Nirma University

Institute of Pharmacy

Programme: **Master of Pharmacy in Pharmaceutical Analysis**

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

I. 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.E-1
2. Recognize the fundamentals, instrumentation and applications of various chromatographic methods S-17

3 Discuss the instrumentation and application of various spectroscopic techniques S-19

4 Describe various electrophoresis and X-ray methods -1

5 Apply the knowledge of various thermal and electro analytical methods in analysis of drugs andexcipients ENT-13

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 ofFT-NMR and ^{13}C NMR. Applications ofNMR 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 A: (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: Modem Methods (Vol. 11). CRC Press.
8. Kalsi, P. S. Spectroscopy of Organic Compounds. Wiley Estem 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 E-1
2. Recognize the basic principle, preparation of antibodies and applications of immunoassays E-1
3. Understand stability aspects for drug substances and drug products.ENT-13
4. Describe the analytical method development and validation for stability testing as per

regulatory guidelines E-1

5. Discuss stability testing for phytopharmaceuticals S-17
6. Explain the analysis of various vaccines and biological products. E-1

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, CH 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 **E-1** **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 ReadingsA: (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 oflndia. 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. 0. 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

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(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 E-1
2. Understand different types of validation NT-13
3. Explain water and HVAC system in pharmaceutical industry. E-1
4. Describe the analytical method development and validation for drug substance and drug product as per regulatory guidelines S-19
5. Discuss IPR issues, patent filing, copyright and trademarks ENT-13

Syllabus: **Teaching hours: 60 Hours**

UNIT-I E 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 ENT 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 E 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 S 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 ENT 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 ofIP 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 ofIPP; Societal responsibility, avoiding unethical practices.

Suggested ReadingsA: (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 Pham1. 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., & Aga lloco, 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 Perfonnance Verification. John Wiley & Sons.

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(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 detennination 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 E-1
2. Discuss different types of lipid and vitamins along with general method of analysis S-17
3. Describe fundamentals of standards and quality for food products and additives. ENT-13
4. Tell food legislation E-1

5. Apply different analytical methods for dairy products and beverages ENT-13
6. Use analytical methods for the determination of pesticides. S-19

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 ENT-13 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 E-1, S-19 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.

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(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

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(M.Pharm. - Pharmaceutical Analysis)

(Semester - I)

L	T	P	C
		7	4

Course Code	**MPA106S**
Course Title	**Seminar /Assignment-I**

Nirma University

Institute of Pharmacy

M. Pharm. Semester - I

COURSE NAME: ADVANCED INSTRUMENTAL METHODS [3PH106]

1. Understand the fundamentals of spectroscopy and chromatographic techniques.
2. Use spectroscopy for the quantitative and qualitative analysis of drugs.
3. Predict the structure of unknown compounds.

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

Theory (Detailed Syllabus) **L P C**

3 3 5

Applications and recent trends in the modem methodology used for the analysis of drugs and their metabolites of the following techniques

A) Spectroscopic Techniques

UV-Visible spectrophotometry: Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effect, applications of UV-Visible spectroscopy, Woodward - Fischer rules for calculating absorption maximum, photometric titrations and its applications

Infra-red spectrophotometry: Absorption in the infrared region, factors influencing molecular vibrations, Canculation of vibrational frequencies, applications, interpretation of infra red spectra, FTIR- Theory, Instrumentation, Attenuated Total reflectance spectroscopy (ATR)

Nuclear Magnetic Resonance Spectroscopy: Basic principles, theory of PMR spectroscopy, Instrumentation, applications, Chemical shift, spin-spin coupling, factors affecting chemical shift and spin coupling, ^{13}C NMR spectroscopy, interpretation of NMR spectra, 2D NMR spectroscopy Mass spectroscopy : Basic principles , ion formation and types, Fragmentation rules, recognition of molecular ion peak, Tandem mass spectroscopy, MALDI, FAB, SIMS, Structure elucidation of pharmaceutical compounds using different spectroscopic Techniques like UV-Visible, IR, NMR, MASS etc..

B) Separation Techniques

Classification of chromatographic methods based upon mechanism of separation, mode of separation, ion pair chromatography and applications

High Pressure Liquid Chromatography: RP-HPLC, chiral, Hydrophobic interaction, exclusion, Ion exchange, Affinity chromatography, ion chromatography

Gas chromatography:

LC-MS, LC-MS/MS, GC-MS,

1. Size

2. column operation, derivatization methods

3. Hyphenated techniques: tandam mass spectroscopy

4. HPTLC

5. Super Critical Fluid Chromatography: Basic Principles, Instrumentation

Practical

1 Analysis of drugs and raw materials using official pharmacopoeia} methods based onmodem instrumental techniques.

2 Testing of related substances and foreign substances in raw materials as per LP.

3 Assay for the raw materials, calculated either on anhydrous or hydrous basis as per LP.

4 Interpretation of UV, IR, NMR and Mass spectra and its use in structure elucidation.

Books Recommended

1. R. M. Silversterin, G. C. Bassler and T. C. Morrihl, Spectrometric Identification of Organic Compounds, 6th edn, John Wiley, New York, 1998.
2. P. S. Kalsi, Spectroscopy of Organic Compounds, New Age Publication, 2002.
3. D. A. Skoog, E. J. Holler and T. A. Nieman, Principles of Instrumental Analysis, Harcourt Asia Pte Ltd, 2001.
4. S. Lindsay, High Performance Liquid Chromatography, Analytical Chemistry by Open Leaming (ACOL), Wiley, 1987.
5. Sethi, P.D., High performance thin layer chromatography: Quantitative analysis of pharmaceutical formulations, 1996.

Nirma University

Institute of Pharmacy

M. Pharm. [Pharmaceutical Analysis] Semester - I

COURSE NAME: MODERN PHARMACEUTICAL ANALYSIS [3PA101]

Learning Outcome:

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

- Demonstrate the importance of dissolution study used for dosage forms of drugs.
- Recognize about advancement in analytical methods specifically which use laser as radiation source.
- Describe solid state chemistry for chemical compounds used as Pharmaceutical substances.

Theory (Detailed Syllabus)

L	*P*	*C*
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1. Atomic absorption and atomic em1ss10n spectroscopy: Basic principles, instrumentation, applications
2. X-ray diffraction methods - Introduction, bragg' s law, X-ray absorption and X- ray diffraction methods and applications.
3. Optical methods - CD circular dientoism, Polarimetry, Electron scanning microscopy
4. Laser spectroscopy - Basic principles, instrumentation, applications
5. Thermal analysis - Thermo-gravimetric analysis (TG , Differential Thermal Analysis IDTA1), Differential Scanning Calorimetry (DSC) and Micro Calorimetry
6. Electrophoresis and capillary electrophoresis: Basic principles, instrumentation, zone electrophoresis, isoelectric focusing and applications.
7. Solid state Pharmaceutical analysis
   a. Molecular level: Crystallinity, crystal habit, polymorphism, amorphous state, solvates, hydrates, analytical techniques for characterization.
   b. Particle level: Particle size, particle shape, porosity, surface area, particle size analysis using different techniques

8. Radiochemical Analysis

   Importance of Radio isotope **in** medicines, Instrumentation and analysis methods, Radio isotopic analysis, Radio immuno assay

9. Dissolution tests

   Dissolution testing devices viz. forced convection, non sink and sink devices, continuous flow through methods, effect of environmental factors during dissolution testing, dissolution rate test apparatus for suspensions, topical and transdermal products, suppositories and controlled release products, in vitro-in vivo correlations.

Practicals

1. Analysis of dosage forms and biological fluids for drugs and metabolites using the modem techniques studied in theory.
2. Extraction techniques for the extraction of drugs from different dosage forms and their subsequent analysis.
3. Dissolution study of different dosage forms and and its correlation with bioavailability of drugs.

Books Recommended

1. Ebdon, L., Evans, E.H., Hill, S.J., An introduction to analytical atomic spectrometry, 1998.
2. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, Thomson, 2004.
3. Ferraro, John R., Nakamoto, Kazuo, Brown, Chris, W, Introductory Raman Spectroscopy, 2005.
4. Hebbar K. Ramakanth, Basics of X-ray diffraction and its applications, 2007.
5. Westmeier, R., Electrophoresis in practice, 2005.

COURSE NAME: VALIDATION IN PHARMCEUTICAL MANUFACTURING [3PA102]

Learning Outcome:

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

- Utilize fundamentals of different types of validations in pharmaceutical manufacturing.
- Set up, develop and validate new analytical methods for new drugs and substances.
- Describe the process and documentation required like SOP, reports of various processes as well as able to carry out calibration of various equipments.

Theory (Detailed Syllabus)

L	*P*	*C*
3	*3*	*5*

1. Definition, Scope and design of process validation , Validation of API and finished products- Parenteral and nonparenteral.

2. Perspective & Retrospective Process Validation: Organization & documentation of process validation . IQ, OQ and PQ. Preparation of validation protocol.

3. Validation of Analytical Methods, Calibration of Instruments and equipment like pH meter, Dry air oven, Autoclave etc.

4. Validation of sterilization methods and equipments, Dry heat sterilization, Autoclaving , Aseptic membrane filtration.

5. Validation of water supply system, distilled water and water for injection, Validation of air handling equipments in sterile and non-sterile areas.

6. Area qualification, Utility Qualification and Equipment Qualification

7. Introduction to validation of computer assisted process.
8. Cleaning validation .
9. PAT-Introduction, Importance and Application of PAT guidelines.

Practicals

1 Calibration of different glasswares.

2 Calibration and validation of Instruments

3 Validation and optimization of manufacturing processes

4 Validation of sterile area.

Books Recommended

1. Validation in Pharmaceutical industry: concepts, approaches and guidelines by P P Sharma, vandana Publications Pvt Ltd., New Delhi, 2007.

2. Pharmaceutical Process Validaton by Robert A. Nash & Alfred **H.** Wachter, 3'd editi on, Marcel dekk:er Inc., New York.

3. Analytical Method Validation and Instrument Perfonnance Verification by Chung Chow Chan, Y.C. Lee., Herman Lam, Xue-Ming Zhang, John-Wiley & Sons Inc., 2004.

4. Validation of Active Pharmaceutical Ingredients by Ira **R.** Berry & Daniel Harpaz, 2nd edition, CRC Press., 2001.

COURSE NAME: COMMUNICATION SKILLS FOR PHARMACISTS [3PH108]

Learning Outcomes:

After successful completion of the course student will be able to :

- Use appropriate vocabulary for fluent and confident oral communication
- Recognize and understand important aspects of non-verbal communication
- Demonstrate communication capacities in speaking, writing, listening and narrating in English
- Prepare curriculum vitae and job application

Tutorial (Detailed Syllabus)

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Practice Assignments based on the following topics will be conducted

1. **Non-verbal communication**

   Meaning and process of pharmaceutical communication kinesics, types of communication, psychological and social aspects of communication, barriers to effective communication.

2. **Oral communication (verbal communication)**

   Effective presentation skills, group discussion dynamics, personal interview techniques, seminar presentation, media choice for oral presentation, active listening through recorded speech. correct pronunciation, group discussion. delivering the speech or presentation, traditional text based oral presentation. visual element of texts, tables, figures, charts, etc.

3. **Written communication**

   Technical - writing and discussion, technical instructions, writing research papers, paragraph development, curriculum vitae and job application.

4. **Mechanics of language and vocabulary building**

5. **Listening skills**

   Types of listening, barriers to effective listening, tips to improve listening skills.

Books Recommended

1. Tindall W.N, Beardsley R.S., Kimberlin C.L., Communication Skills in Pharmacy Practice: A Practical Guide for Students and Practitioners, Lippincott Williams & Wilkins .

2. J. R. Matthews and R.W. Matthews, Successful Scientific Writing, Cambridge University Press Singapore.
3. R. A. Day, How to write and publish a scientific paper, Cambridge University Press Singapore.
4. A. J. Rutherford , Basic Communication Skills for Technology, Pearson.
5. R.C. Shanna and K. Mohan Business Correspondence and Report Writing Tata McGraw

M. Pharm. Semester - I

COURSE NAME: SUBJECT SEMINAR [3PA103]

L	*T*	*C*
		2

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. E-1
2. Describe the principle, instrumentation and applications of HPLC, HPTLC, SFC and GC methods. S-17,19
3. Discuss the principle, instrumentation and applications of various biochromatographic methods. E-1
4. Explain the instrumentation and applications of various spectroscopic techniques. ENT-13
5. Predict the structural information using mass and NMR spectrometry and related hyphenated techniques. S-17,19

Syllabus: **Teaching hours: 60 Hours**

UNITI E

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 S **12 Hours**

Biochromatography:

Size exclusion chromatography, 10n 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 **E** **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.

UNITIV ENT **12 Hours**

Mass spectrometry:

Principle, theory , instrumentation of mass spectrome try, 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.

UNITV S **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 ofFT-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 Leaming.

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. E-1
2. Determine the biopharmaceutical factors for drug absorntion and drug release.S-17
3. Describe pharmacokinetics and its importance along with toxicokinetics. ENT-13
4. IDiscuss the principle techniques and applications of various cell culture methods. ENT-13
5. Apply bioavailability and bioequivalence principles in drug product performance. S-19

6. Predict the possible metabolite formation of drug product. **E-1**

Syllabus: **Teaching hours: 60 Hours**

UNIT I **E**

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 S **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 **ENT** **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.

UNITIV **ENT** **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.

UNITV E **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: S

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

USFDA and EMEA guidelines. 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. E-1
2. Describe the various quality control guidelines by CDSCO, USFDA, EMEA, WHO etc. ENT-13
3. Determine various quality requirements for drugs and finish products. E-1

4. Report various quality related documents for pharmaceutical manufacturing along with quality certification. S-17,19
5. Relate the importance of operations and controls in pharmaceutical manufacturing. S-19

Syllabus: **Teaching hours: 60 Hours**

UNITI E

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 ENT **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. E

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 S **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.

UNITV S **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 Substance s, Excepients and Dosage forms.* World Health Organization.

6. Hirsch, AF. *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/lSO 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.

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(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. NT-13
2. Identify the adulteration and deterioration of herbal drugs. S-17
3. Analyze the natural products and adulterants. E-1
4. Determine herbal drug-drug interaction. E-1
5. Evaluate cosmetic products. S-19

Syllabus: **Teaching hours: 60 Hours**

UNITI ENT

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 S **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 **E** **12 Hours**

Testing of natural products and drugs:

Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modem 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 **E** **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.

UNITV S **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 A: (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

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(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 ofrelated 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.

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(M. Pharm - Pharmaceutical Analysis)

(Semester - II)

L	T	P	C
		12	6

Course Code	**MPA206S**
Course Title	**Seminar / Assignment – II**

M. Pharm Semester - II

COURSE NAME : APPROACHES TO PHARMACEUTICAL RESEARCH [3PH201]

Learning Outcomes:

After successful completion of the course student will be able to :

- Understand the research process, research design and various aspects related to pharmaceutical research.
- Recall the brilliant discoveries done in past from some of the top pharmaceutical industries through case studies.
- Identify the various governmental and non-governmental funding agencies with their basic criterion for getting research grants.
- Apply the concepts of bio-statistics and its role in the pharmaceutical research.

Theory (Detailed Syllabus)

L	T	C
2	2	4

I. Research

- Aim objective & purpose and need for Research,
- Types of Research
- Selecting a problem and preparing a research proposal,
- Methods, Design and Tools used in research
- Literature Survey, Printing & Secondary Sources oflnformation
- E-Resources
- Documentation - How, techniques , importance and uses of computers
- The research Report/Paper writing/thesis writing and Scientific Writing
- Patent Search and Reading of Patents

II. Presentation of Experimental Data

III. Ethics in Research & Publication

IV. Procurement of Research Grants from various agencies, International Agencies, Government bodies and Private bodies.
Industry - Institute Interaction & Interaction with Research Organization.

V. Case studies of development of pharmaceuticals from Lab sources to the market.

VI. Biostatistics:

Probability theory and distributions, sampling distributions and the central limit theorem. Population parameters and their sample estimates; descriptive statistics for central tendency and

dispersion; hypothesis testing and confidence intervals for means, variances , and proportions; the chi-square statistic; categorical data analysis; linear correlation and regression model; analysis of variance; and nonparametric methods, application in pharmaceutical research

Tutorial

1. Case studies of the above topics mentioned in the theory section.
2. Assignments based on the above syllabus. 3. Writing applications to agencies for Research Grants.

Books Recommended

1. Research In education: John V. Best, James V. Kahn
2. Presentation Skills- Michael Halton- Indian Society for Institute Education
3. A practical Introduction to copyright- Gravin Mcfarlane
4. Thesis Projects in science and Engineering_ Richard M. Davis
5. Scientists in legal System- Ann Labor Science
6. Thesis and Assignment Writing- Jonathan Anderson

COURSE NAME: PHARMACEUTICAL QUALITY ASSURANCE [3PA206]

Learning Outcome:

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

- Analyze raw materials, in-process samples, and finished product in accordance with pharmacopoeia compendia standards.
- Demonstrate a variety of Quality Control activities including developing QC policies and Standard Operation Procedures, analyzing and archiving data, and interpreting results.
- Operationalize, validate, and calibrate a variety of laboratory equipment used in pharmaceutical industrial labs.
- Correlate and Identify unexpected results during routine analyses and help to provide solutions based on scientific and regulatory considerations by implementing preventive action and corrective actions programs.
- Describe the concept of quality systems and compliance in the regulated industry and the role of quality assurance.

Theory (Detailed Syllabus)

L	*P*	*C*
3	*6*	*6*

1. Concepts and Philosophy of TQM, GMP, ISO-9000.
2. Organization and personnel, responsibilities, training, hygiene.
3. Premises: Location, Design, Plan Layout, Construction, Maintenance and Sanitations. Environmental control, Sterile areas, control of contamination.
4. Equipments : Selection, purchase specifications, maintenance.
5. Raw Materials: Purchase specifications, Maintenance of stores, Selection of vendors, Controls on Raw materials.
6. Manufacture of and controls on dosage forms: Manufacturing Documents, Master Formula, Batch Formula Records, Quality audits of manufacturing processes and facilities.
7. Standard operating procedures for various manufacturing steps, for the operation of equipments and instruments etc.
8. Packaging and labeling controls, line clearance, reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass. Types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs; Different types of closures and closure liners

9. Finished product release: Quality review, Quality audits, Batch release document.
10. Warehousing: Good warehousing practice, Materials, Managements.
11. Distribution: Good distribution Practice, Distribution of records, Handling of returned goods, Recovered materials and Reprocessing.
12. Complaints and Recalls: Evaluation of complaints, Recall procedures, related records and documents.
13. Waste disposal, Scrap disposal procedure and records.
14. Loan License Auditing: Concepts, Auditing.
15. Risk management
16. Documentation of the records

Practicals

1 Calibration of volumetric glass wares.

2 Testing containers, closures, liners, glass, plastics used for packing.

3 Sterility testing of areas.

4 Testing ofrelated substances and foreign substances in raw materials as per LP.

5 Assay for the raw materials, calculated either on anhydrous or hydrous basis as per LP.

Books Recommended

1. Quality Assurance Guide Vol I and II, Organization of Pharmaceutical products of India.
2. Sandy Weinberg , Good Laboratory Practice Regulations, 2nd Edition, Vo. 69, Decker Series.
3. Quality Assurance of Pharmaceuticals - A compendium of guidelines and related materials - Vol. I - WHO Publications.
4. Kaushik Maitra and Sedhan K.Ghosh, A guide to Total Quality Management.
5. P. P. Sharma , How to practice GMPs , Vandana Publications Pvt Ltd., Delhi, 2001.
6. ISO 9000 and Total Quality Management - Sadhank. G. Ghosh.
7. The International Pharmacopoeia Vol. 1,2,3,4 - 3rd Edition, General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Controller of Publication, Govt. of India - Indian Pharmacopeia , Vol. I, II, III - 2008.

M. Pharm. [Pharmaceutical Analysis]

Semester - II

COURSE NAME: PHARMACOPOEIAL METHODS OF ANALYSIS [3PA204]

Learning Outcome:

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

- Cite examples of basic analytical methodology used for biotech products.
- Prepare, develop and validate analytical methods for biotech products.
- Analyze biotech products as per pharmacopoeia as well as able to differentiate it with conventional dosage forms.

Theory (Detailed Syllabus)

L	*P*	*C*
3	*3*	5

1. Scope of biotechnology in the development of Pharmacopoeia! articles
2. Analytical methodology for biotechnology derived products
   - Amino Acid analysis
   - Protein sequencing
   - Peptide mapping
   - Imrnuno assays
   - Electrophoresis
   - Quantitative assays
3. Stability testing ofBiotech/ biological products
4. Case study of Analysis of some biotechnology derived products like Interferon Alfa-2 concentrated solution, Erythropoeitin.
5. Limit tests
6. Biological methods
   - Efficacy of antimicrobial preservatives
   - Bacterial endotoxins

- Pyrogens
- Microbial contamination
- Microbiological assay of antibiotics
- Sterility
- Tests for CFUMiscellaneous tests
- Tests for Vaccines
- Tests for Blood and Blood related products

Practicals

1 Practical related to Monograph of different raw materials, dosage forms and biotechnological products

2 Practical related to system suitability tests, Microbiological assays of Antibiotics

3 Limit test and bacterial endotoxin tests for different APIs

Books Recommended

1. Indian Pharmacopoeia, 2014.
2. British Pharmacopoeia, 2010.
3. United States Pharmacopoeia, latest edition.
4. Ajay K. Banga , Therapeutic Peptides & Proteins, 2nd Edition, Taylor Francis.
5. Ronald Reid, Peptide And Protein Drug Analysis, Series: Drug Pharmaceutical Science Vol 101, M. D. Newyork
6. Jones, John , Amino Acid And Peptide Synthesis, 2nd Edition, , Oxford Uni Press.
7. Sumine Yashioka , Valentino J. Stella, Stability Of Drug Dosage Forms,Springer

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.

UNITV **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 oflndia 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.

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(M. Pharm – Pharmaceutical Analysis)

(Semester - III)

L	T	P	C
1			1

Course Code	**MPA302T**
Course Title	**Journal Club – I**

(M. Pharm – Pharmaceutical Analysis)

(Semester - III)

L	T	P	C
2			2

Course Code	**MPA303T**
Course Title	**Discussion / Presentation (Proposal Presentation)**

(M. Pharm – Pharmaceutical Analysis)

(Semester - III)

L	T	P	C
		28	14

Course Code	**MPA304P**
Course Title	**Research Work**

(M. Pharm – Pharmaceutical Analysis)

(Semester - IV)

L	T	P	C
1			1

Course Code	**MPA401T**
Course Title	**Journal Club – II**

(M. Pharm – Pharmaceutical Analysis)

(Semester - IV)

L	T	P	C
		31	16

Course Code	**MPA402P**
Course Title	**Research Work and Colloquium**

(M. Pharm – Pharmaceutical Analysis)

(Semester - IV)

L	T	P	C
3			3

Course Code	**MPA403T**
Course Title	**Discussion / Final Presentation**

COURSE NAME: TRACE ANALYSIS, FOOD & FORENSIC ANALYSIS [3PA305]

(Self-Study Course)

Learning Outcome:

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

- Employ the analytical techniques for determination of metal impurities in bulk drug & formulation.
- Assemble solutions for problems of extraction of analytes from biological samples.
- Manage validation of few categories of drugs like anti-cancer, dialysis fluid.
- Recognize about various types of poisons and analytical techniques used for exact quantification of them from various biological matrix.

Theory (Detailed Syllabus)

L	P	C
4		

1. **Trace Analysis:**
   - Trace metal Analysis
   - Organic Analysis
   - Anion Analysis
   - Raw Material Testing
   - Intermediate / Reaction Product Testing (Based on modern Instruments)
   - **Trace Metal analysis in Biological Samples like** Animal / Human Body Fluids, Organs, Bones and Skin
   - **Estimation of Organometallic based drugs including:**
     - Drugs for ulcer treatment
     - Dialysis drugs
     - Anti-cancer drugs
2. **Food Analysis:**
   - Legislation, standards and Nutrition, General Chemical and Instrumental Methods.

- Contaminants
- Food Additives
- Analysis of Sugar and Preservatives, Starch products, Beverages and Chocolate, Herbs and Spices, cereals, Oils and Fats, Dairy Products.

3. Forensic Analysis

- Forensic Drug Analysis and Toxicology - Analysis of commonly abused drugs in their solid dosage form and in biological media. Emphasis on modern instrumental methods and interpretation of results.
- Collection of forensic samples, preservation of the samples and report filling for forensic evidence analysis

Books Recommended

1. G. David: Pharmaceuticals Analysis, A. Textbook of Phannaceutical Chemistry students, Churchill Living Stone Hercourt Publishers.
2. D. A. Skoog, F. **J.** Holler and T. A. Nieman, Principles oflnstrumental Analysis, Harcourt Asia Pvt. Ltd.
3. W. D. Ehmann and D. E. Vance, Radiochemistry and Nuclear Methods of Analysis, Wiley, New York.
4. R. S. Kirk and R. Sawyer Pearson's Composition and Analysis of Foods, Addson- Weskey, England.
5. Moffat 0, Widdop, Clarke's Analysis of Drugs and Poisons, 3'd Edition, Pharmaceutical Press.
6. Frederick P, Handbook of Forensic Drug Analysis, Academic Press, 2005.

M.Pharm. [Pharmaceutical Analysis) SEMESTER- III

COURSE NAME: MAJOR PROJECT PART – I [3PA303]

L	P	C
		16

M.Pharm. [Pharmaceutical Analysis) SEMESTER- IV

COURSE NAME: MAJOR PROJECT PART – II [3PA401]

L	P	C
		20

COURSE NAME: CLINICAL TRIALS AND PHARMACOVIGILANCE

Course Code: 3EP2P36

Learning Outcomes:

After successful completion of course, students will be able to:

- Design and conduct the various phases of clinical trials.
- Evaluate, monitor, prevent and manage the adverse drug reactions
- Develop the pharmacovigilance programmes.

Theory (Detailed Syllabus)	L	P	C
	2		2

1) Introduction to clinical trials

2) Research design and conduct of clinical trials

   a) Role of pharmacist in clinical trial.

   b) Various phases of clinical trials

   c) Planning and execution of clinical trials

   d) Guidelines of good clinical research practice and ethical requirements

   e) Monitoring and auditing of clinical trials

3) Pharmacovigilance

   - Scope, definition and aim
   - Adverse Drug Reactions (ADRs): Classification, mechanism, predisposing factors, causality assessment
   - Reporting, evaluation, monitoring, preventing and management of ADRs
   - Role of pharmacists in management of ADR
   - Counterfeit medicines

Books Recommended

1. Fundamental of Clinical Trials. Lawrence M. Friedman, Curt D. Furberg and David L. DeMets. Springer verlag, New York, Inc.
2. Clinical Trials, A Practical Approach. Stuart J. Pocock. John Wiley & Sons, Ltd.

3. Clinical Trials, A Methodologic Perspective. Steven Piantadosi. John Wiley & Sons, Inc, NZ.

4. Clinical Trials in oncology, Stephanie Green, Jacqueline Benedetti, John Crowley, Chapman & Hall/CRC, London.

COURSE NAME: QUALITY BY DESIGN FOR PHARMACEUTICALS

Course Code: 3EP2T52

Learning outcomes:

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

- Understand the concept of quality by design and its applications in pharmaceutical research
- Apply quality by design for optimization of dosage forms, method development, drug discovery and clinical trials
- Analyze data generated using factorial design, composite design, simplex lattice design etc.
- Evaluate experimental design data using softwares and statistical tools.
- Create methodology to develop cost effective robust formulation/method as er regulatory requirements .

Theory (Detailed Syllabus)

L	P	C
3		3

1. Introduction

History of existing formulation development methodology, Basic concepts & objectives of quality by design (QbD) approaches. Importance with special emphasis on safety, effectiveness and quality from the perspective of patients requirements.

2. Fundamentals of QbD

Defining target product profile, target product quality profile and critical quality attributes, risk assessment, fishbone diagram, Design space and control strategies.

3. QbD for formulation of dosage forms

Implementation of QbD at formulation development and manufacturing liquid, semisolid, solid and sterile formulations.

4. Design of Experiment(DOE) and Process analytical tool (PAT

Introduction, types, scope and applications, brief overview of screening designs, response surface methodology etc., concepts and application of PAT

5. An overview of pharmaceutical development guidelines like Q8, Q9, QlO and other regulatory guidelines related to QbD.

Total Lectures: 45

Books Recommended :

1. Pharmaceutical Statistics by Sanford Bolton, 2nd Editi on, 2008, Marcel Dekker Inc., New York, USA.
2. New Drug Approval Process: Accelerating Global Registrations by Richard A. Guarino, 2005, Marcel Dekker, New York, USA.
3. Pharmaceutical Experimental Design by Gareth A. Lewis, Didier Mathieu and Roger Phan-Tan-Luu,, 2005, Marcel and Dekker, New York, USA.
4. http://www.fda.gov/ Quality by design for ANDAs: An example for imme diate/modified release dosage forms.