JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Analysis & Quality Assurance
(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	17S04101	Quality Management System	4	-	-	4
3	17S04102	Quality control and Quality Assurance	4	-	-	4
4	17S04103	Audit and Regulatory Compliance	4	-	-	4
5	17S01105	Modern Pharmaceutical Analytical Techniques Practical	-	-	6	3
6	17S04104	Quality Control And Quality Assurance Practical - I	-	-	6	3
7	17S04105	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S04201	Hazards and safety management	4	-	-	4
2	17S04202	Pharmaceutical Validation	4	-	-	4
3	17S04203	Advanced Pharmaceutical Analysis	4	-	-	4
4	17S04204	Modern Bio analytical Techniques	4	-	-	4
5	17S04205	Hazards And Safety Management Practical - II	-	-	6	3
6	17S04206	Food Analysis Practical - II0049	-	-	6	3
7	17S04207	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.	17S04301	Journal Club	1	-	-	1
3.	17S04302	Teaching Assignment	10	-	-	2
4.	17S04303	Comprehensive viva voce	-	-	-	2
5.	17S04304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S04305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S04401	Journal Club	1	-	-	1
2.	17S04402	Research work	31	-	-	16
3.	17S04403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

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M. Pharm – I year I Sem. (PA & QA)

L	T	P	C
4	0	0	4

(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

1. 11 hrs

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.

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

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

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

2. 11hrs

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.

3. 11hrs

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

4. 11hrs

Chromatography: Principle, apparatus, instrumentation,chromatographic parameters, factors affecting resolution andapplications of the following: a)Paper chromatography b) Thin Layer chromatographyc) Ion exchange chromatography d) Column chromatographye) Gas chromatography f) High Performance Liquidchromatographyg) Affinity chromatography

5 11hrs

a. Electrophoresis: Principle, Instrumentation, Workingconditions, factors affecting separation and applications of thefollowing:a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundaryelectrophoresis f) 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

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M. Pharm – I year I Sem. (PA & QA)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S04101) QUALITY MANAGEMENT SYSTEMS

Scope

This course is designed to impart fundamental knowledge and concepts aboutvarious quality management principles and systems utilized in themanufacturing industry. It also aids in understanding the quality evaluation in thepharmaceutical industries.

Objectives

At completion of this course it is expected that students will be able tounderstand-

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

THEORY 60 Hrs

1. 12Hrs

Introduction to Quality: Evolution of Quality, Definition ofQuality, Dimensions of Quality, Quality as a Strategic Decision: Meaning of strategy andstrategic quality management, mission and vision statements,quality policy, Quality objectives, strategic planning andimplementation, McKinsey 7s model, Competitive analysis,Management commitment to qualityCustomer Focus: Meaning of customer and customer focus,Classification of customers, Customer focus, Customerperception of quality, Factors affecting customer perception,Customer requirements, Meeting customer needs andexpectations, Customer satisfaction and Customer delight,Handling customer complaints, Understanding customer behavior,concept of internal and external customers. Case studies.

Cost of Quality: Cost of quality, Categories of cost of Quality,Models of cost of quality, Optimising costs, Preventing cost ofquality.

2 12Hrs

Pharmaceutical quality Management: Basics of QualityManagement, Total Quality Management (TQM), Principles of Sixsigma, ISO 9001:2008, 9001:2015, ISO 14001:2004,Pharmaceutical

Quality Management – ICH Q10, Knowledgemanagement, Quality Metrics, Operational Excellence and QualityManagement Review. OSHAS guidelines, NABL certification andaccreditation, CFR-21 part 11, WHO-GMP requirements.

3 12Hrs

Six System Inspection model: Quality Management system,Production system, Facility and Equipment system, Laboratorycontrol system, Materials system, Packaging and labeling system.Concept of self-inspection.

Quality systems: Change Management/ Change control.Deviations, Out of Specifications (OOS), Out of Trend (OOT),Complaints - evaluation and handling, Investigation anddetermination of root cause, Corrective & Preventive Actions(CAPA), Returns and Recalls, Vendor Qualification, AnnualProduct Reviews, Batch Review and Batch Release. Concept ofIPQC, area clearance/ Line clearance.

4 16Hrs

a. Drug Stability: ICH guidelines for stability testing of drugsubstances and drug products.Study of ICH Q8, Quality by Design and Processdevelopment report
b. Quality risk management: Introduction, risk assessment, riskcontrol, risk review, risk management tools, HACCP, risk rankingand filtering according to ICH Q9 guidelines.
c. Statistical Process control (SPC): Definition and Importance ofSPC, Quality measurement in manufacturing, Statistical controlcharts - concepts and general aspects, Advantages of statisticalcontrol, Process capability, Estimating Inherent or potentialcapability from a control chart analysis, Measuring process controland quality improvement, Pursuit of decreased process variability.

5 8Hrs

Regulatory Compliance through Quality Management anddevelopment of Quality CultureBenchmarking: Definition of benchmarking, Reasons forbenchmarking, Types of Benchmarking, Benchmarking process,Advantages of benchmarking, Limitations of benchmarking.

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks andResults, By Al Endres, Wiley, 2000

2. Understanding, Managing and Implementing Quality: Frameworks,Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

3. Organizing for High Performance: Employee Involvement, TQM,Reengineering, and Knowledge Management in the Fortune 1000: TheCEO Report By Edward E. Lawler; Susan Albers Mohrman; GeorgeBenson, Jossey-Bass, 2001

4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001

5. The Quality Management Sourcebook: An International Guide to Materialsand Resources By Christine Avery; Diane Zabel, Routledge, 1997

6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications

7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A.DeFeo, ASQ Publications

8. Root Cause Analysis, The Core of Problem Solving and Corrective Action,DukeOkes, 2009, ASQ Publications.

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M. Pharm – I year I Sem. (PA & QA)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S04102) 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 regulatoryaffairs.

Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable toPharmaceutical industries
- To understand the responsibilities of QA & QC departments.

THEORY 60 Hrs

1. 12Hrs

Introduction: Concept and evolution and scopes of QualityControl and Quality Assurance, Good Laboratory Practice, GMP,Overview of ICH Guidelines - QSEM, with special emphasis on Qseriesguidelines.

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

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, 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 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.

14. Packaging of Pharmaceuticals.

15. Schedule M and Schedule N.

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M. Pharm – I year I Sem. (PA & QA)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S04103) AUDITS AND REGULATORY COMPLIANCE

Scope

This course deals with the understanding and process for auditing inpharmaceutical industries. This subject covers the methodology involved in theauditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

THEORY 60 Hrs

1. 12Hrs

Introduction: Objectives, Management of audit, Responsibilities,Planning process, information gathering, administration,Classifications of deficiencies

2 12Hrs

Role of quality systems and audits in pharmaceuticalmanufacturing environment: cGMP Regulations, Qualityassurance functions, Quality systems approach, Managementresponsibilities, Resource, Manufacturing operations, Evaluationactivities, Transitioning to quality system approach, Audit checklistfor drug industries.

3 12Hrs

Auditing of vendors and production department: BulkPharmaceutical Chemicals and packaging material Vendor audit,Warehouse and weighing, Dry Production: Granulation, tableting,coating, capsules, sterile production and packaging.

4 12Hrs

Auditing of Microbiological laboratory: Auditing themanufacturing process, Product and process information, Generalareas of interest in the building raw materials, Water, Packagingmaterials.

5 12Hrs

Auditing of Quality Assurance and engineering department:Quality Assurance Maintenance, Critical systems: HVAC, Water,Water for Injection systems, ETP.

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsburyand Gil Bismuth, Interpharm/CRC, Boca Raton, London New York,Washington D.C.

2. Pharmaceutical Manufacturing Handbook, Regulations and Quality byShayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc.,Publications.

3. Handbook of microbiological Quality control. Rosamund M. Baird, NormanA. Hodges, Stephen P. Denyar. CRC Press. 2000.

4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis(2005).

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	4	**0**	**0**	**4**

(17S01105) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL

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. (PA & QA)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S04104) QUALITY CONTROL AND QUALITY ASSURANCE PRACTICAL - I

1. Case studies on

- Total Quality Management
- Six Sigma
- Change Management/ Change control. Deviations,
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations

2. Development of Stability study protocol

3. Estimation of process capability

4. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.

5. Assay of raw materials as per official monographs

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

7. To carry out pre formulation study for tablets, parenterals (2 experiments).

8. To study the effect of pH on the solubility of drugs, (1 experiment)

9. Quality control tests for Primary and secondary packaging materials

10. Accelerated stability studies (1 experiment)

11. Improved solubility of drugs using surfactant systems (1 experiment)

12. Improved solubility of drugs using co-solvency method (1 experiment)

14. Determination of Pka and Log p of drugs.

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M. Pharm – I year II Sem. (PA & QA)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S04201) HAZARDS AND SAFETY MANAGEMENT

Scope

This course is designed to convey the knowledge necessary to understandissues related to different kinds of hazard and their management. Basictheoretical and practical discussions integrate the proficiency to handle theemergency situation in the pharmaceutical product development process andprovides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in differentkinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology forprovide safe industrial atmosphere.

THEORY 60Hrs

1. 12Hrs

Multidisciplinary nature of environmental studies: NaturalResources, Renewable and non-renewable resources, Naturalresources and associated problems,

a) Forest resources; b) Water resources; c) Mineral resources; d)Energy resources; e) Land resources

Ecosystems: Concept of an ecosystem and Structure andfunction of an ecosystem. Environmental hazards: Hazardsbased on Air, Water, Soil and Radioisotopes.

2 12Hrs

Air based hazards: Sources, Types of Hazards, Air circulationmaintenance industry for sterile area and non sterilearea,Preliminary Hazard Analysis (PHA) Fire protection system: Fireprevention, types of fire extinguishers and critical Hazardmanagement system.

3 12Hrs

Chemical based hazards: Sources of chemical hazards,Hazards of Organic synthesis, sulphonating hazard, Organicsolvent hazard, Control measures for chemical hazards,Management of combustible gases, Toxic gases and Oxygendisplacing gases management, Regulations for chemical hazard,Management of over-Exposure to chemicals and TLV concept.

4 12Hrs

Fire and Explosion: Introduction, Industrial processes andhazards potential, mechanical electrical, thermal and processhazards. Safety and hazards regulations, Fire protection system:Fire prevention, types of fire extinguishers and critical Hazardmanagement system mechanical and chemical explosion,multiphase reactions, transport effects and global rates.Preventive and protective management from fires and explosionelectricitypassivation, ventilation, and sprinkling, proofing, reliefsystems -relief valves, flares, scrubbers.

5 12Hrs

Hazard and risk management: Self-protective measures againstworkplace hazards. Critical training for risk management, Processof hazard management, ICH guidelines on risk assessment andRisk management methods and ToolsFactory act and rules, fundamentals of accident prevention,elements of safety programme and safety management,Physicochemical measurements of effluents, BOD, COD,Determination of some contaminants, Effluent treatmentprocedure, Role of emergency services.

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers,Bangalore

2. “Quantitative Risk Assessment in Chemical Process Industries” AmericanInstitute of Chemical Industries, Centre for Chemical Process safety.

3. BharuchaErach, The Biodiversity of India, Mapin Pu blishingPvt.Ltd.,Ahmedabad – 380 013, India,

4. Hazardous Chemicals: Safety Management and Global Regulations,T.S.S. Dikshith, CRC press

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M. Pharm – I year II Sem. (PA & QA)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S04202) PHARMACEUTICAL VALIDATION

Scope

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

Objectives

At completion of this course, it is expected that students will be able tounderstand

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture ofpharmaceuticals

THEORY 60 Hrs

1. 10Hrs

Introduction to validation: Definition of Calibration, Qualificationand Validation, Scope, frequency and importance. Differencebetween calibration and validation. Calibration of weights andmeasures. Advantages of Validation, scope of Validation,Organization for Validation, Validation Master plan, Types ofValidation, Streamlining of qualification & Validation process andValidation 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).

2 16Hrs

a. Qualification of manufacturing equipment: Dry PowderMixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membranefiltration, Capsule filling machine.
b. Qualification of analytical instruments: UV-Visiblespectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

c. Qualification of laboratory equipments: Hardness tester,Friability test apparatus, tap density tester, Disintegration tester,Dissolution test apparatus

Validation of Utility systems: Pharmaceutical water system &pure steam, HVAC system, Compressed air and nitrogen.

3 12Hrs

Process Validation: Concept, Process and documentation ofProcess Validation. Prospective, Concurrent &RetrospectiveValidation, Re validation criteria, Process Validation of variousformulations (Coated tablets, Capsules, Ointment/Creams, LiquidOrals and aerosols.), Aseptic filling: Media fill validation, USFDAguidelines on Process Validation- A life cycle approach.

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

4 10Hrs

Cleaning Validation: Cleaning Method development, Validationof analytical method used in cleaning, Cleaning of Equipment,Cleaning of Facilities. Cleaning in place (CIP).Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digitalsignature - 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,

5. (Marcel Dekker).

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

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

8. Pharmaceutical Equipment Validation: The Ultimate QualificationHandbook, Phillip A. Cloud, Interpharm Press

9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker

10. Analytical Method validation and Instrument Performance Verification byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.

11. Huber L. Validation and Qualification in Analytical Laboratories. InformaHealthcare

12. Wingate G. Validating Corporate Computer Systems: Good IT Practice forPharmaceutical Manufacturers. Interpharm Press

13. LeBlanc DA. Validated Cleaning Technologies for PharmaceuticalManufacturing. Interpharm Press

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M. Pharm – I year II Sem. (PA & QA)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S04203) 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. 12Hrs

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 12Hrs

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 12Hrs

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 14Hrs

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 10Hrs

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 Vol I , 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.

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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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QA)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S04204) MODERN BIO-ANALYTICAL TECHNIQUES

Scope

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

Objectives

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

- 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,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

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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.

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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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QA)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S04205) HAZARDS AND SAFETY MANAGEMENT PRACTICAL - II

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO2 using Colorimetric method
7. Check list for Bulk Pharmaceutical Chemicals vendors
8. Check list for tableting production.
9. Check list for sterile production area
10. Check list for Water for injection.

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M. Pharm – I year II Sem. (PA & QA)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S04206) FOOD ANALYSIS PRACTICAL - III

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (PA & QA)	**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 off reedom, 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.