ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS

M – PHARMACY (PHARMACEUTICAL ANALYSIS)

FOR
M.PHARMACY TWO YEAR PG COURSE
(Applicable for the batches admitted from 2022-2023)

SCHOOL OF PHARMACY
ANURAG UNIVERSITY
Venkatapur, Ghatkesar, Hyderabad – 500088

Academic Regulations - for M. Pharm (Regular)

(Effective for the students admitted into I year from the Academic Year **2022-2023** onwards)

ANURAG UNIVERSITY

M. PHARM (PHARMACEUTICAL ANALYSIS)
(R22) COURSE STRUCTURE AND SYLLABUS

I YEAR ISEMESTER

Code	Group	Subject	Hrs/Wk	Credits
MPA101T	Theory	Modern Pharmaceutical Analytical Techniques	4	4
MPA102T	Theory	Advanced Pharmaceutical Analysis	4	4
MPA103T	Theory	Pharmaceutical Validation	4	4
MPA104T	Theory	Food Analysis	4	4
MPA105P	Lab	Pharmaceutical Analysis Practical I	12	6
MPA106T	-	Seminar/Assignment	7	4
		TotalCredits	**35**	**26**

I YEAR IISEMESTER

Code	Group	Subject	Hrs/Wk	Credits
MPA201T	Theory	Advanced Instrumental Analysis	4	4
MPA202T	Theory	Modern Bio-Analytical Techniques	4	4
MPA203T	Theory	Quality Control & Quality Assurance	4	4
MPA204T	Theory	Herbal and Cosmetic Analysis	4	4
MPA205P	Lab	Pharmaceutical Analysis Practical II	12	6
MPA206T	-	Seminar/Assignment	7	4
		TotalCredits	**35**	**26**

II YEAR - ISEMESTER

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion/ Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		**35**	**21**

II YEAR - IISEMESTER

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/ Final Presentation	3	3
Total		**35**	**20**

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M.Pharmacy I year I Sem. **T/P C**

4/- 4

(A41001)MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

60 Hours

SCOPE

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

OBJECTIVES

After completion of course student is able to know,

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

UNIT-I **11 Hours**

a)**UV-Visible spectroscopy**: Introduction, Theory, Laws,Instrumentation associated with UV-Visible spectroscopy,Choice of solvents and solvent effect and Applications of UVVisiblespectroscopy.

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,Data interpretation.

c)**Spectroflourimetry**: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers, Instrumentation andApplications of fluorescence spectrophotometer.

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

UNIT-II **11 Hours**

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

UNIT-III **11 Hours**

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.

UNIT-IV **11 Hours**

Chromatography: Principle, apparatus, instrumentation,chromatographic parameters, factors affecting resolution, isolation of drugs from excipients, data interpretation andapplications of the following:

a) Paper chromatography
b) Thin Layer chromatography
c) High PerformanceThin Layer chromatography

d) Ion exchange chromatography
e) Column chromatography
f) Gas chromatography
g) High Performance Liquidchromatography
h) Ultra High Performance Liquidchromatography
g) Affinity chromatography
h) Gel Chromatography

UNIT-V **16 Hours**

a)**Electrophoresis**: Principle, Instrumentation, Workingconditions, factors affecting separation and applications of thefollowing:
i) Paper electrophoresis
ii) Gel electrophoresis
iii) Capillaryelectrophoresis
iv) Zone electrophoresis
v) Moving boundaryelectrophoresis
vi) Iso electric focusing
b)**X ray Crystallography**: Production of X rays, Different X raydiffraction methods, Bragg's law, Rotating crystal technique, Xray powder technique, Types of crystals and applications of Xraydiffraction.
c)**Immunological assays**: RIA (Radio immuno assay), ELISA,Bioluminescence assays.

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, 3rdEdition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume11, 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.Pharmacy I year I Sem. **T/P C**

4/- 4

(A41008)ADVANCED PHARMACEUTICAL ANALYSIS

60 Hours

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 Phytopharmaceuticals andtheir protocol preparation. It also covers the biological testing of variousvaccines and their principle and procedure.

OBJECTIVES

Upon completion of the course, student shall able to know

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

UNIT-I **10Hrs**

Impurity and stability studies: Definition, classification of impurities in drug Substance or ActivePharmaceutical Ingredients and quantification of impurities as perICH guidelines.

Impurities 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.

UNIT-II **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.

UNIT-III **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.

UNIT-IV **10Hrs**

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

UNIT-V **20Hrs**

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)

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.

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.Pharmacy I year I Sem. **T/P C**

4/- 4

(A41009) PHARMACEUTICAL VALIDATION

60 Hours

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 course, student shall be able to

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

UNIT-I **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.

UNIT-II **12Hrs**

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

UNIT-III **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).

UNIT-IV **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.

UNIT-V **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 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.Pharmacy I year I Sem. **T/P C**

4/- 4

(A41010)FOOD ANALYSIS

60 Hours

SCOPE

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

OBJECTIVES

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

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

UNIT-I **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 carbohydrates.

Proteins: 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.

UNIT-II **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.

UNIT-III **12Hrs**

Foodadditives: 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.

UNIT-IV **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.

UNIT-V **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 emphasis on 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.Pharmacy I year I Sem. **T/P C**

-/12 6

(A41205)PHARMACEUTICAL ANALYSIS PRACTICAL-I

1. Analysis of Pharmacopoeial compounds and their formulations by UV Visspectrophotometer
2.Simultaneous estimation of multi component containing formulations by UVspectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Imupurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acidvalue in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(A42010)ADVANCED INSTRUMENTAL ANALYSIS

60 Hours

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,

1.interpretation of the NMR, Mass and IR spectra of various organiccompounds

2.theoretical and practical skills of the hyphenated instruments

3.identification of organic compounds

UNIT-I **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, nano liquidchromatography in pharmaceutical analysis. Immobilizedpolysaccharide CSP's: Advancement in enantiomeric separations,revised phase Chiral method development and HILICapproaches. HPLC in Chiral analysis of pharmaceuticals.Preparative HPLC, practical aspects of preparative HPLC.

UNIT-II **12Hrs**

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

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

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

UNIT-III **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 method development in CE, Crown ethers as buffer additives in capillaryelectrophoresis. CE-MS hyphenation.

UNIT-IV **12Hrs**

Mass spectrometry: Principle, theory, instrumentation of massspectrometry, 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 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.

UNIT-V **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 DSethi, 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.Pharmacy I year II Sem. **T/P C**

4/- 4

(A42211)MODERN BIO-ANALYTICAL TECHNIQUES

60 Hours

SCOPE

This subject is designed to provide detailed knowledge about the importance ofanalysis of drugs in biological matrices.

OBJECTIVES

Upon completion of this course it is expected that students will be ableunderstand,

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

UNIT-I **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.

UNIT-II **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.

UNIT-III **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.

UNIT-IV **12Hrs**

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

UNIT- V **12Hrs**

Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation.Microsomal approaches (Rat liver microsomes (RLM) and Humanliver microsomes (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,Relative and 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.Pharmacy I year II Sem. **T/P C**

4/- 4

(A42212)QUALITY CONTROL AND QUALITY ASSURANCE

60 Hours

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 regulatoryaffairs.

OBJECTIVES

At the completion of this subject it is expected that the student shall be able toknow

1. thecGMP aspects in a pharmaceutical industry
2. to appreciate the importance of documentation
3. to understand the scope of quality certifications applicable toPharmaceutical industries
4. to understand the responsibilities of QA & QC departments

UNIT-I **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.

UNIT-II **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.

UNIT-III **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.

UNIT-IV **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.

UNIT-V **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.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley& Sons; 2008.

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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(A42213)HERBAL AND COSMETICANALYSIS

60 Hours

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

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

UNIT-I **12Hrs**

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

UNIT-II **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, phototoxin andmicrobial 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.

UNIT-III **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.

UNIT-IV **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.

UNIT-V **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's Perfumes,Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers.Handbook ofCosmetic Science and Technology, 3rd Edition.

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M.Pharmacy I year II Sem. **T/P C**

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(A42005) RESEARCH METHODOLOGY AND BIOSTATICS

UNIT – I **12 hrs**

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 **12 hrs**

Biostatistics: Definition, application, sample size, importance of sample size,factors influencing sample size, dropouts, statistical tests of significance, typeof significance tests, parametric tests(students "t" test, ANOVA, Correlationcoefficient, regression), non-parametric tests (wilcoxan rank tests, analysis ofvariance, correlation, chi square test), null hypothesis, P values, degree offreedom, interpretation of P values.

UNIT – III **12 hrs**

Medical Research: History, values in medical ethics, autonomy, beneficence,non-maleficence, double effect, conflicts between autonomy andbeneficence/non-maleficence, euthanasia, informed consent, confidentiality,criticisms of orthodox medical ethics, importance of communication, controlresolution, 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 **12 hrs**

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 **12 hrs**

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

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M.Pharmacy I year II Sem. **T/P C**

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(A42205) PHARMACEUTICAL ANALYSIS PRACTICAL-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 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 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/Bioanalytical method validation.
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.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

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M.Pharmacy II year II Sem.	T/P	C
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(MRM 301T) RESEARCH METHODOLOGY AND BIOSTATICS

UNIT – I **12 hrs**

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 **12 hrs**

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.

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