NIRMA UNIVERSITY

Institute of Pharmacy

(M.Pharm. - Pharmacology)

(Semester - I)

L	T	P	C
4	-	-	4

Course Code	**MPL101T**
Course Title	**Modern Pharmaceutical Analytical Techniques**

Course Learning Outcomes (CLO):

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

1. About chemicals and excipients
2. Analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

Syllabus: **Teaching hours: 60 Hours**

1. UV-Visible spectroscopy **10 Hours**

Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/Derivative spectroscopy.

IR spectroscopy

Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factor affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

Spectroflourimetry

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

Flame emission spectroscopy and Atomic absorption spectroscopy

Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy 10 Hours

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. Mass Spectroscopy 10 Hours

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4. Chromatography 10 Hours

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drugs from excipients, data interpretation and applications of the following:

- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

5. Electrophoresis 10 Hours

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

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Iso electric focusing

X ray Crystallography:

Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

6. Potentiometry 10 Hours

Principle, working, Ion selective Electrodes and Application of potentiometry.

Thermal Techniques:

Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications

Suggested Readings^: (Latest Edition)

1. Silverstein, R. M., Webster, F. X., Kiemle, D. J., Bryce, D. L. Spectrometric Identification of Organic Compounds. USA: John Wiley & 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. Beckett, A. H., Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry (Vol. 1 & 2). A&C Black.
5. Kemp, W. Organic Spectroscopy. ELBS.
6. Sethi, P.D. Quantitative Analysis of Drugs in Pharmaceutical formulation. New Delhi: CBS Publishers.
7. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.
8. Kalsi, P. S. Spectroscopy of Organic Compounds. Wiley Estern Ltd.
9. Connors, K. A. A Textbook of Pharmaceutical Analysis. USA: John Wiley and Sons.

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

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

L	T	P	C
4	-	-	4

Course Code	MPL102T
Course Title	Advanced Pharmacology-I

Course Learning Outcomes (CLO):

At the end of the course, students will 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

Syllabus: **Teaching hours: 60 Hours**

1. General Pharmacology **12 Hours**

- Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.
- Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

2. Neurotransmission **12 Hours**

- General aspects and steps involved in neurotransmission.
- Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
- Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
- Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems.

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

3. Central nervous system Pharmacology **12 Hours**

- General and local anesthetics
- Sedatives and hypnotics, drugs used to treat anxiety.
- Depression, psychosis, mania, epilepsy, neurodegenerative diseases
- Narcotic and non-narcotic analgesics

4. Cardiovascular Pharmacology **12 Hours**

Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia

Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs

5. Autocoid Pharmacology **12 Hours**

The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins, Opioid autocoids

Pharmacology of antihistamines, 5HT antagonists

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. Shargel, L. Andrew B.C. Yu. Applied biopharmaceutics and Pharmacokinetics. New York: Mc Graw Hills Publishers.
6. Smith D.G., Aronson, J. Oxford textbook of Clinical Pharmacology. London, UK: Oxford University Press.
7. Speight, T.M. Holford, N.H.G. Avery's Drug Treatment. Wiley India.
8. Dipiro, J.T., Talbert, R.L., Yee, G.C., Matzke, G.R. Wells, B.G., Posey, M.L. Pharmacotherapy: A Pathophysiologic approach. New York: Mc Graw Hills Publishers.
9. Kumar, V. Abbas, A.K., Aster, J.C. Robbins & Cortan Pathologic Basis of Disease. Elseveir Publishers.
10. Srivastava, S.K. Complete Textbook of Medical Pharmacology. APC Avichal Publishing Company
11. Tripathi, K.D. Essentials of Medical Pharmacology. New Delhi: Jaypee Publishers.
12. Charles C.R., Stitzel, R.E. Modern Pharmacology with Clinical Applications. Philadelphia: Lippincott Williams & Wilkins Publishers.
13. Rowland, M., Tozer, T.N. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications. Philadelphia: Lippincott Williams & Wilkins Publishers.
14. Kwon, Y. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists. New York : Springer Science.
15. Herfindal, E.T., Gourley. Text book of Therapeutics, Drug and Disease Management. Williams and Wilkins Publication.

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(M.Pharm. - Pharmacology)

(Semester - I)

L	T	P	C
4	-	-	4

Course Code	**MPL103T**
Course Title	**Pharmacological and Toxicological Screening Methods- I**

Course Learning Outcomes (CLO):

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

1. Appraise the regulations and ethical requirement for the usage of experimental animals.
2. Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
3. Describe the various newer screening methods involved in the drug discovery process
4. Appreciate and correlate the preclinical data to humans

Syllabus: **Teaching hours: 60 Hours**

1. **Laboratory Animals** **12 Hours**

   Common laboratory animals: Description, handling and applications of different species and strains of animals

   Transgenic animals: Production, maintenance and applications

   Anaesthesia and euthanasia of experimental animals.

   Maintenance and breeding of laboratory animals

   CPCSEA guidelines to conduct experiments on animals

   Good laboratory practice

   Bioassay-Principle, scope and limitations and methods

2. **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.** **12 Hours**

   General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3. **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models. 12 Hours**

   Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.

4. **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models. 12 Hours**

   Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic, and anti-cancer agents, Hepatoprotective screening methods.

5. **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models. 12 Hours**

   Immunomodulators, Immunosuppressants and Immunostimulants.

   General principles of immunoassay:

   Theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

   Limitations of animal experimentation and alternate animal experiments.

   Extrapolation of *in vitro* data to preclinical and preclinical to humans

Suggested Readings^: (Latest Edition)

1. Burn, J.H., Finney D.J., Goodwin. I.G. Biological standardization. London: Oxford University Press.
2. Turner, R. A., Hebborn, P. Screening Methods in Pharmacology. New York: Academic Press
3. Laurence, D. R., Bacharach, A. L. Evaluation of Drug Activities: Pharmacometrics. London: Academic Press.
4. Schwartz A. Methods in Pharmacology. Plenum New York.
5. Ghosh, M.N. Fundamentals of Experimental Pharmacology. Kolkata: Hilton & Company.
6. McLeod, L. J. Pharmacological Experiment on Intact Preparations. London: Churchill Livingstone.
7. Vogel, H.G. Drug Discovery and Evaluation: Pharmacological Assays. Berlin Heidelberg, Germany: Springer-Verlag.
8. Goyal, R.K. Experimental Pharmacology. Ahmedabad: B. S. Shah Prakashan.
9. Gupta S. K. Preclinical evaluation of new drugs. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd.
10. Kulkarni, S.K. Handbook of Experimental Pharmacology. Delhi: Vallabh Prakashan.
11. Kulkarni, S.K. Practical Pharmacology and Clinical Pharmacy. Delhi: Vallabh Prakashan.
12. Gross, D.R. Animal Models in Cardiovascular Research. London, UK: Kluwer Academic Publishers.
13. Chatterjee, T. K. Rodents for Pharmacological Experiments. Hyderabad: PharmaMed Press.
14. Medhi, B., Prakash, A. Practical Manual of Experimental and Clinical Pharmacology. New Delhi: Jaypee Brothers Medical Publishers Pvt. Ltd.

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(M.Pharm. - Pharmacology)

(Semester - I)

L	T	P	C
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Course Code	**MPL104T**
Course Title	**Cellular and Molecular Pharmacology**

Course Learning Outcomes (CLO):

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

1. Explain the receptor signal transduction processes.
2. Explain the molecular pathways affected by drugs.
3. Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
4. Demonstrate molecular biology techniques as applicable for pharmacology

Syllabus: **Teaching hours: 60 Hours**

1. Cell biology **12 Hours**

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy

2. Cell signaling **12 Hours**

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5- trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway

3. Principles and applications of genomic and proteomic tools **12 Hours**

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,

Recombinant DNA technology and gene therapy

Basic principles of recombinant DNA technology - Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy - Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

4. Pharmacogenomics **12 Hours**

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology

Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

5. Cell culture techniques **12 Hours**

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 application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays

Principles and applications of flow cytometry

Biosimilars

Suggested Readings^: (Latest Edition)

1. Cooper, G. M. Hausman, R.E. The Cell: A Molecular Approach. Sinauer Associates
2. Licinio, J. Wong, Ma-Li. Pharmacogenomics. USA: John Wiley & Sons.
3. Bradshaw, R.A. Handbook of Cell Signaling. Amsterdam: Elsevier.
4. Dickenson, J. Molecular Pharmacology. Chichester: Wiley-Blackwell.
5. Helgason, C.D. Miller C.L. Basic Cell Culture Protocols. USA: Springer Science+Business Media, LLC: Humana.
6. Davis, J. M. Basic Cell Culture. London, UK: Oxford University Press.
7. Masters, J. R. W. Animal Cell Culture. London, UK: Oxford University Press.
8. Ausuvel, F.M., Brent, R., Kingston, R. E. Moore, D. D., Seidman, J.D., Smith, J., Struhl, K. Current Protocols in Molecular Biology. USA: John Wiley & Sons.

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(M.Pharm: Pharmacology)

(Semester - I)

L	T	P	C
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Course Code	**MPL105P**
Course Title	**Pharmacological Practical I**

Syllabus: **Teaching hours: 180 Hours**

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity

22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

Suggested Readings^: (Latest Edition)

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines.
2. Ghosh, M. N. Fundamentals of Experimental Pharmacology. Kolkatta: Hilton & Company.
3. Kulkarni, S. K. Hand book of Experimental Pharmacology. Delhi: Vallabh Prakashan.
4. Vogel, H. G.. Drug Discovery and Evaluation: Pharmacological Assays. Berlin: Springer.
5. Silverstein, R. M., Webster, F. X., Kiemle, D. J., Bryce, D. L. Spectrometric Identification of Organic Compounds. USA: John Wiley & Sons.
6. Skoog, D., Holler, F., Nieman, T. Principles of Instrumental Analysis. Philadelphia, NY: Hartcourt Brace.
7. Mendham, J, Denney, R, Barnes, J, Thomas, M. Vogel's Textbook of Quantitative Chemical Analysis. Harlow (England): Prentice Hall, an imprint of Pearson Education.
8. Helgason, C. D., Miller, C. L. Basic Cell Culture Protocols. New York: Humana Press.
9. Davis, J. M. Basic Cell Culture: A Practical Approach. London, UK: Oxford University Press.
10. Masters, J. R. Animal Cell Culture: A Practical Approach. London, UK:: Oxford University Press.
11. Medhi, B., Prakash, A. Practical Manual of Experimental and Clinical Pharmacology. New Delhi: Jaypee Brothers Medical Pvt. Ltd.

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