M. PHARM. QUALITY ASSURANCE

Total Contact Hours = 34 **Total Marks = 600** **Total Credits = 25**

SEMESTER 1st		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA6- 101	Pharmaceutical Analytical Techniques	3	1	-	40	60	100	4
MPHA6- 102	Process Validation	3	1	-	40	60	100	4
MPHA6- 103	Product Development	3	1	-	40	60	100	4
MPHA6- 104	Basics of Pharmaceutical Research- I	3	1	-	40	60	100	4
MPHA6-105	Quality Assurance Laboratory-I	-	-	14	60	40	100	7
MPHA6- 106	Seminar	-	-	4	100	-	100	2
Total	**Theory = 5 Lab = 1**	**12**	**4**	**18**	**320**	**280**	**600**	**25**

Total Contact Hours = 32 **Total Marks = 600** **Total Credits = 26**

SEMESTER 2nd		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA6 –207	Hazards and Safety Management	4	-	-	40	60	100	4
MPHA6 – 208	Quality Management Systems	4	-	-	40	60	100	4
MPHA6 – 209	Audits and Regulatory Compliance	4	-	-	40	60	100	4
MPHA6 – 210	Pharmaceutical Manufacturing Technology	4	-	-	40	60	100	4
MPHA6 - 211	Pharmaceutical Quality Assurance Practical II	-	-	12	60	40	100	6
MPHA6 - 212	Seminar/Assignment	-	4	-	100	-	100	4
Total		**16**	**4**	**12**	**350**	**300**	**650**	**26**

SEMESTERS 3rd & 4th		Marks			Credits
Subject Code	**Subject Name**	**Int. (Seminar & Viva on Thesis)**	**Ext. (Evaluation of Thesis)**	**Total**	
MPHA6 - 413	Research Work	100	200	300	24

Note: Thesis shall be presented by the candidate at the end of record academic year.

Overall

Semester	Marks	Credits
1st	600	25
2nd	600	26
3rd & 4th	300	24
Total	**1500**	**75**

PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code – MPHA6 -101 **L T P C** **Duration – 45 Hrs**

3 1 0 4

UNIT- I (11 Hrs)

UV-Visible Spectroscopy: Introduction, Energy Level, Choice of Solvent and Solvent Effects and Modern Instrumentation – Design and Working Principle. Applications of UV-Visible Spectroscopy (Qualitative and Quantitative Analysis), Woodward – Fieser Rule, Fieser Kuhn and Nelson Rules, Influence of Substituent for Calculating Absorption Maximum, Photometric Titrations and Its Applications.

Flame Emission Spectrometry and Atomic Absorption Spectroscopy: Principle, Instrumentation, Interferences and Applications in Pharmacy.

UNIT-II (12 Hrs)

Spectrofluorimetry: Theory, Instrumentation, Advantages, Relationship of Chemical Structure to Fluorescence Spectra, Solvent Effect, Effect of Acids and Bases on Fluorescence Spectra, Concentration Effects, Factors affecting Fluorescence Intensity, Comparison of Fluorescence and UV-Visible Absorption Methods and Applications in Pharmacy.

Infrared Spectroscopy: Introduction, Types of Vibrations, Characteristics Regions of the Spectrum, Influence of Substituent, Ring Size, Hydrogen Bonding, Vibrational Coupling, Field Effects on Frequency, Methodology, Spectral Interpretation with Examples, Quantitative IR Applications. FTIR Theory & Applications

UNIT-III (12 Hrs)

Nuclear Magnetic Resonance Spectroscopy: Fundamental Principles and Theory, Instrumentation, Solvents, Chemical Shift, and Factors affecting Chemical Shift, Spin-Spin Coupling, Coupling Constant and Factors Influencing The Value of Coupling Constant, Spin-Spin Decoupling, Proton Exchange Reactions, FT-NMR, 2D -NMR, NMDR, DEPT, APT, NOE, NOESY, COSY, INADEQUATE And Applications In Pharmacy, Interpretation Of Spectra, ^{13}C NMR-Introduction, Natural Abundance, ^{13}C NMR Spectra and Its Structural Applications.

Mass Spectrometry: Basic Principles and Instrumentation, Ion Formation and Types, Fragmentation Processes and Fragmentation Pattern, Chemical Ionization Mass Spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted Laser Desorption/Ionization MS (MALDI-MS), GC-MS, LC-MS, Interpretation of Spectra and Applications in Pharmacy.

UNIT-IV (8 Hrs)

Chromatographic Techniques: Classification of Chromatographic Methods Based on Mechanism of Separation: Paper Chromatography, Thin Layer Chromatography, Ion Exchange & Ion Pair Chromatography, Column Chromatography and Affinity Chromatography, Chiral Chromatography, Size Exclusion – Techniques and Applications.

Gas Chromatography: Theory and Principle, Column Operation, Instrumentation, Derivatisation Methods and Applications in Pharmacy.

High Performance Liquid Chromatography: Principle, Instrumentation, Solvents Used Elution Techniques, RP-HPLC, LC-MS and Applications in Pharmacy.

HPTLC and Super Critical Fluid Chromatography (SFC): Theory and Principle, Instrumentation, Elution Techniques and Pharmaceutical Applications. Theory and Principles, Classifications, Instrumentation, Moving Boundary Electrophoresis, Zone Electrophoresis (ZE), Isoelectric Focusing (IEF) and Applications.

Recommended Books

1. Robert M. Silverstein, 'Spectrometric Identification of Organic Compounds', 6th Edn., Wiley & Sons Publication.
2. Doglass A. Skoog, Holler, Nieman, 'Principles of Instrumental Analysis', 5th Edn., Thomson & Brooks Cole Publication.
3. Hobert H. Willard, 'Instrumental Methods of Analysis', 7th Edn., CBS Publication.
4. Gary D. Christian, 'Analytical Chemistry', Wiley & Sons Publication.
5. A.H. Beckett, J.B. Stenlake, 'Practical Pharmaceutical Chemistry', Volume I & II, 4th Edn., CBS Publications.
6. Skoog, West, Holler and Crouch, 'Fundamentals of Analytical Chemistry', 8th Edn., Thomson & Brooks Cole Publication.
7. B.K. Sharma, 'Instrumental Methods of Chemical Analysis', Goel Publication.
8. William Kemp, 'Organic Spectroscopy', Palgrave Publication.
9. P.D. Sethi, Dilip Charegaonkar, 'Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography', CBS Publication.

PROCESS VALIDATION

Subject Code – MPHA6 -102 **L T P C** **Duration – 45 Hrs**

3 1 0 4

UNIT-I (10 Hrs)

Concepts of Validation, Types of Validation, Validation & Calibration of Manufacturing Instruments and Analytical Equipments, Re-Validation of Validation Processes and Scale-Up and Post Approval Changes (SUPAC).

UNIT-II (10 Hrs)

Process Validation of Pharmaceutical Ingredients and Production of Pharmaceuticals, Validation of Sterilization Processes, Biotechnological Processes, Transdermal Processes, Lyophilisation Processes and Inhalation Aerosol.

UNIT- III (12 Hrs)

Equipment and Facility Qualification, Qualification of Water and Air Handling System, Packaging Validation and Computer System Validation. Precision, Accuracy and Biases, Sampling and Operating Characteristic Curves, Sampling Plans, Statistical Inference in Estimation of Hypothesis Testing.

UNIT-IV (3 Hrs)

Documentation in Pharmaceutical Industry: Three Tier Documentation, Policy, Procedures and Work Instructions, and Records (Formats), Basic Principles- How to Maintain, Retention and Retrieval Etc. Standard Operating Procedures (How to Write), Master Formula Record, Batch Formula Record, Quality Audit Plan and Reports. Specification and Test Procedures, Protocols and Reports. Distribution Records, Electronic Data

Recommended Books

1. Y. Anjaneyulu, R. Marayya, 'Quality Assurance & Quality Management in Pharmaceutical Industry', Pharma Book Syndicate.
2. B.T. Loftus & R.A. Nash, 'Pharmaceutical Process Validation, Drugs and Pharm Sci. Series', Vol. 23, 3rd Edn., Marcel Dekker Inc.
3. S. Bolton, 'Pharamaceutical Statistics: Practical & Clinical Applications, Drugs and Pharm. Sci. Series', Vol. 25, Marcel Dekker Inc.
4. N.K. Jain, 'Pharmaceutical Product Development', CBS Publication.
5. United States Pharmacopoeia, USP Convention Inc.

PRODUCT DEVELOPMENT

Subject Code – MPHA6-103 **L T P C** **3 1 0 4** **Duration - 45 Hrs**

UNIT-I (8 Hrs)

Controlled Drug Delivery: Fundamentals of Controlled Release (CR) Drug Delivery: Rationale of Sustained/Controlled Drug Delivery; Physicochemical and Biological Factors Influencing Design and Performance of CR Products, Therapeutic Status of CDDS. Theory of Mass Transfer; Fick's First and Second Laws and Their Applications in Drug Release and Permeation. Pharmacokinetic/Pharmacodynamics Basis of Controlled Drug Delivery; Bioavailability Assessment of CR Systems

Design and Fabrication of Technology Based CR Systems: Strategies and Design of Oral Controlled Release Delivery Systems, Oral Systems Based on Dissolution, Diffusion and Dissolution, Ion-Exchange Resins, Ph-Independent Formulations, Altered Density Formulations. Bucco/Mucoadhesive Systems. Osmotic Controlled Oral Drug Delivery

UNIT-II (11 Hrs)

Parenteral System: Parenteral Systems, Biopharmaceutic Considerations, Design and Development, Polymeric Microspheres, Dispersed Drug Delivery. Implantable Therapeutic Systems, Biocompatibility of Polymers and Carriers; Intrauterine Devices and Intravaginal Devices.

Transdermal Drug Delivery System: Transdermal Therapeutic Systems (TTS): Drug Absorption Through Skin, Permeation Enhancers, Basic Components of TTS, Approaches to Development and Kinetic Evaluation, Testing of Transdermal Patches, Pressure Sensitive Adhesives; Iontophoresis, Sonophoresis and Electroporation.

UNIT- III (10 Hrs)

Design and Fabrication of Technology Based CR Systems:

Novel Ocular Drug Delivery Systems: Ocular Therapeutics and Constraints to Effective Delivery, Formulation Considerations to Improve the Ocular Bioavailability, Ocular Inserts Including Insoluble and Soluble Inserts, Non-Corneal Routes and Their Use for Systemic Drug Delivery.

Colloidal and Supramolecular Delivery Systems -I

1. Closed Bi-Layered System: Historical Background, Structural Aspects, Preparation, Characterization, Evaluation and Applications, Specialized Liposomes and Niosomes.
2. Nanoparticles, Microspheres: Method of Preparation, Characterization, Evaluation and Pharmaceutical Applications.
3. Multiple W/O/W Emulsions as Drug Vehicles. Introduction, Composition of The Multiple Emulsion and Stability, Influence of The Nature of Oily Phase, Methods for Stabilizing W/O/W Multiple Emulsions, Mechanisms of Transport of Solutes, *IN VIVO* Studies.

UNIT-III (10 Hrs)

Colloidal and Supramolecular Delivery Systems -II: Micro emulsions: Introduction, Structure of Micro emulsions, Solubilisation and Formulation of Micro emulsions, Self-Emulsifying Drug Delivery Systems (SEDDS), Transport Properties and Pharmaceutical Applications of Emulsions

Targeted Drug Delivery: History, Concept, Types and Key Elements; Ideal Carrier System and Approach with Special Reference to Organ Targeting (E.G. Brain, Tumour, Lung, Liver and Lymphatics); Basics of Temperature, pH and Magnetically Induced Targeting Tactics

Recommended Books

1. J.R. Robinson & V.H.L. Lee, 'Controlled Drug Delivery - Fundamentals and Applications', Vol. 29 &Vol. 31, Marcel Dekker, N.Y., **1987.**
2. Y.W. Chien (Ed.), 'Transdermal Controlled Systemic Medications', Marcel Dekker, N.Y., **1987**.
3. S.D. Bruck, 'Controlled Drug Delivery', Vol.1 (Basic Concepts), CRC Press. Florida, **1983.**
4. S.D. Bruck, 'Controlled Drug Delivery', Vol. II (Clinical Applications), CRC Press. Florida, **1983.**
5. L.F. Prescot and W.S. Nimmo, 'Novel Drug and its Therapeutic Applications', John Willy and Sons, Chichester, **1990.**
6. N.K. Jain, 'Controlled and Novel Drug Delivery', CBS New Delhi, **1997.**
7. N.K. Jain, 'Advances in Controlled and Novel Drug Delivery', CBS, New Delhi, **2001.**

BASICS OF PHARMACEUTICAL RESEARCH - I

Subject Code – MPHA6-104 **L T P C** **Duration – 45 Hrs**

3 1 0 4

UNIT-I (8 Hrs)

Drug Design and Discovery: Stages of Drug Discovery, Discovery of Lead Compounds,

Pharmacophore Identification and Structure Modification, Physicochemical Alterations, Quantitative Structure Activity Relationship, High Throuput Screening, Acute, Sub-Acute and Chronic Studies, In-Vivo and In–Vitro Studies, Introduction To Preclinical and Clinical Trials, Toxicological Studies, FDA Review Process and Approval.

UNIT-II (9 Hrs)

Good Laboratory Practice: Scope of GLP, Definitions, Current GLP in manufacturing, responsibilities. General provision, organization and Personnel, Building and Facilities, Equipment, Control of Components and Drug product, Laboratory and Control of Records and Reports, Non-clinical Testing, Controls on Animal House, Report Preparation and Documentation, Application of Computers in Quality Control Laboratory

Good Clinical Practices: Introduction, Regulatory perspectives, Provisions, Documentation.

UNIT –III (16 Hrs)

Principles of Experimental Pharmacology: Common Laboratory Animals in Pharmacological Research, Limitations of Animal Tests, Alternatives to Animal Use, Anesthetics used in Laboratory Animals, Some Standard Techniques Used in Laboratory Animals, Euthanasia of Experimental Animals. Regulations for The Care and Use of Laboratory Animals, CPCSEA, OECD Guidelines.

Analytical Method Validation: General Principles, Validation of Analytical and Bio-analytical Method as Per ICH Guidelines.

Calibration and Qualification of Analytical Instruments: Electronic Balance, Ph Meter, UV-Visible Spectrophotometer, FTIR, GC, HPLC, HPTLC, Disintegration and Dissolution Test Apparatus. **Qualification of Glassware:** Volumetric Flask, Pipette, Beakers and Burette

UNIT-IV (12 Hrs)

Methods in Material Characterization - Particle dimensions: Particle Size and Powder Surface Area, Particle Shape and Surface Morphology.

Characterization of Solid State Structure: Spectroscopy in Pharmaceutical Analysis, X-Ray Diffraction, Solid-State Nuclear Magnetic Resonance, Vibrational Spectroscopy, Calorimetry in Pharmaceutical Analysis, Water Vapor Sorption, Electron and Confocal Microscopy, Density Measurements.

Thermal Methods of Analysis: Theory, Instrumentation and Applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA)

X-Ray Diffraction Methods: Introduction, Generation of X-Rays, X-Ray Diffraction, Bragg's Law, X-Ray Powder Diffraction, Interpretation of Diffraction Patterns and Applications.

Recommended Books

1. M.E. Wolff, 'Burger's Medicinal Chemistry and Drug Discovery, Principle and Practice', John Wiley and Sons, New York.
2. R. Franke, 'Theoretical Drug Design Methods', Vol. VII, Elsevier, New York.
3. R.B. Silverman, 'The Organic Chemistry of Drug Design and Action', Academic Press Inc., San Diego, USA.

4. P.I. Good, 'A Managers Guide to Design and Conduct of Clinical Trials', Wiley-Liss, Hobokem, U.S.A., **2002.**
5. A.C. Cartwright and B.R. Matthews (eds.), 'International Pharmaceutical Product Registration', Elis Horwood, New York, U.S.A., **1994.**
6. H.G. Vogel, 'Drug Discovery and Evaluation-Pharmacological Assays', 2nd Edn., Springer Verlag, Berlin, Germany, **2002.**
7. M.N. Ghosh, 'Fundamentals of Experimental Pharmacology', 2nd Edn., Scientific Book Agency, Calcutta, India, **1984.**
8. Sandy Weinberg, 'Good Laboratory Practices', Vol. 129, Drugs and Pharm. Sci. Series, Marcel Dekker Inc.
9. Robert M. Silverstein, 'Spectrometric Identification of Organic Compounds', 6th Edn., Wiley & Sons Publication.
10. Doglass A. Skoog, Holler, Nieman, 'Principles of Instrumental Analysis', Thomson & Brooks Cole Publication.
11. Hobert H. Willard, 'Instrumental Methods of Analysis', 7th Edn., CBS Publication.
12. Analytical Chemistry, Gary D. Christian, Wiley & Sons Publication.
13. A.H. Beckett, J.B. Stenlake, 'Practical Pharmaceutical Chemistry', Volume I & II, CBS Publications.
14. Skoog, West, Holler and Crouch, 'Fundamentals of Analytical Chemistry', 8th Edn., Thomson & Brooks Cole Publication.

QUALITY ASSURANCE LABORATORY - I

Subject Code – MPHA6-105 **L T P C**
0 0 14 7

1. IR, NMR and Mass Spectroscopy – Interpretation of Spectra & Structural Elucidation (at Least for 4 Compounds Each).
2. Calibration and Validation Of All The Equipments Studied in Theory Such As UV-Visible, IR, Spectrofluorimeter, HPLC, GC, HPTLC, Validation of Autoclave, AHU, Hot Air Oven, Machinery Related to Pharmaceutical Technology, etc.
3. Preparations and Evaluation of Various Novel Drug Delivery Systems & Liquid Dosage Forms.
4. Determination of Various Analytical Method Validation Parameters for any Pharmacopoeial Compound.

SEMINAR

Subject Code – MPHA6-106 **L T P C**
0 0 4 2

1. Introduction, Information and Retrieval Systems.

2. Writing Assignments and Term Papers.
3. Reading Research Papers.
4. Organization and Presentation of Scientific Material, Research Work, Dissertations, Patents, Etc.
5. Skills in Oral and Technical Presentations.

Each student has to present at least three seminars during the semester.

HAZARDS AND SAFETY MANAGEMENT

Subject Code – MPHA6 -207 **L T P C** **Duration – 50 Hrs**
4 0 0 4

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides 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 different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

UNIT- I (12 Hrs)

Multidisciplinary Nature of Environmental Studies

Natural Resources, Renewable and non-renewable resources, Natural resources 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 and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT-II (14 Hrs)

Air Based Hazards

Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

Chemical Based Hazards

Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT-III (12 Hrs)

Fire and Explosion

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

UNIT-IV (12 Hrs)

Hazard and Risk Management

Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory 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 treatment procedure, Role of emergency services.

Recommended Books

1. Y.K. Singh, 'Environmental Science', New Age International Pvt, Publishers, Bangalore
2. 'Quantitative Risk Assessment in Chemical Process Industries', American Institute of Chemical Industries, Centre for Chemical Process Safety.
3. Bharucha Erach, 'The Biodiversity of India', Mapin Publishing Pvt. Ltd., Ahmedabad
4. T.S.S. Dikshith, 'Hazardous Chemicals: Safety Management and Global Regulations', CRC Press

QUALITY MANAGEMENT SYSTEMS

Subject Code – MPHA6 -208 **L T P C** **Duration – 50 Hrs**

4 0 0 4

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives

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

- 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

UNIT-I (14 Hrs)

Introduction to Quality

Evolution of Quality, Definition of Quality, Dimensions of Quality.

Quality as a Strategic Decision

Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality.

Customer Focus

Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, 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 of quality.

UNIT-II (14 Hrs)

Pharmaceutical Quality Management

Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

Six System Inspection Model

Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self-inspection.

UNIT- III (12 Hrs)

Quality Systems

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

Drug Stability

ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

UNIT-IV (10 Hrs)

Statistical Process control (SPC)

Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

Regulatory Compliance through Quality Management and Development of Quality Culture Benchmarking

Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

Recommended Books

1. Al Endres, 'Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results', Wiley, **2000.**
2. Jiju Antony and David Preece, 'Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases', Routledge, **2002.**
3. James W. Fairfield-Sonn, 'Corporate Culture and the Quality Organization', Quorum Books, **2001**
4. Christine Avery and Diane Zabel, 'The Quality Management Sourcebook: An International Guide to Materials and Resources', Routledge, **1997**
5. Nancy R. Tague, 'The Quality Toolbox', ASQ Publications
6. Joseph M. Juran and Joseph A. De Feo, 'Juran's Quality Handbook', ASQ Publications
7. Duke Okes, 'Root Cause Analysis, The Core of Problem Solving and Corrective Action', ASQ Publications. **2009.**

AUDITS AND REGULATORY COMPLIANCE

Subject Code – MPHA6-209 **L T P C** **Duration - 50 Hrs**

4 0 0 4

Scope

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

UNIT-I (14 Hrs)

Introduction:

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

Role of quality systems and audits in pharmaceutical manufacturing environment:

cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT-II (12 Hrs)

Auditing of Vendors and Production Department

Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT- III (12 Hrs)

Auditing of Microbiological Laboratory

Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT-IV (12 Hrs)

Auditing of Quality Assurance and Engineering Department

Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

Recommended Books

1. Boca Raton, Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, London New York, Washington D.C.
2. Shayne Cox Gad, 'Pharmaceutical Manufacturing Handbook, Regulations and Quality', Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar, 'Handbook of microbiological Quality Control', CRC Press. **2000**.
4. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden, 'Laboratory Auditing for Quality and Regulatory Compliance', Taylor and Francis **2000**

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Subject Code – MPHA6-210 **L T P C** **Duration – 50 Hrs**

4 0 0 4

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives

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

- The common practice in the pharmaceutical industry developments, plant layout and production planning.

- Will be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.

UNIT-I (13 Hrs)

Pharmaceutical Industry Developments

Legal requirements and Licenses for API and formulation industry, Plant Location-Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production Planning

General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

Aseptic Process Technology

Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

Advanced Sterile Product Manufacturing Technology

Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

UNIT-II (13 Hrs)

Process Automation in Pharmaceutical Industry

With specific reference to manufacturing of sterile semisolids, Small Volume Parenteral & Large Volume Parenteral (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilisation Technology

Principles, process, equipment.

Non Sterile Manufacturing Process Technology

Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

Advance Non-Sterile Solid Product Manufacturing Technology

Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and palletisation equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipment. Problems encountered.

UNIT –III (12 Hrs)

Coating Technology

Process, equipment, particle coating, fluidized bed coating, application techniques. Problems encountered.

Containers and closures for pharmaceuticals:

Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil /plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

UNIT-IV (12 Hrs)

Quality by Design (QbD) and Process Analytical Technology (PAT)

Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

Recommended Books

1. L. Lachman, H.A. Lieberman, J.L. Kanig, 'The Theory and Practice of Industrial Pharmacy', Varghese Publishers, Mumbai, **1991.**
2. P.J. Sinko, 'Martin's Physical Pharmacy and Pharmaceutical Sciences', B.I. Publications Pvt. Ltd., Noida, **2006.**
3. H.A. Lieberman, L. Lachman, J.B. Schwartz, 'Pharmaceutical Dosage Forms: Tablets', Vol. I-III, CBS Publishers & distributors, New Delhi, **2005.**
4. G.S. Banker, C.T. Rhodes, Modern Pharmaceutics, 4th Edn., Marcel Dekker Inc., New York, **2005**.
5. Sidney H. Willing, Murray M. Tuckerman. Williams Hitchings IV, 'Good Manufacturing of Pharmaceuticals (A Plan for total quality control) 3rd Edn., Bhalani Publishing House Mumbai.
6. 'Indian Pharmacopoeia', Controller of Publication. Delhi, **1996.**
7. 'British Pharmacopoeia', British Pharmacopoeia Commission Office, London, **2008.**
8. 'United States Pharmacopoeia'. United States Pharmacopeial Convention, Inc, USA, **2003**.
9. D.A. Dean, E.R. Evans and I.H. Hall, 'Pharmaceutical Packaging Technology. London', Taylor & Francis, UK.
10. Edward J. Bauer, 'Pharmaceutical Packaging Handbook', Informa Health Care, USA, Inc. New York. **2009.**
11. Shaybe Cox Gad., 'Pharmaceutical Manufacturing Handbook', John Willey and Sons, New Jersey, **2008**.

QUALITY ASSURANCE PRACTICAL - II

Subject Code – MPHA6-211 **L T P C**

0 0 12 6

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. Qualification of following Pharma equipment
   a) Autoclave
   b) Hot air oven
   c) Powder Mixer (Dry)
   d) Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

SEMINAR/ASSIGNMENT

Subject Code – MPHA6-212 **L T P C**
0 4 0 4

- Introduction, Information and Retrieval Systems.
- Writing Assignments and Term Papers
- Reading Research Papers
- Organization and Presentation of Scientific Material, Research Work, Dissertations, Patents Etc.
- Skills in Oral and Technical Presentations
- Tutorials related to subject taught

Each student has to present at least three seminars during the semester.