Appendix-A
Noti.No. NU- 33
Acad.Cou.mtg. – 12.03.24

NIRMA UNIVERSITY

Institute:	**Institute of Pharmacy**
Name of Programme:	**Pharm. D**
Course Code:	**PD301**
Course Title:	**PHARMACOLOGY-II**
Course Type:	(■ Core/☐Value Added Course /☐Departmental Elective/ ☐Institute Elective/☐University Elective/(☐Open Elective Any other)
Year of introduction:	**2024-2025**

L	T	Practical component				C
		LPW	PW	W	S	
3	1	3	-	-	-	12

Course Learning Outcomes (CLO):

Upon completion of the course the student shall be able to

1. Describe the pharmacokinetic and pharmacodynamic profiles of drugs acting on renal system, blood, blood forming agents, immunosuppressants and stimulants, anti-cancer agents and correlate it with the experimental and clinical settings. (BL2)
2. Apply knowledge concerning cell dynamics, cell signaling, genome structure and functions within the realms of experimental and clinical pharmacology (BL3)
3. Discuss basic principles of transcription, transcription factors, RNA processing and altered gene functions. (BL6)
4. Illustrate an understanding of the principles and concepts of animal toxicology. (BL2)
5. Analyse and evaluate the impact of altered gene functions, gene sequencing, mapping and cloning of human disease genes, gene therapy, targeting and recombinant DNA technology in healthcare. (BL6)

Syllabus: **Total Teaching hours: 90 hours**

Unit	Contents	Teaching hours
Unit I	**Pharmacology of Drugs acting on Blood and blood forming agents** a) Anticoagulants b) Thrombolytics and antiplatelet agents c) Haemopoietics and plasma expanders	**10 hours**

Pharmacology of drugs acting on Renal System

a) Diuretics

b) Antidiuretics

Unit II **Chemotherapy** **35 hours**

a) Introduction

b) Sulfonamides and co-trimoxazole

c) Penicillins and Cephalosporins

d) Tetracyclins and Chloramphenicol

e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics

f) Quinolines and Fluroquinolines

g) Antifungal antibiotics

h) Antiviral agents

i) Chemotherapy of tuberculosis and leprosy

j) Chemotherapy of Malaria

k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)

l) Pharmacology of Anthelmintic drugs

m) Chemotherapy of cancer (Neoplasms)

Immunopharmacology

Pharmacology of immunosuppressants and stimulants

Unit III **Principles of Animal toxicology:** Acute, sub-acute and chronic toxicity **10 hours**

Unit IV **The dynamic cell:** The structures and functions of the components of the cell **15 hours**

a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies

b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.

c) DNA replication: General, bacterial and eukaryotic DNA replication.

d) The cell cycle: Restriction point, cell cycle regulators and modifiers.

Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

Unit V **The Gene:** Genome structure and function: **20 hours**

a) Gene structure: Organization and elucidation of genetic code.

b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.

Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.
Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events
Altered gene functions: Mutations, deletions, amplifications, LOH, translocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.
The gene sequencing, mapping and cloning of human disease genes. Introduction to gene therapy and targeting.
Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

Suggested Readings/ References:

Text books

a) Tripathi, K. D. Essentials of medical pharmacology. Latest edition. Publisher: Jaypee, Delhi.
b) Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. Latest edition. Publisher: Popular, Dubai.
c) Rang, H.P. & Dale, M.M. Pharmacology. Latest edition. Publisher: Churchill Living stone.
d) Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books

a) Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. Latest edition. Publisher Mc Graw Hill, Pergamon press.
b) Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
c) Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
d) Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi
e) Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
f) Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
g) Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
h) Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

Tutorials **Teaching hours: 30 hours**

Tutorials will be based on above syllabus

Practical **Teaching hours: 3 hours/Week**

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three-point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three-point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
    a) Analgesic property of drug using analgesiometer.
    b) Antiinflammatory effect of drugs using rat-paw edema method.
    c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
    d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
    e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessional	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

NIRMA UNIVERSITY

Institute:	**Institute of Pharmacy**
Name of Programme:	**Pharm.D**
Course Code:	**PD303**
Course Title:	**PHARMACOTHERAPEUTICS-II**
Course Type:	(■ Core/☐Value Added Course/☐Departmental Elective/ ☐ Institute Elective/☐University Elective/(☐Open Elective Any other)
Year of introduction:	**2024-2025**

L	T	Practical component				C
		LPW	PW	W	S	
3	1	3	-	-	-	12

Course Learning Outcomes (CLO):

Upon completion of the course the student shall be able to

1. Describe the pathophysiology, therapeutic approach and management of infectious, musculoskeletal, renal, oncology, dermatological disease and various method involved in the diagnosis. (BL2)
2. Identify the patient-specific parameters relevant in initiating drug therapy and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects). (BL3)
3. Critically evaluate the controversies in the drug therapy and the rationale behind management of diseases. (BL4)
4. Analyze and appraise the ramifications of patient parameters throughout the clinical admission process. (BL5)
5. Create personalized treatment strategies for the patients by integrating evidence based medicine and aligning with pertinent clinical guidelines. (BL6)

Syllabus: **Total Teaching hours: 90 hours**

Unit	Contents	Teaching hours
Unit-I	**Infectious Disease** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhea and Syphilis	**25 hours**
Unit-II	**Musculoskeletal Disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus, erythematosus	**15 hours**
Unit III	**Renal System** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders	**20 hours**

Unit-IV **Oncology** **20 hours**

Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis.

Unit V **Dermatology** **10 hours**

Psoriasis, Scabies, Eczema, Impetigo

NOTE: Etiopathogenesis and pharmacotherapy of diseases associated with the above-mentioned systems

Suggested Readings/ References:

Text Books (Latest edition)

a) Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
b) Pharmacotherapy - A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books (Latest edition)

a) Pathologic basis of disease - Robins SL, W.B. Saunders publication.
b) Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
c) Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
d) Applied Therapeutics - The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

Tutorials **Teaching hours: 30 hours**

Tutorials will be based on above syllabus

Practicals **Teaching hours:3hrs/wk.**

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge.

Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the Assignment

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. Assignment shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination

	Sessional	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance)

NIRMA UNIVERSITY

Institute:	**Institute of Pharmacy**
Name of Programme:	**Pharm.D**
Course Code:	**PD305**
Course Title:	**MEDICINAL CHEMISTRY**
Course Type:	(■ Core/☐Value Added Course/☐Departmental Elective/ ☐ Institute Elective/☐University Elective/(☐Open Elective Any other)
Year of introduction:	**2024-2025**

L	T	Practical component				C
		LPW	PW	W	S	
3	1	3	-	-	-	12

Course Learning Outcomes (CLO):

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

1. Describe the monograph and synthesis of medicinally important drugs and/or intermediates. BL-2
2. Discuss the metabolism, side effects, and therapeutic activity of important marketed drugs. BL-2
3. Demonstrate the importance of modern techniques of drug design. BL-3
4. Classify medicinal compounds as per their chemical nomenclature and therapeutic actions. BL-4
5. Analyse the therapeutic potential of drugs based on the structural activity relationship studies. BL-4

Theory Syllabus: **Total Teaching hours: 90 hours**

Unit	Contents	Teaching hours
Unit-I	**Modern concept of rational drug design:** A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules. A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects:	**10 hours**
Unit-II	**Anti-infective agents**: (a) Local anti-infective agents, (b) Preservatives, (c) Antifungal agents, (d) Urinary tract anti-infectives, (e) Antitubercular agents, (f) Antiviral agents and Anti-AIDS agents, (g) Antiprotozoal agents (h) Anthelmintics, (i) Antiscabies and Antipedicular agents	**10 hours**

Unit-III	**Sulphonamides and sulphones**	**3 hours**
Unit-IV	**Antimalarials**	**4 hours**
Unit-V	**Antibiotics**	**12 hours**
Unit-VI	**Antineoplastic agents**	**5 hours**
Unit-VII	**Cardiovascular agents:** (a) Antihypertensive agents, (b) Antianginal agents and vasodilators, (c) Antiarrhythmic agents (d) Antihyperlipidemic agents, (e) Coagulants and Anticoagulants, (f) Endocrine	**16 hours**
Unit-VIII	**Hypoglycemic agents**	**7 hours**
Unit-IX	**Thyroid and Antithyroid agents**	**4 hours**
Unit-X	**Diuretics**	**5 hours**
Unit-XI	**Diagnostic agents**	**4 hours**
Unit-XII	**Steroidal Hormones and Adrenocorticoids**	**10 hours**
	Tutorials hours Tutorials will be based on the above syllabus.	**30 Hours**

Suggested Readings/ References:

Textbooks (Theory)

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.

Reference books (Theory)

1. William. O. Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
2. Burgers, Medicinal Chemistry, M.E.,Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
3. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
4. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
5. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
6. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
7. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

Suggested List of Experiments:

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

NIRMA UNIVERSITY

Institute:	**Institute of Pharmacy**
Name of Programme:	**Pharm. D**
Course Code:	**PD304**
Course Title:	**PHARMACEUTICAL JURISPRUDENCE (THEORY)**
Course Type:	(☑ Core/☐Value Added Course /☐Departmental Elective/ ☐Institute Elective/☐University Elective/(☐Open Elective Any other)
Year of introduction:	**2024-2025**

L	T	Practical component				C
		LPW	PW	W	S	
2	-	-	-	-	-	4

Course Learning Outcomes (CLO):

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

1. Explain importance of pharmaceutical laws and code of pharmaceutical ethics. (BL2)
2. Demonstrate regulations related to import, manufacturing, sale, labeling & packing of drugs and related regulations of drugs as per Drug & Cosmetic Act and Rules. (BL3)
3. Explain the functions and constitution of state and central pharmacy council, and discuss laws related to manufacturing of Narcotic and Alcoholic preparations. (BL2)
4. Describe the features of drugs and magic remedies act and its rules, essential commodities act relevant to drugs price control order & current national drug policy, and prevention of cruelty to animals. (BL2)
5. Discuss about the intellectual property rights, and prescription and non-prescription products. (BL2)

Syllabus: **Total Teaching hours: 60 hours**

Unit	Contents	Teaching hours
Unit-I	**Pharmaceutical Legislations A brief review.** Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.	**05 Hours**
Unit-II	**Drugs and Cosmetics Act, 1940, and its rules 1945.** Objectives, Legal definitions, Study of schedules with reference to schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y. Sales, Import, labelling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems. Constitution and Functions of DTAB, DCC, CDL. Qualification and duties Govt. analyst and Drugs Inspector	**20 Hours**

Unit-III	**Pharmacy Act 1948.** Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council. Registration & Procedure, ER. **Medicinal and Toilet Preparation Act 1955.** Objectives, Legal Definitions, Licensing, Bonded and Non-Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.	**22 Hours**
Unit - IV	**Study of Salient Features of Drugs and magic remedies Act and its rules.** **Study of essential Commodities Act Relevant to drugs price control Order.** **Drug Price control Order & National Drug Policy (Current).** **Prevention Of Cruelty to animals Act-1960.**	**08 Hours**
Unit - V	**Patents & design Act-1970.** **Brief study of prescription and Non-prescription Products.**	**05 Hours**

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to:

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

Suggested Readings/ References:

Text books: (Latest edition)

1. Mithal, B M. Textbook of Forensic Pharmacy. Vallabh Prakashan.

Reference books: (Latest edition)

1. Jain, NK. A Textbook of forensic pharmacy. Vallabh prakashan.
2. Reports of the Pharmaceutical enquiry Committee
3. I.D.M.A., Mumbai. DPCO 1995
4. Various reports of Amendments
5. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications.
6. Eastern Book Company. The narcotic and psychotropic substances act 1985, Lucknow: Eastern.

NIRMA UNIVERSITY

Institute:	**Institute of Pharmacy**
Name of Programme:	**Pharm. D**
Course Code:	**PD306**
Course Title:	**PHARMACEUTICAL FORMULATIONS**
Course Type:	(☑ Core/☐Value Added Course /☐Departmental Elective/ ☐Institute Elective/☐University Elective/(☐Open Elective Any other)
Year of introduction:	**2024-2025**

L	T	Practical component				C
		LPW	PW	W	S	
2	1	3	-	-	-	10

Course Learning Outcomes (CLO):
Upon completion of the course the student shall be able to:

1. Explain the principle, merits and demerits of various pharmaceutical dosage forms. (BL2)
2. Describe concepts and rationale for controlled and novel drug delivery systems. (BL2)
3. Demonstrate formulation, manufacturing and quality control of sterile products. (BL3)
4. Recommend ingredients and method of manufacturing for formulation of non-sterile products. (BL5)
5. Evaluate non-sterile formulations. (BL5)

Syllabus: **Total Teaching hours: 60 hours**

Unit	Contents	Teaching hours
Unit-I	a) Pharmaceutical dosage form- concept and classification b) **Liquid orals**: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations	**08 Hours**
Unit-II	**a) Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques, quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet. **b) Capsules**; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.	**24 Hours**
Unit-III	**Parenterals:** Introduction, Containers used for Parenterals (including official tests), Formulation of large and small volume Parenteral, Sterilization.	**12 Hours**

Unit - IV	**Ophthalmic preparations (Semi – Solids):** Introduction and classification, Factors affecting absorption and anatomy of skin. Packaging storage and labeling; Ointments: Types of Ointment, Base, Preparation of ointment; Jellies: Types of jellies, Formulation of jellies; Suppositories: Method of preparation, Types Packaging	**6 Hours**
Unit - V	Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, transdermal, buccal, rectal, nasal, implants, ocular etc.	**10 Hours**

Tutorials

Tutorials will be based on above syllabus

Teaching Hours: 30 Hours

Suggested Readings/ References:

Text books: (Latest edition)

1. Lieberman, H. A, Rieger, M. M., & Banker, G.S. *Pharmaceutical dosage forms – Disperse systems,* Volume 1 to 3, New York, Marcel Dekkar Inc.
2. Lieberman, H. A, Lachman, L., & Avis, K.E. *Pharmaceutical dosage forms – Tablets, Volume 1 to 3*, New York, Marcel Dekkar Inc.
3. Lieberman, H. A, Lachman, L., & Avis, K.E. *Pharmaceutical dosage forms – Parenteral medications*, Volume 1 to 3, New York, Marcel Dekkar Inc.
4. Lachman l., Lieberman H. A., Kanig L. *Theory and practice of industrial pharmacy.* Varghese Publishing House, Mumbai.
5. Carter S. J. *Cooper and Gunn's Tutorial pharmacy.* C. B. S. Publishers & Distributors, Delhi.

Reference books: (Latest edition)

1. Gennaro A. R. *Remington the science and practice of pharmacy.* Lippincott Williams & Wilkins
2. Pharmacopoeias (USP, BP, IP)

Suggested List of Experiments: **(90 Hours)**

1. **Manufacture of Tablets**
   - **a.** Ordinary compressed tablet-wet granulation
   - **b.** Tablets prepared by direct compression.
   - **c.** Soluble tablet.
   - **d.** Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenteral formulations**
   - **a.** Ascorbic acid injection
   - **b.** Calcium gluconate injection
   - **c.** Sodium chloride infusion.
   - **d.** Dextrose and Sodium chloride injection/ infusion.
4. **Evaluation of Pharmaceutical formulations (QC tests)**
   - **a.** Tablets
   - **b.** Capsules
   - **c.** Injections

5. **Formulation of two liquid oral preparations and evaluation by assay**
   a. Solution: Paracetamol Syrup
   b. Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
   a. Salicylic acid and benzoic acid ointment
   b. Gel formulation Diclofenac gel
7. **Cosmetic preparations**
   a. Lipsticks
   b. Cold cream and vanishing cream
   c. Clear liquid shampoo
   d. Tooth paste and tooth powders.
8. Tablet coating

Assignments:

1. Library assignments
2. Report of manufacturing equipment of solid and liquid dosage forms
3. Latest advancement in the novel dosage forms

Scheme of Practical Examination:

	Sessional	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness)

NIRMA UNIVERSITY

Institute:	**Institute of Pharmacy**
Name of Programme:	**Pharm. D**
Course Code:	**PD302**
Course Title:	**PHARMACEUTICAL ANALYSIS**
Course Type:	(☑ Core/☐Value Added Course /☐Departmental Elective/ ☐Institute Elective/☐University Elective/(☐Open Elective Any other)
Year of introduction:	**2024-2025**

L	T	Practical component				C
		LPW	PW	W	S	
3	1	3	-	-	-	12

Course Learning Outcomes (CLO):

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

1. Comprehend the principles of statistical quality control, validation methods, GLP, TQM, ISO, ICH guidelines and regulatory control within the context of QA. (BL2)
2. Evaluate and synthesize different chromatographic techniques to proficiently separate and analyze drugs from excipients. (BL3)
3. Apply advanced analytical skills to assess, interpret and utilize different electrometric methods. (BL3)
4. Critically assess theoretical foundations, instrumentations, data/spectra interpretation and diverse analytical applications of various spectroscopic techniques. (BL3)
5. Describe principles and applications of polarimetry, X-ray methods and thermal analysis in pharmaceutical field. (BL2)

Syllabus: **Total Teaching hours: 90 hours**

Unit	Contents	Teaching hours
Unit-I	**Quality Assurance:** a) Introduction, sources of quality variation, control of quality variation. b) Concept of statistical quality control. c) Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration. d) GLP, ISO 9000. e) Total quality management, quality review and documentation. f) ICH- international conference for harmonization-guidelines. g) Regulatory control.	**15 Hours**

Unit-II **Chromatography:** Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients. **30 Hours**

a) **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
b) **TLC:** Introduction, principle, techniques, Rf value and applications.
c) **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
d) **Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
e) **HPLC:** Introduction, theory, instrumentation, and applications.
f) **HPTLC:** Introduction, theory, instrumentation, and applications.
g) **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
h) **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
i) **Gel filtration and affinity chromatography:** Introduction, technique, applications.

Unit-III **Electrometric Methods:** Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics. **15 Hours**

a) **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
b) **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
c) **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
d) **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

Unit - IV **Spectroscopy:** Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on: **30 Hours**

a) **Absorption Spectroscopy:**
Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, bathochromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.
Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.
Infrared Spectroscopy: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation– IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.
Fluorimetric Analysis: Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

b) **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

c) **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.

d) **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

e) **NMR & ESR (Introduction only):** Introduction, theoretical aspects and applications.

f) **Mass Spectroscopy: (Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.

g) **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

h) **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.

i) **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

Tutorials
Tutorials will be based on above syllabus

Teaching Hours: 30 Hours

Suggested Readings/ References:

Text books: (Latest edition)

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
3. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
4. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
5. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
6. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
7. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
8. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.

Reference books: (Latest edition)

1. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
2. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
3. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
4. How to practice GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
5. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
6. TLC by Stahl, Spring Verlay.
7. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
8. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
9. I.P.-1996, The Controller of Publications, New Delhi.
10. BPC- Dept. of Health, U.K. for HMSO.
11. USP - Mack Publishing Co., Easton, PA.
12. The Extra Pharmacopoeia – The Pharm. Press, London.

Suggested List of Experiments: **(90 Hours)**

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

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

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voice and record maintenance).