JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M.PHARMACY (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)

R19 COURSE STRUCTURE AND SYLLABUS Effective from Academic Year 2019-20 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	Р	Credits
Professional	Modern Pharmaceutics-I	3	0	0	3
Core-I					
Professional	Applied Biopharmaceutics and Pharmacokinetics	3	0	0	3
Core-II					
Professional	Advanced Physical Pharmaceutics	3	0	0	3
Elective-I	Drug Regulatory affairs				
	3. Total Quality Management				
Professional	Cosmetics and Cosmeceuticals	3	0	0	3
Elective-II	2. Pharmaceutical Validation				
	Stability of Drugs and Dosage Forms				
MC	Research methodology and IPR	2	0	0	2
Laboratory- I	Modern Pharmaceutics – I Lab	0	0	4	2
Laboratory- II	Applied Biopharmaceutics and Pharmacokinetics Lab	0	0	4	2
Audit	Audit Course- I	2	0	0	0
	TOTAL	16	0	8	18

I YEAR II Semester

Course Code	Course Title	L	Т	Р	Credits
Professional Core-III	Modern Pharmaceutics-II	3	0	0	3
Professional Core-IV	Advanced Drug Delivery Systems	3	0	0	3
Professional Elective-III	Industrial Pharmacy Herbal Cosmetics Pharmaceutical Management	3	0	0	3
Professional Elective-IV	 Nano based Drug Delivery Systems Nutraceuticals Clinical Research and Pharmacovigilance 	3	0	0	3
Laboratory- III	Modern Pharmaceutics – II Lab	0	0	4	2
Laboratory- IV	Advanced Drug Delivery System Lab	0	0	4	2
	Mini project with seminar	2	0	0	2
Audit	Audit Course- II	2	0	0	0
	Total	16	0	8	18

Audit Courses 1 & 2

- 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

MODERN PHARMACEUTICS – I (Professional Core-I)

Course Objectives: Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

Course Outcome: Students shall explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

UNIT I

Preformulation studies: Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies (ICH)

UNIT II

Formulation development of solid dosage forms – I: New materials, excipients science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipients, co-processed materials, methods of preparation and evaluation.

UNIT III

Formulation development of solid dosage forms— II: Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.

Microencapsulation- types, methodology, problems encountered.

UNIT IV

Formulation development of soft and hard gelatin capsules: Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

TEXT BOOKS

- 1. Pharmaceutics The Science of Dosage form design by ME Aulton.
- 2. Pharmaceutical Dosage forms Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
- 3. Pharmaceutical Dosage forms Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
- 4. Pharmaceutical Dosage forms Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
- 5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.

6. Pharmaceutical statistics by Bolton

RECOMMENDED BOOKS:

- 1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
- 2. Remington's Science and Practice of Pharmacy by A. Gennaro.
- 3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
- 4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
- 5. Dispensing for Pharmaceutical Students by SJ Carter.
- **6.** Industrial Pharmacy Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi 2013

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Core - II)

Course Objectives: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, nonlinear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

Course Outcomes: students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for nonlinear kinetics.

UNIT I

- a. Biological and metabolic factors affecting bioavailability, complexation, dissolution techniques of enhancing dissolution.
- b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
- c. **Bioavailability:** Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo* Correlation analysis and Levels of Correlations.
- d. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

UNIT II

Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

- a. Distribution: Apparent volume of distribution and its determination, factors affecting.
- b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
- c. Elimination: Over all apparent elimination rate constant, and half life.

All the above under the following conditions:

- 1. Intravenous infusion
- 2. Multiple dose injections
- d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
- e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT III

Pharmacokinetics – Absorption: Rate constants – Zero order, first order, Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration.

UNIT IV

Non-linear pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.

Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

UNIT V

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs— (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

❖ Numerical problems associated with all units, if any.

TEXT BOOKS

- 1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
- 2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics
- 3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
- 4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean.
- 5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz

REFERENCE BOOKS

- 1. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
- 2. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
- 3. Biopharmaceutics and Clinical Pharmacokinetics An Introduction by Robert E. Notari.
- 4. Drug drug interactions, scientific and regulatory perspectives by Albert P. G

ADVANCED PHYSICAL PHARMACEUTICS (Professional Elective – I)

Course Objectives: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

Course Outcomes: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

UNIT I

Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive, Hydrodynamically balanced and Transdermal Systems.

UNIT II

Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV

Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

Characterization of API and excipients: Differential Scanning Calorimetry: Principle, thermal transitions, advantages, disadvantages, instrumentation, applications and interpretations

X Ray Diffraction methods: Origin of x-rays, principle, advantages, disadvantages, instrumentation, applications and interpretations.

UNIT V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

TEXT BOOKS

- 1. Physical Pharmacy, 4th Edition by Alfred Martin.
- 2. Theory and Practice of Tablets Lachman, Vol.4

- 3. Pharmaceutical Dosage forms Disperse systems Vol. I & II
- 4. Cartenson "Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
- 5. Industrial Pharmacy Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi 2013

REFERENCE BOOKS

- 1. Dispersive systems I, II, and III
- 2. Robinson. Controlled Drug Delivery Systems

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:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authoritization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

UNIT I

Drug Regulatory Aspects (India)

- 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
- 2. Drugs and Cosmmetics 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 Management, Effluent etc.)
- 5. Quality Assurance and Qulaity Control Basic understanding for in-built quality.

UNIT III

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

UNIT IV

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 Directorate DMF
- 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.** Pharmaceutical Regulatory Affairs Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi 2013

TOTAL QUALITY MANAGEMENT (Professional Elective - I)

Course Objectives: Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc. Which increases the knowledge of students in various quality control & regulatory aspects.

Course Outcomes: Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc to become a perfect budding pharmacist. It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

UNIT - I

Concepts and Philosophy of TQM, GLP, GMP (orange guide).

UNIT - II

Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.)

UNIT - III

Good manufacturing practices: Organization and personnel, responsibilities, training, hygiene. Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination. Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP). Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms. Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. In process quality controls on various dosage forms; sterile and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc., Packaging and labelling control, line clearance, reconciliation of labels, cartons and other packaging materials. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house. Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities. Finished products release, quality review, quality audits, batch release document.

UNIT - IV

Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratoginicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials. Quality assurance standards as per ISO.

UNIT - V

Globalization of drug industry, present status and scope of pharmaceutical industry in India. WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

TEXT AND REFERENCE BOOKS:

1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.

- 2. Quality Assurance of Pharmaceuticals–A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.
- 3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
- 4. GMP by Mehra.
- 5. How to Practice GMP by P.P. Sharma.
- 6. ISO 9000 and Total Quality Management by Sadhan K. Ghosh.
- 7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
- 8. OPPI-Quality Assurance, USP.
- 9. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
- 10. Quality assurance and quality management in pharmaceutical industry by Y. Anjaneyulu and marayya
- 11. Total Quality Management, An integrated Approach by D. R. Kiran, BS Publications
- 12. Total Quality Management, 3rd edition by Joel E. Ross. CRC press

COSMETICS AND COSMECEUTICALS (Professional Elective - II)

Course Objectives: Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- · Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

UNIT I

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

- 1. Harry's Cosmeticology. 8th edition.
- 2. Poucher's perfume cosmetics and Soaps, 10th edition.
- 3. Cosmetics Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
- 4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3 rd edition
- 5. Cosmetic and Toiletries recent suppliers' catalogue.
- 6. CTFA directory.

PHARMACEUTICAL VALIDATION (Professional Elective - II)

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 Outcome: Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments

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, Dissintegration 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 quidelines and USP.

Validate the manufacturing facilities

REFERENCES:

- 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

STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective - II)

Course Objectives: 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: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

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.

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.

Physical stability testing of dosage forms:

- 1. Solids tablets, capsules, powder and granules
- 2. Disperse systems
- 3. Microbial decomposition
- 4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT - III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT - IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

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. Stability studies: Concept of stability studies.

- a) cGMP& ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

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. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

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: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- 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.
- 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"

REFERENCES:

- 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 Technological Age", 2016.
- 7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

MODERN PHARMACEUTICS - I LAB (Laboratory-I)

List of Experiments:

- 1. To carry out the preformulation studies of solid dosage forms.
- 2. To study the effect of compressional force on tablet disintegration time
- 3. To study the micromeritic properties of powders and granules
- 4. To study the effect of particle size on dissolution of tablets
- 5. To study the effect of binders on dissolution of tablets
- 6. To study pharmacokinetic models, to determine similarity factors
- 7. Accelerated stability testing of different tablets
- 8. Determination of first order, second order rate constants by acid and alkaline hydrolysis
- 9. Preparation and evaluation of beta cyclodextrin complexes of new drugs
- 10. Preparation of paracetamol tablets and comparison with marketed products

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS LAB (Laboratory - II)

List of Experiments:

- 1. Analysis of dissolution by various data-kinetic modelling.
- 2. Calibration curve of different API's by UV/HPLC/HPTLC
- 3. Dissolution of immediate release, sustained release and delayed release.
- 4. Evaluation of drug-protein binding analysis
- 5. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.
- 6. Calculation of K_a (absorption rate constant) absorption curve- Wagner nelson method , Loo-Riegel method.
- 7. Calculation of pharmacokinetics parameters of one compartment oral data and two compartment IV data.
- 8. Construction of IVIVC from the data
- 9. Calculation of Urinary Pharmacokinetics
- 10. Calculation of Bioavailability and Bioequivalence Studies
- 11. Permeation studies of Franz diffusion cell
- 12. Drug Release from semisolids by Agar gel method or Franz diffusion cell.

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

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

- 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
- 4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

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

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.

- 1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
- 2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
- 3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

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: Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

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

- 1. "Abhyaspustakam" Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
- 2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
- 3. "India's Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

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: Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

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

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: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP]
 under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct
 elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

UNIT-I:

History of Making of the Indian Constitution: History Drafting 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: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: 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.

- Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
 M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
 D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

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: Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories 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.

- 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.

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: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

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

- 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

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: Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

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

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