Teaching & Examination Scheme and Syllabus of M. Pharm. Programmes

Semester-II

NIRMA UNIVERSITY
Institute of Pharmacy

Teaching & Examination Scheme *(M. Pharm - Pharmaceutics)*

Semester II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPH201T	Molecular Pharmaceutics (Nano Tech & Targeted DDS)	4	-	-	4	3.0	-	0.60	-	0.40
2	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	-	-	4	3.0	-	0.60	-	0.40
3	MPH203T	Computer Aided Drug Delivery System	4	-	-	4	3.0	-	0.60	-	0.40
4	MPH204T	Cosmetics and Cosmeceuticals	4	-	-	4	3.0	-	0.60	-	0.40
5	MPH205P	Pharmaceutics Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MPH206S	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**		**26**					
			35								

L: *Lectures*, P/T: *Practicals/Tutorial*, C: *Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Pharmaceutics)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPH201T**
Course Title	**Molecular Pharmaceutics (Nano Tech & Targeted DDS)**

Scope:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives:

After completion of course student is able to know -

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS.
3. The formulation and evaluation of novel drug delivery systems.

Course Learning Outcomes (CLO):

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

1. Understand the concepts of targeted and nucleic acid based drug delivery systems.
2. Compare various approaches for development of targeted drug delivery systems.
3. Explain types, manufacturing techniques and applications of microparticulate, nanoparticulate and vesicular drug delivery systems.
4. Discuss various approaches for pulmonary drug delivery systems.
5. Analyze various nano and targeted drug delivery systems.

Syllabus:

Teaching Hours: 60 Hours

UNIT I **12 Hours**

Targeted Drug Delivery Systems:

Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

UNIT II **12 Hours**

Targeting Methods:

Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

UNIT III **12 Hours**

Micro Capsules / Micro Spheres:

Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

UNIT IV **12 Hours**

Pulmonary Drug Delivery Systems:

Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNIT V **12 Hours**

Nucleic acid based therapeutic delivery system:

Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

Suggested Readings^: (Latest edition)

1. Chien Y W., *Novel Drug Delivery Systems*, Marcel Dekker, Inc., New York.
2. Vyas S. P. and Khar R. K., *Controlled Drug Delivery - concepts and advances*, Vallabh Prakashan, New Delhi.
3. Jain N. K., *Controlled and Novel Drug Delivery*, CBS Publishers & Distributors, New Delhi.
4. Narang A.S., Mahato R.I.. *Targeted Delivery of Small & Macromolecular Drugs*, CRC Press, Boca Raton.
5. Hillery A. M., Lloyd A. W., Swarbrick J., *Drug Delivery and Targeting: For Pharmacists and Pharmaceutical Scientists*, Taylor & Francis, Inc., New York.
6. Jorgensen L., Nielsen H. M., *Delivery Techniques for Biopharmaceuticals*, Wiley Interscience, UK.
7. Robinson J. R., Lee V. H. L., *Controlled drug delivery: Fundamentals and applications*. New York: Informa Health Care.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm - Pharmaceutics)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPH202T**
Course Title	**Advanced Biopharmaceutics & Pharmacokinetics**

Scope:

This course is designed to impart knowledge and skills necessary for dose calculations, dose

adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives:

After completion of course student is able to know-

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.

Course Learning Outcomes (CLO):

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

1. Understand concept of drug absorption in human body.
2. Correlate dissolution data with its pharmacokinetic data.
3. Derive the pharmacokinetic parameters along with its applications.
4. Estimate pharmacokinetic parameters with its interpretation.
5. Explain development of BA-BE protocol as per various regulatory guidelines.
6. Apply concepts of pharmacokinetics in clinical situations.

Syllabus:

Teaching Hours: 60 Hours

UNIT I **12 Hours**

Drug Absorption From The Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH–partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

UNIT II **12 Hours**

Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance:

Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products. In Vitro–In Vivo Correlation,

Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.

UNIT III **12 Hours**

Pharmacokinetics:

Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extravascular. Multi Compartment model: Two compartment - model in brief, Non Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max}. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

UNIT IV **12 Hours**

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, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process. Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

UNIT V **12 Hours**

Application of Pharmacokinetics:

Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

Suggested Readings^: (Latest edition)

1. Gibaldi Milo. *Biopharmaceutics and Clinical Pharmacokinetics*, Philadelphia, Lea and Febiger.
2. Brahmankar D. M., Jaiswal S. B. *Biopharmaceutics and Pharmacokinetics: A Treatise*, Delhi, Vallabh Prakashan.
3. Shargel L., Andrew Yu, Susanna Wu-Pong, *Applied Biopharmaceutics and Pharmacokinetics*, McGraw Hill Professional, USA.
4. Rani S., Hiremath, R. *Textbook of Biopharmaceutics and Pharmacokinetics*, Prism Book.
5. Gibaldi M., Perrier D. *Pharmacokinetics*, New York, Marcel Dekker Inc.
6. Swarbrick. J, *Current Concepts in Pharmaceutical Sciences: Biopharmaceutics*. Philadelphia, Leaand Febiger.
7. Rowland M., Tozer T. *Clinical Pharmacokinetics, Concepts and Applications*, Philadelphia, Leaand Febiger.
8. Abdou H. M, *Dissolution, Bioavailability and Bioequivalence*, Pennsylvania, Mack Publishing Company.
9. Notari R. E. *Biopharmaceutics and Clinical Pharmacokinetics, An Introduction*, New York, Marcel Dekker Inc,
10. Wagner J. G., Pemarowski M. *Biopharmaceutics and Relevant Pharmacokinetics*, Hamilton, Illinois, Drug Intelligence Publications.
11. Swarbrick J., Boylan J. G. *Encyclopedia of Pharmaceutical Technology*, New York, Marcel Dekker Inc,

12. Jambhekar S. S., Breen P J. *Basic Pharmacokinetics*, Pharmaceutical Press, RPS Publishing.
13. Avdeef A. *Absorption and Drug Development- Solubility, Permeability, and Charge State.* John Wiley & Sons, Inc

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(M. Pharm - Pharmaceutics)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPH203T**
Course Title	**Computer Aided Drug Delivery System**

Scope:

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives:

After completion of course student is able to know -

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence (AI) and Robotics
8. Computational fluid dynamics(CFD)

Course Learning Outcomes (CLO):

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

1. Understand applications of computers in pharmaceutical research and development.
2. Discuss QbD guidelines with its implications in pharmaceutical industry.
3. Relate drug delivery with Artificial intelligence (AI), Robotics and Computational fluid dynamics.
4. Describe significance of computational modeling of drug disposition.
5. Apply optimization techniques in development of pharmaceutical formulation.
6. Interpret computer generated market analysis and clinical development data.

Syllabus: **Teaching Hours: 60 Hours**

UNIT I **12 Hours**

Computers in Pharmaceutical Research and Development:

A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter ,Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

Quality-by-Design In Pharmaceutical Development:

Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

UNIT II **12 Hours**

Computational Modeling of Drug Disposition:

Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

UNIT III **12 Hours**

Computer-aided formulation development:

Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

UNIT IV **12 Hours**

Computer-aided biopharmaceutical characterization:

Gastrointestinal absorption simulation Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations

Computer Simulations in Pharmacokinetics and Pharmacodynamics:

Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

Computers in Clinical Development:

Clinical Data Collection and Management, Regulation of Computer Systems

UNIT V **12 Hours**

Artificial Intelligence (AI), Robotics and Computational fluid dynamics:

General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

Suggested Readings^: (Latest edition)

1. Ekins, S. *Computer Applications in Pharmaceutical Research and Development.* John Wiley & Sons, UK.
2. Djuris, J. *Computer-Aided Applications in Pharmaceutical Technology.* Woodhead Publishing.
3. Swarbrick, J. Boylan, J.G. *Encyclopedia of Pharmaceutical Technology (Volume 20).* New York, Marcel Dekker Inc, USA.

4. Nag, A. Dey, B. *Computer-Aided Drug Design and Delivery Systems*. The McGraw-Hill Companies, Inc. NewYork.
5. Reklaitis G, Seymour C, García-Munoz S. *Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture*. Wiley-Blackwell, UK.

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(M. Pharm - Pharmaceutics)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPH204T**
Course Title	**Cosmetics and Cosmeceuticals**

Scope:

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives:

Upon completion of the course, the students shall be able to know -

1. Key ingredients used in cosmetics and cosmeceuticals.
2. Key building blocks for various formulations.
3. Current technologies in the market.
4. Various key ingredients and basic science to develop cosmetics and cosmeceuticals.
5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Learning Outcomes (CLO):

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

1. Understand regulatory requirements of cosmeceuticals.
2. Discuss safety, stability, and efficacy aspects of cosmetic products.
3. Identify key ingredients used in cosmetics and cosmeceuticals.
4. Explain current technologies for cosmetic manufacturing.
5. Design and develop cosmetics and cosmeceuticals.

Syllabus: **Teaching Hours: 60 Hours**

UNIT I **12 Hours**

Cosmetics – Regulatory:

Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II **12 Hours**

Cosmetics - Biological aspects:

Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III **12 Hours**

Formulation Building blocks:

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.

Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV **12 Hours**

Design of cosmeceutical products:

Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V **12 Hours**

Herbal Cosmetics:

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

Suggested Readings^: (Latest Edition)

1. Rieger, M. *Harry's Cosmeticology: volume 2*. Chemical Publishing Company.
2. Saraf, S., & Saraf, S. *Cosmetics a practical manual*. PharmaMed Press, Hyderabad.
3. Butler, H. *Poucher's perfumes, cosmetics, and soaps*. Dordrecht: Kluwer Academic.
4. Williams, D. F., & Schmitt, W. H. *Chemistry and Technology of the Cosmetics and Toiletries Industry*. Dordrecht: Springer Netherlands.
5. Barel, A. O., Paye, M., & Maibach, H. I. *Handbook of cosmetic science and technology*. New York: Marcel Dekker.
6. *CTFA membership directory*. CTFA, Washington, USA.
7. *Khar, R.* K. *Cosmetic Technology*. Birla Publications, Delhi.
8. *Sharma, P.P. Cosmetic Formulations Manufacturing and Quality Control.* Vandana Publication, Delhi.
9. Sampath K. *A Concise Book of Cosmetic*. Birla Publications Pvt. Ltd., Delhi.

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(M. Pharm - Pharmaceutics)
(Semester – II)

L	T	P	C
-	-	12	6

Course Code	**MPH 205P**
Course Title	**Pharmaceutics Practical II**

PRACTICALS **180 Hours**

1. To study the effect of temperature change , non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands .
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

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NIRMA UNIVERSITY
Institute of Pharmacy
Teaching & Examination Scheme *(M. Pharm - Pharmaceutical Chemistry)*

Semester II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPC201T	Advanced Spectral Analysis	4	-	-	4	3.0	-	0.60	-	0.40
2	MPC202T	Advanced Organic Chemistry - II	4	-	-	4	3.0	-	0.60	-	0.40
3	MPC203T	Computer Aided Drug Design	4	-	-	4	3.0	-	0.60	-	0.40
4	MPC204T	Pharmaceutical Process Chemistry	4	-	-	4	3.0	-	0.60	-	0.40
5	MPC205P	Pharmaceutical Chemistry Practical - II	-	12	-	6	-	6.0	-	1.00	-
6	MPC206S	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**		**26**					
			35								

L: *Lectures*, P/T: *Practicals/Tutorial*, C: *Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

w.e.f. academic year 2017-2018 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Pharmaceutical Chemistry)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPC201T**
Course Title	**Advanced Spectral Analysis**

Scope:

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives:

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

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

Course Learning Outcomes (CLO):

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

1. Understand interpretation of the UV, NMR, Mass and IR spectra of various organic compounds.
2. Describe the concept, principle, instrumentation and applications of the chromatography methods.
3. Explain principle, instrumentation and application of thermal methods of analysis.
4. Apply basic concept of spectroscopy for identification of organic compounds.
5. Predict the chemical structures of compounds using spectroscopic data.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

UV and IR spectroscopy:

Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

UNIT II **12 Hours**

NMR spectroscopy:

1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

UNIT III **12 Hours**

Mass spectroscopy:

Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

UNIT IV **12 Hours**

Chromatography:

Principle, Instrumentation and Applications of the following: a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography

UNIT V **12 Hours**

a) Thermal methods of analysis:

Introduction, principle, instrumentation and application of DSC, DTA and TGA.

b) Raman spectroscopy:

Introduction, Principle, Instrumentation and Applications.

c) Radio immuno assay:

Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

Suggested Readings^: (Latest edition)

1. Robert M Silverstein, *Spectrometric Identification of Organic compounds*, John Wiley & Sons.
2. Doglas A Skoog, F. James Holler, Timothy A. Nieman, *Principles of Instrumental Analysis*, Eastern press, Bangalore.
3. Willards, *Instrumental methods of analysis*, CBS publishers.
4. William Kemp, *Organic Spectroscopy*, ELBS.
5. P D Sethi, *Quantitative analysis of Pharmaceutical formulations by HPTLC*, CBS Publishers, New Delhi.
6. P D Sethi, *Quantitative Analysis of Drugs in Pharmaceutical formulation*, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. J W Munson, *Pharmaceutical Analysis-Modern methods-Part B*, Volume 11, Marcel Dekker Series.

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(M. Pharm - Pharmaceutical Chemistry)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPC202T**
Course Title	**Advanced Organic Chemistry – II**

Scope:

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives:

At the end of the course, students will be able to understand -

1. The principles and applications of Green chemistry.
2. The concept of peptide chemistry.
3. The various catalysts used in organic reactions.
4. The concept of stereochemistry and asymmetric synthesis.

Course Learning Outcomes (CLO):

After successful completion of the course, student will be able to -

1. Understand principles and applications of Green chemistry.
2. Explain Photochemical and Pericyclic reaction.
3. Apply the knowledge of various catalysts in organic reactions.
4. Utilize the concept of peptide chemistry.
5. Correlate the concept of stereochemistry during asymmetric synthesis.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Green chemistry:

a. Introduction, principles of green chemistry

b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis

c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications.

d. Continuous flow reactors: Working principle, advantages and synthetic applications.

UNIT II **12 Hours**

Chemistry of peptides:

a. Coupling reactions in peptide synthesis

b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies

d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

UNIT III **12 Hours**

Photochemical reactions:

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions:

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

UNIT IV **12 Hours**

Catalysis:

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages

b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.

c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs

d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions

e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.

f. Phase transfer catalysis - theory and applications

UNIT V **12 Hours**

Stereochemistry & asymmetric synthesis:

a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.

b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

Suggested Readings^: (Latest edition)

1. Smith, M. B., & March, J. *March's advanced organic chemistry: Reactions, mechanisms, and structure*. New York: Wiley-Interscience.
2. Gould, E. S. *Mechanism and structure in organic chemistry*.
3. Clayden, J., Greeves, N., & Warren, S. G. *Organic chemistry*. Oxford: Oxford University Press.
4. Finar, I. L. *Organic chemistry*. Delhi: Pearson education.
5. Isaacs, N. S. *Reactive intermediates in organic chemistry*. New York, Wiley.
6. Bruice, P. Y. *Organic chemistry: Paula Yurkanis Bruice*. Harlow, Essex, England: Pearson.
7. Wilson, S. R., & Czarnik, A. W. (Eds.). *Combinatorial chemistry: synthesis and application*. John Wiley & Sons.
8. Carey, F. A. *Advanced organic chemistry: reactions and synthesis*. Place of publication not identified: Springer.
9. Norman, R. O., & Coxon, J. M. *Principles of organic synthesis*. CRC Press.
10. Ramsay, O. B. *Stereochemistry*. London: Heyden.
11. Warren, S. G., & Wyatt, P. *Workbook for organic synthesis: the disconnection approach*. Oxford: Wiley-Blackwell.
12. Wyatt, P., & Warren, S. G. *Organic synthesis: strategy and control*. Chichester, England: John Wiley.
13. Furniss, B. S. *Vogel's textbook of practical organic chemistry*. Pearson Education India.
14. Ahluwalia, V. K., & Aggarwal, R. *Organic synthesis: special techniques*. CRC Press.
15. Ahluwalia, V., & Parashar, R. *Organic reaction mechanisms*. Oxford, U.K.: Alpha Science International.

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(M. Pharm - Pharmaceutical Chemistry)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	MPC203T
Course Title	Computer Aided Drug Design

Scope:
The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

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

1. Role of CADD in drug discovery.
2. Different CADD techniques and their applications.
3. Various strategies to design and develop new drug like molecules.
4. Working with molecular modeling softwares to design new drug molecules.
5. The in silico virtual screening protocols.

Course Learning Outcomes (CLO):
After successful completion of the course, students will be able to –

1. Understand role of computer aided drug design in new drug discovery.
2. Explain rational drug design techniques based on the understanding of three-dimensional (3D) structures and molecular properties of drugs and target.
3. Apply their drug design knowledge by access of various CADD software.
4. Calculate some physicochemical properties of drug molecules using various freeware.
5. Create various in-silico models of pharmacophore, QSAR, docking etc.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Introduction to Computer Aided Drug Design (CADD):
History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics
History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

UNIT II **12 Hours**

Quantitative Structure Activity Relationships: Applications

Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.

3D-QSAR approaches and contour map analysis.

Statistical methods used in QSAR analysis and importance of statistical parameters.

UNIT III **12 Hours**

Molecular Modeling and Docking:

a) Molecular and Quantum Mechanics in drug design.

b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

UNIT IV **12 Hours**

Molecular Properties and Drug Design:

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

c) Homology modeling and generation of 3D-structure of protein.

UNIT V **12 Hours**

Pharmacophore Mapping and Virtual Screening:

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

Suggested Readings^: (Latest edition)

1. Stroud, R. M & Moore, J. M.. *Computational and Structural Approaches to Drug Discovery: Ligand–Protein Interactions*. RCS Publishers.
2. Martin, Y. C. *Introduction to Quantitative Drug Design.* CRC Press, Taylor & Francis.
3. Ariens, E. J. *Drug Design: Medicinal Chemistry: A Series of Monographs.* Vol. 1-10. Academic Press, Elsevier.
4. Smith, H. J. & Williams, H. *Introduction to the principles of drug design and action.* CRC Press, Taylor & Francis.
5. Silverman, R. B. & Holladay, M. W. *The organic chemistry of drug design and drug action.* Academic press, Elsevier.
6. Burger, A. *Medicinal chemistry.* John Wiley & Sons.
7. Patrick, G. L. *An introduction to medicinal chemistry.* Oxford university press.
8. Wilson, C. O., Beale, J. M., & Block, J. H. *Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry.* Lippincott Williams & Wilkins.

9. Hansch, C., Sammes, P. G., & Taylor, J. B. *Comprehensive medicinal chemistry.* Pergamon Publisher

L= Lecture, T= Tutorial, P= Practical, C= Credit
^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Chemistry)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPC204T**
Course Title	**Pharmaceutical Process Chemistry**

Scope:

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives:

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

1. The strategies of scale up process of apis and intermediates.
2. The various unit operations and various reactions in process chemistry.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to understand -

1. Remember various aspects of process safety and hazard reduction in the industry.
2. Understand basic concepts involved process chemistry.
3. Describe strategies used for scale up process of APIs and intermediates.
4. Explain principles and pharmaceutical equipments of unit operations.
5. Discuss various reactions in process chemistry with their case studies.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Process chemistry:

Introduction, Synthetic strategy
Stages of scale up process: Bench, pilot and large scale process.
In-process control and validation of large scale process.

Case studies of some scale up process of APIs.
Impurities in API, types and their sources including genotoxic impurities

UNIT II **12 Hours**

Unit operations:

a) Extraction:

Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

b) Filtration:

Theory of filtration, pressure and vacuum filtration, centrifugal filtration.

c) Distillation:

Azeotropic and steam distillation.

d) Evaporation:

Types of evaporators, factors affecting evaporation.

e) Crystallization:

Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

UNIT III **12 Hours**

Unit Processes – I:

a) Nitration:

Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,

b) Halogenation:

Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

c) Oxidation:

Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

UNIT IV **12 Hours**

Unit Processes – II:

a) Reduction:

Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

b) Fermentation:

Aerobic and anaerobic fermentation.
Production of
i. Antibiotics; Penicillin and Streptomycin,
ii. Vitamins: B2 and B12
iii. Statins: Lovastatin, Simvastatin

c) Reaction progress kinetic analysis:

i. Streamlining reaction steps, route selection,
ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

UNIT V **12 Hours**

Industrial Safety:

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)

b) Fire hazards, types of fire & fire extinguishers

c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

Suggested Readings^: (Latest edition)

1. Gadamasetti, K., & Braish, T. (Eds.). *Process chemistry in the pharmaceutical industry: Challenges in an ever changing climate.* CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, Volume 2.
3. Burger, *Medicinal Chemistry*, Volume 1-8.
4. McCabe, W. L., Smith, J. C., & Harriott, P. *Unit operations of chemical engineering.* New York: McGraw-Hill.
5. Brittain, H. G. *Polymorphism in Pharmaceutical Solids,* Volume 192.
6. Murphy, R. M. *Introduction to Chemical Processes: Principles. Analysis, Synthesis.*
7. Harrington, P. J. *Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up.* John Wiley & Sons.
8. Groggins, P. H. *Unit processes in organic synthesis.*
9. Henglein, F. A. *Chemical technology.* Elsevier.
10. Rao, M. G., & Sittig, M. *Dryden's Outlines of Chemical Technology.* East-West press.
11. Clausen, C. A., & Mattson, G. *Principles of Industrial Chemistry.* John Wiley & Sons.
12. Faith, W. L., Keyes, D. B., Clark, R. L., Lowenheim, F. A., & Moran, M. K. *Industrial chemicals.* New York: Wiley.
13. Pandey, G. N., & Shukla, S. D. *A Textbook of Chemical Technology.* Vikas Publishing House.
14. Stille, J.K. *Industrial Organic Chemistry.*
15. Shreve, R. N., & Austin, G. T. *Shreve's chemical process industries.* McGraw-Hill.
16. Sharma, B. K. *Industrial chemistry.* Goel Publishing House.
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

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^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Chemistry)
(Semester - II)

L	T	P	C
-	-	12	6

Course Code	**MPC205P**
Course Title	**Pharmaceutical Chemistry Practical - II**

Syllabus: **Teaching hours: 180 Hours**

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments).

a) Oxidation

b) Reduction/hydrogenation
c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments).
3. Assignments on regulatory requirements in API (2 experiments).
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule.
5. Interpretation of organic compounds by FT-IR.
6. Interpretation of organic compounds by NMR.
7. Interpretation of organic compounds by MS.
8. Determination of purity by DSC in pharmaceuticals.
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra.
10. To carry out the preparation of following organic compounds.
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. $NaBH_4$ reduction of vanillin to vanillyl alcohol.
14. Preparation of umbelliferone by Pechhman reaction.
15. Preparation of triphenyl imidazole.
16. To perform the Microwave irradiated reactions of synthetic importance (Any two).
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares.
18. Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling.
19. 2D-QSAR based experiments.
20. 3D-QSAR based experiments.
21. Docking study based experiment.
22. Virtual screening based experiment.

NIRMA UNIVERSITY
Institute of Pharmacy
Teaching & Examination Scheme *(M. Pharm- Pharmaceutical Analysis)*

Semester - II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPA201T	Advanced Instrumental Analysis	4	-	-	4	3.0	-	0.60	-	0.40
2	MPA202T	Modern Bio-Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
3	MPA203T	Quality Control and Quality Assurance	4	-	-	4	3.0	-	0.60	-	0.40
4	MPA204T	Herbal and Cosmetic Analysis	4	-	-	4	3.0	-	0.60	-	0.40
5	MPA205P	Pharmaceutical Analysis Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MPA-206S	Seminar/Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**	-	**26**	-	-	-	-	-
			35								

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPA201T**
Course Title	**Advanced Instrumental Analysis**

Scope:

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives:

After completion of course student is able to know -

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

Course Learning Outcomes (CLO):

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

1. Understand the fundamental theory of different chromatographic techniques.
2. Describe the principle, instrumentation and applications of HPLC, HPTLC, SFC and GC methods.
3. Discuss the principle, instrumentation and applications of various biochromatographic methods.
4. Explain the instrumentation and applications of various spectroscopic techniques.
5. Predict the structural information using mass and NMR spectrometry and related hyphenated techniques.

Syllabus: **Teaching hours: 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, practical aspects of preparative HPLC.

UNIT II **12 Hours**

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.

UNIT III **12 Hours**

Super critical fluid chromatography:

Principles, instrumentation, pharmaceutical applications.

Capillary electrophoresis:

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

UNIT IV **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, 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.

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 ^{13}CNMR:

Spin spin and spin lattice relaxation phenomenon. ^{13}C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

Suggested Readings^: (Latest edition)

1. Silverstein, R. M., Webster, F. X., Kiemle, D. J., & Bryce, D. L.. *Spectrometric Identification of Organic Compounds*. Johnwiley & sons.
2. Skoog, D. A. H., James, F., & Nieman, T. A. *Principles of Instrumental Analysis. Eastern press.*
3. Hobart, W. H., Merritt LL, Dean John. A., *Instrumental Methods of Analysis*. CBS publishers.
4. Kemp, W. *Organic Spectroscopy*. ELBS.

5. Sethi, P. D. *HPTLC: High performance thin-layer chromatography; quantitative analysis of pharmaceutical formulations*. CBS publishers & distributors.
6. Sethi, P. D. *Quantitative Analysis of Drugs in Pharmaceutical Formulations*. CBS Publishers.
7. Munson, J. W. *Pharmaceutical Analysis: Modern Methods (Vol. 11)*. CRC Press.
8. Pavia, D. L., Lampman, G. M., Kriz, G. S., & Vyvyan, J. A.. *Introduction to spectroscopy*. Cengage Learning.

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^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPA202T**
Course Title	**Modern Bio-Analytical Techniques**

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

Objectives:
Upon completion of the course, the student shall be able to understand -
1. Extraction of drugs from biological samples.
2. Separation of drugs from biological samples using different techniques.
3. Guidelines for BA/BE studies.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to –
1. Understand the basics of drug extraction methods.
2. Determine the biopharmaceutical factors for drug absorption and drug release.
3. Describe pharmacokinetics and its importance along with toxicokinetics.
4. Discuss the principle techniques and applications of various cell culture methods.
5. Apply bioavailability and bioequivalence principles in drug product performance.
6. Predict the possible metabolite formation of drug product.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

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 **12 Hours**

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 **12 Hours**

Pharmacokinetics and Toxicokinetics:

Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

UNIT IV **12 Hours**

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.

UNIT V **12 Hours**

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.

Suggested Readings^: (Latest edition)

1. Chamberlain, J. *The Analysis of Drugs in Biological Fluids*. CRC press.
2. Skoog, D. A., Holler, F. J., & Crouch, S. R. *Principles of instrumental analysis*. Cengage learning.

3. Higuchi, T., Bodin, J. I., & Brochmann-Hanssen, E. *Pharmaceutical analysis*. Interscience Publishers.
4. Munson, J. W. *Pharmaceutical analysis: modern methods (Vol. 11)*. CRC Press.
5. Snyder, L. R., Kirkland, J. J., & Glajch, J. L. *Practical HPLC method development*. John Wiley & Sons.
6. Adamovics, J. A. *Chromatographic analysis of pharmaceuticals (Vol. 74)*. CRC Press.
7. Bertholf, R., & Winecker, R. *Chromatographic methods in clinical chemistry and toxicology*. John Wiley & Sons.
8. Weinberg, S. *Good laboratory practice regulations*. CRC Press.
9. Hirsch, A. F. *Good laboratory practice regulations*. Marcel Dekker.
10. ICH, USFDA & CDSCO Guidelines.

L= Lecture, T= Tutorial, P= Practical, C= Credit
^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPA203T**
Course Title	**Quality Control and Quality Assurance**

Scope:
This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

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

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

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Understand the concepts of quality control, quality assurance, GMP, GLP.
2. Describe the various quality control guidelines by CDSCO, USFDA, EMEA, WHO etc.
3. Determine various quality requirements for drugs and finish products.

4. Report various quality related documents for pharmaceutical manufacturing along with quality certification.
5. Relate the importance of operations and controls in pharmaceutical manufacturing.

Syllabus: **Teaching hours: 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 **12 Hours**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)

Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

UNIT IV **12 Hours**

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 **12 Hours**

Manufacturing operations and controls:

Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

Suggested Readings^: (Latest edition)

1. *Quality Assurance Guide by organization of Pharmaceutical Procedures of India*, Volume I & II, Mumbai.
2. Weinberg, S. *Good laboratory practice regulations*. CRC Press.
3. *World Health Organization. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection (Vol. 1 & 2)*. World Health Organization.
4. Sharma, P. P. *How to practice GMPs*. Vandana publication Pvt. Ltd Delhi.
5. *World Health Organization. The international pharmacopoeia (Vol. 1 to 5). General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms.* World Health Organization.
6. Hirsch, A. F. *Good laboratory practice regulations*. Marcel Dekker.
7. ICH guidelines
8. ISO 9000 and total quality management
9. Deshpande & Gandhi, N. *The drugs and cosmetics act 1940*. Susmit Publishers.
10. Shah D.H., QA *Manual. Business Horizons.*
11. Willig, S. H., & Stoker, J. R. *Good manufacturing practices for pharmaceuticals. A plan for total quality control. Drugs and the pharmaceutical sciences. Vol. 52*. Marcel Dekker Series.
12. Steinborn, L. *GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers,(Volume 1- With Checklists and Software Package)*. Taylor & Francis.
13. Sarker, D. K. *Quality Systems and Controls for Pharmaceuticals*. John Wiley & Sons.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Analysis)

(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPA204T**
Course Title	**Herbal and Cosmetic Analysis**

Scope:

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

Objectives:

At completion of this course student shall be able to understand -

1. Determination of herbal remedies and regulations.
2. Analysis of natural products and monographs.

3. Determination of Herbal drug-drug interaction.
4. Principles of performance evaluation of cosmetic products.

Course Learning Outcomes:

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

1. Understand the herbal drug regulations and standardization.
2. Identify the adulteration and deterioration of herbal drugs.
3. Analyze the natural products and adulterants.
4. Determine herbal drug-drug interaction.
5. Evaluate cosmetic products.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

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 **12 Hours**

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 **12 Hours**

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 **12 Hours**

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 **12 Hours**

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.

Suggested Readings^: (Latest edition)

1. Evans, W. C. *Trease and Evans' Pharmacognosy*. Elsevier Health Sciences.
2. Kokate, C. K., Purohit, A. P., & Gokhale, S. B. *Pharmacognosy*. Nirali Prakashan, Pune.
3. World Health Organization. *Quality control methods for medicinal plant materials*. Geneva.
4. Kar, A. *Pharmacognosy and pharmacobiotechnology*. New Age International.
5. Ansari, S. H. *Essential of Pharmacognosy*, Birla publications Pvt. Ltd, New Delhi.
6. Sharma, P. P. *Cosmetics: Formulation, Manufacturing and Quality Control*. Vandana Publications Pvt Ltd. Delhi.
7. *Bureau of Indian Standards. Indian Standard Specification for Raw Materials*. New Delhi.
8. *Bureau of Indian Standards. Indian Standard Specification for 28 Finished Cosmetics*. New Delhi.
9. Harry, R. G. *Harry's cosmeticology*. Chemical Publishing Company.
10. Suppliers catalogue on specialized cosmetic excipients.
11. Butler, H. *Poucher's perfumes, cosmetics and soaps. Springer Science & Business Media.*
12. Barel, A. O., Paye, M., & Maibach, H. I. *Handbook of cosmetic science and technology*. CRC Press.
13. www.who.int
14. www.ayush.gov.in

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
-	-	12	6

Course Code	**MPA205P**
Course Title	**Pharmaceutical Analysis Practical II**

Syllabus: **Teaching hours: 180 Hours**

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule.
2. Interpretation of organic compounds by FT-IR.

3. Interpretation of organic compounds by NMR.
4. Interpretation of organic compounds by MS.
5. Determination of purity by DSC in pharmaceuticals.
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra.
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams.
13. Quality control tests for Primary and secondary packing materials.
14. Assay of raw materials as per official monographs.
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.

L= Lecture, T= Tutorial, P= Practical, C= Credit

NIRMA UNIVERSITY
Institute of Pharmacy
Teaching & Examination Scheme *(M. Pharm - Regulatory Affairs)*

Semester - II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRA201T	Regulatory Aspscts of Drugs & Cosmetics	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA202T	Regulatory Aspsects of Herbal & Biologicals	4	-	-	4	3.0	-	0.60	-	0.40
3	MRA203T	Regulatory Aspects of Medical Devices	4	-	-	4	3.0	-	0.60	-	0.40
4	MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	-	-	4	3.0	-	0.60	-	0.40
5	MRA205P	Regulatory Affairs Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MRA-206S	Seminar/Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**	-	**26**	-	-	-	-	-
			35								

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

w.e.f. academic year 2017-2018 and onwards

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NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA201T**
Course Title	**Regulatory Aspects of Drugs and Cosmetics**

Scope:

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know -

1. Process of drug discovery and development and generic product development.
2. Regulatory approval process and registration procedures for API and drug products in US, EU.
3. Cosmetics regulations in regulated and semi-regulated countries.
4. A comparative study of India with other global regulated markets.

Course Learning Outcomes (CLO):

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

1. Understand the basics of global regulatory requirements.
2. Describe the process of drug discovery, development and generic product development.
3. Explain the guidelines for registration and approval process for API, drug products (including orphan drugs) and cosmetics in US, Canada and EU.
4. Express the organization, legislations, regulations and registration procedures of PMDA.
5. Apply the knowledge of regulatory requirements for emerging market.
6. Compare the regulatory requirement for registration of drugs in brazil, ASEAN, CIS and GCC countries.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

USA & CANADA:

Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.

UNIT II **12 Hours**

European Union & Australia:

Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

UNIT III **12 Hours**

Japan:

Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan.

UNIT IV **12 Hours**

Emerging Market:

Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC).

WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana).

UNIT V **12 Hours**

Brazil, ASEAN, CIS and GCC Countries:

ASIAN Countries:

Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States):

Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine.

GCC (Gulf Cooperation Council) for Arab states:

Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE.

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

Suggested Readings^: (Latest edition)

1. Shargel, L., & Kanfer, I. *Generic drug product development: solid oral dosage forms*. CRC Press.
2. Ira, Berry, *The Pharmaceutical Regulatory Process*, Marcel Dekker Series, Vol 144.
3. Ira, Berry. & Robert, Martin. *The Pharmaceutical Regulatory Process, Drugs and the pharmaceutical sciences*, Vol.185. Informa Healthcare Publishers.
4. Richard, G. *New Drug Approval Process: Accelerating Global Registrations, Drugs and the Pharmaceutical Sciences*, Vol.190.
5. Weinberg, S. *Guidebook for Drug Regulatory Submissions*. John Wiley & Sons.
6. Ng, R. Drugs: F*rom discovery to approval*. John Wiley & Sons.
7. Mathieu, M. P., Keeney, R., & Milne, C. P. *New drug development: a regulatory overview*. Parexel International Corp.
8. Jeffrey, F., Wayne, Pines & Gary, H. *Pharmaceutical Risk Management.*
9. William, K. *Preparation and Maintenance of the IND Application in eCTD Format.*
10. http://www.pmda.go.jp/english
11. http://www.fda.gov
12. http://portal.anvisa.gov.br/wps/portal/anvisa-ingles
13. http://www.ema.europa.eu
14. Country Specific Guidelines from official websites
15. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
16. Denis, H. *Roadmap to an ASEAN economic community*. ISEAS Publications, Singapore , ISBN981-230-347-2
17. Rodolfo, S. *ASEAN*. ISEAS Publications, Singapore, ISBN 978-981-230-750-7
18. Kobayashi-Hillary, M. *Building a future with BRICS: the next decade for offshoring* (Vol. 4643). Springer Science & Business Media.
19. Kobayashi-Hillary, M. *Outsourcing to India: The offshore advantage*. Springer Science & Business Media.
20. *The world Bank*, Washington, DC, ISBN: 0-8212-5896-0.
21. Abbott, F. M., Dukes, M. N. G., & Dukes, G. *Global pharmaceutical policy: ensuring medicines for tomorrow's world*. Edward Elgar Publishing.
22. Low, L., & Salazar, L. C. *The Gulf Cooperation Council: a rising power and lessons for ASEAN* (No. 12). Institute of Southeast Asian Studies.
23. Bhasin, B. *Doing business in the ASEAN countries*. Business Expert Press.

24. Plummer, M. G., & Yue, C. S. *Realizing the ASEAN economic community: A comprehensive assessment. Institute of Southeast Asian Studies.*

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(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA202T**
Course Title	**Regulatory Aspects of Herbal and Biologicals**

Scope:

This course is designed to impart fundamental knowledge on regulatory requirements, licensing and registration, regulation on labelling of biologics in India, USA and Europe. It prepares the students to learn in detail on regulatory requirements for biologics, vaccines and blood products.

Objectives:

Upon the completion of the course the student shall be able to -

1. Know the regulatory requirements for biologics and vaccines.
2. Understand the regulation for newly developed biologics and biosimilars.
3. Know the pre-clinical and clinical development considerations of biologics.
4. Understand the regulatory requirements of blood and/or its components including blood products and label requirements.

Course Learning Outcomes (CLO):

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

1. Understand the requirement of similar biologics from development to market authorization in India.
2. Discuss the regulatory requirements for the biosimilars in US and EU.
3. Know preclinical and clinical development of biologics.
4. Apply knowledge of regulatory aspects of vaccines, blood products and biological products in India, US and EU.
5. Compare quality, safety, and legislation for herbal products in India, US and EU.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

India :

Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

UNIT II **12 Hours**

USA:

Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.

UNIT III **12 Hours**

European Union:

Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.

UNIT IV **12 Hours**

Vaccine regulations in India, US and European Union:

Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network).

UNIT V **12 Hours**

Herbal Products:

Quality, safety and legislation for herbal products in India, USA and European Union.

Suggested Readings^: (Latest edition)

1. Pisano, D. J., & Mantus, D. S. *FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics*. Taylor & Francis US.
2. Wang, W., & Singh, M. *Biological drug products: development and strategies*. John Wiley & Sons.
3. Singh , M. ,Srivastava, I. *Development of Vaccines: From Discovery to Clinical Testing*. Wiley.
4. www.who.int/biologicals/en

5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. *Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India.*
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)
12. www.ayush.gov.in

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(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA203T**
Course Title	**Regulatory Aspects of Medical Devices**

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know -

1. Basics of medical devices and IVDs, process of development, ethical and quality considerations.
2. Harmonization initiatives for approval and marketing of medical devices and IVDs.
3. Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.
4. Clinical evaluation and investigation of medical devices and IVDs.

Course Learning Outcomes (CLO):

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

1. Understand the definition, classification and principles of medical devices and IVDs.
2. Describe the principle of ethics in clinical investigations of medical devices.

3. Explain the quality system regulations and ISO certification for medical devices.
4. Report regulatory approval process for medical device in US and EU.
5. Apply the knowledge of regulatory approval process for medical device in ASEAN, China and Japan.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Medical Devices:

Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

IMDRF/GHTF:

Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

UNIT II **12 Hours**

Ethics:

Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011).

Quality: Quality System Regulations of Medical Devices:

ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device.

UNIT III **12 Hours**

USA:

Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

UNIT IV **12 Hours**

European Union:

Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

UNIT V **12 Hours**

ASEAN, China & Japan:

Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.

IMDRF study groups and guidance documents.

Suggested Readings^: (Latest edition)

1. Pisano, D. J., & Mantus, D. S. *FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics*. Taylor & Francis US.
2. Kahan, J. S. *Medical Device Development: A Regulatory Overvie.*
3. Tobin, J. J., & Walsh, G. *Medical product regulatory affairs: pharmaceuticals, diagnostics, medical devices*. John Wiley & Sons.
4. Medina, C. *Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics*. CRC Press.
5. Country Specific Guidelines from official websites.
6. http://www.pmda.go.jp/english
7. http://www.fda.gov .
8. http://www.ema.europa.eu
9. www.iso.org
10. www.eng.sfda.gov.cn
11. www.asean.org

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^ this is not an exhaustive list

(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA204T**
Course Title	**Regulatory Aspects of Food & Nutraceuticals**

Scope:
This course is designed to impart the fundamental knowledge on regulatory requirements, registration and labeling regulations of nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on regulatory aspects for nutraceuticals and food supplements.

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

1. Know the regulatory requirements for nutraceuticals.
2. Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Understand the terminologies for food and nutraceuticals.

2. Discuss the guidelines and GMPs for nutraceuticals.
3. Explain regulations for food safety and nutraceuticals in India.
4. Report regulations for food safety and nutraceuticals in US.
5. Apply the knowledge of food safety and nutraceuticals in EU.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Nutraceuticals:

Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

UNIT II **12 Hours**

Global Aspects:

WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

UNIT III **12 Hours**

India:

Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

UNIT IV **12 Hours**

USA:

US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S.

UNIT V **12 Hours**

European Union:

European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements.
Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

Suggested Readings^: (Latest edition)

1. Hasler, C. M. *Regulation of functional foods and nutraceuticals: a global perspective* (Vol. 5). John Wiley & Sons.
2. Bagchi, D. *Nutraceutical and functional food regulations in the United States and around the world*. Academic press.
3. http://www.who.int/publications/guidelines/nutrition/en/

4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf
5. Pathak, Y. V. *Handbook of Nutraceuticals Volume II: Scale-Up, Processing and Automation* (Vol. 2). CRC Press.
6. Fortin, N. D. *Food regulation: law, science, policy, and practice*. John Wiley & Sons.
7. Country Specific Guidelines from official websites
8. www.cdsco.nic.in
9. www.fda.gov
10. www.ema.europa.eu
11. www.who.int
12. www.nsf.org

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^ this is not an exhaustive list

(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
-	-	12	6

Course Code	**MRA205P**
Course Title	**Regulatory Affairs Practical II**

Syllabus: **Teaching hours: 180 Hours**

1. Case studies on change management/ change control deviations and Corrective & Preventive Actions (CAPA).
2. Documentation of raw materials analysis as per official monographs.
3. Preparation of audit checklist for various agencies.
4. Preparation of submission to FDA using eCTD software.
5. Preparation of submission to EMA using eCTD software.
6. Preparation of submission to MHRA using eCTD software.
7. Preparation of Biologics License Applications (BLA).
8. Preparation of documents required for Vaccine Product Approval.
9. Comparison of clinical trial application requirements of US, EU and India of Biologics
10. Preparation of Checklist for Registration of Blood and Blood Products.
11. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization.
12. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization.
13. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization.
14. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization.

15. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization.
16. Checklists for 510k and PMA for US market.
17. Checklist for CE marking for various classes of devices for EU.
18. STED Application for Class III Devices.
19. Audit Checklist for Medical Device Facility.
20. Clinical Investigation Plan for Medical Devices.

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^ this is not an exhaustive list

NIRMA UNIVERSITY
Institute of Pharmacy
Teaching & Examination Scheme *(M. Pharm - Pharmacology)*

Semester II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPL201T	Advanced Pharmacology-II	4	-	-	4	3.0	-	0.60	-	0.40
2	MPL202T	Pharmacological and Toxicological Screening Methods-II	4	-	-	4	3.0	-	0.60	-	0.40
3	MPL203T	Principles of Drug Discovery	4	-	-	4	3.0	-	0.60	-	0.40
4	MPL204T	Clinical research and Pharmacovigilance	4	-	-	4	3.0	-	0.60	-	0.40
5	MPL205P	Pharmacological Practical- II	-	12	-	6	-	6.0	-	1.00	-
6	MPL206S	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**		**26**					
			35								

L: *Lectures*, P/T: *Practicals/Tutorial*, C: *Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPL201T**
Course Title	**Advanced Pharmacology-II**

Scope:

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved.

Objectives:

Upon completion of the course the student shall be able to -

1. Discuss the pathophysiology and pharmacotherapy of certain diseases.
2. Explain the mechanism of drug actions at cellular and molecular level.
3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

Course Learning Outcomes (CLO):

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

1. Explain mechanisms of action, adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.
2. Relate pathogenesis of various diseases with their treatment.
3. Utilize the knowledge of chronopharmacology for treatment of various diseases.
4. Develop understanding of role of oxidative stress in various disease and their treatment.
5. Discuss pharmacological actions of different drugs useful for therapy of various diseases.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Endocrine Pharmacology:

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

UNIT II **18 Hours**

Chemotherapy:

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics, Antifungal, antiviral, and anti-TB drugs, Drugs used in protozoal infections, Drugs used in the treatment of helminthiasis, Chemotherapy of cancer.

UNIT III **06 Hours**

Immunopharmacology:

Cellular and biochemical mediators of inflammation and immune response, Allergic or hypersensitivity reactions, Pharmacotherapy of asthma and COPD, Immunosuppressants and Immunostimulants.

UNIT IV **12 Hours**

GIT Pharmacology:

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology:

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.

UNIT V **12 Hours**

Free radicals Pharmacology:

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus.

Suggested Readings^: (Latest Edition)

1. Goodman Gilman A., Rall T.W., Nies A.I.S. and Taylor, P. *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, New York: Mc Graw Hill, Pergamon Press.
2. Golan, D.E., Tashjian, A.H., Armstrong, E.J., Armstrong, A.W. *Principles of Pharmacology. The Pathophysiologic Basis of Drug Therapy.* Philadelphia: Lippincott Williams & Wilkins Publishers.
3. Katzung, B.G. *Basic and Clinical Pharmacology*, New York: McGraw Hill.
4. Gibaldi, M., Prescott, L. *Hand book of Clinical Pharmacokinetics*. ADIS Health Science Press
5. Herfindal, E.T., Gourley. *Text book of Therapeutics, Drug and Disease Management.* Williams and Wilkins Publication.
6. Shargel, L. Andrew B.C. Yu. *Applied biopharmaceutics and Pharmacokinetics*. New York: Mc Graw Hills Publishers.
7. Kwon, Younggil. *Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.* New York: Kluwer Academic/Plenum.
8. Kumar, V. Abbas, A.K., Aster, J.C. *Robbins & Cortan Pathologic Basis of Disease*. Elsevier Publishers.
9. Srivastava, S.K. *Complete Textbook of Medical Pharmacology*. APC Avichal Publishing Company

10. Tripathi, K.D. *Essentials of Medical Pharmacology*. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd.

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(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPL202T**
Course Title	**Pharmacological and Toxicological Screening Methods- II**

Scope:
This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

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

1. Explain the various types of toxicity studies.
2. Appreciate the importance of ethical and regulatory requirements for toxicity studies.
3. Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Define various types of toxicity studies and their mechanism of action.
2. Demonstrate toxicity of various drugs qualitatively and quantitatively.
3. Illustrate the skills and understanding required to conduct preclinical toxicity studies as per the regulatory and ethical requirements.
4. Interpret results of toxicokinetics of novel drugs.
5. Evaluate various drugs for their safety pharmacological and toxicological actions using animal models to extrapolate them with human beings.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive), Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development

UNIT II **12 Hours**

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies

UNIT III **12 Hours**

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies

UNIT IV **12 Hours**

IND enabling studies (IND studies) - Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

UNIT V **12 Hours**

Toxicokinetics - Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

Suggested Readings^: (Latest Edition)

1. World Health Organization. *Handbook: good laboratory practice (GLP): quality practices for regulated non-clinical research and development.* World Health Organization.
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Ng, R. *Drugs: from discovery to approval.* John Wiley & Sons, New Jersey.
4. Lower, G. M., & Bryan, G. T., *Animal Models in Toxicology*, 3rd Edition, OECD test guidelines.
5. Stine, K. E., & Brown, T. M. *Principles of toxicology.* CRC Press, United states.
6. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

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^ this is not an exhaustive list

(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPL203T**
Course Title	**Principles of Drug Discovery**

Scope:
The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

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

1. Explain various stages of drug discovery.
2. Appreciate importance of the role of genomics, proteomics and bioinformatics in drug discovery.
3. Explain various targets for drug discovery.
4. Explain various lead seeking method and lead optimization.
5. Appreciate the importance of the role of computer aided drug design in drug discovery.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Describe the flow and methods of drug discovery and development process and their challenges.
2. Demonstrate role of genomics, proteomics and bioinformatics in drug discovery.
3. Explain rational drug design based on the understanding of three-dimensional (3D) structures and physicochemical properties of drugs and target.
4. Apply various CADD in-silico techniques like pharmacophore modeling, QSAR, molecular docking, homology modeling etc. for the lead identification and optimization.
5. Make use of rationale and practical considerations for prodrug designing.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

An overview of modern drug discovery process:
Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

UNIT II **12 Hours**

Lead Identification:

Combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT III **12 Hours**

Rational Drug Design:

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

UNIT IV **12 Hours**

Molecular docking:

Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

UNIT V **12 Hours**

QSAR Statistical methods:

Regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

Prodrug design:

Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

Suggested Readings^: (Latest Edition)

1. Sioud, M. *Target Discovery and Validation Reviews and Protocols: Emerging Molecular Targets and Treatment Options*, Volume 2. Totowa: Humana Press Inc., New Jersey.
2. León, D., & Markel, S. (Eds.). *In Silico Technologies in Drug Target Identification and Validation*. CRC Press, United States
3. DiStefano, J. K., *Disease Gene Identification. Methods and Protocols*. Springer New York Dordrecht Heidelberg, London.
4. Mannhold, R., Krogsgaard-Larsen, P., & Timmerman, H. *QSAR: Hansch analysis and related approaches* (Vol. 1). John Wiley & Sons, New Jersey.
5. Bures, M. G. *Structure-based Ligand Design* Edited by K. Gubernator and H.-J. Bohm. Wiley-VCH, Weinheim.
6. Parrill, A. L., & Reddy, M. R. (Eds.). *Rational drug design: novel methodology and practical applications*. American Chemical Society, United States
7. Turner R. J. *New drug development design, methodology and, analysis*. John Wiley & Sons, Inc., New Jersey.

8. Stroud, R. M. & Moore, J. M. *Computational and Structural Approaches to Drug Discovery: Ligand-Protein Interactions.* RCS Publishers.
9. Smith, H. J. & Williams, H. *Introduction to the principles of drug design and action.* CRC Press, Taylor & Francis.
10. Patrick, G. L. *An introduction to medicinal chemistry.* Oxford University Press.

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(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPL204T**
Course Title	**Clinical Research and Pharmacovigilance**

Scope:
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:
After completion of course student is able to know about –
1. Explain the regulatory requirements for conducting clinical trial.
2. Demonstrate the types of clinical trial designs.
3. Explain the responsibilities of key players involved in clinical trials.
4. Execute safety monitoring, reporting and close-out activities.
5. Explain the principles of Pharmacovigilance.
6. Detect new adverse drug reactions and their assessment.
7. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -
1. Understand regulatory perspectives of clinical trials and research.
2. Explain pharmacoepidemiology, pharmacoeconomics, safety pharmacology.
3. Summarize basic aspects, terminologies and establishment of Pharmacovigilance.
4. Discuss methods, ADR reporting and tools used in Pharmacovigilance.
5. Develop clinical trial documentation including ADR reporting.

6. Elaborate about clinical trials.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **10 Hours**

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process.

UNIT II **12 Hours**

Clinical Trials:

Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT III **12 Hours**

Clinical Trial Documentation:

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT.

Adverse Drug Reactions:

Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

UNIT IV **10 Hours**

Basic aspects, terminologies and establishment of Pharmacovigilance:

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centers in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT V **10 Hours**

Methods, ADR reporting and tools used in Pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

UNIT VI **06 Hours**

Health Economics and Outcomes Research:

Pharmacoepidemiology, pharmacoeconomics, safety pharmacology.

Suggested Readings^: (Latest Edition)

1. Central Drugs Standard Control Organization- *Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India*. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; June 2016.
3. *Ethical Guidelines for Biomedical Research on Human Subjects 2000*. Indian Council of Medical Research, New Delhi.
4. Machin, D., Simon D., and Sylvan G., eds. *Textbook of Clinical Trials*. USA. John Wiley & Sons.
5. Rondel, R. K., Varley, S. A., & Webb, C. F. (Eds.). *Clinical Data Management*. New York: Wiley.
6. Lloyd, J., & Raven, A. (Eds.). *Handbook of Clinical Research*. Churchill Livingstone.
7. Di Giovanna, I., & Hayes, G. *Principles of Clinical Research*. UK, Routledge
8. Verma, S., Gulati, Y. *Fundamentals of Pharmacovigilance*. New Delhi, Paras Medical Publishers.
9. Arora, D. *Pharmacovigilance: An Industry Perspective*. Mumbai, Pharma Publishers.

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(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
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Course Code	**MPL205P**
Course Title	**Pharmacological Practical-II**

Syllabus: **Teaching hours: 180 Hours**

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations.
9. Recording of rat BP and heart rate.

10. Recording of rat ECG.
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial. (3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting.

Suggested Readings^: (Latest Edition)

1. Ghosh, M. N. *Fundamentals of Experimental Pharmacology*. Kolkatta: Hilton & Company
2. Kulkarni, S. K. *Hand book of Experimental Pharmacology*. Delhi: Vallabh Prakashan
3. Kitchen, Von Ian. *Textbook of in Vitro Practical Pharmacology*. Oxford: Blackwell Scientific Publications.
4. Rahman, A., Choudhary, I. M. *Bioassay techniques for drug development*. - William J. Thomsen - Harwood Acad. Publ.
5. Shargel, L. Andrew B.C. Yu. *Applied Biopharmaceutics and Pharmacokinetics*. New York: Mc Graw Hills Publishers.
6. Kwon, Younggil. *Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists*. New York: Kluwer Academic/Plenum, Print.
7. https://www.who-umc.org/

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