

Andhra Kesari University, Ongole
M.PHARMACY (PHARMACEUTICAL REGULATORY AFFAIRS)
R24 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2024-25 Admitted Batch

IYEAR I Semester

Components of study	Course code	Course Title	L	T	P	Credits	Internal	External	Total
Professional Core-I	R24PR11	Good Regulatory Practices	3	1	0	4	25	75	100
Professional Core-II	R24PR12	Drug Regulatory Affairs	3	1	0	4	25	75	100
Professional Elective-I	R24PR13A R24PR13B R24PR13C	1.Intellectual Property Rights 2.Total Quality management 3.Pharmaceutical Validation	3	1	0	4	25	75	100
Professional Elective-II	R24PR14A R24PR14B R24PR14C	1. Stability of Drugs and Dosage Forms 2. Pharmaceutical Formulation Technology 3. Documentation and Regulatory Writing	3	1	0	4	25	75	100
	R24PR15	Research methodology and IPR	2	0	0	2	50	--	50
Laboratory-I	R24PR16	Regulatory Practice and Documentation Lab	0	0	6	4	25	75	100
Laboratory-II	R24PR17	Drug Regulation and Registration Lab	0	0	6	4	25	75	100
Audit-I	R24PR18	Audit Course-I (Non Credit)	2	0	0	0	--	--	--
		Seminar & Assignment	0	0	4	2	50 (25+25)	--	50
		Total	16	4	16	28	250	450	700

I YEAR II Semester

Components Of study	Course code	Course Title	L	T	P	Credits	Internal	External	Total
Professional Core-III	R24PR21	Regulatory aspects of herbals and biologicals	3	1	0	4	25	75	100
Professional Core-IV	R24PR22	Regulatory aspects of medical devices	3	1	0	4	25	75	100
Professional Elective-III	R24PR23A R24PR23B R24PR23C	1. Regulatory aspects of Foods and Nutraceuticals 2. Pharmaceutical-quality Control and Quality Assurance 3. Nano Based Drug Delivery Systems	3	1	0	4	25	75	100
Professional Elective-IV	R24PR24A R24PR24B R24PR24C	1. Clinical Research and Pharmacovigilane 2. Nutraceuticals 3. Advanced Drug Delivery Systems	3	1	0	4	25	75	100
Laboratory-III	R24PR25	Regulatory aspects of herbals and Biological lab	0	0	6	4	25	75	100
Laboratory-IV	R24PR26	Regulatory aspects of medical devices lab	0	0	6	4	25	75	100
	R24PR27	Mini project (with presentation)& assignment	2	0	0	4	100 (50+50)	--	100
Audit-II	R24PR28	Audit Course-II(Non-credit)	2	0	0	0	--	--	--
		Total	16	4	16	28	250	450	700

Andhra Kesari University, Ongole

M.PHARMACY (PHARMACEUTICAL REGULATORY AFFAIRS)

R24 COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2024-25 Admitted Batch

II YEAR I Semester

Components of study	Course code	Course Title	L	T	P	Credits	Internal	External	Total
Professional Elective-V	R24PR31A	1. Biostatistics	3	1	0	4	25	75	100
	R24PR31B	2. Scale up and Technology Transfer							
	R24PR31C	3. Production area, Design and Packaging Development							
Open Elective	R24PR32A	1. Screening Methods In Pharmacology	3	1	0	4	25	75	100
	R24PR32B	2. Entrepreneurship Management							
	R24PR32C	3. Cosmetic Science							
	R24PR32D	4. Hazards and Safety Management							
	R24PR32E	5. Audits and Regulatory Compliance							
	R24PR33	Comprehensive Viva Voce	0	0	8	4	–	100	100
	R24PR34	Dissertation Work Review-II	0	0	24	10	50	50	100
		Total	6	2	32	22	100	300	400

II YEAR II Semester

Components of study	Course code	Course Title	L	T	P	Credits	Internal	External	Total
Dissertation	R24PR41	Dissertation Work Review - III	0	0	24	10	50	50	100
Dissertation	R24PR42	Dissertation Viva-Voce	0	0	20	10		100	100
		Total	0	0	44	20	50	150	200
		Grand Total				98	Total Marks		2000

Andhra Kesari University, Ongole

M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR11) GOOD REGULATORY PRACTICES (Professional Core - I)

Course Objective: This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Course Outcome: At completion of this course it is expected that students will be able to understand

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices.
- Implement Good Regulatory Practices in the Healthcare and related Industries.
- Prepare for the readiness and conduct of audits and inspections.

UNIT I

Current Good Manufacturing Practices: Introduction, US Cgmp Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

UNIT II

Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards

UNIT III

Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

UNIT IV

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards

UNIT V

Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

TEXT AND REFERENCE BOOKS:

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

Andhra Kesari University, Ongole

M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR12) DRUG REGULATORY AFFAIRS (Professional Core - II)

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 authorization 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 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 Licenses – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan license 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 Quality 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 (EMA/ National Authorities) EDMF
 - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
 - 3) MHRA – Medicines and Health Care Products Regulatory Agency

- b. Product Filing
- c. Responding Regulatory Deficiencies
- d. 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

Andhra Kesari University, Ongole
M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR13A) INTELLECTUAL PROPERTY RIGHTS
(Professional Elective - I)

Course Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Course Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

UNIT - I

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

UNIT - II

- a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
- b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
- c. Opposition - pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
- d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT - III

- a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
- b. Background, Salient Features and Impact of International Treaties / Conventions like
 1. Paris Convention, Berne convention
 2. World Trade Organization (WTO)
 3. World Intellectual Property Organization (WIPO)
 4. Trade Related Aspects of Intellectual Property Rights (TRIPS)
 5. Patent Co-operation Treaty (PCT), Madrid Protocol

UNIT - IV

- a. PCT Application procedure and review procedure
- b. National phase application procedure for US & EU
- c. Patent prosecution procedure in US and EU
- d. WIPO and its role in IPR
- e. Hatch- Waxman provision for IPR

UNIT - V

- a. Patent in validation process in India, US and Europe
- b. IPR related to copyright, trade mark, trade secret and geographical indication.
- c. Patent application writing
- d. Claim construction and claims.

RECOMMENDED BOOKS:

1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi
2. Draft manual of Patent Practice and Procedure -2008, The Patent Office, India
3. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press
4. Fundamentals of Patents and Patenting, Vivekananda Mandal, Pharmamed Press
5. Manual of Patent Office Practice and Procedure -2010
6. Original Laws Published by Govt. of India
7. Protection of Industrial Property rights by P. Das and Gokul Das
8. Law and Drugs, Law Publications by S.N. Katju
9. Laws of drugs in India, Hussain
10. New drug approval process, 5th edition, by Guarino
11. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
12. Drugs and Cosmetics act by Vijay Malik
13. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
14. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
15. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
16. Pharmaceutical Regulatory affairs –selected topics. CVS subhramanyam and J Thimma settee. Delhi, Vallabh Prakashan, 2012

Andhra Kesari University, Ongole
M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)
(R24PR13B) 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. Equipment's: 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 teratogenicity. 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

Andhra Kesari University, Ongole
M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)
(R24PR13C) PHARMACEUTICAL VALIDATION
(Professional Elective - I)

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, 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.

- Validate the manufacturing facilities

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-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide 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

Andhra Kesari University, Ongole
M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)
(R24PR14A) 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. Sawnsen – 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.

Andhra Kesari University, Ongole

M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs) (R24PR14B) PHARMACEUTICAL FORMULATION TECHNOLOGY (Professional Elective - II)

Course Objective: Students will know the pre-formulation 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 pre-formulation 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

Pre-formulation: Goals of pre-formulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle size distribution.

Flow of Powders: Physical properties and importance. Angle of repose, Carr's index, compressibility, bulk density, tapped density.

UNIT II

Excipients used in various dosage forms like tablets, capsules, emulsions, suspensions, semisolids and sterile products. Knowledge of packing materials. Drug- excipient compatibility- Drug stability, factors affecting stability, stabilization methods.

UNIT III

Tablets: Types of tablets, granulation methods, highlighting operations such as mixing, drying, milling, blending, lubrication and compression.

Tablet coating: Types of coating, steps involved in coating process- pan coating and fluid bed coating and problems associated with coating.

Hard Gelatin Capsules: General principles and steps involved in the production of drug loaded hard gelatin capsules, filling operation, filling of powders, granules and pellets.

UNIT IV

Dissolution: Principles of dissolution, factors influencing dissolution, official methods and apparatus. Dissolution of immediate release, controlled release and delayed release products.

UNIT V

Stability testing: Chemical degradation and preventive measures. Various stability testing conditions and use of stabilizers in packaging

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. Pharmaceutical Dosage Form: Basics and Beyond, Kamlesh J. Wadher, Pharmamed Press
6. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
7. Pharmaceutical statistics by Bolton Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

REFERENCE 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.

Andhra Kesari University, Ongole

M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR14C) DOCUMENTATION AND REGULATORY WRITING

(Professional Elective - II)

Course Objective: This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Course Outcomes: Upon completion of the course the student shall be able to,

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

UNIT I

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

UNIT II

Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). None CTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

UNIT III

Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third-party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

UNIT IV

Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

UNIT - V

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Affected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

TEXT AND REFERENCE 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. Academic Writing, Ajay Semalty, Pharmamed Press
5. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
6. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
7. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
8. 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
9. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
10. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
11. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
12. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
13. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
14. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

Andhra Kesari University, Ongole
M.Pharmacy I Year I Sem (Pharmaceutical Regulatory
Affairs) (R24PR15) 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 emphasize 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"
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

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

Andhra Kesari University, Ongole
M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR16) REGULATORY PRACTICE AND DOCUMENTATION LAB

(Laboratory - I)

List of Experiments:

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR) Labeling comparison between brand & generics.
5. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
6. Case studies on response with scientific rationale to USFDA Warning Letter
7. Preparation of submission checklist of IMPD for EU submission.
8. Comparison study of marketing authorization procedures in EU.

Andhra Kesari University, Ongole
M.Pharmacy I Year I Sem (Pharmaceutical Regulatory Affairs)
(R24PR17) DRUG REGULATION & REGISTRATION LAB

(Laboratory - II)

List of Experiments:

1. Case studies on Change Management/ Change control. Deviations and Corrective & Preventive Actions (CAPA)
2. Import of drugs for research and developmental activities
3. GMP Audit Requirements as per CDSCO
4. Preparation of checklist for registration of IND as per ICH CTD format.
5. Preparation of checklist for registration of NDA as per ICH CTD format.
6. Preparation of checklist for registration of ANDA as per ICH CTD format.
7. Comparative study of DMF system in US, EU and Japan
8. Preparation of regulatory submission using eCTD software
9. Documentation of raw materials analysis as per official monographs
10. Preparation of audit checklist for various agencies
11. Preparation of submission to FDA using eCTD software
12. Preparation of submission to EMA using eCTD software
13. Preparation of submission to MHRA using eCTD software

Andhra Kesari University, Ongole
M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)

(R24PR21) REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS

(Professional Core - III)

Course Objective: This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

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

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

UNIT - I

India: Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

UNIT - II

USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.

UNIT - III

European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ bio similarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.

UNIT - IV

Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorization, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network)

UNIT - V

Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.

TEXT AND REFERENCE BOOKS:

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus; Informa, 2008
2. Biological Drug Products: Development and Strategies; Wei Wang, Manmohan Singh; wiley, 2013

3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh, Indresh K. Srivastava; Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdscsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodvaccines/guidancecompliance Regulatory Information (Biologics)

Andhra Kesari University, Ongole
M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)
(R24PR22) REGULATORY ASPECTS OF MEDICAL DEVICES
(Professional Core - IV)

Course Objective: This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Course Outcome: Upon completion of the course, the student shall be able to know;

- Basics of medical devices and IVDs, process of development, ethical and quality considerations.
- Harmonization initiatives for approval and marketing of medical devices and IVDs.
- Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.
- Clinical evaluation and investigation of medical devices and IVDs.

UNIT - I

Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

UNIT - II

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

UNIT - III

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Pre-market Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

UNIT - IV

European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

UNIT - V

ASIAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.

REFERENCE BOOKS:

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina

Andhra Kesari University, Ongole

M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)

(R24PR23A) REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (Professional Elective – III)

Course Objective: This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Course Outcome: Upon completion of the course, the student shall be able to

- a. Know the regulatory Requirements for nutraceuticals
- b. Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

UNIT - I

Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

UNIT - II

Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

UNIT - III

India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

UNIT - IV

USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S

UNIT - V

European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

TEXT AND REFERENCE BOOKS:

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler(Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. <http://www.who.int/publications/guidelines/nutrition/en/>
4. [http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU\(2015\)536324_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf)
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

Andhra Kesari University, Ongole
M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)
(R24PR23B) PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE (Professional Elective – III)

Course Objectives: 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 Outcome: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

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 sanitation, 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

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, 2005.

Andhra Kesari University, Ongole
M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)

(R24PR23C) NANO BASED DRUG DELIVERY SYSTEMS
(Professional Elective – III)

Course Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Course Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT I

Introduction to Nanotechnology

- a. Definition of nanotechnology
- b. History of nanotechnology
- c. Unique properties and classification of nanomaterials
- d. Role of size and size distribution of nanoparticles properties.
- e. Marketed formulations based on nanotechnology and science behind them

UNIT II

Synthesis of Nanomaterials Physical, chemical and biological Methods Methods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferosomes, micelles, aquasomes and nanoemulsions

UNIT III

Biomedical applications of Nanotechnology

- a. Nanotechnology products used for in vitro diagnostics
- b. Improvements to medical or molecular imaging using nanotechnology
- c. Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

REFERENCE BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatfoms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulkarni, Springer (2007)

5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano-Carrier Systems Theories, Methods & Applications, Amit K. Goyal, Goutam Rath, Pharmamed Press.
7. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
8. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley - VCH Verlag, Weiheim (2003)
9. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons, 2009
10. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
11. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016
12. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006

Andhra Kesari University, Ongole
M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)

(R24PR24A) CLINICAL RESEARCH AND PHARMACOVIGILANCE
(Professional Elective - IV)

Course Objectives: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

Course Outcomes: Upon completion of the course, the student shall be able to;

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT I

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH- GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT II

Clinical Trials: Types and Design:

Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT III

Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT IV

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT V

Methods, ADR reporting and tools used in pharmacovigilance: International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

REFERENCE BOOKS:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

Andhra Kesari University, Ongole

M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)

(R24PR24B) NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations.

Course Outcomes: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
- b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Ginkgo, Flaxseeds

UNIT II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

- a) Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, lutein
- b) Sulfides: Diallylsulfides, Allyltrisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillum
- f) Phytoestrogens: Isoflavones, daidzein, Geobustin, lignans
- g) Tocopherols

UNIT III

- a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
- b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

- a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α -Lipoic acid, melatonin. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCE BOOKS:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T. Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

Andhra Kesari University, Ongole

M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs) (R24PR24C) ADVANCED DRUG DELIVERY SYSTEMS (Professional Elective - IV)

Course Objectives: The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bio adhesives and targeted drug delivery systems.

Course Outcomes: Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

UNIT I

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

- a. Controlled release oral drug delivery systems
- b. Parenteral controlled release drug delivery systems

UNIT II

Design, fabrication, evaluation and applications of the following

- a. Implantable Therapeutic systems
- b. Transdermal delivery systems
- c. Ocular and Intrauterine delivery systems
- d. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT III

Biochemical and molecular biology approaches to controlled drug delivery of

- a. Bioadhesive drug delivery systems
- b. Nasal drug delivery systems
- c. Drug delivery to Colon

UNIT IV

Biochemical and molecular biology approaches to control drug delivery of

- a. Liposomes
- b. Niosomes
- c. Microspheres
- d. Nanoparticles
- e. Resealed erythrocytes

UNIT V

Drug targeting to particular organs

- a. Delivery to lungs
- b. Delivery to the brain and problems involved
- c. Drug targeting in neoplasms

TEXT BOOKS:

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Advances in Drug Delivery, Vol 1, 2, 3,4 by Y. Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

Andhra Kesari University, Ongole
M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)

(R24PR25) REGULATORY ASPECTS OF HERBALS AND BIOLOGICAL LAB
(Laboratory - III)

List of Experiments:

1. Preparation of Biologics License Applications (BLA)
2. Preparation of documents required for Vaccine Product Approval
3. Comparison of clinical trial application requirements of US, EU and India of Biologics
4. Preparation of Checklist for Registration of Blood and Blood Products
5. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
6. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
7. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
8. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
9. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
10. Preparation of document required for the approval of herbal products of diverse dosage forms(3products) as per regulations requirements

Practical work shall be carried out based on the theory syllabus.

Andhra Kesari University, Ongole
M.Pharmacy I Year II Sem (Pharmaceutical Regulatory Affairs)
(R24PR26) REGULATORY ASPECTS OF MEDICAL DEVICES LAB
(Laboratory - IV)

List of Experiments:

1. Checklists for 510k and PMA for USmarket
2. Checklist for CE marking for various classes of devices for EU
3. STED Application for Class III Devices
4. Audit Checklist for Medical Device Facility
5. Clinical Investigation Plan for Medical Devices
6. Preparation and submission of medical devices for approval (3 products)
7. GMP of manufacturing of medical devices of diverse nature (3 products)
8. preparation and submission of nutraceuticals devices for approval (3 products)

Practical work shall be carried out based on the theory syllabus

Andhra Kesari University, Ongole

M.Pharmacy II Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR31A) BIOSTATISTICS (Professional Elective - V)

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

Course Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data

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.

Andhra Kesari University, Ongole
M.Pharmacy II Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR31B) SCALE UP AND TECHNOLOGY TRANSFER
(Professional Elective - V)

Course Objective: 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 Outcome: On completion of this course it is expected that students will be able to;

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

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 vendor 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, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,
10. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

Andhra Kesari University, Ongole
M.Pharmacy II Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR31C) 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 Outcome: At the end of the semester student will get an idea about Industrial area design and packaging of different formulations and its stability conditions.

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
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

Andhra Kesari University, Ongole
M.Pharmacy II Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR32A) SCREENING METHODS IN PHARMACOLOGY
(Open Elective)

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 Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

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, Springer-Verlag, Berlin Heidelberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Guidelines and Screening Methods of Pharmacology, Surendra H. Bodakhe, 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.

Andhra Kesari University, Ongole
M.Pharmacy II Year I Sem (Pharmaceutical Regulatory Affairs)

(R24PR32B) ENTREPRENEURSHIP MANAGEMENT
(Open Elective)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes: On completion of this course it is expected that students will be able to;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co- ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

RECOMMENDED BOOKS:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

Andhra Kesari University, Ongole
M.Pharmacy II Year I Sem (Pharmaceutical Regulatory Affairs)
(R24PR32C) COSMETIC SCIENCE
(Open Elective)

Course Objectives: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcomes: The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

UNIT I

Classification of cosmetics and cosmeceutical products.

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.

Skin: Basic structure and function of skin.

Hair: Basic structure of hair, hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II

Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Anti perspirants and Deodorants: Actives and MOA.

Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.

Chemistry and formulation of Para-phenylene di amine-based hair dye.

Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III

Sun protection, classification of sunscreens and SPF.

Role of herbs in cosmetics:

Skin care – Aloe and turmeric

Hair care – Henna and amla

Oral care – Clove and neem

Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV

Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tawl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.

Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.

Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor. **Anti-perspirants and deodorants –** Actives and MOA

RECOMMENDED BOOKS:

1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

Andhra Kesari University, Ongole
M.Pharmacy II Year I Sem (Pharmaceutical Regulatory Affairs)
(R24PR32D) HAZARDS AND SAFETY MANAGEMENT
(Open Elective)

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

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

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

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.

RECOMMENDED 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. Safety and Health in Industry: A Handbook by AM Sarma, Pharmamed Press
4. Occupational Hazards Safety and Environmental Studies by A M Sarma Pharmamed Press
5. Occupational Health and Hygiene in Industries, Raja Sekhar Mamillapalli, Visweswara Rao
6. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380013, India.
7. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

Andhra Kesari University, Ongole
M.Pharmacy II Year I Sem (Pharmaceutical Regulatory Affairs)
(R24PR32E) AUDITS AND REGULATORY COMPLIANCE
(Open Elective)

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 this course the student should be able to;

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

UNIT I

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.

RECOMMENDED 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-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

MODEL PAPER
ANDHRA KESARI UNIVERSITY
M. Pharmacy

Follows all Semesters

Time:3 Hours

Maximum Marks: 75

SECTION-A

Answer any FIVE Questions

5X10=50 Marks

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

SECTION-B

Answer any FIVE Questions

5X5=25 Marks

- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.