PHARMACEUTICAL ANALYSIS (MPA)

SEMESTER - I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPA 101T)

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

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

THEORY 60 Hrs

1. a. 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. — 10 Hrs

   b. 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.

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

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

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. — 10 Hrs

3 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. — 10 Hrs

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

a. Thin Layer chromatography
b. High Performance Thin Layer Chromatography
c. Ion exchange chromatography
d. Column chromatography
e. Gas chromatography
f. High Performance Liquid chromatography
g. Ultra High Performance Liquidchromatography
h. Affinity chromatography
i. Gel Chromatography

10 Hrs

5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
b. 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

10 Hrs

6 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.

10 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACEUTICAL ANALYSIS
(MPA 102T)

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,

- Appropriate analytical skills required for the analytical method development.
- 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.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY — 60 Hrs

1. **Impurity and stability studies:** — 10 Hrs

   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

2. **Elemental impurities:** — 10 Hrs

   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.

3	Impurity profiling and degradent characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products	10 Hrs
4	Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.	10 Hrs
5	Biological tests and assays of the following: a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)	10 Hrs
6	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.	10 Hrs

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I, II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION
(MPA 103T)

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

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

	THEORY	60 Hrs
1.	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.	12 Hrs
2	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.	12 Hrs
3	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).	12 Hrs
4	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.	12 Hrs

5	General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	12 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Upl, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

FOOD ANALYSIS
(MPA 104T)

Scope

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

Objectives

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

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY — 60 Hrs

1. Carbohydrates: 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. — 12 Hrs

2 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 of vitamins of B-series. — 12 Hrs

3 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. — 12 Hrs

4	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.	12 Hrs
5	Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine 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.	12 Hrs

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICAL - I
(MPA 105PA)

1. Calibration of glasswares
2. Calibration of pH meter
3. Calibration of UV-Visible spectrophotometer
4. Calibration of FTIR spectrophotometer
5. Calibration of GC instrument
6. Calibration of HPLC instrument
7. Cleaning validation of any one equipment
8. Imupurity profiling of drugs
9. Assay of official compounds by different titrations
10. Assay of official compounds by instrumental techniques.
11. Estimation of riboflavin/quinine sulphate by fluorimetry
12. Estimation of sodium/potassium by flame photometry
13. Quantitative determination of hydroxyl group.
14. Quantitative determination of amino group
15. Colorimetric determination of drugs by using different reagents

PHARMACEUTICAL ANALYSIS PRACTICAL - II
(MPA 105PB)

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. Determination of total reducing sugar
6. Determination of proteins
7. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
8. Determination of fat content and rancidity in food products
9. Analysis of natural and synthetic colors in food
10. Determination of preservatives in food
11. Determination of pesticide residue in food products
12. Analysis of vitamin content in food products
13. Determination of density and specific gravity of foods
14. Determination of food additives

SEMESTER - II

ADVANCED INSTRUMENTAL ANALYSIS
(MPA 201T)

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,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

THEORY		60 Hrs
1.	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.	12 Hrs
2	Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.	12 Hrs
3	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	12 Hrs

4	Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.	12 Hrs
5	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.	12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES
(MPA 202T)

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY	60 Hrs
1. 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.	12 Hrs
2 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.	12 Hrs
3 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.	12 Hrs
4 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.	12 Hrs

5 Metabolite identification: 12 Hrs

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met–ID. Regulatory perspectives.

In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

QUALITY CONTROL AND QUALITY ASSURANCE
(MPA 203T)

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

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

THEORY — 60 hrs

1. Concept and Evolution of Quality Control and Quality Assurance — 12 Hrs

   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 nonclinical testing, control on animal house, report preparation and documentation.

2. 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. — 12 Hrs

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) — 12 Hrs

   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.

4. 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. 12 Hrs

5. 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. 12 Hrs

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

HERBAL AND COSMETIC ANALYSIS
(MPA 204T)

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

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

	THEORY	60 Hrs
1.	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.	12 Hrs
2	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.	12 Hrs
3	Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.	12 Hrs

4	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.	12 Hrs
5	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.	12 Hrs

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr. S.H. Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PHARMACEUTICAL ANALYSIS PRACTICAL - III
(MPA 205PA)

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.

PHARMACEUTICAL ANALYSIS PRACTICAL - IV
(MPA 205PB)

1. In process and finished product quality control tests for tablets, capsules, parenterals and creams
2. Quality control tests for Primary and secondary packing materials
3. Assay of raw materials as per official monographs
4. Testing of related and foreign substances in drugs and raw materials
5. Preparation of Master Formula Record.
6. Preparation of Batch Manufacturing Record.
7. Quantitative analysis of rancidity in lipsticks and hair oil
8. Determination of aryl amine content and Developer in hair dye
9. Determination of foam height and SLS content of Shampoo.
10. Determination of total fatty matter in creams (Soap, skin and hair creams)
11. Determination of acid value and saponification value.
12. Determination of calcium thioglycolate in depilatories

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

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.

UNIT – III

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

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.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

(R-13) PA-QC - 16-17

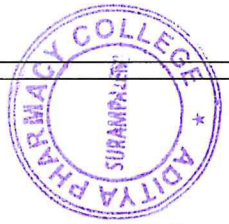
ACADEMIC EGULATIONS COURSE STRUCTURE AND DETAILED SYLLABUS

For

M.PHARMACY

Pharmaceutical analysis & Quality Control

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India



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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

ACADEMIC REGULATIONS R13 FOR M. Tech (REGULAR) DEGREE COURSE

Applicable for the students of M. Tech (Regular) Course from the Academic Year 2013-14 onwards

The M. Tech Degree of Jawaharlal Nehru Technological University Kakinada shall be conferred on candidates who are admitted to the program and who fulfil all the requirements for the award of the Degree.

1.0 ELIGIBILITY FOR ADMISSIONS

Admission to the above program shall be made subject to eligibility, qualification and specialization as prescribed by the University from time to time.

Admissions shall be made on the basis of merit/rank obtained by the candidates at the qualifying Entrance Test conducted by the University or on the basis of any other order of merit as approved by the University, subject to reservations as laid down by the Govt. from time to time.

2.0 AWARD OF M. Tech DEGREE

2.1 A student shall be declared eligible for the award of the M. Tech Degree, if he pursues a course of study in not less than two and not more than four academic years.
2.2 The student shall register for all 80 credits and secure all the 80 credits.
2.3 The minimum instruction days in each semester are 90.

3.0 A. COURSES OF STUDY

The following specializations are offered at present for the M. Tech course of study.

1. M.Tech- Structural Engineering
2. M.Tech- Transportation Engineering
3. M.Tech- Infrastructure Engineering & Management
4. ME- Soil Mechanics and Foundation Engineering
5. M.Tech- Power Electronics
6. M.Tech- Power & Industrial Drives
7. M.Tech- Power Electronics & Electrical Drives
8. M.Tech- Power System Control & Automation
9. M.Tech- Power Electronics & Drives
10. M.Tech- Power Systems
11. M.Tech- Power Systems Engineering
12. M.Tech- High Voltage Engineering
13. M.Tech- Power Electronics and Power Systems
14. M.Tech- Power System and Control
15. M.Tech- Power Electronics & Systems
16. M.Tech- Electrical Machines and Drives
17. M.Tech- Advanced Power Systems
18. M.Tech- Power Systems with Emphasis on High Voltage Engineering
19. M.Tech- Control Engineering
20. M.Tech- Instrumentation & Control
21. M.Tech- Control Systems
22. M.Tech- Thermal Engineering
23. M.Tech- CAD/CAM
24. M.Tech- Machine Design
25. M.Tech- Computer Aided Design and Manufacture
26. M.Tech- Advanced Manufacturing Systems
27. M.Tech- Systems and Signal Processing
28. M.Tech- Digital Electronics and Communication Systems

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29. M.Tech- Electronics & Communications Engineering
30. M.Tech- Communication Systems
31. M.Tech- Communication Engineering & Signal Processing
32. M.Tech- Microwave and Communication Engineering
33. M.Tech- Telematics
34. M.Tech- Digital Systems & Computer Electronics
35. M.Tech- Embedded System
36. M.Tech- VLSI
37. M.Tech- VLSI Design
38. M.Tech- VLSI System Design
39. M.Tech- Embedded System & VLSI Design
40. M.Tech- VLSI & Embedded System
41. M.Tech- VLSI Design & Embedded Systems
42. M.Tech- Computer Science & Engineering
43. M.Tech- Computer Science
44. M.Tech- Computer Science & Technology
45. M.Tech- Image Processing
46. M.Tech- Digital Image Processing
47. M.Tech- Computers & Communication
48. M.Tech- Computers & Communication Engineering
49. M.Tech- Computer Networks
50. M.Tech- Computer Networks & Information Security
51. M.Tech- Information Technology
52. M.Tech- Software Engineering
53. M.Tech- Neural Networks
54. M.Tech- Chemical Engineering
55. M.Tech- Biotechnology
56. M.Tech- Nano Technology
57. M.Tech- Remote Sensing
58. M.Tech- Food Processing
59. M.Tech- Avionics

and any other course as approved by AICTE/ University from time to time.

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3.0 B. Departments offering M. Tech Programmes with specializations are noted below:

Civil Engg.	1. M.Tech- Structural Engineering 2. M.Tech- Transportation Engineering 3. M.Tech- Infrastructure Engineering & Management 4. ME- Soil Mechanics and Foundation Engineering
EEE	1. M.Tech- Power Electronics 2. M.Tech- Power & Industrial Drives 3. M.Tech- Power Electronics & Electrical Drives 4. M.Tech- Power System Control & Automation 5. M.Tech- Power Electronics & Drives 6. M.Tech- Power Systems 7. M.Tech- Power Systems Engineering 8. M.Tech- High Voltage Engineering 9. M.Tech- Power Electronics and Power Systems 10. M.Tech- Power System and Control 11. M.Tech- Power Electronics & Systems 12. M.Tech- Electrical Machines and Drives 13. M.Tech- Advanced Power Systems 14. M.Tech- Power Systems with Emphasis on High Voltage Engineering 15. M.Tech- Control Engineering 16. M.Tech- Instrumentation & Control 17. M.Tech- Control Systems
ME	1. M.Tech- Thermal Engineering 2. M.Tech- CAD/CAM 3. M.Tech- Machine Design 4. M.Tech- Computer Aided Design and Manufacture 5. M.Tech- Advanced Manufacturing Systems
ECE	1. M.Tech- Systems and Signal Processing 2. M.Tech- Digital Electronics and Communication Systems 3. M.Tech- Electronics & Communications Engineering 4. M.Tech- Communication Systems 5. M.Tech- Communication Engineering & Signal Processing 6. M.Tech- Microwave and Communication Engineering 7. M.Tech- Telematics 8. M.Tech- Digital Systems & Computer Electronics 9. M.Tech- Embedded System 10. M.Tech- VLSI 11. M.Tech- VLSI Design 12. M.Tech- VLSI System Design 13. M.Tech- Embedded System & VLSI Design 14. M.Tech- VLSI & Embedded System 15. M.Tech- VLSI Design & Embedded Systems 16. M.Tech- Image Processing 17. M.Tech- Digital Image Processing 18. M.Tech- Computers & Communication 19. M.Tech- Computers & Communication Engineering
CSE	1. M.Tech- Computer Science & Engineering 2. M.Tech- Computer Science 3. M.Tech- Computer Science & Technology 4. M.Tech- Computer Networks

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	5. M.Tech- Computer Networks & Information Security 6. M.Tech- Information Technology 7. M.Tech- Software Engineering 8. M.Tech- Neural Networks
Others	1. M.Tech- Chemical Engineering 2. M.Tech- Biotechnology 3. M.Tech- Nano Technology 4. M.Tech- Remote Sensing 5. M.Tech- Food Processing 6. M.Tech- Avionics

4.0 ATTENDANCE

4.1 A student shall be eligible to write University examinations if he acquires a minimum of 75% of attendance in aggregate of all the subjects.

4.2 Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester shall be granted by the College Academic Committee.

4.3 Shortage of Attendance below 65% in aggregate shall not be condoned.

4.4 Students whose shortage of attendance is not condoned in any semester are not eligible to write their end semester examination of that class.

4.5 A prescribed fee shall be payable towards condonation of shortage of attendance.

4.6 A student shall not be promoted to the next semester unless he satisfies the attendance requirement of the present semester, as applicable. They may seek readmission into that semester when offered next. If any candidate fulfills the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.

5.0 EVALUATION

The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks for theory and 100 marks for practicals, on the basis of Internal Evaluation and End Semester Examination.

5.1 For the theory subjects 60 marks shall be awarded based on the performance in the End Semester Examination and 40 marks shall be awarded based on the Internal Evaluation. The internal evaluation shall be made based on the **average** of the marks secured in the two Mid Term-Examinations conducted-one in the middle of the Semester and the other immediately after the completion of instruction. Each mid term examination shall be conducted for a total duration of 120 minutes with 4 questions (without choice) each question for 10 marks. End semester examination is conducted for 60 marks for 5 questions to be answered out of 8 questions.

5.2 For practical subjects, 60 marks shall be awarded based on the performance in the End Semester Examinations and 40 marks shall be awarded based on the day-to-day performance as Internal Marks.

5.3 There shall be two seminar presentations during III semester and IV semester. For seminar, a student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the department in a report form and shall make an oral presentation before the Project Review Committee consisting of Head of the Department, Supervisor and two other senior faculty members of the department. For each Seminar there will be only internal evaluation of 50 marks. A candidate has to secure a minimum of 50% of marks to be declared successful.

5.4 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End semester Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

5.5 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 5.4) he has to reappear for the End semester Examination in that subject. A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and has failed in the end examination. In such a case, the candidate must re-register for the subject(s) and secure the required minimum

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attendance. The candidate's attendance in the re-registered subject(s) shall be calculated separately to decide upon his eligibility for writing the end examination in those subject(s). In the event of the student taking another chance, his internal marks and end examination marks obtained in the previous attempt stand cancelled. For re-registration the candidates have to apply to the University through the college by paying the requisite fees and get approval from the University before the start of the semester in which re-registration is required.

5.6 In case the candidate secures less than the required attendance in any re registered subject (s), he shall not be permitted to write the End Examination in that subject. He shall again re-register the subject when next offered.

5.7 Laboratory examination for M. Tech. courses must be conducted with two Examiners, one of them being the Laboratory Class Teacher or teacher of the respective college and the second examiner shall be appointed by the university from the panel of examiners submitted by the respective college.

6.0 EVALUATION OF PROJECT/DISSERTATION WORK

Every candidate shall be required to submit a thesis or dissertation on a topic approved by the Project Review Committee.

6.1 A Project Review Committee (PRC) shall be constituted with Head of the Department and two other senior faculty members.

6.2 Registration of Project Work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects, both theory and practical.

6.3 After satisfying 6.2, a candidate has to submit, in consultation with his project supervisor, the title, objective and plan of action of his project work for approval. The student can initiate the Project work, only after obtaining the approval from the Project Review Committee (PRC).

6.4 If a candidate wishes to change his supervisor or topic of the project, he can do so with the approval of the Project Review Committee (PRC). However, the Project Review Committee (PRC) shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of project proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

6.5 A candidate shall submit his status report in two stages at least with a gap of 3 months between them.

6.6 The work on the project shall be initiated at the beginning of the II year and the duration of the project is two semesters. A candidate is permitted to submit Project Thesis only after successful completion of theory and practical course with the approval of PRC not earlier than 40 weeks from the date of registration of the project work. The candidate has to pass all the theory and practical subjects before submission of the Thesis.

6.7 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College/School/Institute.

6.8 The thesis shall be adjudicated by one examiner selected by the University. For this, the Principal of the College shall submit a panel of 5 examiners, eminent in that field, with the help of the guide concerned and head of the department.

6.9 If the report of the examiner is not favourable, the candidate shall revise and resubmit the Thesis, in the time frame as decided by the PRC. If the report of the examiner is unfavorable again, the thesis shall be summarily rejected. The candidate has to re-register for the project and complete the project within the stipulated time after taking the approval from the University.

6.10 If the report of the examiner is favourable, Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the examiner who adjudicated the Thesis. The Board shall jointly report the candidate's work as one of the following:

A. Excellent
B. Good
C. Satisfactory
D. Unsatisfactory

The Head of the Department shall coordinate and make arrangements for the conduct of Viva-Voce examination.

6.11 If the report of the Viva-Voce is unsatisfactory, the candidate shall retake the Viva-Voce examination only after three months. If he fails to get a satisfactory report at the second Viva-

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Voce examination, the candidate has to re-register for the project and complete the project within the stipulated time after taking the approval from the University.

7.0 AWARD OF DEGREE AND CLASS

After a student has satisfied the requirements prescribed for the completion of the program and is eligible for the award of M. Tech. Degree he shall be placed in one of the following four classes:

Class Awarded	% of marks to be secured
First Class with Distinction	70% and above (Without any Supplementary Appearance)
First Class	Below 70% but not less than 60%
	70% and above (With any Supplementary Appearance)
Second Class	Below 60% but not less than 50%

The marks in internal evaluation and end examination shall be shown separately in the memorandum of marks.

8.0 WITHHOLDING OF RESULTS

If the student has not paid the dues, if any, to the university or if any case of indiscipline is pending against him, the result of the student will be withheld. His degree will be withheld in such cases.

8.0 TRANSITORY REGULATIONS (for R09)

9.1 Discontinued or detained candidates are eligible for re-admission into same or equivalent subjects at a time as and when offered.

9.2 The candidate who fails in any subject will be given two chances to pass the same subject; otherwise, he has to identify an equivalent subject as per R13 academic regulations.

10. GENERAL

10.1 Wherever the words "he", "him", "his", occur in the regulations, they include "she", "her", "hers".

10.2 The academic regulation should be read as a whole for the purpose of any interpretation.

10.3 In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.

10.4 The University may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the University.

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KAKINADA - 533 003, Andhra Pradesh, India

MALPRACTICES RULES

DISCIPLINARY ACTION FOR / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive	Cancellation of the performance in that subject.

	language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	
6.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.

11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions : (if the squad reports that the college is also involved in encouraging malpractices)
   - (i) A show cause notice shall be issued to the college.
   - (ii) Impose a suitable fine on the college.
   - (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

For Constituent Colleges and Affiliated Colleges of JNTUK

Ragging

Prohibition of ragging in educational institutions Act 26 of 1997

Salient Features

- Ragging within or outside any educational institution is prohibited.
- Ragging means doing an act which causes or is likely to cause Insult or Annoyance of Fear or Apprehension or Threat or Intimidation or outrage of modesty or Injury to a student

	Imprisonment upto		Fine
Teasing, Embarrassing and Humiliation	6 Months	+	Rs. 1,000/-
Assaulting or Using Criminal force or Criminal intimidation	1 Year	+	Rs. 2,000/-
Wrongfully restraining or confining or causing hurt	2 Years	+	Rs. 5,000/-
Causing grievous hurt, kidnapping or Abducts or rape or committing unnatural offence	5 Years	+	Rs. 10,000/-
Causing death or abetting suicide	10 Months	+	Rs. 50,000/-

In Case of Emergency CALL TOLL FREE NO. : 1800 - 425 - 1288

LET US MAKE JNTUK A RAGGING FREE UNIVERSITY

ADITYA PHARMACY COLLEGE SURAMPALEM

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

For Constituent Colleges and Affiliated Colleges of JNTUK

Ragging
ABSOLUTELY
NO TO RAGGING

1. Ragging is prohibited as per Act 26 of A.P. Legislative Assembly, 1997.
2. Ragging entails heavy fines and/or imprisonment.
3. Ragging invokes suspension and dismissal from the College.
4. Outsiders are prohibited from entering the College and Hostel without permission.
5. Girl students must be in their hostel rooms by 7.00 p.m.
6. All the students must carry their Identity Cards and show them when demanded
7. The Principal and the Wardens may visit the Hostels and inspect the rooms any time.

Jawaharlal Nehru Technological University Kakinada
For Constituent Colleges And Affiliated Colleges of JNTUK

In Case of Emergency CALL TOLL FREE NO. : 1800 - 425 - 1288

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL

I SEMESTER

Paper 101	-	Modern Analytical Techniques
Paper 102	-	Research Methodologies
Paper 103	-	Advanced Pharmaceutical Analysis - I
Paper 104	-	Chromatographic and Other Special Techniques
Paper 105	-	Advanced Pharmaceutical Analysis-I - LAB
Paper 106	-	Chromatographic and Other Special Techniques - LAB
Paper 107	-	Seminar

II SEMESTER

Paper 201	-	Advanced Pharmaceutical Analysis - II
Paper 202	-	Quality Control of Pharmaceuticals
Paper 203	-	Quality Assurance of Pharmaceuticals – I
Paper 204	-	Drug Regulatory Affairs
Paper 205	-	Advanced Pharmaceutical Analysis - II - LAB
Paper 206	-	Quality Control of Pharmaceuticals - LAB
Paper 207	-	Seminar

III SEMESTER

Paper 301	-	Seminar-I
Paper 302	-	Project Work – I

IV SEMESTER

Paper 401	-	Seminar-II
Paper 402	-	Project Work – II
Paper 403	-	Comprehensive Viva Voce

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
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SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL

I SEMESTER							
Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60			100	3
Paper – 102	Research Methodologies	40	60			100	3
Paper – 101	Advanced Pharmaceutical Analysis-I	40	60			100	3
Paper – 102	Chromatographic and Other Special Techniques	40	60			100	3
Paper – 104	Advanced Pharmaceutical Analysis-I Practical			40	60	100	2
Paper – 105	Chromatographic and Other Special Techniques Practical			40	60	100	2
Paper – 106	Seminar					100	2
	TOTAL					700	18

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II SEMESTER							
Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 201	Advanced Pharmaceutical Analysis-II	40	60			100	3
Paper –202	Quality Control of Pharmaceuticals	40	60			100	3
Paper – 203	Quality Assurance of Pharmaceuticals-I	40	60			100	3
Paper – 204	Drug Regulatory affairs	40	60			100	3
Paper – 205	Advanced Pharmaceutical Analysis-II Practical			40	60	100	2
Paper – 206	Quality Control of Pharmaceuticals			40	60	100	2
Paper – 207	Seminar					100	2
	TOTAL					700	18

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III SEMESTER			
Paper No.		Marks	Credits
Paper - 301	Seminar – I	50	2
Paper - 302	Project work – I	100	14
	Total	150	16

IV SEMESTER			
Paper No.		Marks	Credits
Paper - 401	Seminar – II	50	2
Paper – 402	Project work – II	100	14
Paper - 403	Comprehensive Viva Voce	100	4
	Total	250	20
Grand Total (Four Semesters)		1800	72

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

M.PHARM SYLLABUS FOR PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL

I-I	MODERN ANALYTICAL TECHNIQUES (Paper Common for all Specializations)	L / P / Credits -- / -- / 3

Principles, instrumentation and applications of the following Instruments and Chromatography techniques

UNIT- I

i. UV- Visible Spectrophotometry
ii. Infrared Spectroscopy
iii. Spectrofluorimetry

UNIT- II

i. NMR Spectroscopy
ii. Electron Spin Resonance Spectroscopy
iii. Atomic Emission Spectroscopy

UNIT- III

i. HPLC
ii. HPTLC
iii. Exclusion Chromatography
iv. Super Critical Fluid Chromatography

UNIT- IV

i. Mass Spectroscopy including LCMS & GCMS
ii. GLC

UNIT- V

i. Phase Emission Spectroscopy
ii. X-Ray Diffractometry
iii. Optical Rotatory Diffusion
iv. Vapour phase Chromatography
v. Affinity Chromatography
vi. Ion-exchange Chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. I &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy B Silversterin

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I-I	RESEARCH METHODOLOGIES (Paper common for all Specializations)	L / P / Credits -- / -- / 3

UNIT I

Statistical Methods:

Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution

Error and its significance-Measures of Error- Control of Error in Experimental Investigations – Problem Solving.

UNIT II

Correlation and Regression, Multiple Regression - Problem Solving

UNIT III

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples – Problem Solving

UNIT IV

Design of Experiments

Criteria of a good design with examples.

Principles- Randomization, replication and local control.

Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples – Problem Solving

UNIT V

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research- Problem Solving

Optimisation Techniques: Optimisation Techniques based on Factorial Experiments - Problem Solving.

Recommended Books:

1. Fundamentals of Biostatistics by Khan & Khanum, Ukaaz Publications, Hyderabad
2. Theory & Practice of Industrial Pharmacy by Leon Lachman and Others
3. Remingtons Practice of Pharmaceutical sciences, (Latest Edition)
4. Principles of Biostatistics by Marcello Pagnano, Published by Brooks/Cole, (Saurabh Printers Pvt. Ltd)
5. Introduction To Biostatistics – A text book of biometry By Pranab Kumar Banerjee

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

I-I ADVANCED PHARMACEUTICAL ANALYSIS-I **L / P / Credits**
-- / -- / 3

UNIT-I

1. Good Laboratory practices (GLP), Laboratory maintenance, standard operating procedures (SOPS), Validation of analytical instruments and methods. – Quality Control Laboratory Regulatory requirements

UNIT-II

1. Theory, Instrumentation and application with regard to drug analysis, decomposition product identification and estimation and metabolite analysis based on the following:

a) Ultraviolet visible spectrophotometry
b) Infrared Spectrophotometry
c) Fluoremetry, Nephelometry and Turbidimetry

UNIT-III

1. Polarography.
2. Flame emission spectroscopy and atomic absorption spectroscopy. Principle, Instrumentation and applications in Pharmacy.

UNIT-IV

1. Thermal Methods of Analysis: Theory of Thermo gravimetric analysis (TGA), Differential Thermal analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).
2. An advanced study of non - aqueous titrations involving the following:

a) Primary, Secondary and Tertiary amines
b) Halogenated salts and bases
c) Acidic substances
d) Assays of official drugs in IP 1996 by non - aqueous titrimetry
e) Aquametry: Determination of water by titration with Karl Fischer Reagent (KFR).

UNIT-V

1. Principles and pharmaceutical applications of redox titrations involving:

a) Potassium lodate / bromate titrations
h) Ceric ammonium sulphate titrations
c) Tanus Chloride titration
d) Examples of assays of official drugs in IP 1996.

2. Principles and Pharmaceutical applications of complexometric titrations involving:

a) Direct titration of Polymetallic system with Sodium EDTA
b) Back titration with sodium EDTA
c) titration involving the displacement of one complex by another
d) PM indicators
e) Examples of assays official drugs in IP 1996.

ADITYA PHARMACY COLLEGE SURAMPALEM

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KAKINADA - 533 003, Andhra Pradesh, India

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

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I-I	CHROMATOGRAPHIC AND OTHER SPECIAL TECHNIQUES	L / P / Credits -- / -- / 3

UNIT-I

An advanced study of the following and their applications.
Basic principle and separation by Column chromatography, thin layer chromatography, paper chromatography and ion exchange chromatography.

UNIT-II

Gas Chromatography: Introduction, theory, column operation, instrumentation and detection, GCMS.

UNIT-III

High Pressure Liquid Chromatography: Principle, Instrumentation procedure, solvents used, elution techniques, LCMS and applications.

UNIT-IV

1. HPTLC and Supercritical Fluid Chromatography (SFC): Principle, instrumentation procedure, elution technique and pharmaceutical applications.
2. H.P.C.P.C

UNIT-V

1. Electrophoreses (gel and capillary)
2. Radio immuno assay and related immuno assays — RIA, ELISA

TEXT BOOKS

1. Instrumental Methods of Analysis by Scog and West.
2. Instrumental Mcthods of Analysis by B.K.Sharma
3. Instrumental methods of Analysis by Willard & Merrit.
4. High Performance Liquid Chromatography by P. D. Sethy.
5.Liquid Chromatography-Mass Spectrometry, Third Edition by by Wilfried M.A. Niessen

REFERENCE BOOKS

1. USP
2. Remington's Pharmaceutical Sciences.
3. Spectroscopy by Silversterin
4. Instrumental methods of Analysis by Hibart. H. Willard.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

I-I ADVANCED PHARMACEUTICAL ANALYSIS –I **L / P / Credits**
-- / -- / 2

1. Use of spectrophotometer for analysis of Pharmacopoeial compounds and their formulations.
2. Use of fluorimeter for analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for analysis of Na, K & Ca etc in Biological fluids and formulations.
4. Use of Nephelo- Turbidimetric analysis of dispersions and limit tests.
5. Assays involving following procedures: Non – Aqueous, Diazotisation, Complexation and Redox titrations.
6. Official (I.P) Assays based on theory.

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

I-I	CHROMATOGRAPHIC AND OTHER SPECIAL TECHN1QUES LAB	L / P / Credits -- / -- / 2

1. Experiments on Electrophoresis.
2. Experiments of Chromatography:
   a) Ascending technique
   b) Descending technique
   c) Circular technique
3. Experiments using HPLC & GC.

TEXT BOOKS

1. Instrumental Methods of Analysis by Scog and West.
2. Instrumental Methods of Analysis by B.K.Sharma
3. Instrumental methods of Analysis by Willard & Merrit.
4. High Performance Liquid Chromatography by P. D. Sethy.

REFERENCE BOOKS

1. USP
2. Remington's Pharmaceutical Sciences.
3. Spectroscopy by Silversterin
4. Instrumental methods of Analysis by Hibart. H. Willard.

R-13
QA
(16-17)

ACADEMIC REGULATIONS COURSE STRUCTURE AND DETAILED SYLLABUS

For
M.PHARMACY
PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA
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KAKINADA - 533 003, Andhra Pradesh, India

3.0 B. Departments offering M. Tech Programmes with specializations are noted below:

Civil Engg.	1. M.Tech- Structural Engineering 2. M.Tech- Transportation Engineering 3. M.Tech- Infrastructure Engineering & Management 4. ME- Soil Mechanics and Foundation Engineering
EEE	1. M.Tech- Power Electronics 2. M.Tech- Power & Industrial Drives 3. M.Tech- Power Electronics & Electrical Drives 4. M.Tech- Power System Control & Automation 5. M.Tech- Power Electronics & Drives 6. M.Tech- Power Systems 7. M.Tech- Power Systems Engineering 8. M.Tech- High Voltage Engineering 9. M.Tech- Power Electronics and Power Systems 10. M.Tech- Power System and Control 11. M.Tech- Power Electronics & Systems 12. M.Tech- Electrical Machines and Drives 13. M.Tech- Advanced Power Systems 14. M.Tech- Power Systems with Emphasis on High Voltage Engineering 15. M.Tech- Control Engineering 16. M.Tech- Instrumentation & Control 17. M.Tech- Control Systems
ME	1. M.Tech- Thermal Engineering 2. M.Tech- CAD/CAM 3. M.Tech- Machine Design 4. M.Tech- Computer Aided Design and Manufacture 5. M.Tech- Advanced Manufacturing Systems
ECE	1. M.Tech- Systems and Signal Processing 2. M.Tech- Digital Electronics and Communication Systems 3. M.Tech- Electronics & Communications Engineering 4. M.Tech- Communication Systems 5. M.Tech- Communication Engineering & Signal Processing 6. M.Tech- Microwave and Communication Engineering 7. M.Tech- Telematics 8. M.Tech- Digital Systems & Computer Electronics 9. M.Tech- Embedded System 10. M.Tech- VLSI 11. M.Tech- VLSI Design 12. M.Tech- VLSI System Design 13. M.Tech- Embedded System & VLSI Design 14. M.Tech- VLSI & Embedded System 15. M.Tech- VLSI Design & Embedded Systems 16. M.Tech- Image Processing 17. M.Tech- Digital Image Processing 18. M.Tech- Computers & Communication 19. M.Tech- Computers & Communication Engineering
CSE	1. M.Tech- Computer Science & Engineering 2. M.Tech- Computer Science 3. M.Tech- Computer Science & Technology 4. M.Tech- Computer Networks 5. M.Tech- Computer Networks & Information Security 6. M.Tech- Information Technology 7. M.Tech- Software Engineering 8. M.Tech- Neural Networks

Others	1. M.Tech- Chemical Engineering 2. M.Tech- Biotechnology 3. M.Tech- Nano Technology 4. M.Tech- Remote Sensing 5. M.Tech- Food Processing 6. M.Tech- Avionics

4.0 ATTENDANCE

4.1 A student shall be eligible to write University examinations if he acquires a minimum of 75% of attendance in aggregate of all the subjects.

4.2 Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester shall be granted by the College Academic Committee.

4.3 Shortage of Attendance below 65% in aggregate shall not be condoned.

4.4 Students whose shortage of attendance is not condoned in any semester are not eligible to write their end semester examination of that class.

4.5 A prescribed fee shall be payable towards condonation of shortage of attendance.

4.6 A student shall not be promoted to the next semester unless he satisfies the attendance requirement of the present semester, as applicable. They may seek readmission into that semester when offered next. If any candidate fulfills the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.

5.0 EVALUATION

The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks for theory and 100 marks for practicals, on the basis of Internal Evaluation and End Semester Examination.

5.1 For the theory subjects 60 marks shall be awarded based on the performance in the End Semester Examination and 40 marks shall be awarded based on the Internal Evaluation. The internal evaluation shall be made based on the **average** of the marks secured in the two Mid Term-Examinations conducted-one in the middle of the Semester and the other immediately after the completion of instruction. Each mid term examination shall be conducted for a total duration of 120 minutes with 4 questions (without choice) each question for 10 marks. End semester examination is conducted for 60 marks for 5 questions to be answered out of 8 questions.

5.2 For practical subjects, 60 marks shall be awarded based on the performance in the End Semester Examinations and 40 marks shall be awarded based on the day-to-day performance as Internal Marks.

5.3 There shall be two seminar presentations during III semester and IV semester. For seminar, a student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the department in a report form and shall make an oral presentation before the Project Review Committee consisting of Head of the Department, Supervisor and two other senior faculty members of the department. For each Seminar there will be only internal evaluation of 50 marks. A candidate has to secure a minimum of 50% of marks to be declared successful.

5.4 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End semester Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

5.5 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 5.4) he has to reappear for the End semester Examination in that subject. A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and has failed in the end examination. In such a case, the candidate must re-register for the subject(s) and secure the required minimum attendance. The candidate's attendance in the re-registered subject(s) shall be calculated separately to decide upon his eligibility for writing the end examination in those subject(s). In the event of the student taking another chance, his internal marks and end examination marks obtained in the previous attempt stand cancelled. For re-registration the candidates have to apply to the University through the college by paying the requisite fees and get approval from the University before the start of the semester in which re-registration is required.

5.6 In case the candidate secures less than the required attendance in any re registered subject (s), he shall not be permitted to write the End Examination in that subject. He shall again re-register the subject when next offered.

5.7 Laboratory examination for M. Tech. courses must be conducted with two Examiners, one of them being the Laboratory Class Teacher or teacher of the respective college and the second examiner shall be appointed by the university from the panel of examiners submitted by the respective college.

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KAKINADA - 533 003, Andhra Pradesh, India

6.0 EVALUATION OF PROJECT/DISSERTATION WORK

Every candidate shall be required to submit a thesis or dissertation on a topic approved by the Project Review Committee.

6.1 A Project Review Committee (PRC) shall be constituted with Head of the Department and two other senior faculty members.

6.2 Registration of Project Work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects, both theory and practical.

6.3 After satisfying 6.2, a candidate has to submit, in consultation with his project supervisor, the title, objective and plan of action of his project work for approval. The student can initiate the Project work, only after obtaining the approval from the Project Review Committee (PRC).

6.4 If a candidate wishes to change his supervisor or topic of the project, he can do so with the approval of the Project Review Committee (PRC). However, the Project Review Committee (PRC) shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of project proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

6.5 A candidate shall submit his status report in two stages at least with a gap of 3 months between them.

6.6 The work on the project shall be initiated at the beginning of the II year and the duration of the project is two semesters. A candidate is permitted to submit Project Thesis only after successful completion of theory and practical course with the approval of PRC not earlier than 40 weeks from the date of registration of the project work. The candidate has to pass all the theory and practical subjects before submission of the Thesis.

6.7 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College/School/Institute.

6.8 The thesis shall be adjudicated by one examiner selected by the University. For this, the Principal of the College shall submit a panel of 5 examiners, eminent in that field, with the help of the guide concerned and head of the department.

6.9 If the report of the examiner is not favourable, the candidate shall revise and resubmit the Thesis, in the time frame as decided by the PRC. If the report of the examiner is unfavorable again, the thesis shall be summarily rejected. The candidate has to re-register for the project and complete the project within the stipulated time after taking the approval from the University.

6.10 If the report of the examiner is favourable, Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the examiner who adjudicated the Thesis. The Board shall jointly report the candidate's work as one of the following:

A. Excellent
B. Good
C. Satisfactory
D. Unsatisfactory

The Head of the Department shall coordinate and make arrangements for the conduct of Viva-Voce examination.

6.11 If the report of the Viva-Voce is unsatisfactory, the candidate shall retake the Viva-Voce examination only after three months. If he fails to get a satisfactory report at the second Viva-Voce examination, the candidate has to re-register for the project and complete the project within the stipulated time after taking the approval from the University.

7.0 AWARD OF DEGREE AND CLASS

After a student has satisfied the requirements prescribed for the completion of the program and is eligible for the award of M. Tech. Degree he shall be placed in one of the following four classes:

Class Awarded	% of marks to be secured
First Class with Distinction	70% and above (Without any Supplementary Appearance)
First Class	Below 70% but not less than 60%
	70% and above (With any Supplementary Appearance)
Second Class	Below 60% but not less than 50%

The marks in internal evaluation and end examination shall be shown separately in the memorandum of marks.

ADITYA PHARMACY COLLEGE * SURAMPALEM *

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8.0 WITHHOLDING OF RESULTS

If the student has not paid the dues, if any, to the university or if any case of indiscipline is pending against him, the result of the student will be withheld. His degree will be withheld in such cases.

8.0 TRANSITORY REGULATIONS (for R09)

9.1 Discontinued or detained candidates are eligible for re-admission into same or equivalent subjects at a time as and when offered.

9.2 The candidate who fails in any subject will be given two chances to pass the same subject; otherwise, he has to identify an equivalent subject as per R13 academic regulations.

10. GENERAL

10.1 Wherever the words "he", "him", "his", occur in the regulations, they include "she", "her", "hers".

10.2 The academic regulation should be read as a whole for the purpose of any interpretation.

10.3 In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.

10.4 The University may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the University.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

MALPRACTICES RULES

DISCIPLINARY ACTION FOR / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.
6.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the

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	instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions : (if the squad reports that the college is also involved in encouraging malpractices)
   - (i) A show cause notice shall be issued to the college.
   - (ii) Impose a suitable fine on the college.
   - (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year.

ADITYA PHARMACY COLLEGE * SURAMPALEM *

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

For Constituent Colleges and Affiliated Colleges of JNTUK

Ragging

Prohibition of ragging in educational institutions Act 26 of 1997

Salient Features

- Ragging within or outside any educational institution is prohibited.
- Ragging means doing an act which causes or is likely to cause Insult or Annoyance of Fear or Apprehension or Threat or Intimidation or outrage of modesty or Injury to a student

	Imprisonment upto		Fine
Teasing, Embarrassing and Humiliation	6 Months	+	Rs. 1,000/-
Assaulting or Using Criminal force or Criminal intimidation	1 Year	+	Rs. 2,000/-
Wrongfully restraining or confining or causing hurt	2 Years	+	Rs. 5,000/-
Causing grievous hurt, kidnapping or Abducts or rape or committing unnatural offence	5 Years	+	Rs. 10,000/-
Causing death or abetting suicide	10 Months	+	Rs. 50,000/-

In Case of Emergency CALL TOLL FREE NO. : 1800 - 425 - 1288

LET US MAKE JNTUK A RAGGING FREE UNIVERSITY

ADITYA PHARMACY COLLEGE SURAMPALEM

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

Ragging

ABSOLUTELY NO TO RAGGING

1. Ragging is prohibited as per Act 26 of A.P. Legislative Assembly, 1997.
2. Ragging entails heavy fines and/or imprisonment.
3. Ragging invokes suspension and dismissal from the College.
4. Outsiders are prohibited from entering the College and Hostel without permission.
5. Girl students must be in their hostel rooms by 7.00 p.m.
6. All the students must carry their Identity Cards and show them when demanded
7. The Principal and the Wardens may visit the Hostels and inspect the rooms any time.

Jawaharlal Nehru Technological University Kakinada
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ADITYA PHARMACY COLLEGE * SURAMPALEM *

PRINCIPAL
Aditya Pharmacy College
SURAMPALEM-533 437

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

M.PHARMACY

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

I SEMESTER

Paper 101	-	Modern Analytical Techniques
Paper 102	-	Research Methodologies
Paper 103	-	Advanced Pharmaceutical Analysis - I
Paper 104	-	Chromatographic and Other Special techniques
Paper 105	-	Advanced Pharmaceutical Analysis-I - LAB
Paper 106	-	Chromatographic and Other Special techniques - LAB
Paper 107	-	Seminar

II SEMESTER

Paper 201	-	Advanced Pharmaceutical Analysis - II
Paper 202	-	Phytopharmaceutical and Biological Analysis
Paper 203	-	Quality Assurance of Pharmaceuticals – I
Paper 204	-	Drug Regulatory Affairs
Paper 205	-	Advanced Pharmaceutical Analysis - II - LAB
Paper 206	-	Phytopharmaceutical and Biological Analysis - LAB
Paper 207	-	Seminar

III SEMESTER

Paper 301	-	Seminar-I
Paper 302	-	Project Work – I

IV SEMESTER

Paper 401	-	Seminar-II
Paper 402	-	Project Work – II
Paper 403	-	Comprehensive Viva Voce

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

I SEMESTER							
Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60			100	3
Paper – 102	Research Methodologies	40	60			100	3
Paper – 101	Advanced Pharmaceutical Analysis-I	40	60			100	3
Paper – 102	Chromatographic and Other Special Techniques	40	60			100	3
Paper – 104	Advanced Pharmaceutical Analysis-I Practical			40	60	100	2
Paper – 105	Chromatographic and Other Special Techniques Practical			40	60	100	2
Paper – 106	Seminar					100	2
	TOTAL					700	18

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KAKINADA - 533 003, Andhra Pradesh, India

II SEMESTER							
Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 201	Advanced Pharmaceutical Analysis-II	40	60			100	3
Paper –202	Phytopharmaceutical and Biological Analysis	40	60			100	3
Paper – 203	Quality Assurance of Pharmaceuticals-I	40	60			100	3
Paper – 204	Drug Regulatory affairs	40	60			100	3
Paper – 205	Advanced Pharmaceutical Analysis-II Practical			40	60	100	2
Paper – 206	Phytopharmaceutical and Biological Analysis Practical			40	60	100	2
Paper – 207	Seminar					100	2
	TOTAL					700	18

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KAKINADA - 533 003, Andhra Pradesh, India

III SEMESTER			
Paper No.		**Marks**	**Credits**
Paper - 301	**Seminar – I**	**50**	**2**
Paper - 302	**Project work – I**	**100**	**14**
	Total	**150**	**16**

IV SEMESTER			
Paper No.		**Marks**	**Credits**
Paper - 401	**Seminar – II**	**50**	**2**
Paper – 402	**Project work – II**	**100**	**14**
Paper - 403	**Comprehensive Viva Voce**	**100**	**4**
	Total	**250**	**20**
Grand Total (Four Semesters)		**1800**	**72**

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KAKINADA - 533 003, Andhra Pradesh, India

M.PHARM SYLLABUS FOR PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

I-I **MODERN ANALYTICAL TECHNIQUES** **L / P / Credits**
(Paper Common for all Specializations) **-- / -- / 3**

Principles, instrumentation and applications of the following Instruments and Chromatography techniques

UNIT- I

i. UV- Visible spectrophotometry
ii. Infrared spectroscopy
iii. Spectrofluorimetry

UNIT- II

i. NMR spectroscopy
ii. Electron Spin Resonance spectroscopy
iii. Atomic Emission spectroscopy

UNIT- III

i. HPLC
ii. HPTLC
iii. Exclusion chromatography
iv. Super critical fluid chromatography

UNIT- IV

i. Mass Spectroscopy including LCMS & GCMS
ii. GLC

UNIT- V

i. Phase Emission spectroscopy
ii. X-Ray diffractometry
iii. Optical Rotatory Diffusion
iv. Vapour phase chromatography
v. Affinity chromatography
vi. Ion-exchange chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

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I-I	RESEARCH METHODOLOGIES (Paper common for all Specializations)	L / P / Credits -- / -- / 3

UNIT I

Statistical Methods:
Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution Error and its significance-Measures of Error- Control of Error in Experimental Investigations – Problem Solving.

UNIT II
Correlation and Regression., Multiple Regression - Problem Solving

UNIT III
Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples – Problem Solving

UNIT IV
Design of Experiments
Criteria of a good design with examples.
Principles- Randomization, replication and local control.
Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples – Problem Solving

UNIT V
Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research- Problem Solving
Optimisation Techniques : Optimisation Techniques based on Factorial Experiments - Problem Solving.

Recommended Books:
1. Fundamentals of Biostatistics by Khan & Khanum, Ukaaz Publications, Hyderabad
2. Theory & Practice of Industrial Pharmacy by Leon Lachman and Others
3. Remingtons Practice of Pharmaceutical sciences, (Latest Edition)
4. Principles of Biostatistics by Marcello Pagnano, Published by Brooks/Cole, (Saurabh Printers Pvt. Ltd)
5. Introduction To Biostatistics – A text book of biometry By Pranab Kumar Banerjee

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I-I ADVANCED PHARMACEUTICAL ANALYSIS-I L / P / Credits
-- / -- / 3

UNIT-I

1. Good Laboratory practices (GLP), Laboratory maintenance, standard operating procedures (SOPS), Validation of analytical instruments and methods. – Quality Control Laboratory Regulatory requirements

UNIT-II

1. Theory, Instrumentation and application with regard to drug analysis, decomposition product identification and estimation and metabolite analysis based on the following:
a) Ultraviolet visible spectrophotometry
b) Infrared Spectrophotometry
c) Fluoremetry, Nephelometry and Turbidimetry

UNIT-III

1. Polarography.
2. Flame emission spectroscopy and atomic absorption spectroscopy. Principle, Instrumentation and applications in Pharmacy.

UNIT-IV

1. Thermal methods of analysis: Theory of Thermo gravimetric analysis (TGA), Differential Thermal analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).
2. An advanced study of non - aqueous titrations involving the following:
a) Primary, Secondary and Tertiary amines
b) Halogenated salts and bases
c) Acidic substances
d) Assays of official drugs in IP 1996 by non - aqueous titrimetry
e) Aquametry: Determination of water by titration with Karl Fischer Reagent (KFR).

UNIT-V

1. Principles and pharmaceutical applications of redox titrations involving:
a) Potassium lodate / bromate titrations
h) Ceric ammonium sulphate titrations
c) Tanus Chloride titration
d) Examples of assays of official drugs in IP 1996.
2. Principles and Pharmaceutical applications of complexometric titrations involving:
a) Direct titration of Polymetallic system with Sodium EDTA
b) Back titration with sodium EDTA
c) titration involving the displacement of one complex by another
d) PM indicators
e) Examples of assays official drugs in IP 1996.

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TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

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I-I	CHROMATOGRAPHIC AND OTHER SPECIAL TECHNIQUES	L / P / Credits -- / -- / 3

UNIT-I

An advanced study of the following and their applications.

1. Basic principle and separation by Column chromatography, thin layer chromatography, paper chromatography and ion exchange chromatography.

UNIT-II

1. Gas Chromatography: Introduction, theory, column operation, instrumentation and detection, GCMS.

UNIT-III

1. High Pressure Liquid Chromatography: Principle, Instrumentation procedure, solvents used, elution techniques, LCMS and applications.

UNIT-IV

1. HPTLC and Supercritical Fluid Chromatography (SFC): Principle, instrumentation procedure, elution technique and pharmaceutical applications.
2. H.P.C.P.C

UNIT-V

1. Electrophoreses (gel and capillary)
2. Radio immuno assay and related immuno assays — RIA, ELISA

TEXT BOOKS

1. Instrumental Methods of Analysis by Scog and West.
2. Instrumental Methods of Analysis by B.K.Sharma
3. Instrumental methods of Analysis by Willard & Merrit.
4. High Performance Liquid Chromatography by P. D. Sethy.
5.Liquid Chromatography-Mass Spectrometry, Third Edition by by Wilfried M.A. Niessen

REFERENCE BOOKS

1. USP
2. Remington's Pharmaceutical Sciences.
3. Spectroscopy by Silversterin
4. Instrumental methods of Analysis by Hibart. H. Willard.

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I-I	ADVANCED PHARMACEUTICAL ANALYSIS –I	L / P / Credits -- / -- / 2

1. Use of spectrophotometer for analysis of Pharmacopoeial compounds and their formulations.
2. Use of fluorimeter for analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for analysis of Na, K & Ca etc in Biological fluids and formulations.
4. Use of Nephelo- Turbidimetric analysis of dispersions and limit tests.
5. Assays involving following procedures: Non – Aqueous, Diazotisation, Complexation and Redox titrations.
6. Official (I.P) Assays based on theory.

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
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3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

TEXT BOOKS

1. Instrumental Methods of Analysis by Scog and West.
2. Instrumental Methods of Analysis by B.K.Sharma
3. Instrumental methods of Analysis by Willard & Merrit.
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I-I	**CHROMATOGRAPHIC AND OTHER SPECIAL TECHN1QUES LAB**	**L / P / Credits** -- / -- / 2

1. Experiments on Electrophoresis.
2. Experiments of Chromatography:
a) Ascending technique
b) Descending technique
c) Circular technique
3. Experiments using HPLC & GC.

TEXT BOOKS

1. Instrumental Methods of Analysis by Scog and West.
2. Instrumental Mcthods of Analysis by B.K.Sharma
3. Instrumental methods of Analysis by Willard & Merrit.
4. High Performance Liquid Chromatography by P. D. Sethy.

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1. USP
2. Remington's Pharmaceutical Sciences.
3. Spectroscopy by Silversterin
4. Instrumental methods of Analysis by Hibart. H. Willard.