NIRMA UNIVERSITY

NAAC ACCREDITED 'A' GRADE

NU/AC/170417/IP/MP/TES_Sylb/Sem-I/17- 78
Date: 20 .05.2017

NOTIFICATION

Read:
1. **Regulation No. 44 of Academic Regulations for Admission to University, etc. published vide notification No. NU-442 dated 27.1.2004 – Empowering Academic Council to approve teaching & examination scheme, syllabus, etc.**
2. **Notifications mentioned in Handbook-IV, updated up to April, 2015**
3. **Resolution No. 1 – Faculty of Pharmacy Meeting – 05.04.2017**
4. **Resolution No. 5 – Academic Council Meeting – 17.04.2017**

Sub: **Introduction of Teaching & Examination Scheme and Syllabus of Semester-I of all specializations of M.Pharm programme**

It is, hereby, notified for information of all concerned that, the Academic Council in its meeting held on 17.04.2017 under resolution No. 5; in exercise of powers conferred upon it by the Board of Governors under regulation mentioned at serial 1 above, taking into consideration the recommendation of Faculty of Pharmacy, has resolved to approve the *introduction* of Teaching & Examination Scheme and Syllabus of **Semester-I** of following specializations of **Master of Pharmacy (M.Pharm.)** programme (as prescribed by PCI), to be made effective from academic year 2017-18 and onwards as per ***Appendix-A*** attached herewith:

(a) Pharmaceutics
(b) Pharmaceutical Chemistry
(c) Pharmaceutical Analysis
(d) Regulatory Affairs
(e) Pharmacology

Executive Registrar

Encl.: Appendix – A [Pages 1 to 56]

To,
1. Dean, Faculty of Pharmacy
2. All Heads, Academic Area Committee
3. Dy. Registrar (Examination)

Copy to: OS – IP/IS, Librarian-IP, P.A. to ER

c.f.w.cs. for information to:
1. Vice President
2. Director General
3. Director (A&GA)

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of *(M. Pharm. - Pharmaceutics)*

Semester I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MPH101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
2	MPH102T	Drug Delivery Systems	4	-	-	4	3.0	-	0.60	-	0.40
3	MPH103T	Modern Pharmaceutics	4	-	-	4	3.0	-	0.60	-	0.40
4	MPH104T	Regulatory Affairs	4	-	-	4	3.0	-	0.60	-	0.40
5	MPH105P	Pharmaceutics Practical I	-	12	-	6	-	6.0	-	1.00	-
6	-	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*

1

Appendix-A
(Noti. No. NU-
AC Rtg.-17417)

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm. : Pharmaceutics)
(Semester - I)

L	T	P	C
4	-	-	4

Course Code	**MPH101T**
Course Title	**Modern Pharmaceutical Analytical Techniques**

Scope:
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives:
After completion of course student is able to know,

1. Chemicals and Excipients.
2. The analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments

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

1. Recall the fundamental concepts of different spectroscopic techniques.
2. Understand the basics of immunological assays.
3. Recognize the fundamentals, instrumentation and applications of various chromatographic methods
4. Discuss the instrumentation and application of various spectroscopic techniques
5. Describe various electrophoretic techniques

Syllabus: **Teaching hours: 60 Hours**

UNIT I **11 Hours**

- **UV-Visible spectroscopy:**
  Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
  IR spectroscopy:
  Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.
  Spectroflourimetry:
  Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
  Flame emission spectroscopy and Atomic absorption spectroscopy:
  Principle, Instrumentation, Interferences and Applications.

UNIT II **11 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 and 13C NMR. Applications of NMR spectroscopy.

UNIT III **11 Hours**

- **Mass Spectroscopy:**

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

UNIT IV **11 Hours**

- **Chromatography:**

  Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

  - Paper Chromatoraphy
  - Thin Layer chromatography
  - Ion exchange chromatography
  - Column chromatography
  - Gas chromatography
  - High Performance Liquid chromatography
  - Affinity chromatography

UNIT V **16 Hours**

- **Electrophoresis:**

  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 diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

- **Immunological assays:**

  RIA (Radio immune assay), ELISA, Bioluminescence assays.

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. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part II Fourth Edition (Vol. 2). A&C Black.

5. Kemp, W. Organic Spectroscopy. ELBS.
6. Shethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. CBS Publishers.
7. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.

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

^ this is not an exhaustive list

(M. Pharm. : Pharmaceutics)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPH 102T**
Course Title	**Drug Delivery Systems**

Scope:

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

Objectives:

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

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of delivering systems
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 and approaches of sustained/controlled and novel drug delivery systems.
2. Demonstrate techniques for formulation development of novel drug delivery
3. Discuss various approaches for site specific drug delivery systems.
4. Describe types of drug targeting and its applications.
5. Evaluate novel oral, topical and parenteral drug delivery systems.

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **10 Hours**

- **Sustained Release (SR) and Controlled Release (CR) formulation:**
  Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

UNIT – II **10 Hours**

- **Rate Controlled Drug Delivery Systems:**

Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems: Mechanically activated, PH activated , Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

UNIT – III **10 Hours**

- **Gastro-Retentive Drug Delivery Systems:**
  Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

UNIT – IV **16 Hours**

- **Occular Drug Delivery Systems:**
  Barriers of drug permeation, Methods to overcome barriers.
- **Trans Dermal Drug Delivery Systems:**
  Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation

UNIT – V **14 Hours**

- **Protein and Peptide Delivery:**
  Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.
- **Vaccine delivery systems:**
  Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Suggested Readings^: (Latest Edition)

1. Chien, Y W. Novel Drug Delivery Systems, New York: Marcel Dekker, Inc.
2. Robinson, J. R., Lee V. H. L. Controlled Drug Delivery Systems, New York: Marcel Dekker, Inc.
3. Edith Mathiowitz, Encyclopedia of controlled delivery, New York: Wiley Interscience Publication, John Wiley and Sons, Inc.
4. Jain, N.K. Controlled and Novel Drug Delivery, New Delhi: CBS Publishers & Distributors.
5. Vyas, S. P. and Khar, R. K. Controlled Drug Delivery - concepts and advances, New Delhi: Vallabh Prakashan.

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

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

^ this is not an exhaustive list

(M. Pharm. : Pharmaceutics)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPH 103T**
Course Title	**Modern Pharmaceutics**

Scope:

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives:

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

1. The elements of preformulation studies.
2. The Active Pharmaceutical Ingredients and Generic drug Product development
3. Industrial Management and GMP Considerations.
4. Optimization Techniques & Pilot Plant Scale Up Techniques
5. Stability Testing, sterilization process & packaging of dosage forms.

Course Learning Outcomes (CLO):

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

1. Identify key preformulation parameters for various dosage forms
2. Recognize the importance of optimization techniques and its selection
3. Explain types, protocol and process of validation
4. Correlate GMP with pharmaceutical production including pilot scale up
5. Estimate diffusion and dissolution parameters for drug release
6. Prepare stability, sterilization and packaging protocol of various dosage forms

Syllabus: **Teaching hours: 60 Hours**

UNIT I **10 Hours**

- **Preformation Concepts:** Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability, Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

UNIT II **10 Hours**

- **Optimization techniques in Pharmaceutical Formulation**: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

UNIT III **10 Hours**

- **Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & PQ of facilities

UNIT IV **10 Hours**

- **cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

UNIT V **20 Hours**

- **Compression and compaction**: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.
- **Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors – f2 and f1, Higuchi and peppas plot, Linearity Concept of significance, Standard deviation , chi square test , student T-test , Anova test.

Suggested Readings^: (Latest Edition)

1. Leon Lachmann, & Herbert, A.L. The Theory and Practice of Industrial Pharmacy. New Delhi: CBS Publishers & Distributors Pvt. Ltd.
2. Lieberman, H.A., Leon, Lachmann, Schwartz, J. B. Pharmaceutical dosage forms: Tablets Vol. 1-3, New York: Marcel Dekker
3. Lieberman, H.A., Leon, Lachmann, Schwartz, J. B. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2, New York: Marcel Dekker
4. Lieberman, H.A., Leon, Lachmann, Schwartz, J. B. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2, New York: Marcel Dekker
5. Gilbert, S.B. and Rhodes, C.T. Modern Pharmaceutics, New York: Marcel Dekker
6. Remington, J. P., & Gennaro, A. R. Remington: The Science and Practice of Pharmacy. Lippincott Williams.
7. Bean, H.S. and Beckett, A.H. Advances in Pharmaceutical Sciences, London: Academic Press
8. Sinko, Martyns Physical Pharmacy and Pharmaceutical Sciences, Lippincott Williams and Walkins.
9. Bentley, A.O., & Rawlins, E.A. Bentley's Text Book of Pharmaceutics. USA: Elsevier Health Sciences.
10. Sidney, H. W. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, New York: Marcel Dekker.
11. Organization of Pharmaceutical producers of India. Quality Assurance Guide.
12. Kohli, D.P.S. and Shah, D.H. Drug formulation manual, New Delhi: Eastern publishers
13. Sharma, P.P. How to practice GMPs, Agra: Vandhana Publications.
14. Berry, F.R. and Nash, R.A. Pharmaceutical Process Validation, Marcel Dekker
15. Wells, J. J. Pharmaceutical Preformulations, Ellis Horwood Limited
16. Evans J.R., Anderson Sweeney and Williams. Applied production and operations management, south-Western.
17. Swarbrick, J. Encyclopaedia of Pharmaceutical technology, Vol I – III, CRC press.

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

^ this is not an exhaustive list

(M. Pharm. : Pharmaceutics)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPH 104T**
Course Title	**Regulatory Affairs**

Scope:

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

1. The Concepts of innovator and generic drugs, drug development process
2. The Regulatory guidance's and guidelines for filing and approval process
3. Preparation of Dossiers and their submission to regulatory agencies in different countries
4. Post approval regulatory requirements for actives and drug products
5. Submission of global documents in CTD/ eCTD formats
6. Clinical trials requirements for approvals for conducting clinical trials
7. Pharmacovigilence and process of monitoring in clinical trials.

Course Learning Outcomes (CLO):

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

1. Understand the drug approval processes for various regulatory agencies
2. Explain various types of documentation in pharmaceutical Industries
3. Understand preparation of Dossiers and their submission including post approval requirements for different countries
4. Describe global submission of IND, NDA and ANDA.
5. Review the requirements for approvals for conducting clinical trials
6. Interpret various regulations for clinical trials and pharmacovigilance

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

- **Documentation in pharmaceutical industry**: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments , CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

UNIT II **12 Hours**

- **Regulatory requirement for product approval**: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

UNIT III **12 Hours**

- **Regulatory requirements of various countries:** CMC, post approval regulatory affairs. Regulation for combination products and medical devices CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q,S E,M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

UNIT IV **12 Hours**

- **Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

UNIT V **12 Hours**

- **Clinical trials: Developing** clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

Suggested Readings^: (Latest Edition)

1. Leon Shargel and IsaderKaufer, Generic Drug Product Development, Solid Oral Dosage forms, Marcel Dekker series.
2. Berry, I. R. and Robert, P. M. The Pharmaceutical Regulatory Process, Drugs and the Pharmaceutical Sciences, Informa Health care Publishers.
3. Richard, A. G., New Drug Approval Process: Accelerating Global Registrations, Drugs and the Pharmaceutical Sciences, Informa Healthcare
4. Sandy Weinberg. Guidebook for drug regulatory submissions, Wiley & Sons.Inc.
5. Douglas J. P., David Mantus. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics Informa Healthcare
6. Fay A. R. and Rodney K. A. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance, John Wiley & Sons.
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

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

^ this is not an exhaustive list

(M. Pharm. : Pharmaceutics)
(Semester – I)

L	T	P	C
-	-	12	6

Course Code	**MPH 105P**
Course Title	**Pharmaceutics Practical I**

PRACTICALS **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
7. To perform *In-vitro* dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Mucoadhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

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

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

Semester I

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	MPC101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
2	MPC102T	Advanced Organic Chemistry -I	4	-	-	4	3.0	-	0.60	-	0.40
3	MPC103T	Advanced Medicinal Chemistry	4	-	-	4	3.0	-	0.60	-	0.40
4	MPC104T	Chemistry of Natural Products	4	-	-	4	3.0	-	0.60	-	0.40
5	MPC105P	Pharmaceutical Chemistry Practical - I	-	12	-	6	-	6.0	-	1.00	-
6	-	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**		**26**					
			35								

11

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

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

NIRMA UNIVERSITY
Institute of Pharmacy

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

L	T	P	C
4	-	-	4

Course Code	**MPC101T**
Course Title	**Modern Pharmaceutical Analytical Techniques**

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Objective:

After completion of course, student is able to know about -

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

Course Learning Outcomes (CLO):

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

1. Recall the fundamental theory of different spectroscopic techniques.
2. Recognize the fundamentals, instrumentation and applications of various chromatographic methods.
3. Discuss the instrumentation and application of various spectroscopic techniques.
4. Describe various electrophoresis and X-ray methods.
5. Apply the knowledge of various thermal and electro analytical methods in analysis of drugs and excipients.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **10 Hours**

UV-Visible spectroscopy:

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

IR spectroscopy:

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

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.

UNIT II **10 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 and 13C NMR. Applications of NMR spectroscopy.

UNIT III **10 Hours**

Mass spectroscopy:

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

UNIT IV **10 Hours**

Chromatography:

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug 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

UNIT V **10 Hours**

Electrophoresis:

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.

UNIT VI **10 Hours**

Potentiometry:

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. 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. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry (Vol. 1 & 2). A&C Black.
5. Kemp, W. Organic Spectroscopy. ELBS.
6. Shethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. 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. NJ: Johnwiley and sons.

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

^ this is not an exhaustive list

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

L	T	P	C
4	-	-	4

Course Code	**MPC102T**
Course Title	**Advanced Organic Chemistry - I**

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:

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

1. The principles and applications of reterosynthesis.
2. The mechanism & applications of various named reactions.
3. The concept of disconnection to develop synthetic routes for small target molecule.
4. The various catalysts used in organic reactions.
5. The chemistry of heterocyclic compounds.

Course Learning Outcomes (CLO):

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

1. Understand the basic aspects of organic chemistry.
2. Explain reaction and reaction mechanism of different name reactions.
3. Apply knowledge of different synthetic reagents and protecting groups for the synthesis of small molecules.
4. Draw different heterocyclic ring, chemical reactions and synthesis of various five and six membered heterocyclic compounds.
5. Develop synthetic routes for small target molecule using retrosynthetic approach.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Basic aspects of organic chemistry:

- Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
- Types of reaction mechanisms and methods of determining them,
- Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Addition reactions:

- Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
- Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
- Rearrangement reaction

UNIT II **12 Hours**

Study of mechanism and synthetic applications of following named reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

UNIT III **12 Hours**

Synthetic reagents & applications:

Aluminium isopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate,

Triphenylphosphine, Benzotriazol-1-yloxy) tris(dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups:

- Role of protection in organic synthesis
- Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
- Protection for the Carbonyl Group: Acetals and Ketals
- Protection for the Carboxyl Group: amides and hydrazides, esters
- Protection for the Amino Group and Amino acids: carbamates and amides

UNIT IV **12 Hours**

Heterocyclic chemistry:

- Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.
- Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine

UNIT V **12 Hours**

Synthon approach and retrosynthesis applications:

- Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA)
- C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
- Strategies for synthesis of three, four, five and six-membered ring.

Suggested Readings^: (Latest edition)

1. March, J. Advanced organic chemistry: reactions, mechanisms, and structure. John Wiley & Sons.
2. Gould, E. S. Mechanism and structure in organic chemistry. London: Holt, Rinehart and Winston.
3. Clayden, J., Greeves, N., & Warren, S. Organic chemistry. Oxford: Oxford University Press.
4. Finar, I. Organic chemistry (Vol 1 and 2), Delhi: Pearson education.,
5. Sykes, P. A guidebook to mechanism in organic chemistry. Harlow, Essex: Longman Scientific & Technical.
6. Tandom and Gowel, Reactive Intermediates in Organic Chemistry, Oxford & IBH Publishers.
7. Wilson, S. & Czarnik, A. Combinatorial chemistry:Synthesis and applications. Blackwell: Wiley.
8. Carey, F. & Giuliano, R. Organic chemistry. New York: McGraw-Hill Education.
9. Warren, S. Organic Synthesis - The Disconnection Approach, Wiley India.
10. Norman, R. O., & Coxon, J. M. Principles of organic synthesis. CRC Press.
11. Ahluwalia, V. K., & Aggarwal, R. Organic synthesis: special techniques. CRC Press.

12. Ahluwalia, V. & Parashar, R. Organic reaction mechanisms. Oxford, U.K.: Alpha Science International.

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

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

L	T	P	C
4	-	-	4

Course Code	**MPC103T**
Course Title	**Advanced Medicinal Chemistry**

Scope:
The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

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

1. Different stages of drug discovery.
2. Role of medicinal chemistry in drug research.
3. Different techniques for drug discovery.
4. Various strategies to design and develop new drug like molecules for biological targets.
5. Peptidomimetics.

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

1. Describe different stages and techniques of drug discovery.
2. Understand biological drug targets, prodrug design and analog design.
3. Discuss medicinal chemistry aspects of anti-hypertensive, antineoplastic, antiviral agents, and drugs acting on ANS and CNS.
4. Demonstrates rational drug design methods for the design of enzyme inhibitors.
5. Correlate stereochemistry of chemical compounds and their mechanism of action.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Drug discovery:
Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.

Biological drug targets:

Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

UNIT II **12 Hours**

Prodrug design and analog design:

- **Prodrug design:**
  Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, 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.
- **Combating drug resistance:**
  Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
- **Analog design:**
  Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

UNIT III **12 Hours**

Medicinal chemistry aspects of the following class of drugs:

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

Stereochemistry and drug action:

Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

UNIT IV **12 Hours**

Rational design of enzyme inhibitors:

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

UNIT V **12 Hours**

Peptidomimetics:

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

Suggested Readings^: (Latest edition)

1. Burger, A. Burger's Medicinal chemistry (Vol. 1-6). John Wiley & Sons.
2. Wilson, C., Beale, J., & Block, J. Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry. Baltimore, MD: Lippincott Williams & Wilkins.
3. Hansch, C., Sammes, P., & Taylor, J. Comprehensive medicinal chemistry. Oxford: Pergamon Press.

4. Stroud, R. M., & Finer-Moore, J. Computational and structural approaches to drug discovery: ligand-protein interactions. Royal Society of Chemistry.
5. Martin, Y. C. Quantitative Drug Design: A Critical Introduction. CRC Press.
6. Williams, D. A., Foye, W. O., & Lemke, T. L. (Eds.). Foye's Principles of Medicinal Chemistry. Lippincott Williams & Wilkins.
7. Ariëns, E. J. (Ed.). Drug Design: Medicinal Chemistry: A Series of Monographs. Elsevier.
8. Smith, H. J., & Williams, H. Smith and Williams' introduction to the principles of drug design and action. CRC Press.
9. Silverman, R. B., & Holladay, M. W. The organic chemistry of drug design and drug action. Academic press.
10. Patrick, G. L. An introduction to medicinal chemistry. Oxford university press.
11. Brahmankar, D. M., & Jaiswal, S. B. Biopharmaceutics and pharmacokinetics: A treatise. Vallabh prakashan.
12. Guarna, A., & Trabocchi, A. Peptidomimetics in Organic and Medicinal Chemistry. John Wiley & Sons.

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

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

L	T	P	C
4	-	-	4

Course Code	**MPC104T**
Course Title	**Chemistry of Natural Products**

Scope:

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives:

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

1. Different types of natural compounds and their chemistry and medicinal importance.
2. Importance of natural compounds as lead molecules for new drug discovery.
3. Concept of rDNA technology tool for new drug discovery.
4. General methods of structural elucidation of compounds of natural origin.

5. Isolation, purification and characterization of simple chemical constituents from natural source.

Course Learning Outcomes (CLO):

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

1. Remember general methods for structure elucidation of simple chemical constituents from natural sources.
2. Understand the chemistry, isolation, purification and characterization techniques of simple chemical constituents from natural sources.
3. Describe different types of natural compounds and their medicinal importance.
4. Discuss importance of natural compounds as leads for new drug discovery.
5. Explain fundamentals of rDNA technology tool for new drug discovery.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Study of natural products as leads for new pharmaceuticals for the following class of drugs:

- Drugs Affecting the Central Nervous System: Morphine Alkaloids
- Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
- Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
- Neuromuscular Blocking Drugs: Curare alkaloids
- Anti-malarial drugs and Analogues
- Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

UNIT II **12 Hours**

Alkaloids:

General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

Flavonoids:

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

Steroids:

General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

UNIT III **12 Hours**

Terpenoids:

Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).

Vitamins:

Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

UNIT IV **12 Hours**

Recombinant DNA technology and drug discovery:

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

Active constituent of certain crude drugs used in indigenous system diabetic therapy:

Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graecum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

UNIT V **12 Hours**

Structural characterization of natural compounds:

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

Suggested Readings^: (Latest edition)

1. Paech, K., & Tracey, M. V. Modern Methods of Plant Analysis. Springer Science & Business Media.
2. Miller, L. P. Phytochemistry (Vol. 1 & 2). Van Nostrand Reinhold.
3. Runeckles, S. Recent advances in Phytochemistry (Vol. 1 to 4), Springer Science & Business Media
4. Chemistry of natural products Vol I onwards IWPAC
5. Nakanishi, K., Goto, T., & Itô, S. (Eds.). Natural products chemistry. Academic press.
6. Ikan, R. Natural products: a laboratory guide. Elsevier.
7. Manske, R. H. F. The Alkaloids: Chemistry and Physiology. Academic Press.
8. Wells, C. H. J. Introduction to molecular Phytochemistry. Chapmannstall.
9. Chatwal, G. R. Organic Chemistry of Natural products (Vol. I and II). Himalaya Publishing House
10. Agarwal, O. P. Organic Chemistry Natural Products (Vol. 2). Krishna Prakashan Media.
11. Finar, I. L. Organic chemistry (Vol 1 and 2), Delhi: Pearson education.
12. Gupta, P. K. Elements of Biotechnology, Rastogi Publishers.
13. Vyas, S. P., & Dixit, V.K. Pharmaceutical Biotechnology, CBS Publishers
14. Purohit, S. S., & Mathur, S. K. Drugs in Biotechnology fundamentals and applications.
15. Harborne, A. J. Phytochemical methods a guide to modern techniques of plant analysis. Springer Science & Business Media.
16. Burger, A. Burger's Medicinal chemistry (Vol. 1-6). John Wiley & Sons.

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

^ this is not an exhaustive list

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

L	T	P	C
-	-	12	6

Course Code	**MPC105P**
Course Title	**Pharmaceutical Chemistry Practical - I**

Syllabus: **Teaching hours: 180 Hours**

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

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography.
2. Claisen-schmidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement.
6. Mannich reaction.
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments).
8. Estimation of elements and functional groups in organic natural compounds.
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents.

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

Semester - I

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	MPA101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
2	MPA102T	Advanced Pharmaceutical Analysis	4	-	-	4	3.0	-	0.60	-	0.40
3	MPA103T	Pharmaceutical Validation	4	-	-	4	3.0	-	0.60	-	0.40
4	MPA104T	Food Analysis	4	-	-	4	3.0	-	0.60	-	0.40
5	MPA105P	Pharmaceutical Analysis Practical I	-	12	-	6	-	6.0	-	1.00	-
6		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 2017-18 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

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

L	T	P	C
4	-	-	4

Course Code	**MPA101T**
Course Title	**Modern Pharmaceutical Analytical Techniques**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

1. The analysis of various drugs in single and combination dosage forms
2. Theoretical and practical skills of the instruments

Course Learning Outcomes (CLO):

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

1 Recall the fundamental theory of different spectroscopic techniques.
2 Recognize the fundamentals, instrumentation and applications of various chromatographic methods
3 Discuss the instrumentation and application of various spectroscopic techniques
4 Describe various electrophoresis and X-ray methods
5 Apply the knowledge of various thermal and electro analytical methods in analysis of drugs and excipients

Syllabus: **Teaching hours: 60 Hours**

UNIT-I **10 Hours**

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

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

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:

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

UNIT – II **10 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 and ^{13}C NMR. Applications of NMR spectroscopy.

UNIT – III **10 Hours**

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

UNIT – IV **10 Hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug 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

UNIT – V **10 Hours**

Electrophoresis: 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

UNIT – VI **10 Hours**

Potentiometry: 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. 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. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part II Fourth Edition (Vol. 2). A&C Black.
5. Kemp, W. Organic Spectroscopy. ELBS.
6. Shethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. 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. NJ: Johnwiley and sons.

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

^ this is not an exhaustive list

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

L	T	P	C
4	-	-	4

Course Code	**MPA102T**
Course Title	**Advanced Pharmaceutical Analysis**

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

1. Appropriate analytical skills required for the analytical method development.
2. Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
3. Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

Course Learning Outcomes (CLO):

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

1. Define the impurities and classification of the impurities
2. Recognize the basic principle, preparation of antibodies and applications of immunoassays
3. Understand stability aspects for drug substances and drug products.
4. Describe the analytical method development and validation for stability testing as per regulatory guidelines
5. Discuss stability testing for phytopharmaceuticals
6. Explain the analysis of various vaccines and biological products.

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **10 Hours**

Impurity and stability studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

UNIT – II **10 Hours**

Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C,H, N and S analysis

Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

UNIT – III **10 Hours**

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

UNIT – IV **10 Hours**

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

UNIT – V **10 Hours**

Biological tests and assays of the following:

- Adsorbed Tetanus vaccine
- Adsorbed Diphtheria vaccine
- Human anti haemophilic vaccine
- Rabies vaccine
- Tetanus Anti toxin
- Tetanus Anti serum
- Oxytocin
- Heparin sodium IP
- Antivenom.

- PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

UNIT – VI **10 Hours**

Immunoassays (IA): Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

Suggested Readings^: (Latest edition)

1. Mendham, J. Vogels Textbook of Quantitative Chemical Analysis. Pearson Education India.
2. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part II Fourth Edition (Vol. 2). A&C Black.
3. Connors, K. A. A Textbook of Pharmaceutical Analysis. NJ: Johnwiley and sons.
4. Higuchi, T., Bodin, J. I., & Brochmann-Hanssen, E. Pharmaceutical Analysis. Interscience Publishers.
5. Shethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. CBS Publishers.
6. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.
7. Carratt, D. C. The Quantitative Analysis of Drugs. CBS Publishers.
8. Indian Pharmacopoeia,. Government of India. Ministry of health and family welfare.
9. Methods of Sampling and Microbiological Examination of Water, First Revision, BIS.
10. Snyder, L. R., Kirkland, J. J., & Glajch, J. L. Practical HPLC Method Development. John Wiley & Sons.
11. O. Brien, M., McCauley, J., & Cohen, E. Analytical Profile of Drug Substances, Klaus Florey.
12. Brittain, H. G. Analytical Profiles of Drug Substances and Excipients (Vol. 23). Academic Press.
13. Chamberlain, J. The Analysis of Drugs in Biological Fluids 2nd Edition. CRC press.
14. ICH Guidelines for impurity profiles and stability studies

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

^ this is not an exhaustive list

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

L	T	P	C
4	-	-	4

Course Code	**MPA103T**
Course Title	**Pharmaceutical Validation**

Scope

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

Objectives

Upon completion of the subject student shall be able to

1. Explain the aspect of validation
2. Carryout validation of manufacturing processes
3. Apply the knowledge of validation to instruments and equipments
4. Validate the manufacturing facilities

Course Learning Outcomes (CLO):

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

1. Define qualification for the analytical instruments and laboratory equipments
2. Understand different types of validation
3. Explain water and HVAC system in pharmaceutical industry.
4. Describe the analytical method development and validation for drug substance and drug product as per regulatory guidelines
5. Discuss IPR issues, patent filing, copyright and trademarks

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

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

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

UNIT – II **12 Hours**

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC,

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT – III **12 Hours**

Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT – IV **12 Hours**

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

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

UNIT - V **12 Hours**

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

patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

Suggested Readings^: (Latest edition)

1. Loftus, B. T., & Nash, R. A. Pharmaceutical Process Validation. Drugs and Pharm Sci. Series (Vol. 129) M. Dekker.
2. Lachman, L., Lieberman, H. A., & Kanig, J. L. The Theory and Practice of Industrial Pharmacy. Philadelphia: Lea & Febiger. Varghese Publishing House.
3. Terveeks, & Deeks. Validation Master Plan. Davis Harwood International Publishing.
4. Carleton, F. J., & Agalloco, J. P. Validation of Aseptic Pharmaceutical Processes, Marcel Dekker.
5. Levin Michael, Pharmaceutical Process Scale-Up II, Drugs and Pharm. Sci. Series (Vol. 157). Marcel Dekker Inc.
6. Validation Standard Operating Procedures, Step by step guide for achieving compliance in the pharmaceutical, Medical device and biotech industries. Syed Imtiaz Haider. CRC Press.
7. Cloud, P. Pharmaceutical Equipment Validation: The Ultimate Qualification Guidebook. CRC Press.
8. Carleton, F. J., & Agalloco, J. P. Validation of Pharmaceutical Processes: Sterile Products. Informa Healthcare.
9. Chan, C. C., Lee, Y. C., Lam, H., & Zhang, X. M. (Eds.). Analytical Method Validation and Instrument Performance Verification. John Wiley & Sons.

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

^ this is not an exhaustive list

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

L	T	P	C
4	-	-	4

Course Code	**MPA104T**
Course Title	**Food Analysis**

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

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

1. Food constituents
2. Food additives
3. Finished food products
4. Pesticides in food
5. And also student shall have the knowledge on food regulations and legislations

Course Learning Outcomes (CLO):

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

1. Recall and classify different carbohydrate and protein
2. Discuss different types of lipid and vitamins along with general method of analysis
3. Describe fundamentals of standards and quality for food products and additives.
4. Tell food legislation
5. Apply different analytical methods for dairy products and beverages
6. Use analytical methods for the determination of pesticides.

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Carbohydrates: Chemistry & classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates

Proteins: Chemistry and classification of amino acids and proteins, Physico- Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins

UNIT – II **12 Hours**

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay and physiological significance of vitamins of B-series.

UNIT – III **12 Hours**

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes

UNIT – IV **12 Hours**

General Analytical methods: General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

UNIT – V **12 Hours**

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorous and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

Suggested Readings^: (Latest edition)

1. Pearson, D. The Chemical Analysis of Foods Longman Group Ltd.
2. Nielsen, S. S. (Ed.). Introduction to the Chemical Analysis of Foods. Sudbury, MA: Jones and Bartlett.
3. Cuniff, P. Official Methods of Analysis of AOAC International. AOAC International.
4. Multon, J. L. Analysis of Food Constituents. John Wiley & Sons.
5. Horwitz, W. Official Methods of Analysis of the AOAC International. The Association.

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

^ this is not an exhaustive list

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

L	T	P	C
-	-	12	6

Course Code	MPA105P
Course Title	Pharmaceutical Analysis 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
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer

16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

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

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

Semester - I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MRA101T	Good Regulatory Practices	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA102T	Documentation and Regulatory Writing	4	-	-	4	3.0	-	0.60	-	0.40
3	MRA103T	Clinical Research Regulations	4	-	-	4	3.0	-	0.60	-	0.40
4	MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	-	-	4	3.0	-	0.60	-	0.40
5	MRA105P	Regulatory Affairs Practical I	-	12	-	6	-	6.0	-	1.00	-
6		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. - Regulatory Affairs)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MRA101T**
Course Title	**Good Regulatory Practices**

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives

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

1. The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
2. Prepare and implement the check lists and SOPs for various Good Regulatory Practices
3. Implement Good Regulatory Practices in the Healthcare and related Industries
4. Prepare for the readiness and conduct of audits and inspections.

Course Learning Outcomes (CLO):

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

1. Understand the concepts of cGMP and GLP
2. Describe the guidance documents for medical device and IVDs
3. Discuss principles and requirements of GALP
4. Review supply chain integrity in GDP
5. Utilize the various elements of QMS
6. Prepare SOP for equipments and processes

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

UNIT – 2 **12 Hours**

Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards

UNIT – III **12 Hours**

Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

UNIT – IV **12 Hours**

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards

UNIT – V **12 Hours**

Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

Suggested Readings^: (Latest edition)

1. Weinberg, S. Good Laboratory Practice Regulations. Informa Healthcare.
2. Robinson, D. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by John Sharp. CRC Press.
3. Bliesner, D. M. Establishing a CGMP Laboratory Audit System: A Practical Guide. John Wiley & Sons.
4. Sharma, P. P. How to Practice GLP Good Laboratory Practice. Vandana Publications.
5. Singer, D. C., Stefan, R. I., & Van Staden, J. F. Laboratory Auditing for Quality and Regulatory Compliance. Taylor & Francis.
6. Drugs & Cosmetics Act, Rules & Amendments.

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

^ this is not an exhaustive list

(M.Pharm. - Regulatory Affairs)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MRA102T**
Course Title	**Documentation and Regulatory Writing**

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives

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

1. Know the various documents pertaining to drugs in pharmaceutical industry
2. Understand the basics of regulatory compilation
3. Create and assemble the regulation submission as per the requirements of agencies
4. Follow up the submissions and post approval document requirements

Course Learning Outcomes (CLO):

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

1. List the different types of documents required for drug product management
2. Understand the concept, content and format of CTD and eCTD submission
3. Describe various types of audits and audit strategies for manufacturing facilities
4. Explain the inspection process of pharmaceutical manufacturing practices along with CAPA
5. Express life cycle management of different types of pharmaceutical dosage form

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

UNIT – II **12 Hours**

Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

UNIT – III **12 Hours**

Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

UNIT – IV **12 Hours**

Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

UNIT – V **12 Hours**

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

Suggested Readings^: (Latest edition)

1. Ginsbury, K., & Bismuth, G. Compliance Auditing for Pharmaceutical Manufacturers: A Practical Guide to In-Depth Systems Auditing. CRC Press.
2. Gad, S. C. (Ed.). Pharmaceutical manufacturing handbook: regulations and quality (Vol. 6). John Wiley & Sons.
3. Baird, R. M., Hodges, N. A., & Denyer, S. P. (Eds.). Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices. CRC Press.
4. Singer, D. C., Stefan, R. I., & Van Staden, J. F. Laboratory Auditing for Quality and Regulatory Compliance. Taylor & Francis.
5. Endres, A. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results. John Wiley & Sons.
6. Antony, J., & Preece, D. (Eds.). Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases. Routledge.
7. Lawler, E. E., Mohrman, S. A., & Benson, G. Organizing For High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO report. Jossey-Bass.
8. Fairfield-Sonn, J. W. Corporate Culture and the Quality Organization. Greenwood Publishing Group.
9. Avery, C., & Zabel, D. The Quality Management Sourcebook: An International Guide to Materials and Resources. Routledge.
10. Tague,N. The Quality Toolbox. ASQ Publications
11. Joseph, M., Feo, J. Juran's Quality Handbook. ASQ Publications.
12. Okes, D. Root Cause Analysis: The Core of Problem Solving and Corrective Action-Chapter 1.ASQ Publications.
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP).

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

^ this is not an exhaustive list

(M.Pharm. - Regulatory Affairs)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MRA103T**
Course Title	**Clinical Research Regulations**

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives

Upon completion of the course, the student shall be able to (know, do and appreciate)

1. History, origin and ethics of clinical and biomedical research and evaluation
2. Clinical drug, medical device development process and different types and phases of clinical trials
3. Regulatory requirements and guidance for conduct of clinical trials and research

Course Learning Outcomes (CLO):

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

1. Understand different phases of clinical trials for drug development process
2. Describe the importance of ethics and documentation for clinical trials
3. Differentiate clinical research regulations for drug products filing in India, USA and Europe
4. Discuss different aspects of good clinical practices as per regulatory guidelines.
5. Prepare different modules for dossier filing in USA and Europe

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Clinical Drug Development Process

- Different types of Clinical Studies
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post Marketing Studies; PSUR)

Clinical Investigation and Evaluation of Medical Devices & IVDs

Different Types of Studies

Key Concepts of Medical Device Clinical Evaluation

Key concepts of Clinical Investigation

UNIT – II **12 Hours**

Ethics in Clinical Research:

- Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials

- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

UNIT – III **12 Hours**

Regulations governing Clinical Trials

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

UNIT – IV **12 Hours**

Clinical Research Related Guidelines

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

GHTF study group 5 guidance documents

Regulatory Guidance on Efficacy and Safety ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population
- General biostatics principle applied in clinical research

UNIT – V **12 Hours**

USA & EU Guidance

USA: FDA Guidance

- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions
- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch

- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

- EU Directives 2001
- EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR)
- Volume 9A – Pharmacovigilance for Medicinal Products for Human Use
- EU MDD with respect to clinical research
- ISO 14155

Suggested Readings^: (Latest edition)

1. Rozovsky, F. A., & Adams, R. K. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance.
2. Barnes, M., Kulynych, J. HIPAA and Human Subjects Research: A Question and Answer.
3. Gallin, J. I., & Ognibene, F. P. (Eds.). Principles and Practice of Clinical Research. Academic Press.
4. Karlberg, J. P. E., & Speers, M. A. (Eds.). Reviewing Clinical Trials: A Guide for the Ethics Committee. Clinical Trials Centre.
5. Cartwright, A. C., & Matthews, B. R. (Eds.). International Pharmaceutical Product Registration. CRC Press.
6. Guarino, R. New Drug Approval Process. Marcel Dekker Inc.
7. Pisano, D. J., & Mantus, D. FDA Regulatory Affairs. CRC Press.
8. Country Specific Guidelines from Official Websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc /clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
7. Medicines and Healthcare products Regulatory Agency: http://www .mhra.gov.uk
8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf

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

^ this is not an exhaustive list

(M.Pharm. - Regulatory Affairs)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	MRA104T
Course Title	**Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights**

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives

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

1. Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
2. Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

Course Learning Outcomes (CLO):

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

1. Understand the rules and regulations for biologicals, herbals, food and nutraceuticals
2. Describe the regulatory requirements and approval procedures for drugs, cosmetics, medical devices etc.
3. Discuss pharmacopoeial standards and other standards like BIS and ISO
4. Explain regulatory requirements for bioequivalence study
5. Tell IPR issues, patent filing, copyright and trademarks

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):

- Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
- Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

UNIT – II **12 Hours**

Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- Format and contents of Regulatory dossier filing Clinical trial/ investigations

UNIT – III **12 Hours**

Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards

UNIT – IV **12 Hours**

Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study

Stability requirements: ICH and WHO

Guidelines for Drug testing in animals/Preclinical Studies

Animal testing: Rationale for conducting studies, CPCSEA Guidelines

Ethical guidelines for human participants

ICMR-DBT Guidelines for Stem Cell Research

UNIT – V **12 Hours**

Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

Suggested Readings^: (Latest edition)

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India.
2. Bessen, J., & Meurer, M. J. (2008). Patent failure: How judges, bureaucrats, and lawyers put innovators at risk. Princeton University Press.
3. Chin, R., & Lee, B. Y. (2008). Principles and practice of clinical trial medicine. Elsevier.
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA).
6. ICH E6 Guideline — Good Clinical Practice‖ by ICH Harmonised Tripartite.
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation).
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO.
10. Guidelines from official website of CDSCO.

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

^ this is not an exhaustive list

(M.Pharm. - Regulatory Affairs)
(Semester – I)

L	T	P	C
-	-	12	6

Course Code	MRA105P
Course Title	Regulatory Affairs Practical I

Syllabus: **Teaching hours: 180 Hours**

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

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

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of *(M. Pharm. - Pharmacology)*

Semester I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MPL101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
2	MPL102T	Advanced Pharmacology-I	4	-	-	4	3.0	-	0.60	-	0.40
3	MPL103T	Pharmacological and Toxicological Screening Methods-I	4	-	-	4	3.0	-	0.60	-	0.40
4	MPL104T	Cellular and Molecular Pharmacology	4	-	-	4	3.0	-	0.60	-	0.40
5	MPL105P	Pharmacological Practical I	-	12	-	6	-	6.0	-	1.00	-
6	-	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*

SN

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

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Objectives:

After completion of course student is able to know about –

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

Course Learning Outcomes (CLO):

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

1. Recall knowledge of various chemicals and excipients.
2. Understand fundamental theories of various analytical techniques.
3. Apply practical skills of the instruments.
4. Interpret the results of various spectroscopic and chromatographic techniques.
5. Analyze various drugs in single and combination dosage forms using various qualitative and quantitative analysis methods.
6. Predict the structure of a molecule using various spectral data.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **10 Hours**

UV-Visible spectroscopy

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

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.

UNIT II **10 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 and 13C NMR. Applications of NMR spectroscopy.

UNIT III **10 Hours**

Mass Spectroscopy

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

UNIT IV **10 Hours**

Chromatography

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

UNIT V **10 Hours**

Electrophoresis

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

UNIT VI **10 Hours**

Potentiometry

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

^ This is not an exhaustive list

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

L	T	P	C
4	-	-	4

Course Code	**MPL102T**
Course Title	**Advanced Pharmacology-I**

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.

Course 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. Recall basic concepts of pharmacokinetics.
2. Describe the fundamental aspects of pharmacodynamics.
3. Discuss principles of neurotransmission.
4. Explain the pathophysiology of various diseases.
5. Give in own words the pharmacology of drugs acting on autonomic nervous system, central nervous system, cardiovascular system and autacoids.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

General Pharmacology

- 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.

UNIT II **12 Hours**

Neurotransmission

- 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

UNIT III **12 Hours**

Central nervous system Pharmacology

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

UNIT IV **12 Hours**

Cardiovascular Pharmacology

- Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia
- Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs

UNIT V **12 Hours**

Autocoid Pharmacology

- 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.

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

^ This is not an exhaustive list

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

L	T	P	C
4	-	-	4

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

Scope:

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Course Objectives:

Upon completion of the course the student shall 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.

Course Learning Outcomes (CLO):

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

1. Understand pharmacology, physiology and pathophysiology of disease qualitatively and quantitatively
2. Demonstrate the skills for handling and use of small animals for experiments as per ethical guidelines and interpret data obtained for human co-relation.
3. Interpret results of pharmacometric evaluation of novel drugs
4. Evaluate various drugs for their pharmacological and toxicological actions using animals models to extrapolate them with human
5. Propose pharmacological screening of novel drugs.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Laboratory Animals

- 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

UNIT II **12 Hours**

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

- 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.

UNIT III **24 Hours**

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

- Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti-allergics.
- Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents.
- Gastrointestinal drugs: anti-ulcer, anti-emetic, anti-diarrheal and laxatives.
- Cardiovascular Pharmacology: anti-hypertensives, anti-arrythmics, antianginal, anti-atherosclerotic agents and diuretics.
- Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic, and anti-cancer agents, Hepatoprotective screening methods.

UNIT IV **12 Hours**

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

- 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.

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

^ This is not an exhaustive list

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

L	T	P	C
4	-	-	4

Course Code	**MPL104T**
Course Title	**Cellular and Molecular Pharmacology**

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Course Objectives:

Upon completion of the course, the student shall 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.

Course Learning Outcomes (CLO):

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

1. Explain the signal transduction mechanisms.
2. Describe pharmacogenomics, proteomic and immunotherapeutic and their applications.
3. Demonstrate the molecular mechanism of pathways affected by various drugs.
4. Discuss the molecular biology techniques as applicable for pharmacology
5. Determine the regulating mechanisms involved in cellular function.
6. Evaluate the applicability of molecular pharmacology and biomarkers in drug discovery process.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Cell biology

- 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

UNIT II **12 Hours**

Cell signaling

- 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

UNIT III **12 Hours**

Principles and applications of genomic and proteomic tools

- 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

UNIT IV **12 Hours**

Pharmacogenomics

- 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

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 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.

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

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

L	T	P	C
-	-	12	6

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.

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

^ This is not an exhaustive list

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

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	**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.

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	**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.

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

^ this is not an exhaustive list

(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 .

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

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	MPC-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 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.

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	**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.

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	**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

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

^ 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	MPA206S	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.

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	**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	MRA206S	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 - 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.*

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

(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

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

(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

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

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

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

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

(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)

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

^ 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.

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

(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.

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

^ this is not an exhaustive list

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

L	T	P	C
-	-	12	6

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/

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

^ this is not an exhaustive list

NIRMA UNIVERSITY
NAAC ACCREDITED 'A' GRADE

NU/AC/4 (C)/18- 71
Date: 05 .05.2018

NOTIFICATION

Read:
1. **Regulation No. 44 of Academic Regulations for Admission to University, etc. published vide notification No. NU-442 dated 27.1.2004 – Empowering Academic Council to approve teaching & examination scheme, syllabus, etc.**
2. **Notifications mentioned in Handbook-IV, updated up to April, 2015**
3. **Resolution No. 4, 5(II), 6(II) and 8(II)- Faculty of Pharmacy meeting-28.02.2018**
4. **Resolution No. 4(C)– Academic Council meeting – 20.04.2018**

Sub: **Introduction of Teaching & Examination Scheme and Syllabus of Semester-III & IV of following M. Pharm programmes in pursuance to new curriculum as prescribed by Pharmacy Council of India (PCI)**

It is, hereby, notified for information of all concerned that, the Academic Council in its meeting held on 20.04.2018 under resolution No. 4(C), in exercise of powers conferred upon it by the Board of Governors under regulation mentioned at serial 1 above, taking into consideration the recommendation of the Faculty of Pharmacy, has resolved to approve the *introduction* of Teaching & Examination Scheme and Syllabus of Semester-III & IV of following M. Pharm programmes in pursuance to new curriculum as prescribed by Pharmacy Council of India (PCI), to be made effective for the students admitted in **M. Pharm. programmes** from academic year 2017-18 onwards as per ***Appendix-A*** attached herewith.

i. Pharmaceutics
ii. Pharmaceutical Analysis
iii. Regulatory Affairs
iv. Pharmaceutical Chemistry
v. Pharmacology

Executive Registrar

Encl.: Appendix-A [Pages 1 to 7]

To,
1. Dean, Faculty of Pharmacy
2. Coordinator of Exam, IP
3. Dy. Registrar: Examination

Copy to: OS-IP; Librarian-IP; P.A. to ER

c.f.w.cs. for information to: 1. Vice President
2. Director General

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of (M.Pharm. - Pharmaceutics)

Semester - III

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	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MPH302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MPH303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MPH304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

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	MPH401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MPH402P	Research work and Colloquium		31	-	16	-	1.0		1.0	-
3	MPH403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

Appendix - A
Noti. No. - NU - 31
Acmtx - 20.04.18

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of (M. Pharm- Pharmaceutical Analysis)

Semester - III

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	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MPA302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MPA303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MPA304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

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	MPA401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MPA402P	Research work and Colloquium	-	31	-	16	-	1.0		1.0	-
3	MPA403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

w.e.f. academic year 2018-2019 and onwards

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of (M. Pharm - Regulatory Affairs)

Semester - III

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	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MRA302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MRA303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MRA304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

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	MRA401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MRA402P	Research work and Colloquium	-	31	-	16	-	1.0		1.0	-
3	MRA403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

w.e.f. academic year 2018-2019 and onwards

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

Semester - III

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MPC302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MPC303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MPC304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MPC401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MPC402P	Research work and Colloquium	-	31	-	16	-	1.0	-	1.0	-
3	MPC403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of (M.Pharm. - Pharmacology)

Semester - III

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	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MPL302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MPL303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MPL304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

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	MPL401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MPL402P	Research work and Colloquium	-	31	-	16	-	1.0		1.0	-
3	MPL403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm)
(Semester - III)

L	T	P	C
4	-	-	4

Course Code	**MRM301T**
Course Title	**Research Methodology & Biostatistics**

Course Learning Outcomes (CLO):

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

1. List various types of research and significance of review of literature
2. Describe the parametric and non- parametric tests related to biostatistics
3. Discuss various types of medical research
4. Explain CPCSEA guidelines for laboratory animal facility
5. Express the role of declaration of Helsinki

Syllabus: **Teaching hours: 60 Hours**

UNIT I **15 Hours**

General Research Methodology: Research, objective, protocol design, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding and related labelling techniques, conduct, monitoring, analysis and interpretation, reporting and record keeping, Scientific writing.

UNIT II **20 Hours**

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

UNIT III **10 Hours**

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

UNIT IV **05 Hours**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals, Import of animals.

UNIT V **10 Hours**

General Guidelines of clinical research, ICH E9 guidelines, Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Suggested Readings^: (Latest Edition)

1. Best, J.W., Kahn, J.V., *Research In Education*. New Delhi, Prentice Hall of India Pvt. Ltd.
2. Halton, M., *Presentation Skills*. Indian Society for Institute Education
3. Mcfarlane, G., *A Practical Introduction to Copyright*. McGraw Hill
4. Davis, R.M., *Thesis Projects in Science and Engineering*. St. Martin's Press.
5. Anderson, J., *Thesis and Assignment Writing*. John Wiley & Sons.

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

^ this is not an exhaustive list