JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Analysis
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	17S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2	17S07101	Advanced Pharmaceutical Analysis	4	-	-	4
3	17S07102	Pharmaceutical Validation	4	-	-	4
4	17S07103	Food Analysis	4	-	-	4
5	17S07104	Pharmaceutical Analysis Practicals	-	-	6	3
6	17S07105	Food Analysis Practical - I	-	-	6	3
7	17S07106	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S07201	Advanced Instrumental Analysis	4	-	-	4
2	17S07202	Modern Bio-Analytical Techniques	4	-	-	4
3	17S07203	Quality Control And Quality Assurance	4	-	-	4
4	17S07204	Herbal and Cosmetic Analysis	4	-	-	4
5	17S07205	Pharmaceutical Analysis Practical II	-	-	6	3
6	17S07206	Pharmaceutical Analysis Practical III	-	-	6	3
7	17S07207	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

III SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S01301	Research Methodology and Biostatistics	4	-	-	4
2.	17S07301	Journal Club	1	-	-	1
3.	17S07302	Teaching Assignment	10	-	-	2
4.	17S07303	Comprehensive viva voce	-	-	-	2
5.	17S07304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S07305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S07401	Journal Club	1	-	-	1
2.	17S07402	Research work	31	-	-	16
3.	17S07403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

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

Objectives

After completion of course student is able to know about chemicals andexcipients

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

THEORY 60 Hrs

1. 10Hrs

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

b. IR spectroscopy: Theory, Modes of Molecular vibrations,Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrationalfrequencies and Applications of IR spectroscopy, DataInterpretation.

c. Spectroflourimetry: Theory of Fluorescence, Factors affectingfluorescence (Characterestics of drugs that can be analysedbyflourimetry), Quenchers, Instrumentation and Applications offluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle, Instrumentation, Interferences andApplications.

2 10Hrs

a) 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-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR and 13C NMR. Applicationsof NMR spectroscopy.

10Hrs

b) Mass Spectroscopy: Principle, Theory, Instrumentation of MassSpectroscopy, Different types of ionization like electron impact,chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers

ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Massspectroscopy.

3 10Hrs

Chromatography: Principle, apparatus, instrumentation,chromatographic parameters, factors affecting resolution, isolationof drug from excipients, data interpretation and applications of thefollowing:

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 Liquid chromatography

h) Affinity chromatography

i) Gel Chromatography

4 10Hrs

a.Electrophoresis: Principle, Instrumentation, Workingconditions, factors affecting separation and applications of thefollowing:

a) Paper electrophoresis b) Gel electrophoresis c) Capillaryelectrophoresis d) Zone electrophoresis e) Moving boundaryelectrophoresis f) Iso electric focusing

b.X ray Crystallography: Production of X rays, Different X raymethods, Bragg‘s law, Rotating crystal technique, X ray powdertechnique, Types of crystals and applications of X-ray diffraction.

5 10Hrs

a. Potentiometry: Principle, working, Ion selective Electrodesand Application of potentiometry.

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

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, 4thedition, 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, Vol11, Marcel. Dekker Series

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.

9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07101) ADVANCED PHARMACEUTICAL ANALYSIS

Scope

This subject deals with the various aspects of Impurity, Impurities in new drugproducts, in residual solvents, Elemental impurities, Impurity profiling andcharacterization of degradents, Stability testing of phytopharmaceuticalsandtheir protocol preparation. It also covers the biological testing of variousvaccines 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. 10Hrs

Impurity and stability studies:

Definition, classification of impurities in drug Substance or ActivePharmaceutical Ingredients and quantification of impurities as perICHguidelinesImpurities in new drug products:Rationale for the reporting and control of degradation products,reporting degradation products content of batches, listing ofdegradation products in specifications, qualification of degradationproducts

Impurities in residual solvents:General principles, classification of residual solvents, Analyticalprocedures, limits of residual solvents, reporting levels of residualsolvents

2 10Hrs

Elemental impurities:

Element classification, control of elemental impurities, PotentialSources of elemental Impurities, Identification of PotentialElemental 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 ofresults, concept of stability, commitment etc. Importantmechanistic and stability related information provided by results ofstudy of factors like temperature, pH, buffering species ionicstrength and dielectric constant etc. on the reaction rates. Withpractical considerations.

3 10Hrs

Impurity profiling and degradent characterization: Methoddevelopment, Stability studies and concepts of validationaccelerated stability testing & shelf life calculation, WHO and ICHstability testing guidelines, Stability zones, steps in development,practical considerations. Basics of impurity profiling anddegradent characterization with special emphasis. Photostabilitytesting guidelines, ICH stability guidelines for biological products

4 16Hrs

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

b) Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccinec. 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 generegulation, instrumentation (Principle and Procedures)

5 14Hrs

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of boundand unbound drug, Radioimmunoassay, Optical IA, Enzyme IA,Fluoro IA, Luminiscence IA, Quantification and applications of IA.

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, 4thEdition, CBS publishers, New Delhi, 1997.

3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, JohnWiley& 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, CBSPublishers, NewDelhi, 1964.

8. Indian Pharmacopoeia VolI , II & III 2007, 2010, 2014.

9. Methods of sampling and microbiological examination of water, firstrevision, 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.

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07102) PHARMACEUTICAL VALIDATION

SCOPE

The main purpose of the subject is to understand about validation and how itcan be applied to industry and thus to improve the quality of the products. Thesubject covers the complete information about validation, types, methodologyand 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. 12Hrs

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

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

2 12Hrs

Qualification of analytical instruments: Electronic balance, pHmeter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLCQualification of Glassware: Volumetric flask, pipette, Measuringcylinder, beakers and burette.

3 12Hrs

Validation of Utility systems: Pharmaceutical Water System &pure steam, HVAC system, Compressed air and nitrogen.Cleaning Validation: Cleaning Validation - Cleaning Methoddevelopment, Validation and validation of analytical method usedin cleaning. Cleaning of Equipment, Cleaning of Facilities.Cleaning in place (CIP).

4 12Hrs

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

Computerized system validation: Electronic records and digitalsignificance-21 CFR part 11 and GAMP.

5 12Hrs

General Principles of Intellectual Property: Concepts ofIntellectual 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 patentapplications; patent application forms and guidelines. Typespatent applications-provisional and non-provisional, PCT andconvention patent applications; International patenting requirementprocedures and costs; Rights and responsibilities of a patentee;Practical aspects regarding maintaining of a Patent file; Patentinfringement meaning and scope. Significance of transfertechnology (TOT),IP and ethics-positive and negative aspectsof IPP; Societal responsibility, avoiding unethical practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharm 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 Internationalpublishing.

4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton&Agalloco, (Marcel Dekker).

5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci.Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide forAchieving Compliance in the Pharmaceutical, Medical Device, and BiotechIndustries, Syed ImtiazHaider

7. Pharmaceutical Equipment Validation: The Ultimate QualificationHandbook, 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 byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07103) FOOD ANALYSIS

Scope

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

Objectives

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

- 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. 12Hrs

Carbohydrates: classification and properties of foodcarbohydrates, General methods of analysis of foodcarbohydrates, Changes in food carbohydrates during processing,Digestion, absorption and metabolism of carbohydrates, Dietaryfibre, Crude fibre and application of food carbohydratesProteins: Chemistry and classification of amino acids andproteins, Physico-Chemical properties of protein and theirstructure, general methods of analysis of proteins and aminoacids, Digestion, absorption and metabolism of proteins.

2 12Hrs

Lipids: Classification, general methods of analysis, refining of fatsand oils; hydrogenation of vegetable oils, Determination ofadulteration in fats and oils, various methods used formeasurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis ofvitamins, Principles of microbial assay of vitamins of B-series.

3 12Hrs

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

Pigments and synthetic dyes: Natural pigments, theiroccurrence and characteristic properties, permitted syntheticdyes, Non-permitted synthetic dyes used by industries, Method ofdetection of natural, permitted and non-permitted dyes.

4 12Hrs

General Analytical methods for milk, milk constituents and milkproducts like ice cream, milk powder, butter, margarine, cheeseincluding adulterants and contaminants of milk.Analysis of fermentation products like wine, spirits, beer andvinegar.

5 12Hrs

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 emphasison BIS, Agmark, FDA and US-FDA.

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.

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S07104) PHARMACEUTICAL ANALYSIS PRACTICALS

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Qunatitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography
13. Calibration of UV – Visible Spectrophtometer/ HPLC/ GC/ FTIR
14. Cleaning validation of any one analytical equipment

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M. Pharm – I year I Sem. (Pharmaceutical Analysis)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S07105) FOOD ANALYSIS PRACTICAL - I

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of food additives
11. Determination of Aspartame in soft drinks
12. Determination of 4- imidazole in caramel
13. Determination of benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
14. UV Spectrophotometric methods for determination of sorbic acid in dairy products
15. Determination of nitrite and nitrate in food products

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M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07201) ADVANCED INSTRUMENTAL ANALYSIS

Scope

This subject deals with various hyphenated analytical instrumental techniquesfor identification, characterization and quantification of drugs. Instruments dealtare 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 organiccompounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY 60 Hrs

1. 12Hrs

HPLC: Principle, instrumentation, pharmaceutical applications,peak shapes, capacity factor, selectivity, plate number, plateheight, resolution, band broadening, pumps, injector, detectors,columns, column problems, gradient HPLC, HPLC solvents,trouble shooting, sample preparation, method development, Newdevelopments in HPLC-role and principles of ultra, nanoliquidchromatography in pharmaceutical analysis. Immobilizedpolysaccharide CSP's: Advancement in enantiomericseparations,revised phase Chiral method development and HILICapproaches. HPLC in Chiral analysis of pharmaceuticals.Preparative HPLC, practical aspects of preparative HPLC.

2 12Hrs

Biochromatography: Size exclusion chromatography, ionexchange chromatography, ion pair chromatography, affinitychromatography general principles, stationary phases and mobilephases.

Gas chromatography: Principles, instrumentation, derivatization,head space sampling, columns for GC, detectors, quantification.

High performance Thin Layer chromatography: Principles,instrumentation, pharmaceutical applications.

3 12Hrs

Super critical fluid chromatography: Principles,instrumentation, pharmaceutical applications.

Capillary electrophoresis: Overview of CE in pharmaceuticalanalysis, basic configuration, CE characteristics, principles of CE,methods and modes of CE. General considerations and

methoddevelopment in CE, Crown ethers as buffer additives in capillaryelectrophoresis. CE-MS hyphenation.

4 12Hrs

Mass spectrometry: Principle, theory, instrumentation of massspectrometry, different types of ionization like electron impact,chemical, field, FAB and MALD, APCI, ESI, APPI massfragmentation and its rules, meta stable ions, isotopic peaks andapplications of mass spectrometry. LC-MS hyphenation andDART 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.

5 12Hrs

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-Spincoupling, 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-Dand 2-D NMR, NOESY and COSY techniques, Interpretation andApplications of NMR spectroscopy. LC-NMR hyphenations.

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.

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M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07202) MODERN BIO-ANALYTICAL TECHNIQUES

Scope

This subject is designed to provide detailed knowledge about the importance ofanalysis 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. 12Hrs

Extraction of drugs and metabolites from biological matrices:General need, principle and procedure involved in theBioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novelsample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2 12Hrs

Biopharmaceutical Consideration:Introduction, Biopharmaceutical Factors Affecting DrugBioavailability, In Vitro: Dissolution and Drug Release Testing,Alternative Methods of Dissolution Testing Transport models,Biopharmaceutics Classification System. Solubility: Experimentalmethods. Permeability: In-vitro, in-situ and In-vivo methods.

3 12Hrs

Pharmacokinetics and Toxicokinetics:Basic consideration, Drug interaction (PK-PD interactions), Theeffect of protein-binding interactions, The effect of tissue-bindinginteractions, Cytochrome P450-based drug interactions, Druginteractions linked to transporters. Microsomal assaysToxicokinetics-Toxicokinetic evaluation in preclinical studies,Importance and applications of toxicokinetic studies. LC-MS inbioactivity screening and proteomics.

4 12Hrs

Cell culture techniquesBasic 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 ofcells and their applications. Principles and applications of cellviability assays (MTT assays), Principles and applications of flowcytometry.

5 12Hrs

Metabolite identification:In-vitro / in-vivo approaches, protocols and sample preparation.Microsomal approaches (Rat liver microsomes (RLM) and Humanlivermicrosomes (HLM) in Met –ID. Regulatory perspectives.In-vitro assay of drug metabolites & drug metabolizing enzymes.Drug Product Performance, In Vivo: Bioavailability andBioequivalence:Drug Product Performance, Purpose of Bioavailability Studies,Relativeand Absolute Availability. Methods for AssessingBioavailability, Bioequivalence Studies, Design and Evaluation ofBioequivalence Studies, Study Designs, Crossover StudyDesigns, Generic Biologics (Biosimilar Drug Products), ClinicalSignificance 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 LBertholf, 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

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M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07203) QUALITY CONTROL AND QUALITY ASSURANCE

Scope

This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It covers the important aspectslike 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 cGMPaspects 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. 12Hrs

Concept and Evolution of Quality Control and QualityAssuranceGood Laboratory Practice, GMP, Overview of ICH Guidelines -QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Qualityassurance unit, protocol for conduct of non clinical testing, controlon animal house, report preparation and documentation.

2. 12Hrs

cGMP guidelines according to schedule M, USFDA (inclusiveof CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnelresponsibilities, training, hygiene and personal records, drugindustry location, design, construction and plant lay out,maintenance, sanitation, environmental control, utilities andmaintenance of sterile areas, control of contamination and GoodWarehousing Practice. CPCSEA guidelines.

3. 12Hrs

Analysis of raw materials, finished products, packagingmaterials, in process quality control (IPQC), Developingspecification (ICH Q6 and Q3)Purchase specifications and maintenance of stores for rawmaterials. In process quality control and finished products qualitycontrol for following formulation in Pharma industry according toIndian, US and British pharmacopoeias: tablets, capsules,ointments, suppositories, creams, parenterals, ophthalmic andsurgical products (How to refer pharmacopoeias), Quality controltest for containers, closures and secondary packing materials.

4. 12Hrs

Documentation in pharmaceutical industry: Three tierdocumentation, Policy, Procedures and Work instructions, andrecords (Formats), Basic principles- How to maintain, retention andretrieval etc. Standard operating procedures (How to write), MasterFormula Record, Batch Formula Record, Quality audit plan andreports. Specification and test procedures, Protocols and reports.Distribution records. Electronic data.

5. 12Hrs

Manufacturing operations and controls: Sanitation ofmanufacturing premises, mix-ups and cross contamination,processing of intermediates and bulk products, packagingoperations, IPQC, release of finished product, process deviations,charge-in of components, time limitations on production, drugproduct inspection, expiry date calculation, calculation of yields,production record review, change control, sterile products, asepticprocess control, packaging.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures ofIndia, 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 andRelated 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 Methodsof 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, MarcelDekker Series, 1989.

7. ICH guidelines

8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4thedition, Susmit Publishers, 2006.

10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total qualitycontrol – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturersand Their Suppliers, Sixth Edition, (Volume 1 - With Checklists andSoftware Package). Taylor & Francis; 2003.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07204) HERBAL AND COSMETIC ANALYSIS

Scope

This course is designed to impart knowledge on analysis of herbal products.Regulatory requirements, herbal drug interaction with monographs.Performance evaluation of cosmetic products is included for the betterunderstanding 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. 12Hrs

Herbal remedies- Toxicity and Regulations: Herbals vsConventional drugs, Efficacy of herbal medicine products,Validation of Herbal Therapies, Pharmacodynamic andPharmacokinetic issues. Herbal drug standardization: WHO andAYUSH guidelines.

2 12Hrs

Adulteration and Deterioration: Introduction, types ofadulteration/substitution of herbal drugs, Causes and Measure ofadulteration, Sampling Procedures, Determination of ForeignMatter, DNA Finger printing techniques in identification of drugs ofnatural origin, heavy metals, pesticide residues, phototoxinandmicrobial contamination in herbal formulations.Regulatory requirements for setting herbal drug industry:Global marketing management, Indian and international patentlaw as applicable herbal drugs and natural products and itsprotocol.

3 12Hrs

Testing of natural products and drugs: Effect of herbalmedicine on clinical laboratory testing, Adulterant Screening usingmodern analytical instruments, Regulation and dispensing ofherbal drugs, Stability testing of natural products, protocol.Monographs of Herbal drugs: Study of monographs of herbaldrugs and comparative study in IP, USP, AyurvedicPharmacopoeia, American herbal Pharmacopoeia, British herbalPharmacopoeia, Siddha and Unani Pharmacopoeia, WHOguidelines in quality assessment of herbal drugs.

4 12Hrs

Herbal drug-drug interaction: WHO and AYUSH guidelines forsafety monitoring of natural medicine, Spontaneous reportingschemes for bio drug adverse reactions, bio drug-drug and biodrug-food interactions with suitable examples. Challenges inmonitoring the safety of herbal medicines.

5 12Hrs

Evaluation of cosmetic products: Determination of acid value,ester value, saponification value, iodine value, peroxide value,rancidity, moisture, ash, volatile matter, heavy metals, fineness ofpowder, density, viscosity of cosmetic raw materials and finishedproducts. Study of quality of raw materials and general methodsof analysis of raw material used in cosmetic manufacture as perBIS.

Indian Standard specification laid down for sampling and testingof various cosmetics in finished forms such as baby careproducts, skin care products, dental products, personal hygienepreparations, lips sticks. Hair products and skin creams by theBureau Indian Standards.

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 AshutoshKar

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'sPerfumes,Cosmetics and Soaps

12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook ofCosmetic Science and Technology, 3rd Edition,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S07205) PHARMACEUTICAL ANALYSISPRACTICALS - II

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 Massspectra

7. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by gel electrophoresis.

8. Bio molecules separation utilizing various sample preparation techniquesand 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/Bioanalyticalmethodvalidation.

11. Protocol preparation for the conduct of BA/BE studies according toguidelines.

12. In process and finished product quality control tests for tablets, capsules,parenterals and creams

13. Quality control tests for Primary and secondary packing materials

14. Assay of raw materials as per official monographs

15. Testing of related and foreign substances in drugs and raw materials

16. Preparation of Master Formula Record.

17. Preparation of Batch Manufacturing Record.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)	L	T	P	C
	0	0	6	3

(17S07206) PHARMACEUTICAL ANALYSISPRACTICALS - III

1. Quantitative analysis of rancidity in lipsticks and hair oil
2. Determination of aryl amine content and Developer in hair dye
3. Determination of foam height and SLS content of Shampoo.
4. Determination of total fatty matter in creams (Soap, skin and hair creams)
5. Determination of acid value and saponification value.
6. Determination of calcium thioglycolate in depilatories
7. Determination of tannins
8. Determination of microorganisms in herbal products
9. Specifications for adsorbents used in TLC
10. Determination of total phenol content
11. Determination of aflatoxins
12. Determination of swelling index and foaming index
13. Quality control methods for herbal materials/ Medicinal plant materials

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S01301) 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.