SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)
R25 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2025-26 Admitted Batch

I YEAR I Semester

Course Code	Course Title		L	T	P	Credits
Professional Core-I	Modern Pharmaceutical Analytical Techniques		3	1	0	4
Professional Core-II	Pharmaceutical Quality Control & Quality Assurance		3	1	0	4
Professional Elective-I	1. Quality Management Systems 2. Drug Regulatory Affairs 3. Pharmaceutical Food Analysis		3	1	0	4
Professional Elective-II	1. Product Development & Technology Transfer 2. Advanced Pharmaceutical Analysis 3. Pharmaceutical Management		3	1	0	4
	Research methodology and IPR		2	0	0	2
Laboratory- I	Modern Pharmaceutical Analytical Techniques Lab		0	0	6	3
Laboratory- II	Pharmaceutical Quality Control & Quality Assurance Lab		0	0	6	3
Audit - I	Audit Course - I		2	0	0	0
	Seminar & Assignment		0	0	4	2
	Total		**16**	**4**	**16**	**26**

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Pharmaceutical Validation	3	1	0	4
Professional Core-IV	Pharmaceutical Manufacturing Technology	3	1	0	4
Professional Elective-III	1. Hazards and Safety Management 2. Spectral Analysis 3. Screening Methods in Pharmacology	3	1	0	4
Professional Elective-IV	1. Audits and Regulatory Compliance 2. Herbal Drug Technology 3. Stability of Drugs and Dosage Forms	3	1	0	4
Laboratory- III	Pharmaceutical Validation Lab	0	0	6	3
Laboratory- IV	Pharmaceutical Manufacturing Technology Lab	0	0	6	3
	Mini project	2	0	0	2
Audit - II	Audit Course - II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Scale up and Technology Transfer 3. Production area, Design and Packaging Development	3	1	0	4
Open Elective	Open Elective	3	1	0	4
	Comprehensive Viva Voce	0	0	8	4
	Dissertation Work Review - II	0	0	24	12
	Total	**6**	**2**	**32**	**24**

II YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	Total	**0**	**0**	**44**	**22**

***For Dissertation Work Review - I, Please refer R25 Academic Regulations.**

Audit Courses I & II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

Open Electives:

1. Entrepreneurship Management
2. Pharmaceutical administration
3. Cosmetic Science
4. Environmental and Health safety
5. Vaccines and Biologicals

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Professional Core - I)

Course Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

Course Outcome: Upon completion of the course a learner shall be able to

CO 1. Explain the principles and procedures of various chromatographic techniques such as column, thin layer, and paper chromatography and their applications in pharmaceutical analysis
CO 2. Demonstrate understanding of the principles, instrumentation, and applications of advanced chromatographic methods including GC, HPLC, and HPTLC
CO 3. Interpret UV-Visible and IR spectra by applying basic principles, instrumentation knowledge, and spectral analysis techniques for pharmaceutical compound
CO 4 : Apply the principles of mass spectrometry and ionization techniques to interpret mass spectra for structure elucidation and pharmaceutical applications
CO 5. Analyze NMR spectra using concepts of chemical shift, splitting patterns, and coupling to elucidate the structure of pharmaceutical compounds.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

a. **Column Chromatography:** Adsorption and partition, theory, preparation, procedure and methods of detection
b. **Thin Layer Chromatography:** Theory, preparation, procedures, detection of compounds
c. **Paper Chromatography:** Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II

a. **Gas chromatography:** Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, derivatization.
b. **HPLC:** Basic parameters, Principles and instrumentation, solvents and columns used, Operational modes, detection and applications of HPLC
c. **HPTLC:** Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. **UV-Visible spectroscopy:** Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. **IR spectroscopy:** Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS and applications for identification and structure determination.

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect (NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

REFERENCE BOOKS:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma 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. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
5. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
6. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
7. Organic Chemistry by I. L. Finar
8. Organic spectroscopy by William Kemp
9. Quantitative Analysis of Drugs by D. C. Garrett
10. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
11. Spectrophotometric identification of Organic Compounds by Silverstein
12. HPTLC by P.D. Seth
13. Indian Pharmacopoeia 2007
14. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
15. Introduction to instrumental analysis by Robert. D. Braun
16. A Textbook of Analytical Chemistry by Y. Anjaneyulu, K. Chandrasekhar, Valli Manickam, Pharmed Press.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)

PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE (Professional Core - II)

Course Objective: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain and apply the principles of impurity profiling, stability studies, and residual solvent analysis as per ICH guidelines to ensure the purity and safety of pharmaceutical products.
CO 2. Evaluate and implement Quality Assurance systems, including Total Quality Management (TQM) and current Good Manufacturing Practices (cGMP), to maintain product consistency and regulatory compliance.
CO 3. Analyze the organizational structure, personnel responsibilities, facility design, and equipment maintenance involved in maintaining pharmaceutical manufacturing standards.
CO 4. Demonstrate understanding of packaging and labeling controls, Good Laboratory Practices (GLP), and data management to ensure accuracy, traceability, and integrity in quality control laboratories.
CO 5. Prepare and manage manufacturing and quality control documentation, including Master Formula Records and SOPs, and perform in-process quality control (IPQC) for various dosage forms.

UNIT I

a. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
b. **Impurities in new drug products**: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

UNIT II

a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
b. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

UNIT III

a. Organization and personnel, responsibilities, training hygiene
b. **Premises**: Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
c. **Equipments:** Selection, purchase specifications, maintenance, clean in place, sterilize in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT IV

a. Packaging and labeling controls, line clearance and other packaging materials.
b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

UNIT V

Manufacture and controls on dosage forms

a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra
4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma
6. A Textbook of Pharmaceutical Quality Assurance by K. P. R. Chowdary, Pharmamed Press.

REFERENCES BOOKS:

1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. SOP Guidelines by D.H. Shah
5. Quality Assurance Guide by OPPI
6. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
7. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier,

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)
QUALITY MANAGEMENT SYSTEMS (Professional Elective - I)

Course Objective: 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.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Understand and apply principles of quality management, strategic planning, customer focus, and cost of quality to enhance organizational performance and customer satisfaction.
CO 2. Apply principles of pharmaceutical quality management, including TQM, Six Sigma, ISO standards, ICH Q10, and regulatory guidelines, to ensure compliance, operational excellence, and continuous improvement.
CO 3. Apply comprehensive quality systems and inspection principles, including GMP, CAPA, OOS/OOT handling, vendor qualification, and IPQC, to ensure product quality, compliance, and continuous improvement in pharmaceutical operations.
CO 4. Apply ICH guidelines and quality risk management principles, including stability testing, QbD, and risk assessment tools, to ensure the safety, efficacy, and quality of pharmaceutical products.
CO 5. Utilize statistical process control, benchmarking, and quality management principles to monitor, improve, and ensure regulatory-compliant pharmaceutical manufacturing processes.

UNIT I

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 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, Optimizing costs, preventing cost of quality.

UNIT II

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.

UNIT III

Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control 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 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.

UNIT IV

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 V

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.

TEXT AND REFERENCE BOOKS:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Pharmaceutical Quality Assurance and Management, K. P. Bhusari, Pharmamed Press.
4. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
5. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
6. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997
7. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
8. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
9. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)

DRUG REGULATORY AFFAIRS (Professional Elective - I)

Course Objectives: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the structure, roles, and functions of Indian drug regulatory authorities and interpret the key provisions of the Drugs and Cosmetics Act, Rules, and Schedules related to drug approval and licensing.

CO 2. Describe the principles and requirements of Good Manufacturing Practices (GMP), ICH quality guidelines, and plant layout considerations to ensure pharmaceutical product quality and safety.

CO 3. Compare global regulatory frameworks and guidelines governing drug development, manufacturing, and marketing in major regions such as the USA, Europe, and Brazil.

CO 4. Demonstrate understanding of Good Documentation Practices (GDP) in pharmaceutical manufacturing and quality systems, including procedures for records, batch release, complaints, and recalls.

CO 5. Identify and differentiate the roles of international regulatory authorities and outline the processes for preparation and submission of Drug Master Files (DMFs) and responses to regulatory queries.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC& BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Managemant, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

UNIT III

Global Regulatory Affairs

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA, Europe and Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Good Documentation Practices

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product DirectorateDMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
    3) MHRA – Medicines and Health Care Products Regulatory Agency
d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

TEXT AND REFERENCE BOOKS

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Text Book of Forensic Pharmacy by C K Kokate, Pharmamed Press
6. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)
PHARMACEUTICAL FOOD ANALYSIS (Professional Elective-I)

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

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the chemical composition, properties, and analytical methods used for the qualitative and quantitative estimation of food carbohydrates, proteins, and amino acids.

CO 2. Describe the characteristics, mechanisms, and applications of probiotics in food and health, along with their analytical identification methods.

CO 3. Discuss the classification, analytical techniques, and quality evaluation of lipids, including detection of adulteration and processes such as refining and hydrogenation.

CO 4 Apply appropriate analytical and microbial assay techniques for the estimation of vitamins and evaluate their significance in food quality assessment.

CO 5. Analyze the composition, quality, and adulteration of milk and milk products, as well as fermentation-based food products like wine, beer, and vinegar, using standard analytical procedures.

UNIT I

a. Carbohydrates: Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates,

b. Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids

UNIT II

Probiotics: Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT III

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

UNIT IV

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT V

a. **General Analytical methods** for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

b. **Analysis of fermentation products** like wine, spirits, beer and vinegar.

TEXT BOOKS:

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
6. 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

REFERENCE BOOKS:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Food Chemistry and Nutrition: A Comprehensive Treatise, Sumathi S, Pharmamed Press
3. David Pearson. The Chemical Analysis of Foods, 7th ed., Churchill Livingstone, Edinburgh, 1976.
4. Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
5. Indian Pharmacopoeia 2012

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (Professional Elective - II)

Course Objective: This topic will impart the knowledge about principles of drug discovery development of INS, NDA and ANDA. This also gives the information about pre-formulation studies, protocols of stability studies, pilot plant scale up and packaging of pharmaceuticals.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the principles and regulatory framework governing drug discovery and development, including IND, NDA, ANDA, SUPAC, and post-marketing requirements.

CO 2. Describe the concepts and procedures involved in pre-formulation studies, including evaluation of physicochemical properties, solubility enhancement, polymorphism, and stability testing of drug substances.

CO 3. Demonstrate understanding of pilot plant scale-up principles, design considerations, and large-scale manufacturing processes for various pharmaceutical dosage forms.

CO 4 Discuss the types, materials, and quality evaluation of pharmaceutical packaging systems, highlighting their role in product protection, stability, and regulatory compliance.

CO 5. Outline the process and documentation involved in technology transfer from R&D to production, ensuring smooth scale-up and regulatory conformity for pharmaceutical products.

UNIT I

Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA

UNIT II

Pre-formulation studies: Introduction/concept, organolepti properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

UNIT III

Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

UNIT IV

Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.

UNIT V

Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

REFERENCE BOOKS:

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rdEdition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T. Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn (1995) OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)

ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - II)

Course Objective: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are also discussed.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the principles and procedures involved in various titrimetric analytical methods such as non-aqueous, redox, complexometric, diazotization, neutralization, and acid–base analysis for official compounds.

CO 2. Describe the quantitative analytical techniques used for the estimation of organic functional groups such as amines, esters, carbonyls, hydroxy, carboxyl, and amino acids in pharmaceutical substances.

CO 3. Discuss the preparation and application of reference standards and various chromogenic and analytical reagents (MBTH, Folin–Ciocalteu, PDAB, etc.) in pharmaceutical analysis.

CO 4 Analyze the physicochemical properties and quality parameters of pharmaceutical excipients, including their functions and evaluation tests for formulation suitability.

CO 5. Demonstrate understanding of dissolution testing principles and microbiological assays used for quality control, sterility, and potency determination of pharmaceutical products.

UNIT I

Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques:

A. Non-aqueous
B. Oxidation-reduction
C. Complexometric
D. Diazotization methods
E. Neutralization
F. Acid – Base

UNIT II

A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

A. Amines
B. Esters
C. Carbonyl compounds
D. Hydroxy and carboxyl
E. Amino Acids

UNIT III

a. Reference Standards: Types, preparation methods and uses.

b. Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP

a. MBTH (3-methyl-2-benzothiazolone hydrazone)
b. F.C. Reagent (Folin-Ciocalteu)
c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
d. 2, 3, 5 - *tri*Phenyltetrazolium salt
e. 2,6 *di* -ChloroquinoneChlorimide
f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
g. Carr – Price Reagent
h. 2,4 - DNP

UNIT IV

a. Analysis of Excipients: Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), loss on drying, ash content, conductivity.

b. Excipients of interest: Disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT V

a. Dissolution Tests: Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms, coated, uncoated, enteric coated, gelatin capsules etc.

b. Microbiological assays and Biological tests: Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

TEXT BOOKS:

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

REFERENCE BOOKS:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (Pharmaceutical Quality Assurance)
PHARMACEUTICAL MANAGEMENT (Professional Elective - II)

Course Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the principles, evolution, and processes of pharmaceutical management, including key managerial functions such as planning, organizing, staffing, directing, coordinating, and controlling.
CO 2. Describe the fundamental concepts of production, financial, personnel, legal, and marketing management in the pharmaceutical industry, along with budgeting, costing, and entrepreneurship development.
CO 3. Analyze the structure and functioning of various pharmaceutical organizations and service units, including hospital pharmacy, bulk drug, formulation, Ayurvedic, Unani, and testing laboratories.
CO 4. Discuss the roles, skills, and leadership styles of professional managers and apply principles of decision-making, personnel management, and time management in organizational settings.
CO 5. Demonstrate understanding of industrial relations, motivation, communication, conflict resolution, and stress management for effective human resource and organizational performance in the pharmaceutical industry.

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing, and budgetary control. Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

UNIT IV

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

TEXT AND REFERENCE BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill".
11. Personnel Management and Industrial Relations by P. C. Tripathi.
12. Pharmaceutical Industrial Management by G. Vidya Sagar, Pharmamed Press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (Pharmaceutical Quality Assurance)
RESEARCH METHODOLOGY AND IPR

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Understand research problem formulation.
CO 2. Analyze research related information. Follow research ethics.
CO 3. Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
CO 4. Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
CO 5. Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"
3. Pharmaceutical Research Methodology and BioStatistics B Subba Rao, Pharmamed

4. Intellectual Property Rights in Pharmaceutical Industry B Subba Rao, Pharmamed

REFERENCE BOOKS:

1. Ranjit Kumar, 2nd Edition, “Research Methodology: A Step by Step Guide for beginners”
2. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd ,2007.
3. Mayall, “Industrial Design”, McGraw Hill, 1992.
4. Niebel, “Product Design”, McGraw Hill, 1974.
5. Asimov, “Introduction to Design”, Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “Intellectual Property in New
7. Technological Age”, 2016.
8. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (Laboratory – I)

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Perform quantitative analysis of pharmaceutical compounds using UV-Visible spectrophotometry and evaluate parameters such as assay, content uniformity, and drug release.
CO 2. Apply UV spectrophotometric methods for simultaneous estimation of multi-component formulations and validate analytical results
CO 3. Operate and perform analytical separations using HPLC and HPTLC techniques, interpret chromatograms, and calculate retention parameters
CO 4. Operate and perform analytical separations using HPLC and HPTLC techniques, interpret chromatograms, and calculate retention parameters
CO 5. Calibrate analytical instruments and laboratory glassware, including UV-Visible spectrophotometer, FTIR, HPLC, and pH meter, to ensure accuracy, precision, and regulatory compliance

LIST OF EXPERIMENTS:

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Calibration of glasswares
7. Calibration of pH meter
8. Calibration of UV-Visible spectrophotometer
9. Calibration of FTIR spectrophotometer
10. Calibration of HPLC instrument

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (Pharmaceutical Quality Assurance)

PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE LAB
(Laboratory – II)

Course Outcomes: Upon completion of the course a learner shall be able to

CO1: Perform quality control (QC) tests for various dosage forms such as tablets, capsules, oral liquids, and parenterals in compliance with pharmacopoeial standards

CO2: Conduct forced degradation studies and stability assessments to evaluate the degradation behavior of pharmaceutical drugs.

CO3: Interpret IR, NMR, and Mass spectra to identify structural features and functional groups of pharmaceutical compounds.

CO4: Estimate drug content using colorimetric and UV spectrophotometric methods and demonstrate understanding of assay procedures for different formulations.

CO5: Carry out physicochemical analyses such as water testing and solubility studies to assess the quality and performance of pharmaceutical substances.

LIST OF EXPERIMENTS:

1. QC tests for tablets and capsules (minimum 3 experiments)
2. QC tests for oral liquids and parenterals (minimum 3 experiments)
3. Forced degradation studies of some drugs.
4. Interpretation of spectras by IR, NMR and MASS
5. Estimation of drugs by specified colorimetric reagents
6. Assay of drug formulations using UV-Spectrophotometer (Any four)
7. Demonstration of functional groups of the given samples by IR Spectrophotometer.
8. Physicochemical tests for water
9. Solubility studies of weakly acidic and weakly basic drugs.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)

PHARMACEUTICAL VALIDATION (Professional Core - III)

Course Objective: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the fundamental concepts, advantages, and processes involved in equipment and instrument qualification and validation in pharmaceutical manufacturing.
CO 2. Demonstrate understanding of qualification procedures for analytical instruments and laboratory glassware to ensure accuracy and reliability in analytical testing.
CO 3. Describe the qualification of laboratory equipment and validation of critical utility systems such as water, HVAC, and compressed gases in compliance with regulatory standards.
CO 4. Apply the principles of cleaning validation to develop, validate, and monitor cleaning procedures for equipment and facilities in pharmaceutical environments
CO 5. Explain the principles and regulatory requirements for analytical method validation as per ICH and USP guidelines to ensure method reliability and accuracy

UNIT I

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

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

UNIT II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

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.

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

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

REFERENCE BOOKS:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.

3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Upll, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (Pharmaceutical Quality Assurance)

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (Professional Core–IV)

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

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the principles of pharmaceutical industry developments, legal requirements, plant layout, production planning, and production control for API and formulation manufacturing.
CO 2. Describe aseptic manufacturing processes, advanced sterile product technologies, process automation, and lyophilization techniques used in the production of sterile dosage forms.
CO 3. Demonstrate understanding of non-sterile manufacturing processes, including solid dosage forms, process automation, granulation, coating technologies, and quality control measures.
CO 4. Analyze the types, materials, quality evaluation, and stability aspects of pharmaceutical packaging systems and containers to ensure product integrity and compliance.
CO 5. Apply the concepts of Quality by Design (QbD) and Process Analytical Technology (PAT) to optimize pharmaceutical manufacturing processes, improve product quality, and comply with regulatory standards.

UNIT I

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.

UNIT II

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. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (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). Lyophilization technology: Principles, process, equipment.

UNIT III

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 palletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, and application techniques. Problems encountered.

UNIT IV

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 - V

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.

REFERENCE BOOKS:

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida,2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms:tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi,2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th Inc, New York, 2005. ed., Marcel Dekker
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. 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. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition.UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (Pharmaceutical Quality Assurance)
HAZARDS AND SAFETY MANAGEMENT (Professional Elective - III)

Course Objectives: 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.

Course Outcomes: Upon completion of the course a learner shall be able to

CO1. Explain the multidisciplinary nature of environmental studies and analyze the impact of resource utilization and environmental hazards.
CO2. Identify and assess air-based industrial hazards and apply appropriate fire protection and hazard control systems.
CO3. Evaluate sources and effects of chemical hazards and implement safety regulations and control measures for chemical risk management.
CO4. Analyze causes and preventive measures for industrial fires and explosions, applying engineering and regulatory safety systems.
CO5. Apply hazard and risk management principles, including ICH guidelines and safety programs, for workplace accident prevention.

UNIT I

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

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.

UNIT III

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 IV

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 V

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 Program and safety management, Physicochemical measurements of effluents,

BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

REFERENCE BOOKS:

1. Y.K. Sing, 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 – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T. S. S. Dikshith, CRC press
5. Safety and Health in Industry: A Handbook by AM Sarma, BS Publications

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (Pharmaceutical Quality Assurance)
SPECTRAL ANALYSIS (Professional Elective - III)

Course Objective: The students will acquire the knowledge about the various aspects of X-Ray diffraction methods, all types of IR methods, particle sizing methods, also DSC, DTA, TGA etc

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the principles of X-ray diffraction methods, crystal structure analysis, and their applications in structural elucidation of pharmaceutical compounds.
CO 2. Describe the principles, instrumentation, advantages, and applications of FT-NIR and ATR spectroscopy for qualitative and quantitative pharmaceutical analysis.
CO 3. Apply the concepts of electrometric techniques, including potentiometry, amperometry, conductometry, and polarography, for analytical measurements in pharmaceuticals.
CO 4 Demonstrate understanding of spectrofluorimetry, flame emission, and atomic absorption spectroscopy, including their instrumentation, influencing factors, and pharmaceutical applications.
CO 5. Analyze the principles and applications of FT-Raman spectroscopy in pharmaceutical research, including detection of counterfeit drugs.

UNIT I

X-Ray diffraction methods: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal techniques, single crystal diffraction, power diffraction, structural elucidation, and applications.

UNIT II

a. FT-NIR: Principle (overtones, combinations, fermi resonance, interferences etc.), instrumentation (dispersion spectrometer and FT-NIR), advantage, and disadvantage, qualitative and quantitative applications, including PAT and non-destructive analysis.
b. ATR: Principle (total internal reflection, evanescent wave, etc.), instrumentation (ATR crystal, IR beam), advantages, and disadvantages, pharmaceutical applications.

UNIT III

Electrometric Techniques: Principle, instrumentation and applications of Potentiometer, Amperometer, Conductometer and Polarography.

UNIT IV

a. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation, and Applications of fluorescence spectrophotometer.
b. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences, and applications.

UNIT V

FT- Raman: Principle (absorption, diffraction, scattering and emission of wave, molecular interaction), instrumentation (Dispersive Raman, FT-Raman), advantage and disadvantage, pharmaceutical applications including detection of counterfeit

REFERENCE BOOKS:

1. Instrumental Methods of Chemical Analysis by B. K. Sharma
2. Organic spectroscopy by Y. R. Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A. I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J. B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp

8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P. D. Seth
12. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)
SCREENING METHODS IN PHARMACOLOGY (Professional Elective - III)

Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the care, handling, and breeding of laboratory animals, ethical guidelines, and alternatives to animal studies in accordance with CPCSEA and GLP standards.
CO 2. Describe the principles and methods of bioassays for biological standardization, including vaccines, hormones, antitoxins, and pyrogen testing.
CO 3. Apply toxicity testing protocols, including acute, sub-acute, and chronic studies, following OECD guidelines to assess drug safety.
CO 4 Organize and perform pharmacological screening of new substances for cardiac and anti-diabetic activities using standard experimental models.
CO 5. Conduct pharmacological evaluation of new substances for psychopharmacological, anti-inflammatory, and analgesic activities using appropriate screening methods.

UNIT I

Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II

Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III

Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert. A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heidelberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Guidelines and Screening Methods of Pharmacology by Surendra H. Bodakh, Pharmamed Press.

REFERENCE BOOKS:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (Pharmaceutical Quality Assurance)

AUDITS AND REGULATORY COMPLIANCE (Professional Elective - IV)

Course Objectives: 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.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the objectives, responsibilities, planning, and information-gathering processes involved in pharmaceutical audits.

CO 2. Describe the role of quality systems, cGMP regulations, and audit checklists in ensuring compliance within pharmaceutical manufacturing environments.

CO 3. Apply auditing methodologies to vendors and production departments, including bulk chemicals, packaging materials, and various manufacturing processes.

CO 4 Perform audits in microbiological laboratories and manufacturing processes, including assessment of raw materials, water, and packaging systems.

CO 5. Evaluate quality assurance and engineering departments, including critical systems such as HVAC, water systems, and effluent treatment plants, to ensure compliance and operational integrity.

UNIT - I

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

UNIT - II

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 - III

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 - IV

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 - V

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

REFERENCES BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. 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).

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)

HERBAL DRUG TECHNOLOGY (Professional Elective - IV)

Course Objectives: Helps the students in getting exposed to methods of extraction, preparation and purification of herbal extracts. To acquire knowledge on the preparation and standardization of herbal preparation. They will expose to various research institutions of natural products.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the principles, process, and equipment used for preparing herbal extracts, including size reduction, filtration, evaporation, drying, and solvent recovery.
CO 2. Describe the sources, chemical nature, pharmaceutical uses, and storage conditions of natural excipients used in herbal drug formulations.
CO 3. Apply methods for preparation and evaluation of herbal dosage forms such as tablets, capsules, and ointments, including formulation analysis and quality assessment.
CO 4. Understand regulations, label claims, and compliance standards for herbal products, including FDA, FPO, MPO, BIS, and AGMARK guidelines.
CO 5. Analyze the sources, chemical properties, and applications of natural colorants and sweeteners used in herbal drug and nutraceutical formulations.

UNIT I

Equipment for preparing herbal extracts: Process and equipments- Name of the equipment and its uses with merits and demerits in each of the following unit operations in the extraction process.

1. Size reduction
2. Filtration
3. Evaporation/Distillation
4. Drying of extracts
5. Solvent recovery

UNIT II

Definition, classification of natural excipient: Sources, Chemical nature, Description parameters Pharmaceutical uses and storage conditions of following Natural excipients, Binding agents, disintegrating agents, diluents, emulsifying agents: Acacia, Tragacanth, Alginates, CMC, Gelatin, Pectin, Lactose, Starches, Talc, Ointment bases, suppository bases and Hardening agents: Beeswax, Cocoa butter, Lanolin, Hard paraffin

UNIT III

Methods of preparation and Evaluation of Herbal Tablets, Capsules, Ointments and other dosage forms. Study of any three formulations under each category with respect to their formulas and claims for various herbs used in them

UNIT IV

a. Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, health claims, Dietary Supplements Claims.
b. Food Laws and Regulations, FDA, FPO, MPO, BIS, AGMARK.

UNIT V

a) Natural colorants: Biological Source, coloring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric

b) Natural sweeteners:

i. Definition of nutritive and non-nutritive sweeteners, qualities of an ideal sweetener and sweetness potency.
ii. Biological source, chemical nature, extraction details and usage of the following: Steviosides, Glycyrrhizin, Rebaudoside

REFERENCE BOOKS:

1. Textbook of Pharmacognosy by G. E. Trease, W. C. Evans, ELBS
2. Textbook of HPTLC by P.D. Seth.
3. Herbal Perfumes and cosmetics by Panda
4. Pharmacognosy by V.E Tyler, LR Brandy and JE Robbers (KM Varghese & co., Mumbai)
5. Natural Excipients by R. S Gaud, Surana.
6. Herbal Drug industry by RD Chowdary
7. Herbal Drug Technology by SS Agarwal
8. Herbal Drug Technology by SL Deore, Pharmamed Press.
9. Pharmacognosy and Phytochemistry by VD Rangari.
10. Indian Pharmacopoeia
11. Dietetics by Sri Lakshmi
12. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
13. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
14. Research methods and Quantity methods by G. N.Rao

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.PharmI Year II Sem (Pharmaceutical Quality Assurance)

STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective –IV)

Course Objective: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the mechanisms of drug decomposition, including hydrolysis, oxidation, photolysis, and thermal degradation, and describe strategies for stabilization.
CO 2. Analyze the chemical decomposition of drugs in the solid state, including drug-excipient and drug-drug interactions, and methods for stabilization.
CO 3. Evaluate the physical stability of various dosage forms, including solids, disperse systems, and novel drug carriers like liposomes and nanoparticles.
CO 4 Apply stability testing principles to cosmetic and personal care products, considering container-closure compatibility and compliance with cGMP and ICH guidelines.
CO 5. Assess the quality, safety, and legislation requirements for finished cosmetic products using analytical, toxicity, and regulatory evaluation methods.

UNIT-I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.
4. Thermal decomposition

UNIT-II

Solid state chemical decomposition: Kinetic of solids state decomposition, pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

UNIT-III

Physical stability testing of dosage forms:

Solids – tablets, capsules, powder and granules

Disperse systems

Microbial decomposition

Overview, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT-IV

Physical stability testing of cosmetics dosage forms:

Dental products

Baby care products

Cosmetics

Stability studies: Concept of stability studies.

cGMP& ICH guidelines for Accelerated stability Testing.

Interaction of containers & closure Compatibility Testing.

UNIT-V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

REFERENCE BOOKS:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W. Grimm.
11. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year II Sem (PHARMACEUTICAL QUALITY ASSURANCE)

PHARMACEUTICAL VALIDATION LAB (Laboratory – III)

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Perform calibration and qualification of analytical and pharmaceutical equipment to ensure accuracy, precision, and compliance with regulatory standards.
CO 2. Execute analytical method validation experiments in accordance with ICH and regulatory guidelines to establish method reliability and reproducibility
CO 3. Demonstrate process and cleaning validation techniques for manufacturing and analytical equipment to ensure consistent product quality and contamination control
CO 4. Validate critical pharmaceutical processes and utilities, including granulation and controlled area environments, to maintain Good Manufacturing Practices (GMP).
CO 5. Prepare and maintain essential pharmaceutical documentation such as Master Formula Records (MFR) and Batch Manufacturing Records (BMR) for effective process traceability and regulatory compliance

LIST OF EXPERIMENTS:

1. Calibration of Electronic Balance and pH meter,
2. Validation of analytical methods (2 Experiments)
3. Validation of processing area
4. Cleaning validation of one equipment
5. Validation of granulation process
6. Validation of the following equipment
    a. Autoclave
    b. Hot air oven
    c. Tablet compression machine
    d. Dryer
7. Qualification of pharmaceutical testing equipment (Dissolution testing apparatus, friability apparatus, Disintegration testing)
8. Cleaning validation of **any 2** analytical instruments
9. Preparation of Master Formula Record.
10. Preparation of Batch Manufacturing Record

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)

PHARMACEUTICAL MANUFACTURING TECHNOLOGY LAB (Laboratory – IV)

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Demonstrate practical skills in the preparation and evaluation of various semisolid dosage forms, ensuring understanding of formulation techniques, consistency, and stability.
CO 2. Perform comparative evaluation of marketed pharmaceutical products (tablets and capsules) to assess quality attributes, efficacy, and compliance with pharmacopeial standards.
CO 3. Conduct stability testing of tablet dosage forms, analyze results, and interpret data to predict shelf life and storage conditions.
CO 4. Apply advanced formulation techniques for enteric-coated pellets and tablets, including evaluation of drug release profiles and coating efficiency.
CO 5. Develop an understanding of quality assurance and regulatory requirements by performing case studies on QbD application, designing sterile/non-sterile plant layouts, and preparing checklists for sterile production areas and water for injection systems.

LIST OF EXPERIMENTS:

i. Preparation of four different types of semisolid dosage forms and their evaluation (2 experiments)
ii. Comparative evaluation of different marketed products (tablets, capsules) of the same API (4 experiments)
iii. Stability study testing of tablet dosage forms (any three products)
iv. Preparation and evaluation of enteric coated pellets/tablets
v. Case study of application of QbD
vi. Check list for sterile production area
vii. Check list for water for injection
viii. Design of plant layout-sterile and non-sterile

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)

BIOSTATISTICS (Professional Elective - V)

Course Objectives: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the scope of biostatistics in pharmacy, methods of data collection, and techniques for arranging and presenting data using tables and charts.

CO 2. Calculate and interpret measures of central tendency (mean, median, mode) and measures of dispersion (variance, standard deviation, standard error) for grouped and ungrouped data.

CO 3. Apply concepts of correlation, regression, and probability distributions (Binomial, Poisson, Normal) to analyze pharmaceutical data.

CO 4 Design experiments using principles of replication, randomization, and analyze results using Analysis of Variance (ANOVA) for one-way and two-way data.

CO 5. Perform hypothesis testing using Student's t-test, Chi-square test, and non-parametric tests such as Sign Test, Sign Rank Test, and Wilcoxon Signed Rank Test.

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression

Probability rules: Binomial, Poison and Normal distribution.

UNIT IV

Experimental designing, planning of an experiment, replication and randomization.

Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V

Hypothesis testing: Student 't' test, Chi square test,

Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCE BOOKS:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
6. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students, KPR Chowdary, Pharmamed Press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)

SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Design pilot plant facilities and manage the scale-up and technology transfer process for various pharmaceutical dosage forms, ensuring product uniformity and stability.
CO 2. Apply validation concepts, procedures, and documentation, including analytical method validation, cleaning validation, and vendor qualification.
CO 3. Perform equipment qualification (IQ, OQ, PQ) for critical pharmaceutical manufacturing equipment and validate aseptic production areas.
CO 4 Implement process validation for manufacturing operations such as mixing, granulation, drying, compression, coating, liquid filling, sterilization, and environmental control systems.
CO 5. Identify and manage industrial hazards, implement monitoring and prevention systems, and control environmental pollution in pharmaceutical manufacturing.

UNIT I

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

UNIT II

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

UNIT III

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

UNIT IV

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT V

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCE BOOKS:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
7. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
8. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.
9. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)
PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT (Professional Elective - V)

Course Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Design and organize production areas for various pharmaceutical dosage forms, considering utilities, air handling, material and personnel flow, and warehouse management.
CO 2. Implement Current Good Manufacturing Practices (cGMP) for building layout, clean room classification, environmental control, documentation, and record-keeping in pharmaceutical manufacturing.
CO 3. Understand principles of pharmaceutical packaging, including package design, components, materials, labeling, and packaging research.
CO 4 Evaluate the stability of packaging systems under different environmental conditions, including photo-stability and climatic testing, in compliance with regulatory guidelines.
CO 5. Apply appropriate packaging strategies for solids, semisolids, parenterals, ophthalmics, and aerosols, ensuring proper inspection, storage, labeling, and material selection.

UNIT I

Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II

Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III

Pharmaceutical packaging and Design: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV

Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V

Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

REFERENCE BOOKS:

1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New York, USA.
6. Pharmaceutical Facilities: Design, Layouts and Validation,Potdar, Pharmamed Press

7. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
8. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor
9. Pharmaceutical Packaging Technology, UK jain, Pharmamed Press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Plan and structure sentences and paragraphs, write concisely, and avoid ambiguity, redundancy, and vague expressions.

CO 2. Understand how to clearly present findings, paraphrase correctly, avoid plagiarism, and effectively write abstracts and introductions.

CO 3. Organize and write all sections of a research paper, including literature review, methods, results, discussion, and conclusions.

CO 4. Gain key skills for writing strong titles, abstracts, introductions, and literature reviews

CO 5. Develop skills to write methods, results, discussions, and conclusions effectively, using useful phrases and strategies for successful first-time submissions.

UNIT-I:
Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:
Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:
Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

UNIT-IV:
key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:
skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXT BOOKS/ REFERENCES:

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011
5. Academic Writing,Ajay Semalty, Pharmamed Press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the concepts, types, and impact of natural and man-made disasters.
CO 2. Describe the economic, environmental, and social repercussions of various disasters.
CO 3. Discuss disaster preparedness, monitoring, and community participation methods.
CO 4. Evaluate disaster risk assessment techniques and strategies for risk reduction.
CO 5. Summarize mitigation strategies and programs implemented for disaster management in India.

UNIT-I:

Introduction:

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:

Repercussions of Disasters and Hazards:

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:

Disaster Preparedness and Management:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

Disaster Mitigation:

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXT BOOKS/ REFERENCES:

1. Disaster Management: Hazard and Risk Awareness – A Comprehensive Approach, N. V. S. Raju,BS Publications
2. R. Nishith, Singh AK, “Disaster Management in India: Perspectives, issues and strategies “’New Royal book Company.
3. Sahni, Pardeep Et. Al. (Eds.),” Disaster Mitigation Experiences and Reflections”, Prentice Hall of India, New Delhi.
4. Goel S. L., Disaster Administration and Management Text and Case Studies”, Deep &Deep Publication Pvt. Ltd., New Delhi

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Recognize and pronounce Sanskrit alphabets correctly.
CO 2. Form simple sentences using basic tenses in Sanskrit.
CO 3. Understand the roots and grammatical order in Sanskrit.
CO 4. Identify technical information in Sanskrit literature.
CO 5. Relate Sanskrit concepts to modern engineering and scientific fields.

UNIT-I:
Alphabets in Sanskrit,

UNIT-II:
Past/Present/Future Tense, Simple Sentences

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

UNIT-V:
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

1. “Abhyaspustakam” – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. “Teach Yourself Sanskrit” Prathama Deeksha-VempatiKutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. “India’s Glorious Scientific Tradition” Suresh Soni, Ocean books (P) Ltd., New Delhi.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the role of values and ethics in self and social development.
CO 2. Demonstrate the importance of cultivating moral and human values.
CO 3. Develop positive thinking and integrity for personal growth.
CO 4. Practice tolerance, cooperation, and love for nature.
CO 5. Apply principles of self-management, honesty, and good health for character building.

UNIT-I:
Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:
Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:
Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:
Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:
Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford University Press, New Delhi
2. Indian Culture Values and Professional Ethics, P. S. R. Murty,BS Publications

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None
Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Describe the history, philosophy, and salient features of the Indian Constitution.
CO 2. Explain the fundamental rights, duties, and directive principles of state policy.
CO 3. Discuss the structure and functions of various organs of governance.
CO 4. Analyze the role of local administration and importance of grassroot democracy.
CO 5. Summarize the role and functioning of the Election Commission and welfare bodies.

UNIT-I:
History of Making of the Indian Constitution: HistoryDrafting Committee, (Composition & Working),
Philosophy of the Indian Constitution: Preamble**,** Salient Features.

UNIT-II:
Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality**,** Right to Freedom**,** Right against Exploitation**,** Right to Freedom of Religion**,** Cultural and Educational Rights**,** Right to Constitutional Remedies, Directive Principles of State Policy**,** Fundamental Duties.

UNIT-III:
Organs of Governance: Parliament**,** Composition**,** Qualifications and Disqualifications**,** Powers and Functions**,** Executive**,** President**,** Governor**,** Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:
Local Administration: District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative,CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: ZilaPachayat. Elected officials and their roles, CEO ZilaPachayat: Position and role.Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials,Importance of grass root democracy.

UNIT-V:
Election Commission: Election Commission: Role and Functioning.Chief Election Commissioner and Election Commissioners.State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Understand the theories of learning and research methodologies in pedagogy.
CO 2. Describe pedagogical practices used in formal and informal learning environments.
CO 3. Evaluate the effectiveness of teaching methods and teacher education programs.
CO 4. Explain the importance of professional development and support systems for teachers.
CO 5. Identify research gaps and future directions in pedagogy and education systems.

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework andterminologyTheories of learning, Curriculum, Teacher education.Conceptual framework, Research questions**.** Overview of methodology and Searching.

UNIT-II:

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT-IV:

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:

Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher education**,** Curriculum and assessment**,** Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the eight components (Ashtanga) of yoga and their significance.
CO 2. Describe the principles of Yam and Niyam in daily life.
CO 3. Apply ethical and moral disciplines (Do's and Don'ts) for mental well-being.
CO 4. Demonstrate various Asanas and Pranayama techniques.
CO 5. Analyze the benefits of yoga poses and breathing practices on mind and body.

UNIT-I:
Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:
Yam and Niyam.

UNIT-III:
Do`s and Don't's in life.
i) Ahinsa, satya, astheya, bramhacharya and aparigraha
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:
Asan and Pranayam

UNIT-V:
i) Various yog poses and their benefits for mind & body
ii) Regularization of breathing techniques and its effects-Types of pranayam

TEXT BOOKS/ REFERENCES:

1. 'Yogic Asanas for Group Tarining-Part-I": Janardan Swami Yogabhyasi Mandal, Nagpur
2."Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Interpret Neetishatakam verses for wisdom, virtue, and personality development.
CO 2. Apply moral guidance from Neetishatakam to everyday conduct.
CO 3. Understand the teachings of Bhagavad Gita for performing duties with discipline.
CO 4. Relate basic philosophical knowledge from Gita to self-awareness and attitude.
CO 5. Develop enlightened personality traits based on spiritual and ethical values.

UNIT-I:

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont's)
- Verses- 71,73,75,78 (do's)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

TEXT BOOKS/ REFERENCES:

1. "Srimad Bhagavad Gita" by Swami SwarupanandaAdvaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.