	Total
2515PY02	I	Advanced Pharmaceutical Analysis	IC	4			4	25	75	100
2515PY03		Pharmaceutical Validation	IC	4			4	25	75	100
2515PY05		Pharmaceutical analysis Practical I	AC			3	3	25	50	75
2515PY06		Pharmaceutical analysis Practical II	AC			3	3	25	50	75
2515PY04		Food analysis	IC	4			4	25	75	100
2515PY08	II	Advanced Instrumental Analysis	AC	4			4	25	75	100
2515PY09		Modern Bio-Analytical Techniques	AC	4			4	25	75	100
2515PY10		Quality Control and Quality Assurance	AC	4			4	25	75	100
2515PY11		Herbal and Cosmetic Analysis	AC	4			4	25	75	100
2515PY12		Pharmaceutical Analysis Practical III	AC			3	3	25	50	75
2515PY13		Pharmaceutical Analysis Practical IV	AC			3	3	25	50	75
			Total	**28**		**12**	**40**			

Multidisciplinary Courses (MDC)

Course Code	Sem	Course Name	Level	L	T	P	C	CIE	SEE	Total
2515PY01	I	Modern Pharmaceutical Analytical Techniques	IC	4			4	25	75	100
			Total	**4**			**4**			

Skill Enhancement Courses (SEC)

Course Code	Sem	Course Name	Level	L	T	P	C	CIE	SEE	Total
2515PY15	III	Research Methodology and Biostatistics*	IC	4			4	25	75	100
			Total	**4**			**4**			

* DLE: Department Level Evaluation

Ability Enhancement Courses (AEC)

Course Code	Sem	Course Name	Level	L	T	P	C	CIE	SEE	Total
2515PY07	I	Seminar/Assignment*	AC			4	4	-	-	100
2515PY14	II	Seminar/Assignment*	AC			4	4	-	-	100
2515PY16	III	Journal Club*	AC			1	1	25	-	25
2515PY17	III	Discussion / Presentation (Proposal)*	AC			2	2	50	-	50
2515PY19	IV	Journal Club*	AC			1	1	25	-	25
2515PY22		Student Activity Based Learning (SABL)*	AC							
2515PY23		Co-curricular Activities*					2-7			
			Total			**12**	**14$^{\#}$-19$^{\$}$**			

* DLE: Department Level Evaluation

Full Semester Internship / Project Work (PROJ)

Course Code	Sem	Course Name	Level	L	T	P	C	CIE	SEE	Total
2515PY18	III	Project-I *	AC			14	14	-	350	350
2515PY20	IV	Project-II	AC			16	16	-	400	400
2515PY21	IV	Discussion / Final Presentation*	AC			3	3	75	-	75
Total						**33**	**33**			

* DLE: Department Level Evaluation

LEVEL-WISE COURSES

Intermediate Courses:

S.No.	Abbreviation	Course Name
1.	MPAT	Modern Pharmaceutical Analytical Techniques
2.	APA	Advanced Pharmaceutical Analysis
3.	PV	Pharmaceutical Validation
4.	FA	Food Analysis
5.	RMBS	Research Methodology and Biostatistics

Advanced Courses:

S.No.	Abbreviation	Course Name
1.	PAP-I	Pharmaceutical analysis Practical I
2.	PAP-II	Pharmaceutical analysis Practical II
3.	S/A-I	Seminar/Assignment
4.	AIA	Advanced Instrumental Analysis
5.	MBAT	Modern Bio-Analytical Techniques
6.	QCQA	Quality Control and Quality Assurance
7.	HCA	Herbal and Cosmetic Analysis
8.	PAP-III	Pharmaceutical Analysis Practical III
9.	PAP-IV	Pharmaceutical Analysis Practical IV
10.	S/A-II	Seminar/Assignment
11.	JC-I	Journal Club
12.	D/P	Discussion / Presentation (Proposal)
13.	PROJ-I	Project-I
14.	JC-II	Journal Club
15.	PROJ-II	Project –II
16.	D/P-II	Discussion / Final Presentation

SEMESTER WISE CURRICULUM

SEMESTER- I`

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	C	
2515PY01	Modern Pharmaceutical Analytical Techniques	MDC	IC	4			4	4
2515PY02	Advanced Pharmaceutical Analysis	MCC	IC	4			4	4
2515PY03	Pharmaceutical Validation	MCC	IC	4			4	4
2515PY04	Food Analysis	MCC	IC	4			4	4
2515PY05	Pharmaceutical analysis Practical I	MCC	AC			3	3	6
2515PY06	Pharmaceutical analysis Practical II	MCC	AC			3	3	6
2515PY07	Seminar/Assignment*	AEC	AC			4	4	7
			Total	**16**		**10**	**26**	**35**

* DLE: Department Level Evaluation

SEMESTER- II

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	C	
2515PY08	Advanced Instrumental Analysis	MCC	AC	4			4	4
2515PY09	Modern Bio-Analytical Techniques	MCC	AC	4			4	4
2515PY10	Quality Control and Quality Assurance	MCC	AC	4			4	4
2515PY11	Herbal and Cosmetic Analysis	MCC	AC	4			4	4
2515PY12	Pharmaceutical Analysis Practical III	MCC	AC			3	3	6
2515PY13	Pharmaceutical Analysis Practical IV	MCC	AC			3	3	6
2515PY14	Seminar/Assignment*	AEC	AC			4	4	7
			Total	**16**		**10**	**26**	**35**

* DLE: Department Level Evaluation

SEMESTER - III

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	C	
2515PY15	Research Methodology and Biostatistics*	SEC	IC	4			4	4
2515PY16	Journal Club*	AEC	AC			1	1	1
2515PY17	Discussion / Presentation (Proposal)*	AEC	AC			2	2	2
2515PY18	PROJ-I*	PROJ	AC			14	14	28
			Total	**4**		**17**	**21**	**35**

* DLE: Department Level Evaluation

SEMESTER - IV

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	C	
2515PY19	Journal Club*	AEC	AC			1	1	1
2515PY20	PROJ-II	PROJ	AC			16	16	31
2515PY21	Discussion / Final Presentation*	PROJ	AC			3	3	3
			Total			**20**	**20**	**35**

* DLE: Department Level Evaluation

During the Program

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	C	
2515PY22	Student Activity Based Learning (SABL)*	AEC	AC					
2515PY23	Co -curricular activities*	AEC	AC	-	-	-	2-7	-
			Total				**2 - 7**	**-**

* DLE: Department Level Evaluation

PHARMACEUTICAL ANALYSIS (MPA)

SEMESTER - I

L	T	P	C
4	0	0	4

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject code: 2514PY01

Course Objectives: Upon completion of the subject student shall be

COB1: Understand the spectroscopic concept upon pharmaceuticals, NMR with new compounds,

COB2: Apply NMR with new compounds

COB3: Integrate the mass data for molecules

Course Outcomes:

Course Outcome	STATEMENT
CO1	**Understand:** The basic concepts of Spectroscopic method
CO2	**Apply: C**omputation of NMR Spectroscopy
CO3	**Generate:** Mass spectroscopy of compounds by using instrumentation and ionisation techniques
CO4	**Remember:** Quantification methods of Chromatography
CO5	**Classify:** analytical method of electrophoresis and x-ray crystallography
CO6	**Evaluate:** Predict the unknown concentrations of samples using ion selective methods (Potentiometry) and thermal methods for Pharmaceuticals

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	2	2	3
CO2	3	3	3	2	2	3
CO3	3	3	3	2	2	3
CO4	3	3	3	2	2	3
CO5	3	3	3	2	2	3
CO6	3	3	3	2	2	3

Mapping of Course Outcomes with Program Specific Outcomes:

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	3
CO3	3	3
CO4	3	3
CO5	3	3

Course content **60Hours**

UNIT -I **10 Hours**

Basic Methods of Spectroscopy:

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, Data Interpretation.

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

UNIT-II **10Hours**

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.

UNIT-III **10Hours**

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, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT-IV **10Hours**

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) High Performance Thin Layer Chromatography
c) Ion exchange chromatography

d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High-Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

UNIT -V **10Hours**

Electrophoresis

Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Isoelectric focusing

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

UNIT-VI **10Hours**

a. Potentiometry : Principle, working, Ion selective Electrodes and Application of potentiometry.

b. 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.

Textbook

1. Spectrometric Identification of Organic compounds- Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Instrumental methods of analysis Willards, 7th edition, CBS publishers.

Reference text books

1. Quantitative Analysis of Drugs in Pharmaceutical formulation- PD Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
2. Pharmaceutical Analysis- Modern Methods– Part B- JW Munson, Vol 11, Marcel. Dekker Series
3. Textbook of Pharmaceutical Analysis, KA. Connors, 3rdEdition, John Wiley & Sons, 1982.

Weblinks

W1: https://link.springer.com/chapter/10.1007/978-1-4684-9984-1_5
W2:https://www.smacgigworld.com/blog/instrumentation-and-methodology-of-electrophoresis.php
W3: https://archive.nptel.ac.in/content/storage2/courses/102103047/PDF/mod3.pdf
W4: https://microbenotes.com/affinity-chromatography/
W5: https://www.sciencedirect.com/science/article/pii/S1878535213001056

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ADVANCED PHARMACEUTICAL ANALYSIS

Subject Code: 2515PY02

Course Objectives: Upon completion of the subject student shall be

COB1: Understand the impurity profile and stability study

COB2: Enumerate the Elemental impurities

COB3: Determination of impurity profile

COB4: Develop biological products potency and evaluation tests

Course Outcomes:

Course Outcome	Statements
CO1	Review of the impurity profile and Stability studies in pharmaceuticals
CO2	Enumerate the Elemental impurities and stability testing protocol
CO3	Determination of Impurity profiling and degradant characterization and Impurity profiling and degradant characterization with special emphasis.
CO4	Analyze the Stability testing of phytopharmaceuticals
CO5	Evaluate the Biological tests and assays
CO6	Develop the Immunoassays.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	2	2	3
CO2	3	3	3	3	2	3
CO3	3	3	3	2	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	2	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	2
CO3	3	3
CO4	3	3
CO5	3	3
CO6	3	3

Course content **60Hours**

UNIT-I

Brief understanding of impurity and stability studies **10Hours**

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, and reporting levels of residual solvents.

UNIT-II **10Hours**

Elemental impurities and stability testing protocol

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

UNIT-III **10 Hours**

Management of impurity profiling and degradant characterization and regulatory guidilines

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

UNIT –IV **10Hours**

Analyse the stability testing of phytopharmaceuticals

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

UNIT –V **10Hours**

Evaluate the biological assay

Biological tests and assays of the following:

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

UNIT-VI 10Hours

Construct and set up radio immune assays (ria)

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radio immunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and

applications of IA.

Text books

1. Biotechnology, U.Satyanarayana, latest edition.
2. Pharmaceutical Bioassays: Methods and Applications, Shiqi Peng,Ming Zhao, 2009.

Reference books

1. Vogel ‘s textbook of quantitative chemical analysis- Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
3. ICH Guidelines for impurity profiles and stability studies

Weblinks

1. https://www.youtube.com/watch?v=Bz6-D4CUCJc
2. https://www.youtube.com/watch?v=Tdc4U8aKG_A
3. https://www.youtube.com/watch?v=g3Kth0rD4Yo
4. https://www.youtube.com/watch?v=G3w3qxQoKlo
5. https://www.youtube.com/watch?v=DI0pLbQ7LuQ

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PHARMACEUTICAL VALIDATION (Theory)

SUBJECT CODE: 2515PY03

Course objectives: Upon completion of the subject student shall be

COB1: Explain the aspect of validation

COB2: Carryout validation of manufacturing processes

COB3: Apply the knowledge of validation to instruments and equipments

COB4: Validate the manufacturing

COB5: Recognize the importance of intellectual property rights and ethical practices in Pharmaceutical validation.

Course Outcomes:

Course Outcome	Statement
CO1	**Describe** about Qualification and Validation, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Types of Qualifications, Re- Qualification.
CO2	**Demonstrate** Qualification of Manufacturing Equipments, Analytical Instruments and Laboratory equipments.
CO3	**Summarize** the concept of Qualification of Analytical Instruments, Qualification of Glassware.
CO4	**Classify** about Validation of utility systems.
CO5	**Explain** the importance of Analytical Method Validation - General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation.
CO6	**Contrast** about General Principles, Types and Concepts of Intellectual Property Rights, PCT, International Patenting Requirements, Societal Responsibility, Avoiding Unethical Practices

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	3	2	2
CO2	3	3	2	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	1
CO2	3	1
CO3	3	1
CO4	2	1
CO5	3	1
CO6	1	1

Course contents **60 Hours**

UNIT-I **12 Hours**

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

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

UNIT-II **12 Hours**

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

UNIT-III **12 Hours**

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

UNIT- IV **12 Hours**

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

Computerized System Validation: Electronic records and digital significance- 21 CFR part 11 and GAMP 5.

UNIT-V **12 Hours**

General principles of intellectual property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types of 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.

Text Books

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.

Reference books:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker

Web Links

W1: https://www.pharmaguideline.com/2019/03/validation-of-utility-systems.html
W2: https://www.pharmaguideline.com/2018/02/factory-acceptance-test-fat.html
W3: https://www.pharmaguideline.com/2010/12/qualification-of-systems-and-equipment.html
W4: https://www.pharmaguideline.com/2010/12/analytical-method-validation.html
W5: https://www.pharmaguideline.com/2015/07/technology-transfer-in-pharmaceuticals.html

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FOOD ANALYSIS

Course Code: 2515PY04
Course Objectives: At completion of this course student shall be able to understand various analytical techniques in the determination
COB1: Food constituents.
COB2: Food additives.
COB3: Finished food.
COB4: Pesticides in food.
COB5: Have the knowledge on food regulations and legislations.

Course Outcomes:

Course Outcom	STATEMENT
CO1	**Explain** about Carbohydrates**,** Dietary fibre, Crude fibre & Chemistry, Classification of amino acids, absorption and metabolism of proteins.
CO2	**Enumerate** about Lipids, refining of fats and oils, hydrogenation of vegetable oils.
CO3	**Calculate** Adulteration and its types, Vitamins, Methods of analysis of Vitamins, Microbial assay of vitamins of B-series.
CO4	**Evaluate** about Food additives, Pigments and synthetic dyes.
CO5	**Characterize** the general Analytical methods for milk, milk constituents and milk products and their adulteration & fermentation products.
CO6	**Design** Pesticide analysis & effects of pest and insects on various food, Pesticides in agriculture, Pesticide cycle, & Pesticide residues in grain, fruits, vegetables, milk and milk products, BIS, Agmark, FDA and US-FDA.

Mapping of Course Outcomes with Program Outcomes

CO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	2	3	3
CO2	3	3	2	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	2	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	2
CO3	3	3
CO4	3	3
CO5	3	3
CO6	3	3

Course contents 60 HOURS

UNIT-I **12 Hours**

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 applications 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.

UNIT-II **12 Hours**

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.

UNIT-III **12 Hours**

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 dyes, non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

UNIT- IV **12 Hours**

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.

UNIT-V **12 Hours**

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.

Text books

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.

References:

1] Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
2] Analysis of Food constituents – Multon, Wiley VCH.
3] Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

Web Links

W1: https://www.jlr.org/article/S0022-2275(20)38151-7/pdf
W2: https://www.ijsr.net/archive/v6i5/ART20173280.pdf
W3: https://www.fssai.gov.in/upload/uploadfiles/files/MILK_AND_MILK_PRODUCTS.pdf
W4:https://www.researchgate.net/publication/316618578_Pesticide_Residues_in_Food_Grains_Vegetables_and_Fruits_A_Hazard_to_Human_Health
W5: https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements
W6:https://projects.iq.harvard.edu/files/lifesciences1abookv1/files/5_-_proteins_and_amino_acids_revised_9-24-2018.pdf

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PRACTICAL PHARMACEUTICAL ANALYSIS – I

Subject Code: 2515PY05

Course Objectives:

COB1: Understand about calibration of instruments
COB2: Practical approach for Assay of official compounds
COB3: Estimation of Vitamins, quinine sulphates
COB4: Quantitative determination of Hydroxyl and amino groups in pharmaceuticals
COB5: Application of colorimetric determination of drugs by different reagents

COURSE OUTCOMES :

CO	STATEMENT
CO1	**Understand** the calibration procedures with acceptance criteria
CO2	**Determine** the cleaning validation
CO3	**Apply** the assay methodology for official compounds by different titrations and instrumental methods
CO4	**Select** the estimation methods for the Vitamins and Ion concentrations.
CO5	**Judge** the Quantification methods for hydroxyl and amino groups
CO6	**Design and construct** colorimetric methods for drugs by using different reagents

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	2
CO4	2	3
CO5	2	3
CO6	2	3

List of Experiments

Expt. No	Title	CO
1.	Calibration of glass wares pH meter, UV and Visible Spectrophotometer, FTIR Spectrophotometer, HPLC and gas chromatography, Cleaning validation of any one equipment	**CO1, CO2**
2.	Assay of official compounds by different titrations	**CO3**
3.	**Assay of official compounds by instrumental techniques**	**CO3,**
4.	Estimation of riboflavin/quinine sulphate by fluorimetry	**CO4**
5.	Estimation of sodium/potassium by flame photometry	**CO4**
6.	Quantitative determination of hydroxylgroup.	**CO5**
7.	Quantitative determination of aminogroup	**CO5**
8.	Colorimetric determination of drugs by using different reagents	**CO6**

Text books

1. A.H.Beckett & J.B .Stenlake's , Practical Pharmaceutical Chem Vol I & II ,Stahlone press of university of London.
2. A.I.Vogel , Text book of Quantitative inorganic analysis

References

1. Bentley and Driver's Text book of Pharmaceutical Chemistry
2. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
3. Indian Pharmacopoeia

Web links

1. https://books.google.com.bd/books?id=Up3L2dAI7k8C&printsec=frontcover#v=onepage&q&f=false
2. https://chem.hbcse.tifr.res.in/wp-content/uploads/2019/10/vogels-textbook-of-quantitative-chemical-analysis-5th-edition.pdf
3. https://www.pharmtech.com/view/pharmacopoeia-compliance-a-practical-guide
4. https://www.shimadzu.com/an/service-support/technical-support/analysis-basics/basic/what_is_hplc.html
5. himadzu.com/an/sites/shimadzu.com.an/files/pim/pim_document_file/technical/primers/13296/icc120006

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PRACTICAL PHARMACEUTICAL ANALYSIS – II

Subject Code: 2515PY06

Course Objectives:

COB1: To learn objective of this course practically for pharmacopoeia compounds

COB2: To handling of HPLC and GC instruments and learn their objectives and applications

COB3: Determination of biological compounds in pharmaceuticals

COB4: Determination of food additive content

COB5: Evaluate the density and specific gravity of foods

Course out comes:

CO	STATEMENT
CO1	**Remember:** Analyze pharmacopoeial compounds and their formulations using UV-Vis spectrophotometry to determine their concentration and quality
CO2	**Understand:** Perform simultaneous estimation of multi-component formulations using UV spectrophotometry, applying appropriate techniques for accurate measurement of each component in complex mixtures.
CO3	**Apply:** Conduct experiments using HPLC to separate, identify, and quantify components in pharmaceutical and food samples, demonstrating competence in method development and optimization.
CO4	**Analyze:** Perform experiments using Gas Chromatography to analyze volatile compounds in food, including pesticides, food additives, and flavoring agents, ensuring product safety and compliance with standards.
CO5	**Evaluate:** Evaluate the quality of food products by determining saponification value, iodine value, peroxide value, and acid value to assess the stability and composition of fats and oils in food.
CO6	**Create:** Employ analytical techniques to determine the presence of food additives, preservatives, and pesticide residues in food products, ensuring safety and compliance with regulatory standards.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	2
CO3	3	2
CO4	3	3
CO5	3	3
CO6	3	3

Contents **06 Hours/ Week**

List of Experiments

S.No	Title of the experiment	CO
1.	Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer, Simultaneous estimation of multi component containing formulations by UV Spectrophotometry	**CO1, CO2**
2.	Experiments based on HPLC Experiments based on Gas Chromatography	**CO3**
3.	Determination of total reducing sugar Determination of proteins	**CO4**
4.	Determination of saponification value, Iodine value, Peroxide value, Acid value in food Products, Determination of fat content and rancidity in food products , Analysis of natural and synthetic colors in food, Determination of preservatives in food	**CO5**
5.	Determination of pesticide residue in food products Analysis of vitamin content in foodproducts Determination of density and specific gravity of foods Determination of food additives	**CO6**

Text Books

1. A.H.Beckett & J.B .Stenlake's , Practical Pharmaceutical Chem Vol I & II ,Stahlone press of university of London.
2. A.I.Vogel , Text book of Quantitative inorganic analysis

Reference Books

1. Bentley and Driver's Text book of Pharmaceutical Chemistry
2. Indian Pharmacopoeia
3. Here is the corrected table with the six course outcomes based on your provided data:

Web Links

1. https://home.iitk.ac.in/~madhav/expt2.html
2. https://www.youtube.com/watch?v=fQ1hSNGnXYY
3. https://www.youtube.com/watch?v=Oaa3aI-ymIQ
4. https://www.iitg.ac.in/biotech/BTechProtocols/BCExp[1].+3.pdf
5. https://www.itwreagents.com/uploads/20180114/A173_EN.pdf

SEMESTER – II

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ADVANCED INSTRUMENTAL ANALYSIS (Theory)

Subject code: 2515PY08
Course Objectives: Upon completion of the course the student shall be able to **COB1**: Interpretation of the NMR, Mass and IR spectra of various organic compounds
COB2: Theoretical and practical skills of the hyphenated instruments
COB3: Identification of organic compounds
COB4: To understand advanced chromatographic techniques for separation and quantification.
COB5: To learn validation, calibration, and maintenance of analytical instruments.
COB6: To apply advanced methods in quality control, impurity profiling, and stability studies.

COURSE OUTCOMES:

Course outcome	Statement
CO1	**Explain**- basics of chromatography and principle, instrumentation, Pharmaceutical applications for HPLC,and HILIC approaches.
CO2	**Explain**-size exclusion, ion exchange, affinity, ion pair chromatography for stationary phases and mobile phases, gas chromatography principle, instrumentation, derivatization, head space, columns.
CO3	**Explain** -High performance Thin Layer chromatography, Principles, instrumentation, pharmaceutical applications
CO4	**Explain**- principle, instrumentation, Pharmaceutical applications for Supercritical fluid chromatography, capillary electrophoresis, method development.
CO5	**Explain**-principle, instrumentation, Pharmaceutical applications for Mass spectroscopy, Ionization Techniques and Mass Analysers.
CO6	**Compare**-principle, instrumentation, Pharmaceutical applications for NMR Spectroscopy. FT-NMR, C13NMR , 2-DNMR, LC–NMR

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	2	2	3
CO2	3	3	3	3	2	3
CO3	3	3	3	2	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	3
CO3	3	2
CO4	3	3
CO5	3	3
CO6	3	3

Course contents **60 Hours**

UNIT-I **12 Hours**

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, and practical aspects of preparative HPLC.

UNIT-II **12 Hours**

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion air 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.

UNIT-III **12 Hours**

Super critical fluid chromatograph

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

UNIT-IV **12 Hours**

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, metastable ions, isotopic peaks and applications of mass spectrometry. LC- MS hyphenation and DART MS analysis. Mass analyzers (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.

UNIT-V **12 Hours**

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.

Text books

1. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, and Stanley R. Crouch, Cengage Learning..
2. Instrumental methods of Analysis by G. Willard, L.L. Merritt, J.A. Dean, and F.A. Settle, CBS Publishers & Distributors.

Reference books

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

Web links:

W1:https://www.smithers.com/services/testing/testcapabilities/chemistry/chromatography-and-spectrometry
W2:https://tech.chemistrydocs.com/Books/Spectroscopy/A-Complete-Introduction-to-MODERN-NMR-Spectroscopy-by-Roger-S-Macomber.pdf
W3: https://scienceinfo.com/supercritical-fluid-chromatography-principle/
W4:https://www.chromatographyonline.com/view/biochromatography-size-exclusion-and-ion-exchange-techniques
W5: https://pubs.sciepub.com/bb/7/1/2/bb-7-1-2.pdf

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MODERN BIOANALYTICAL TECHNIQUES

Subject Code: 2515PY09

Course Objectives: Upon completion of the subject student shall be

COB1: Remember the Extraction procedures & review of bioanalytical method validation guidelines

COB2: Discuss Biopharmaceutical factors affecting drug bioavailability and biopharmaceutical system

COB3: Differentiate Pharmaco kinetics and toxic kinetic drug interactions

COB4: Recommend of Cell culture, MTT Assay, flow cytometry

COB5: integration of Metabolite identification and drug product performance

Course Outcomes :

Course outcome	Statement
CO1	**Remember:** Enumerate the drug extraction
CO2	**Explain:** Guidelines of Bioanalytical Validation
CO3	**Summarize:** Bioavailability and BCS Classification
CO4	**Interpretate:** Drug interactions and Toxicokinetic evaluation
CO5	**Evaluate:** The Cell culture techniques & MTT Assays
CO6	**Construct:** Development of protocols for Drug product performance

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	3	3	2
CO2	3	3	2	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes:

CO/PSO	PSO1	PSO2
CO1	3	1
CO2	3	2
CO3	3	3
CO4	3	3
CO5	3	3
CO6	3	3

Course Contents **60Hours**

UNIT-I **12Hours**

Extraction of Drug and Metabolites

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid-Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

UNIT-II **12Hours**

Biopharmaceutical Consideration

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

UNIT-III **12Hours**

Pharmacokinetics and Toxicokinetic

Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, the effect of tissue-binding interactions, Cytochrome P450- based drug interactions, Drug interactions linked to transporters. Microsomal assays.

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC- MS in bioactivity screening and proteomics.

UNIT -IV **12Hours**

Cell culture techniques

Basic equipment's 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.

UNIT -V **12Hours**

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.

Text books

1. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
2. ICH, USFDA & CDSCO Guidelines.

Reference books

1. Analysis of drugs in biological fluids- Joseph Chamberlain, 2nd Edition, CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis- Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publications, 1961.

Web links

1. https://www.youtube.com/watch?v=8cGE80m1ySM
2. https://www.youtube.com/watch?v=BG6wOVcgYHc
3. https://www.youtube.com/watch?v=72enQBWtGF8
4. https://www.youtube.com/watch?v=2mJ8lKfOgs0
5. https://www.youtube.com/watch?v=Wf7la6To9x4

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QUALITY CONTROL AND QUALITY ASSURANCE (Theory)

Subject code: 2515PY10

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

COB1: Understand the principles of QA, QC, GLP, and cGMP in pharmaceutical manufacturing.
COB2: Recognize global regulatory guidelines applicable to pharmaceutical industries.
COB3: Apply quality control tests for materials and products as per pharmacopoeial standards.
COB4: Appreciate the importance of documentation in pharmaceutical operations.
COB5: Understand the roles of QA and QC in ensuring pharmaceutical product quality.

Course outcomes:

Couse outcome	Statement
CO1	Review the concepts of QAQC, GLP.GMP, ICH guidelines
CO2	Discuss about cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER), PIC, WHO and EMEA along with CPCSEA guidelines.
CO3	Determine the Analysis of raw materials, finished products, packaging materials, IPQC and Finished product quality control as per IP, BP, USP
CO4	Summarize the Developing specification (ICH Q6 and Q3)
CO5	Review the documentation in pharmaceutical industry
CO6	Evaluate Manufacturing operations and controls in pharmaceutical industry

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	3	3	3
CO2	3	3	2	2	2	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes:

CO/PSO	PSO1	PSO2
CO1	3	1
CO2	3	1
CO3	3	2
CO4	3	1
CO5	2	1
CO6	2	1

Course contents **60 Hours**

UNIT-I **12 Hours**

Concept and Evolution of Quality Control and Quality assurance

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

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

UNIT-II **12 Hours**

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

UNIT-III **12Hours**

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.

UNIT-IV **12Hours**

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

UNIT-V **12Hours**

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, and packaging.

Text 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.

Reference Books

1. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
2. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
3. ICH guidelines

Web Links:

W1: https://www.pharmaguideline.com/p/glp.html

W2:https://www.pharmaguideline.com/2012/08/current-good-manufacturing-practice-cgmp.html

W3: https://care.edu.in/wp-content/uploads/2020/03/cpcsea.pdf

W4: https://www.pharmaguideline.com/p/sop-for-stores.html

W5:https://www.pharmaguideline.com/2017/05/controlled-areas-in-sterile-manufacturing.html

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HERBAL AND COSMETIC ANALYSIS

Subject Code: 2515PY11
Course Objectives: Upon completion of the course the student shall be able to understand,
COB1: Principles of performance evaluation of cosmetic products.
COB2: Determination of Herbal drug-drug interaction
COB3: Analysis of natural products and monographs
COB4: Determination of herbal remedies and regulations

COURSE OUTCOMES :

COURSE OUTCOME	STATEMENT
CO1	**Describe** about Herbal remedies &Toxicity and Regulations WHO and AYUSH guidelines.
CO2	**Demonstrate** about Adulteration and Deterioration, causes and measures techniques in identification of drugs microbial contamination.
CO3	**Generate** Regulatory requirements Global marketing management, patent law and its protocol.
CO4	**Create** Set up for testing of natural products and drugs & monographs
CO5	**Explain**. Herbal drug-drug interaction, WHO and AYUSH guidelines for safety monitoring.
CO6	**Discuss** . 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

Mapping of Course Outcomes with Program Outcomes

CO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	3	3	3
CO2	3	3	2	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	3
CO3	3	3
CO4	3	3
CO5	3	3
CO6	3	3

Course contents **60 Hours**

UNIT-I **12Hours**

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

UNIT-II **12Hours**

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

UNIT-III **12Hours**

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

UNIT-IV **12Hours**

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 .

UNIT-V **12Hours**

Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards

Text books

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale

Reference text books

1. Quality Control Methods for Medicinal Plant, WHO, Geneva
2. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
3. Essential of Pharmacognosy by Dr.S.H.Ansari
4. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi

Weblinks

W1:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6425497/
W2:https://www.researchgate.net/publication/281086847_WHO_WORLD_HEALTH_ORGANIZATION_GUIDELINES_FOR_STANDARDIZATION_OF_HERBAL_DRUGS
W3: https://link.springer.com/chapter/10.1007/978-81-322-2283-5_9
W4: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3868382/
W5: https://www.researchgate.net/publication/298263402_Stability_testing_of_herbal_products

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PRACTICAL PHARMACEUTICAL ANALYSIS – III

Subject code: 2515PY12
Course Objectives: Upon completion of the course the student shall be able to
COB1: Wood ward fissure
COB2: FT-IR
COB3: Mass
COB4: Electrophoresis
COB5: HPLC
COB6: Protocol for BA/BE

COURSE OUTCOMES :

CO	STATEMENT
CO1	**Comparison** of absorption spectra by UV and Wood ward – Fiesure rule.
CO2	**Interpretation** of organic compounds by FT-IR, NMR, Mass,
CO3	**Determination** of purity by DSC in pharmaceuticals
CO4	**Apply** Bio molecules separation utilizing varioussample preparation techniques and Quantitative analysis of components by gel electrophoresis.
CO5	**Evaluate** -Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques & Isolation of analgesics from biological fluids (Blood serum and urine)
CO6	**Apply**-Protocol preparation and performance of analytical/Bio analytical method validation and BA/BE studies according to guidelines.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	2	3
CO3	2	3
CO4	2	3
CO5	2	3
CO6	3	2

List of Experiments

S.No	Title of the experiment	CO
1.	Comparison of absorption spectra by UV and Wood ward -Fiesure rule	**CO1**
2.	Interpretation of organic compounds by FTIR	**CO2**
3.	Interpretation of organic compounds by NMR	**CO2**
4.	Interpretation of organic compounds by MS	**CO2**
5.	Determination of purity by DSC	**CO3**
6.	Identification of organic molecules using FT –IR, by ^{1}H NMR, ^{13}C NMR and Mass	**CO2**
7.	Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.	**CO4**
8.	Isolation of analgesics from biological fluids (Blood serum and urine).	**CO5**
9.	Protocol preparation and performance of analytical / Bioanalytical method validation. Protocol preparation for the conduct of BA/BE studies according to guidelines.	**CO6**

Text books

1. H. Beckett & J.B .Stenlake's, Practical Pharmaceutical Chem Vol I & II, Stahlone press of university of London.
2. I. Vogel , Text book of Quantitative inorganic analysis

Reference

1. Bentley and Driver's Text book of Pharmaceutical Chemistry
2. Indian Pharmacopoeia

Weblinks

1. lec 2 2025 | PDF | Ultraviolet–Visible Spectroscopy | Absorbance
2. download.e-bookshelf.de/download/0008/2860/94/L-G-0008286094-0016536535.pdf
3. https://doi.org/10.1016/B978-0-12-322150-6.50007-8
4. https://doi.org/10.1016/0040-6031(72)85022-6
5. www.academia.edu/117436921/New_Drugs_and_Clinical_Trials_Rules_2019_Towards_Fast_track_Accessibility_of_New_Drugs_to_the_Indian_Population

LT	P	C
0 0	6	3

PRACTICAL PHARMACEUTICAL ANALYSIS – IV

Subject Code: 2515PY13
Course Objectives: At completion of this course student shall be able to understand various analytical techniques in the determination
COB1: Finished product QC
COB2: Raw material Testing
COB3: Master Formula Record
COB4: Batch Manufacturing Record
COB5: Determination of different products of significant values

COURSE OUTCOMES :

CO	STATEMENT
CO1	**Evaluation** of in process and finished product
CO2	**Assessment** of raw materials and drugs
CO3	**Understand** preparation of BMR and MFR
CO4	**Apply** the quantitative analysis of rancidity
CO5	**Characterization** of related substances
CO6	**Remember &** Determine purity, foam height, fatty mater, acid value for pharmaceuticals

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes:

CO/PSO	PSO1	PSO2
CO1	3	
CO2	3	
CO3	3	
CO4	3	
CO5	3	2
CO6	3	

Course Content **06 Hours/ Week**

List of Experiments

S.	Title of Experiment	CO
1	In process and finished product quality control tests for tablets, capsules, Parenteral and creams	**CO1**
2.	Quality control tests for Primary and secondary packing materials	**CO1**
3.	Assay of raw materials as per official monographs	**CO2**
4.	Testing of related and foreign substances in drugs and raw materials	**CO2**
5.	Preparation of Master Formula Record.	**CO3**
6.	Preparation of Batch Manufacturing Record.	**CO3**
7.	Quantitative analysis of rancidity in lipsticks and hair oil	**CO4**
8.	Determination of aryl amine content and Developer in hair dye	**CO4**
9.	Determination of foam height and SLS content of Shampoo.	**CO5, CO6**
10.	Determination of total fatty matter in creams (Soap, skin and hair creams)	**CO5, CO6**
11.	Determination of acid value and saponification value.	**CO6**
12.	Determination of calcium thioglycolate in depilatories	**CO6**

Text Books

1. A.H. Beckett & J. B. Sten lake's, Practical Pharmaceutical Chem Vol I & II, Stahlone press of university of London.
2. A.I. Vogel, Text book of Quantitative inorganic analysis

Reference Books

1. Bentley and Driver's Text book of Pharmaceutical Chemistry
2. Indian Pharmacopoeia.
3. Martindale

Weblinks

W1.Unders Dissolution profile calculation

W2.https://www.youtube.com/watch?v=SJlVmGmfNuc

W3.https://pubmed.ncbi.nlm.nih.gov/18280687/

W4.https://www.pharmacy180.com/article/evaluation-of-lipsticks-817/

W5.depilators information

SEMESTER – III

L	T	P	C
4	0	0	4

RESEARCH METHODOLOGY & BIOSTATISTICS (THEORY)

Subject Code: 2515PY15

Course Objectives: Upon completion of the subject student shall be

COB1: Understand general research methodology, practical difficulties, and the process of reviewing literature.

COB2: Gain comprehensive knowledge of study design, types of studies, and strategies to eliminate errors/bias, including controls, randomization, crossover design, and blinding.

COB3: Acquire fundamental concepts in biostatistics, including parametric and non-parametric tests, sample size calculation, and statistical significance.

COB4: Learn about ethics in medical research, including autonomy, beneficence, non-maleficence, ethical guidelines, and the Declaration of Helsinki.

COB5: Understand the CPCSEA guidelines for laboratory animal facilities, including animal husbandry, SOPs, and personnel training.

.Course Outcomes:

COURSE OUTCOM	STATEMENT
CO1	Understand general research methodology, practical difficulties, review of literature, study design, and types of studies, and strategies.
CO2	Gain knowledge about biostatistics: students' "t" test, ANOVA, correlation coefficient, non-parametric tests, null hypothesis, P values, degree of freedom, and interpretation of P values.
CO3	Acquire knowledge about medical research, non-maleficence, double effect, euthanasia, criticisms of orthodox medical ethics, communication, control resolution, guidelines, and ethics committees.
CO4	Understand CPCSEA guidelines for laboratory animal facility, anesthesia, euthanasia, physical facilities, environment, animal husbandry, SOPs, personnel, and training. .
CO5	Gain knowledge about Declaration of Helsinki, including introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	2	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	2	3
CO4	2	3	3	3	2	3
CO5	2	2	2	3	2	3
CO6	3	2	3	2	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	2	3
CO2	3	3
CO3	3	2
CO4	2	3
CO5	3	2
CO6	2	2

Course Contents **60 Hours**

UNIT-I10 Hours

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

UNIT-II **20 Hours**

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

UNIT-III **15 Hours**

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

UNIT- IV **9 Hours**

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, anaesthesia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT-V **6 Hours**

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Text Books

1. Kothari, C.R., "Research Methodology: Methods and Techniques", New Age International Publishers.
2. Rosner, B., "Fundamentals of Biostatistics", Cengage Learning.

Reference Books

1. Wayne W. Daniel, "Biostatistics: A Foundation for Analysis in the Health Sciences", Wiley.
2. S.K. Gupta, "Biostatistics", Jaypee Brothers Medical Publishers.
3. Beauchamp, T.L., Childress, J.F., "Principles of Biomedical Ethics", Oxford University Press.

Web Links

W1: https://researchmethodsresources.nih.gov/
W2: https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
W3: https://cpcsea.nic.in/
W4: https://www.openintro.org/book/os/
W5: https://www.who.int/ethics/en/