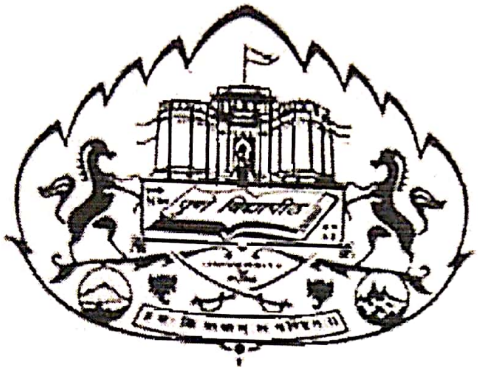
UNIVERSITY OF PUNE

FACULTY OF PHARMACEUTICAL SCIENCES



MASTER OF PHARMACY (M.PHARM.) in

1. Pharmaceutics
2. Pharmaceutical chemistry
3. Pharmacology
4. Pharmacognosy
5. Quality assurance techniques

COURSE STRUCTURE & SYLLABI

(EFFECTIVE FROM ACADEMIC YEAR 2013-2014)

MASTER OF PHARMACY COURSE STRUCTURE
SPECIALIZATION : QUALITY ASSURANCE TECHNIQUES

Sem. No	Paper	Scheme of Teaching Hrs/Weeks		Scheme of Credit		Scheme of Examination Theory			Practical			Total (Including 50 marks of Internal assessment)
						Hrs.	Marks		Hrs.	Marks		
		Theory	Practical	Theory	Practical	UE	UE	IE	UE	UE	IE	
I	M Advanced Analytical Techniques	4	8	4	4	3	50	50	8	50	50	200
	M-2 Research Methodology	4		4		3	50	50				100
	M-I-1 Advanced Quality Assurance Techniques (CGMP & Documentation)	4	8	4	4	3	50	50	8	50	50	200
	M-I-2 Elective-I	3		3		3	50	50				100
	Seminar				2			50				50
II	M-I-3 Pharmaceutical Validation	4	8	4	4	3	50	50	8	50	50	200
	M-3 Drug Regulatory Affairs	4		4		3	50	50				100
	M-I-4 Quality Planning and Analysis	4		4		3	50	50				100
	M-I-5 Elective-II	3		3		3	50	50				100
	Seminar		4		2			50				50
	Research work		12		6			50				50
III	Seminar on Research Envisaged for Dissertation				4		50					50
	Seminar on recent trends in Quality Assurance Techniques				4			50				50
	Research work		36		18			150				150
IV	Seminar on Dissertation				4		50					50
	Research work		36		18		150					150
	Dissertation & Defense (viva/voce)						100					100
			Total	30	70						Grand Total	1800
			Total Credits = 100									

Principal
College of Pharmacy, Chincholi
Tal. Sinnar, Dist. Nashik 422102

ELECTIVE SUBJECTS OF ALL SEMESTERS

(E.1.1) QUALITY CONTROL & ASSURANCE OF PHARMACEUTICALS
(Theory 3 Hrs/Week)
CREDITS 03

Note: Students of M. Pharm. in Quality Assurance Techniques cannot take this subject as elective.

UNIT I

1. Quality control and Assurance technique: Basis concepts of Quality:- Developing quality culture.
2. Quality Assurance General Concepts: Definition of quality assurance concept and components of Q. A., Good Manufacturing Practices, Quality control – The concept
3. Personnel, Premises and Equipments: Qualification, experience, training responsibilities and hygiene of personnel. Drainage system, Sewage, Sanitation, Lighting, maintenance of building and premises; Design, size, location, construction, cleaning and maintenance of equipments. Documents and formats related to personnel, premises and equipment.

UNIT II

4. Material Management: Purchasing, Raw material, packaging materials, Intermediate and Bulks products, Finished products, Rejected and recovered materials, recalled products, returned gods, Reagents and culture media, Waste materials, reference standards, Miscellaneous material. Documents and formats.
5. Manufacturing operations and control: Revised schedule M, sanitation of manufacturing premises, Mix –ups and cross contamination, processing of intermediates and Bulk product, Packaging operations, I.P.Q.C., Release of finished products process deviations, Drug product inspection, expiration dating, Document and formats.

UNIT III

6. Documents and Records: Specification, Master production and control record, Batch production and control record, Significance of SOPs and record, change control, Drug Master file, Documents and formats.
7. Pharmaceutical Validation: Definition & concept of validation, validation of building, equipments, instruments and facilities, process validation, cleaning –validation, validation master plan, Documents and formats.
8. Quality control of Biological products: International Biological standards, safety testing of pharmaceutical Quality control of antibiotics.
9. Pharmaceutical Plant Audit: Department wise documents and audit questionnaire.

10. Sterile Pharmaceutical Products: GMP aspects related to sterile products- General guidelines, personnel, building and premises, equipment, sanitation, processing, sterilization, Quality control and validation, Documentation

Recommended Books:

1. Pharmaceutical Quality Assurance, MA Potdar, Nirali Prakashan, Pune
2. Validation of Pharmaceutical process, F. J. Carleton and J. Agalloco, Marcel Dekker Inc.
3. Pharmaceutical Process Validation, Second Ed., Ira R. Ferry & Robert Nash., Marcel Dekker Inc.
4. Quality Planning & Analysis by J. M. Juran and F. M. Gryna, Tata Mcgraw Hill, India.
5. Improving Quality through Planned experimentation by Moen, Tata Mcgraw Hill.
6. Good Manufacturing Practices for Pharmaceutical; A Plan for total Quality Control, 4 th Ed, Sidney willing.
7. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
8. Pharmaceutical Process Validation; By F. R., Berory and Robert A. Nash
9. Impurities Evaluation of Pharmaceutical; Satinder Ahiya Marcel Decker.42
10. Quality Control of Packaging material in the Pharmaceutical Industry: Kenneth Harburn, Marcel Dekker.
11. Juran's Quality Control Handbook J.M. Jupron.4th Ed. Good design practices for GMP Pharmaceutical facilities. Andrew A Signature, Marcel Dekker.
12. cGMP for Pharmaceuticals. Pharma. Med. Press, I st edition by Manohar H. Potdar

(E.1.2) PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

(Theory 3 Hrs/Week)

CREDITS 03

UNIT I

1. Regulatory requirements of Pharma facilities with reference to cGMP, revised schedule M and Factory Act
2. Design, layout and operational facilities with services and utilities for Tablets, Capsules, Liquid orals, Ointments and Dry syrups.

UNIT II

3. Design, layout and operational facilities with services and utilities for sterile products powders ready for reconstitution

4. Design and operation of Q.C. Laboratory

UNIT III

5. Design of utility services - Water - stream- Compressed air and other gases
6. Design of effluent treatment plant

UNIT IV

7. Designing of plant support services like security office, vehicle parking, fuel storage, canteen and cooking, garden and horticulture, scrap yards, Administrative block and training centre, sports and entertainment block, resident managers bungalow, residences for essential service staff, toilet facilities, medical services, crush

Recommended Books:

1. Project Management by Clifford F. Gray and Erik W. Larson Publisher: McGraw Hill company.
2. Pharmaceutical Production facilities: Design and applications by Graham Cole. Publisher: Taylor & Francis
3. Production/Operations Management by: El wood Bufa Publisher: Wiley Eastern Limited (New Delhi)
4. S. J. Turco; Sterile Dosage Forms: their Preparation and Clinical Applications; Lee and Febiger.
5. N. K. Jain; Controlled and novel drug delivery: CBS Publication.
6. J. R. Robinson and H. L. Lee; Controlled Drug Delivery: Fundamentals and Applications; Marcel Dekker.
7. F.J. Carleton and J.P.Agalloco; Validation of aseptic pharmaceutical processes: Marcel Dekker.
8. L. A. Trissel: Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.43
9. N.A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.
10. Planning and control by: Samuel Eilon Publisher: Universal book corporation, Mumbai.

(E.1.3) BIOPHARMACEUTICS AND PHARMACOKINETICS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Dissolution:- Noyes- Whitney's dissolutions rate law, Study of various approaches to improve dissolution of poorly soluble drug, In –vitro dissolution testing models, In-vitro-In –vivo correlation.
2. Bioavailability:- Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.

UNIT II

3. Study of different in-vitro and in-vivo / biological models for determination of absorption, distribution, metabolism and excretion and permeability of drug
4. Study of physiological transporter systems like A B C. Dosage form design and physiological barriers like BBB, blood testis barrier and blood placental barrier

UNIT III

5. Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Compartment modeling: One compartment model – IV bolus, IV infusion, Extra-vascular; Multi Compartment models; Two compartment model – Iv bolus, IV infusion, Extra-vascular, Three Compartment model in brie, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.
6. Non-Linear Pharmacokinetics:- Causes of non-linearity, Detection of non – linearity, Michaelis-Menten equation, Estimation of Km and Vmax .with respect to individualization of a drug

UNIT IV

7. Drug Distribution: - significance and kinetics of protein binding and drug displacement interactions
8. Case studies based on pharmacokinetic principles
9. Determination of various pharmacokinetic parameters.

Recommended Books:

1. Biopharmaceutics and Pharmacokinetic, A Treatise, D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan, Pitampura, Delhi

2. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbick. J, Lea and Febiger, Philadelphia.1970.
3. Clinical Pharmacokinetics Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1987.
1. 44
4. Dissolution, Bioavailability and Bioequivalence, Abdou. H. M. Mack Publishing Company, Pennsylvania, 1989.
5. Biopharmaceutics and Clinical Pharmacokinetics, an Introduction, 4th edition, revised and expanded by Robert, E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
6. Biopharmaceutics and relevant Pharmacokinetics, by John. G. Wagner and M. Pernarowski, Ist edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
7. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C. Boylan, Marcel Dekker Inc, New York, 1996.
8. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
9. Biopharmaceutics and Pharmacokinetics, A Treatise, D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan, Pitampura, Delhi
10. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC, 2nd edition, Connecticut, Appleton Century Crofts, 1985.
11. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Books Pvt Ltd, Banglore, 2000.

(E.1.4) STERILE PRODUCTS FORMULATION & TECHNOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I
A) FORMULATIONS

1. Preformulation: Physico-chemical properties of materials used in perenteral formulations. Selection of polymeric components. Selection of packaging components of packaging components.
2. Formulation of SVP and LVP: Requirement, components, materials, Pharmacopoeial requirements, special types of parenterals such as suspensions, emulsions, dried forms, Variables in formulation development.

3. Ophthalmic Products: Ocular anatomy and physiology relevant to ocular drug delivery, ocular Pharmacokinetics, conventional products, ocular inserts, particulate and liposome drug delivery, protein and peptide delivery.
4. Sustained Release Parenterals: Liposome's, and niosomes, nanoparticles, proteins and peptides, implants, loaded erythrocytes.

UNIT II

B) TECHNOLOGY- Manufacturing of Parenterals

6. Layout of parenteral facilities, FFS and BFS technology for parenterals.
7. Environmental control: Temperature and humidity control, air handing systems and their validation.
8. Industrial sterilization: Large-scale sterilization processes, process selection, specifications, development and validation of process and equipment.
9. Parenteral devices such as syringes, cannula, catheters.
10. Guidelines: Overview of GMP and regulatory guidelines.
11. Hazards associated with parenteral therapy

Recommended Books:

1. K. E. Avis, H. A. Liebermann and Lachman; Pharmaceutical dosage forms: Parenteral Medications: Vol. 1,2,3, Marcel Dekker.
2. S. J. Turco Sterile Dosage Forms: their preparation and clinical application; Lee and Febiger.
3. N. K. Jain; Controlled and Novel drug delivery: CBS Publication.
4. J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamentals and Applications; Marcel Dekker.
5. F. J. Carleton and J. P. Agalloco: Validation of aseptic pharmaceutical processes: Marcel Dekker.
6. L. A. Trissel: Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.
7. N. A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.

(E.1.5) ACTIVE PHARMACEUTICAL INGREDIENTS (APIS) MANUFACTURING TECHNOLOGY

(Theory 3 Hrs/Week)

CREDITS 03

UNIT I

Introduction to basic pharmaceutical and fine chemical chemistry: Definitions of basic pharmaceuticals, intermediates, fine chemicals, heavy chemicals. Technology involved in manufacturing of pharmaceuticals. Unit processes in synthesis, biochemical processes in synthesis.

UNIT II

Unit processes: Study of the following chemical processes (with references to reagents, mechanisms, equipments and manufacture of drugs given below): Acylation, esterification, alkylation, amination, halogenation, hydrolysis, nitration, oxidation and reduction.

UNIT III

Industrial processes & scale up techniques

Industrial manufacturing methods and flow charts of Sulphamethoxazole, Ciprofloxacin, Benzocaine, Adrenaline, Rifampicin, Aspirin and Pentothal sodium.

UNIT IV

Bioethics and Bio-Safety

Health hazards in manufacturing facility, The forms of Atmospheric contaminants, Chemical mixtures, Detection and sampling, Atmospheric contamination, industrial noise, criteria for hearing damage, Noise measuring instruments, effects of sound and ultrasound, the control of noise, vibration, Radiation Hazards, Radiation detection and measurement, personal protection, eye protection, Types of eye protection equipment. Finger & Arm protection, Foot & leg protection. Environmental protection laws related to industry.

Reference

1. M.G. Larians: Fundamentals of Chemical Engineering Operations.
2. W. L. Badger and Banchero: Introduction to Chemical Engineering.
3. L. Lachman-The Theory and Practice of Industrial Pharmacy.
4. Ganderton G.: Unit Processes in Pharmacy.
5. Groggin P. K.: Unit Processes in Organic Synthesis.
6. Marshall Sitting: Organic Chemical Processes.
7. Dryden C. L.: Outlines of Chemical Technology.

(E.1.6) CHEMISTRY OF MEDICINAL NATURAL PRODUCTS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Primary and Secondary metabolites in plants.
2. Various metabolic pathways in plants.

UNIT II

3. General isolation and purification techniques of phytochemicals covering alkaloids, glycosides, terpenoids, carbohydrates and flavanoids.
4. (a) Detailed chemistry and properties of Alkaloids (general)

(b) Chemistry, structural elucidation by chemical and physical methods, methods of analysis for following: Alkaloids, Morphine, piperine, lobeline, atropine, caffeine, and ephedrine.

UNIT III

5. (a) Detailed chemistry and properties of plant steroids (general)

(b) Chemistry, structural elucidation by physical and chemical methods, methods of analysis for following: (1) Solasodine. (2) Diosgenin.

6. (a) Detailed chemistry and properties of Flavanoids.

(b) Detailed chemistry and properties of various plant pigments.

UNIT IV

7. Detailed chemistry and properties of terpenoids.
8. Detailed Chemistry and properties of carbohydrates – mono & disaccharides.

Recommended Books:

1. Chemistry of organic natural products, Vol I and II by O. P. Agarwal.
2. Pharmacognosy by Trease and Evans, 13th Ed. (Baillier- Tindall)
3. Phytochemistry, Vol. I, II, III by Miller.
4. Organic Chemistry, Vol I by Finar.
5. Recent Advances in Phytochemistry V.C. Runeckles (Elenum Press).
6. Chemistry of Natural Products, P.S Kalsi
7. Natural Products Chemistry - K. Nakanishi Ed. , Vol I and II

(E.1.7) TRADITIONAL SYSTEMS OF MEDICINE & AYURVEDIC FORMULATIONS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Ethnopharmacognosy – General account.
2. A brief idea about Ayurveda. Chinese systems of medicine. Unani system of medicine. Homeopathy.

UNIT II

3. Comparative account of drugs used in above systems of medicine.
4. Ayurvedic dosage forms-Basic idea.

UNIT III

5. The formulation and evaluation of Ayurvedic dosage forms: Churna, Bhasma, Kwatha Asava, Arishta, Avaleha, Gutika, Vati, Rasa, Rasayana, Taila, Ghrita, Guggulu, Arka.
6. Ayurvedic Cosmetic formulations,

UNIT IV

7. Standardization of Ayurvedic dosage forms using:

a. Physical methods
b. Chemical methods
c. Biological methods.

Recommended Books:

1. Charaka Samhita
2. Sushrut Samhita
3. Sharangardhar Samhita
4. Ayurvedic formulary of India Govt of India.
5. Pharmacopocial standards for Ayurvedic drugs C.C.A.R.A., New delhi
6. Dravyagunavigyan
7. Homorpathic Materia medica.
8. World health W.H.O. 1977

(E.1.8) MEDICINAL PLANT BIOTECHNOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Introduction to genetics & molecular biology.

a. Structural and molecular organization of Cell.

b. Genetic Material-DNA, RNA, Protein, Replication, Genetic Code, Regulation of Gene Expression, Structure & Complexity of Genome.

c. Cell Cycle, Cell signaling.

d. Mutation.

e. Recombinant DNA Technology –Principles, Tools, Process & Applications.

2. Methods of improving quality of crops & their application.

a. Plant Breeding.

b. Chemodemes.

c. Hybridization.

d. Mutation.

e. Polyploidy.

UNIT II

3. Tissue Culture & its Applications

a. Types, Techniques & Application of Callus, Suspension, Haploid, Embryo, Organ and Immobilized Culture.

b. Organogenesis, Embryogenesis, Synthetic seed & Somaclonal variation.

c. Micropropagation.

d. Production of Secondary metabolites – Strategies involving use of
Precursor, Growth regulators & Elicitors: Production of Shikonin.

e. Hairy Root Culture & Multiple Shoot Culture & their Applications.

f. Protoplast culture & Protoplast fusion.

g. Biotransformation.

h. Bioreactors

i. Cryopreservation and germplasm conservation

4. Germplasm Conservation.

a. In- situ Conservation

b. In- vitro methods of Conservation.

UNIT III

5. Gene Transfer in Plants.

a. (i) Using vectors of Agarobacterium.

(ii) DNA Mediated gene transfer – Electroporation, Microprojectile, Macro & Microinjection, Liposomes, Ultrasonication & Chemical mediated gene transfer.

b. Localization of transferred gene in genetically modified plants:

i Nucleic acid Hybridization.

ii Use of Radioisotopes & Molecular Markers.

- Auto Radiography.
- Electrophoresis.

6. Applications of Transgenic Plants.

a. Resistance of herbicide.

b. Resistance to insect, fungus, & virus.

c. Resistance to Physiological stress.

d. Production of Phytopharmaceuticals.

e. Edible vaccine.

UNIT IV

7. Gene Mapping & Molecular Maps of Plant Genomes.

a. Plant Chromosome Analysis.

b. Uses of PCR in gene mapping.

c. Molecular Maps-RFLP, RAPD.

d. Physical maps using in- situ hybridization.

8. Enzymes

a. Types & Properties of enzymes.

b. Isolation & Purification of enzymes.

c. Immobilization of enzymes & its applications.

d. Enzyme reactors.

e. Detailed study of Plant enzymes – Papain & Bromelain.

Recommended Books:

1. Pharmaceutical biotechnology S.P. Vyas and V.K. Dixit, CBS Publishers and Distributors, 2001

2. Advanced methods in plant breeding & biotechnology by David R. Murray. CAB International Panima book distributors.1991.

3. Plant tissue culture by Dixon IRL Press Oxford Washington DC, 1985.

4. Role of Biotechnology in Medicinal and Aromatic Plants Vol I & II By Irfan A Khan and Atiya Khanum Ukaoz Publications.1998

5. Plant Chromosome analysis, manipulation and engineering by Arun And Archana Sharma 1st Edition Harwood Academic Publishers 1999

6. Comprehensive Biotechnology by Murray Moo-Young Vol I- IV Pergamon Press LTD, 1985.

7. Transgenic Plants by R Ranjan Agrobotanica.1999

Recommended Journals:

1. Journal of plant biochemistry and biotechnology
2. Current Science

(E.1.9) NATURAL PRODUCTS MANAGEMENT
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

I) Farm Analysis & Farm Planning

- Management exercise before farm planning / analysis.
- Appraisal of farm resources, capital resources, management factor, land resources, Enterpreural aspects
- Management of resources: land, labour, machinery & equipment.
- Farm planning & budgeting.
- Application of research in farm management.

II) Marketing

- Demand & Supply: Meaning, factors affecting demand & supply.
- Market: Meaning process of a agricultural marketing.
- Processing practice & industries in India.
- Study of co-operative processing / efforts among collectors & growers to store, transport & market the natural products.
- Processing of cocoa and oil seeds.
- Mechanization / Modernization of natural products market.

UNIT II

III) Prioritized Medicinal Plant of India

- Protocols for cultivation & quality control.
- State wise natural habitat of prioritized species.
- Cultivation economics / project proposal for few prioritize species.
- Ex-situ / in-situ cultivation & conservation.
- National & International Trade of prioritized species.

IV) Concerned ministers / Departments / Organization / State / UT Government on policy matters

- Relating to scheme & programmers for development of medicinal plants in India.

UNIT III

V) Study of General Requirement to establish extraction unit based on herbs/ Herbal products.

VI) Patent Right & IPR in relation to medicinal herbs and herbal products.

UNIT IV

VII) Import – export of natural Products –

Legal requirement & processing / techniques for marketing of raw material & value-added products (Medicine, food supplements, herbal cosmetics)

VIII) Review of Trade of herbs, phytoconstituents, Nutraceuticals & other. National medicinal products in national & international market.

Recommended Books:

1. Text Book of Agricultural Business Management, Kalyani Publisher, New Delhi, Brodway A C.
2. Acharya S.S. and Agrawal N.N. Agriculture Marketing in India, Oxford IDH Publication, New Delhi.
3. Memoria C.B. and Joshi Principal and Marketing in India, Kitab Mahal Agency, New Delhi.
4. Das Dilipkumar, Introductory Soil Science Kalyani Publisher, New Delhi.
5. Chaudhary – Herbal Industries
6. Kapoor & Attal – Cultivation and Utilization of Medicinal Plants.
7. Kapoor & Attal – Cultivation and Utilization of Aromatic Plants.
8. Chopra – Indigenous Drugs.
9. Wealth of India NISCAIR Publication, New Delhi.
10. www.nmpb.nic.in.
11. Official Journals, Periodicals, Magazines, Bulletin, Newspapers & Website be referred.

(E.1.10) QUALITY ASSURANCE TECHNIQUES IN HERBAL PRODUCTS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Quality Management – Change as per following
    a. Introduction to GMP
    b. Elements of QA
    c. Information on various regulatory bodies like US FDA, MHRA, TGA, MCC, ICH
    d. Outsorcing
    e. Quality Audits
2. GMP Requirements for herbal medicinal products, Ayurvedic and other Drug of traditional origin - overview and reference to various regulations - Drug and Cosmetic Act and Rules, , Australian/EMEA guidelines for herbal products, WHO Guidelines for Herbal Medicines
3. Surrounding, Building, and Facility – Design for processing of herbal products – Cleaning, pulverization and processing of herbal extracts/ products etc.

UNIT II

4. Equipment URS, and qualifications
5. Standardization of herbal products with reference to WHO and cGMP guidelines
6. Quality control and standardization of medicinal plant, plant based products, neutraceuticals and cosmetics.

UNIT III

7. Analytical methods development guidelines for materials and products/ formulations of herbal/natural origin viz. extracts, herbal formulations, isolated compounds, modern herbal formulations etc.
8. Study of compendial methods for evaluation of crude drug and herbal formulation
9. Stability issues guidelines for studies related to herbal formulations, extracts, fractions and natural products/isolated compounds.

UNIT IV

10. Safety issues related to herbals products and storage of herbal raw materials and herbal products.

11. Pharmacovigilance for herbal products

12. Packaging development: Types of packages, Flexible packaging, primary, secondary & tertiary, quality evaluation as applicable to packages, Child resistant, tamper evident, advancement in packaging.

13. Cleaning and sanitization of plant and equipment. Cleaning validation

Reference Books:

1. Mukherjee Pulok K., **Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals**. Business Horizons, 2002. ISBN 8190078844.

2. Prof. Dr. Robert Verpoorte and Dr. Pulok K. Mukherjee **GMP for Botanicals**

3. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.

4. G. Sudesh Kumar **Regulatory Roadmap for Herbal Medicines**

5. Peter Houghton , Pulok Mukherjee **Evaluation of Herbal Medicinal Products**

6. Willow J.H. Liu, **Traditional Herbal Medicine Research Methods**

7. Jian-guo Zeng, Man-liang Tan, Xuan Peng, and Qi Luo, **Standardization and Quality Control of Herbal Extracts and Products**

8. John Sharp, **Good Pharmaceutical Manufacturing Practice Rationale And Compliance**

9. J.T. Carstensen**, Drug Stability,** Marcel Dekker, New York.

10. **WHO Guidelines: Good manufacturing practices: guidelines for the manufacture of herbal medicines**

11. **Quality Assurance of Medicinal Herbs (Eddie Pang) RIRDC Publication No. 11/093**

(E.1.11) TOXICOLOGY
(Theory 3Hrs/Week)
CREDITS 03

UNIT I

1. Principles of Toxicology:
   a) Tolerance, addiction, habituation, idiosyncrasy, allergy, hypersensitivity, antagonism, synergism, potentiation, tachyphylaxis,
   b) Types of Toxicology (General Toxicology, Mechanistic Toxicology, Regulatory Toxicology, Descriptive Toxicology and Clinical Toxicology).

c) Classification and sources of Toxic Agents.

2. Preclinical toxicology:
   a) Preclinical toxicological requirements for biological and biotechnological products, safety analysis, problems specific to recombinant products, toxicikinetics.
   b) Principles of GLP as per OECD/ICH etc. guidelines for conducting preclinical toxicity studies.

UNIT II

3. Single dose and repeat dose toxicity:
   a) Factors influencing such studies such as species, sex, size, route, dose level.
   b) Data evaluation and regulatory requirements.
   c) Determination of Maximum Tolerated Dose (MTD) and LD50 as per revised OECD guidelines.
   d) Allergenicity testing, dermal toxicity immunotoxicology and in situ methods of toxicology
4. Toxic Responses to Xenobiotics:
   a) Molecular Changes
   b) Subcellular Changes
   c) Cellular Changes
   d) Allergic or Sensitization of Reactions
   e) Idiosyncracy

UNIT III

06 Target Organ Toxicity and management:
   a) Ocular toxicity, Neuronal and Behavioural toxicity, renal toxicity, pulmonary toxicity, cardiotoxicity, hepatotoxicity, genetic toxicity, Mutagenecity, Carcinogenesis and reproductive toxicity.
   b) Enviormental and industrial toxicology.

c) Management of toxicity reaction in humans.

07 Biochemical and Molecular techniques in toxicology

a) Cell culture techniques
b) Molecular cloning
c) cDNA and Genomic libraries
d) PCR, Northern and southern Blot analysis
e) Immunochemical techniques.

08 Applications of Toxicology:

a. Research, Academic and Industrial Applications.
b. Regulatory Toxicology, Forensic Toxicology, Clinical Toxicology.

Recommended Books:

1. Ernest Hodgson. A Textbook of Modern Toxicology, Third Edition.
2. Michael J. Derelanko and Mannfred A. Hollinger, Handbook of Toxicology, second edition, 2002, Taylor & Francis.
3. Frank A. Barile. Principles of Toxicology Testing. CRC press, Taylor & Francis group.
4. Dipiro, Joseph L. Pharmacotherapy: A Pathophysiological Approach, Elsevier.
5. Davidson's Principles of Internal Medicine, Vol-I and II, 14th Edition, Mc Graw-Hill.
6. Harrison's Principle and Practice Of Medicine, 18th Edition, Churchill, Livingston, London.

(E.1.12) SAFETY PHARMACOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

01 Definition and scope of safety pharmacology

02 Regulatory requirements for the new drug safety assessment: Important guidelines such as ICH, OECD, USFDA, EMEA, Japan MHW

UNIT II

03 Principals and study design of safety evaluation:

a. Acute toxicity- rodent and non-rodent

b. Repeated dose studies (sub acute and chronic)
c. Analysis of safety pharmacological data

04 Preclinical safety pharmacology:

In vitro and in vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive and ocular toxicity, Safety testing for dermatological product

05 Application of In vitro techniques in drug safety assessment

UNIT III

06 Clinical Safety pharmacology:

definition, data collection, reporting methods and assessment and analysis of adverse event (AE) monitoring during clinical trials

07 Pharmacovigilance:

Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment.

Recommended Books:

1. Sogliero-Gilbert G. Drug safety assessment in clinical trials. Statistics, textbooks and monographs.New York: Dekker.
2. Marx U and Sandig V. Drug testing in vitro: breakthroughs and trends in cell culture technology. 2007, Weinheim: Wiley-VCH.
3. Gad SC. Safety assessment for pharmaceuticals. 1995, New York: Van Nostrand Reinhold.
4. Turner JR. New drug development: design, methodology, and analysis. 2007, Hoboken, N.J.: Wiley-Interscience.
5. Smith CG and O'Donnell J. The process of new drug discovery and development. 2nd ed. 2006, New York: Informa Healthcare.
6. Benichou C. Adverse drug reactions: a practical guide to diagnosis and management.1994, Chichester, West Sussex, England; New York: Wiley.
7. World Health Organization. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. 2004, Geneva: World Health Organization.
8. Cobert BL. Manual of drug safety and pharmacovigilance. 2007, Sudbury, Mass. Jones and Bartlett Publishers.

9. Cobert BL and Biron P. Pharmacovigilance from A to Z: adverse drug event surveillance. 2002, Malden, MA: Blackwell Science.

(E.1.13) CLINICAL TRIALS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

01 Introduction to clinical Trial :

History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments.

02 Clinical Research Organizations in India and Schedule "Y" as per D&C Rules.

UNIT II

03 Regularly affairs in clinical trials:

IND, NDA, ANDA- Parts and contents, Safety monitory boards, FDA in various countries including India.

04 Ethical issues in clinical trials:

Principal, responsible conduct, supervision of ethics, (Informed Consent,
Institutional Review Board (Role responsibility, members and auditing),
Protection of participants, The Nuremberg Code, The Declaration of Helsinki, T6he Belmont Report.

UNIT III

05 Clinical trial design:

Designs used in clinical trials with their advantages and disadvantages,
hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls.

06 Clinical trial protocol Development

Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial.

UNIT IV

07 Good Clinical Practice:

Concept, importance, and GCP guidelines including ICH guidelines

02 Management of Clinical trials:

Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials.

UNIT V

09 Bioavailability, bioequivalence and Therapeutic Drug Monitoring:

Concept, organization, advantages, special issues, applications, bioequivalence.

10 Data analysis issues in Clinical Trials:

Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials.

Recommended Books:

1. Dipiro Joseph L. Pharmacotherapy: A Pathophysiological Approach, Elsevier
2. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc Graw-Hill
3. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
6. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York

(E.1.14) CLINICAL PHARMACOKINETICS AND PHARMACODYNAMICS

(Theory 3 Hrs/Week)

CREDITS 03

UNIT I

1 Basic considerations: Therapeutic relevance, fundamental concepts and terminology

2 Exposure and response after a single dose: Kinetics following intravenous bolus dose, Membranes and distribution, elimination, kinetics following an extra vascular dose, absorption, response following a single dose

UNIT II

3 Therapeutic regimens: Therapeutic window, constant rate input, multiple drug regimen

4 Individualization: Variability, genetics, age, weight and gender, disease, non-linearities, drug interactions, initiating and managing therapy

UNIT III

5 Distribution Kinetics: One compartment model, Plasma concentration data, clearance and half life associated with elimination

6 Metabolites and Drug response

UNIT IV

7 Protein Drugs

8 Prediction and refinement of human kinetics from in vitro preclinical and early clinical data

9 Principles, Calculations and Basic Assessments: AUC, ionization and pH partition hypothesis, distribution of drugs extensively bound to plasma proteins, plasma to blood concentration ratio, Well-stirred model of hepatic clearance, absorption kinetics, Wagner-Nelson method, Mean residence time, amount of the drug in the body on accumulation to plateau

Recommended Books:

1. Malcolm Rowland and Thomas N. Tozer. Clinical Pharmacokinetics and Pharmacodynamics: Concept and Application, Lippincott Williams & Wilkins
2. Wolfgang A. Ritschel and Gregory L. Kearns. Handbook of Basic Pharmacokinetics including Clinical Applications, American Pharmacist Association
3. Michael E. Winter. "Basic Clinical Pharmacokinetics".2010, Lippincott Williams &Wilkins.
4. Robert E. Notari. Biopharmaceutics and Clinical Pharmacokinetics, Marcel Dekker Inc. New York
5. Larry Bauer and P.B. Bauer Larry, Clinical Pharmacokinetics. Mc-Graw Hil New Delhi .
6. Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu, Applied Biopharmaceutics and Pharmacokinetics, Mc-Graw Hill. New Delhi

7. Milo Gibaldi and Donald Perrier, Pharmacokineties. Marcel Dekker. Inc.
8. V. Venkateshwarlu, Biopharmaceutics and Pharmacokinetics. 2008, Pharm Med Press
9. Ronald Schoenwald. Pharmacokinetic Principles of Dosing Adjustments. CRC press, New York

(E.1.15) CLINICAL IMMUNOLOGY AND ENZYMOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1 General Considerations:

Basics of Immunology- Innate Immunity, Specific Acquired Immunity, The Recognition of antigen, antibody, membrane receptors of antigen and their interactions.

2 Immunodeficiency:

Primary immunodeificiency states in the human, deficiency of innate immune mechanisms, primary T-cell deficiency, acquired immunodeficiency

UNIT II

3 Hypersensitivity:

General consideration of in appropriate immune response, anaphylactic hypersensitivity, antibody dependent cytotoxic hypersensitivity, immune complex mediated hypersensitivity, cell mediated hypersensitivity.

4 Transplantation:

Basic consideration of graft rejection and immunology, Genetic control of transplantation, consequences of MHC incompatibility, mechanisms and prevention of graft rejection, interference by xenobiotics.

UNIT III

5 Tumor Immunology:

Changes in the surface of tumor cell, immune response to tumors, lymphoproliferative disorders, approaches to cancer immunotherapy.

6 Autoimmune diseases-Scope and etiology:

The scope of auto immune diseases, autoreactivity, role of T-helper cells, mechanisms, pathogenic effect of humoral autoantibody, pathologic effects of complexes with autoantigens, T-cell mediated hypersensitivity, diagnostic values of autoantibodies

UNIT IV

7 Hybridoma techniques –

fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in clinical diagnosis, immunotherapy and pharmaceutical research.

8 Enzymology:

General considerations, properties and sources of enzymes, Enzyme kinetics and regulations. Application of enzymology: biological preparations/ analytical reagents, diagnostics, therapeutics, inborn errors of enzymes, of production of important enzymes (examples), Techniques of immobilization of enzymes and their applications in industry, Biosensor technology, Immobilized Enzyme engineering, Kinetics of immobilized enzymes.

Books Recommended:

1. Jan Klein and Vaclav Horejsi, Immunology, 2nd Editions, Blackwell Science, Meldom MA, USA.
2. Dennis K. Flaherty, Immunology of Pharmacy. Elsevier, New York.
3. Ivon Roitt, Roitt's Essential Immunology. Blackwell Science, Meldom, MA, USA.
4. Jenet M. Decker, Introduction to Immunology. Blackwell Science, Meldom, MA, USA.
5. Immunology by Ivan Roitt, Jonathan Brostooff and David Male.
6. Weir DM, Stewart John. Immunology, 8th edition, Churchill Livingstone.
7. Abdul K Abbas, Andrew H Lichtman, Shiv Pillai. Cellular and molecular immunology. 6th edition. Saunders.
8. Robert K. Murray. Harper's Illustrated Biochemistry.
9. Lehninger. The foundations of biochemistry.
10. Nicholas C. Price, Lewis Stevens. Fundamentals of Enzymology: Cell and Molecular Biology of Catalytic Proteins. Oxford University Press.

(E.1.16) INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT

(Theory 3 hours/week)

CREDITS 03

UNIT I

1.Pilot plant scale - up, pilot plant design: tablets, capsules, liquid orals. parenterals, and semisolid preparations. Basis requirements for design of product, facility, equipment selection, personnel. Pharmaceutical process validation for' various products.

2.Quality Assurance: GMP considerations, quality assurance and process control. Total quality management and productivity. ISO 9000 Series salient features.

UNIT II

3. Optimization Techniques: Optimization parameters, classical optimization, statistical design and applied optimization methods.
4. Production Planning: Plant site selection, layout and organization of pharmaceutical industries. Vendor development capacity (plant, machine, human resources) assessment of production rate changes, inventory management costing of product and cost controls, planning product mix.

UNIT III

5.Machinery Engineering: Introduction to mechanical, electrical and electronic parts of pharmaceutical machinery, equipments. Material handling for various pharmaceutical products.

6.Drugs and Cosmetics Act: Requirements related to manufacture and sale of drugs.

UNIT IV

7.Safety: Industrial hazards due to fire, accident, mechanical and electrical equipment, chemical and pharmaceuticals, monitoring and preventive system.

8.Effluent Testing and Treatment: For pharmaceutical industry.

9.Automation: Flexible manufacturing system, computer control systems: data acquizition, distributed control and centralized control system. Typical models for solid and liquid manufacturing.

Recommended Books:

1.P. R. Watt; Tablet machine instruments in pharmaceuticals; John Wiely and Sons.

2.B. Rothery; ISO 14000 and ISO 9000; Gower.

3.G.C. Cole; Pharmaceutical production facilities, design and applications; Taylor and Francis.

4.J.R.Berry and R.A. Nash; Pharmaceutical process validation; Marcel Dekker.

5.S. Bolton; Pharmaceutical statistics; Marcel Dekker.

6.S.H.Wili and J.R. Stoker; Good Manufacturing Practices for Pharmaceuticals; Marcel Dekker.

7.R. F. Brewer; Design of Experiments for process improvement and quality Assurance; Narosa.

8.A. Jaiswal; Management of quality control and standardisation; Kanishka Publisher, New Delhi.

9.D.H.Stamatis; Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.

10.P. Gilson, G. Green halgh and K. Kerr; Manufacturing management; Chapman and Hall.

11.S.S.Rao; Optimization theory and applications; Wiley Eastern Limited.

12.J.F. Despautz; Automation and validation of information in pharmaceutical processing; Marcel Dekker.

13.J.M. Juran and A..B. Godfrey; Juraris quality handbook; McGraw Hill.

14.S.N. Katju's; Law and drugs; Law Publishers(l) Pvt. Ltd.

(E.1.17) FERMENTATION TECHNOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

Basic principle of Bioprocess engineering

Isolation, screening and maintenance of industrially important microbes; Strain improvement for increased yield and other desirable characteristics. Isolation and screening of industrially important microbes; Large scale cultivation of industrial microbes; Strain improvement to improve yield of selectee' compounds e.g. antibiotics. enzymes or recombinant proteins (Cellular control regulating production of microbial metabolites
- Primary and Secondary metabolite - Induced mutation technique - Analogue resistant mutant - Catabolic derepressed mutants - Genetically engineered strain - Protoplast fusion technique). Industrial microbes as cloning hosts (Streptomyces/Yeast). Recombinant protein production in microbes; Commercial issues pertaining to the production recombinant products from microbes.

UNIT II

Bioreactors and Fermenter Design

Introduction to bioreactors; Batch and Fed-batch bioreactors, Continuous bioreactors; immobilized cells; Bioreactor operation; Sterilization; Aeration; Instrumentation & control,

Culture-specific design aspects: plant/mammalian cell culture reactors. Description of industrial processes. Solid substrate, surface and submerged fermentation; Fermentation media; Fermenter design, Mechanically agitated; Pneumatic and hydrodynamic fermenters; Large scale animal and plant cell cultivation and air sterilization; Upstream processing: Media formulation; Sterilization; Aeration and agitation in bioprocess; Measurement and control of bioprocess parameters; Scale up and scale down process.

UNIT III

Principles of enzyme catalysis and microbial growth

Proteins as enzymes; Michaelis-Menten kinetics; Kinetics and Statistics. Inhibition; Effect of pH and temperature; Enzymology; Immobilized enzymes: methods, mass transfer considerations: Industrial enzymes: Factors affecting microbial growth; Stoichiometry: mass balances: energy balances; Growth kinetics; Measurement of growth (an example from each group, particuiarty with reference to mdusuiauy useful microorganisms).

UNIT IV

Applications of enzymes in food processing

Enzymic bioconversions e.g. starch and sugar conversion processc HI0il F-'u':tose Corn Syrup: Inter- esterified fat; Hydrolyzed protein etc. and their downstream pro' 'C<: I)'j. baking by amylases, deoxygenation and desugaring by glucosesoxidase, beer mashing arvt cl 'I i (0 imq, cheese making by proteases and various other enzyme catalytic actions in food processing. Applications of Microbes in food process operations and production: Fermented foods and beverages: Food ingredients and additives prepared by fermentation and their purification; fermentation as a method of preparing and preserving foods; producing colours and flavours. alcoholic beverages and other products; Production of Bioethanol, Biohydrogen and biopesticides.

Recommended Books:

1. Michael Shuler and Fikret Kargi, Bioprocess Engineering: Basic Concepts, 2nd Edition, Prentice Hall, Englewood Cliffs, NJ, 2002.
2. Stanbury RF and Whitaker A., Principles of Fermentation Technology, Pergamon press, Oxford, 1997.
3. Baily JE and Ollis DF., Biochemical Engineering fundamentals, 2nd Edition. McGraw-Hili Book Co., New York, 1986.
4. Pauline Doran. Bioprocess engineering principles. 1 Edition. Academic Press. 1995.
5. Colin Ratledge. Bjorn Kristiansen. Basic Biotechnology. 2nd Edition. Cambridge University Press, 2001
6. Hamson et al., Broseparations Science and Engineering, Oxford University Press. 2003.

7. Jackson AT.. Bioprocess Engineering in Biotechnology, Prentice Hall, Engelwood Cliffs, 1991.
8. Aiba S, Humphrey AE and Millis NF, Biochemical Engineering, 2nd Edition, University of Tokyo press, Tokyo. 1973.

(E.1.18) PROJECT MANAGEMENT
(Theory 3 hours/week)
CREDITS 03

UNIT I

Pre Planning For Project Management:

1. Importance of project management
2. Organizing for project management
3. Role of project manager
4. Role of clients, customers and others
5. Setting lip planning and control system

UNIT II

Project Planning Process:

1. Defining project
2. Creating work breakdown structure
3. Estimating activities
4. Sequencing activities
5. Calculating the critical path
6. Scheduling project
7. Resources planning
8. Preparing planning budgets
9. Approval of projects
10. Setting up a monitoring and control process

UNIT III

Executing the Project

1. Initiating the project
2. Controlling project objectives
3. Reporting on project objectives
4. Controlling changes in the project
5. Conducting project evaluations

6. Managing risks in project management
7 Closing the project

UNIT IV

Heading The Project Team

1. Developing project teams
2. Managing conflicts
3. Communicating effectively
4. Holding effective meetings
5. Making team decisions
6. Using sources of power wisely
7. Making changes
8. Managing performance

Recommended books:

1. Project management; step by step By Larry Richman Publisher: Prentice-Hall of India Pvt. LId Year of publication 2008
2. Project management: The managerial process By Clifford F. Gray and Eric W Larson Publisher: Tara Mc Graw Hill Third edition
3. Rethinking project management By Erling S. Andersen Publisher: Prentice- Hall Year of publication 2008
4. Project management By Jeffery K. Pinto Publisher: Prentice-Hall Year of publication 2007

(E.1.19) PHARMACEUTICAL ADMINISTRATION

(Theory 3 Hours/Week)

CREDITS 03

UNITI

I. Introduction to administration

1. Concept of management and administration
2. Management social responsibility and ethics
3. Function of management

II. Planning and decision making

1. Types of plans and steps in planning
2. Planning process
3. Concept of objectives & MBO

4. Strategic planning process
5. Effective implementation and strategies
6. Process of decision making

UNIT II

I. Organising

1. Formal and informal organizations
2. Concept of span of control
3. Structure and process of organizing
4. Departmentalisation
5. Line and staff concept
6. Making organizations effective and developing positive organization culture

II. Staffing

1. Definition of staffing
2. Systems approach to human resource management and an overview of staffing function
3. Performance appraisal of staffing function
4. Manager development process and training

UNIT III

I. Leading

1. Human factors in managing
2. Human motivation theories of:-

Abraham Maslow

McClelland's needs theory

3. Communication process in organizations

II. Controlling

1. BaSIC control process
2 Critical control pomts and standards
3. Feedback and feed forward controls
4. Requirements for effective control

UNIT IV

I. Productivity and operations management

1. Productivity problems and measurement
2. Production and operations management
3. Controlling and improving productivity

II. Overall and preventive control

1.Control of overall performance

2.Direct control

3.Preventive control

Recommended Books:

1. Essentials of management by Dr.Herold Koontz and Heinz Weitnrich, published by McGraw Hill publishing company.
2. Managing productivity in organizations by Kopelman, published by McGraw Hill publishing company.
3. Effective supervision: A practical approach by Hodgetts, published by McGraw Hill publishing company.

(E.1.20) COSMETICOLOGY
(Theory 3 Hours/Week)
CREDITS 03

UNITI

1) Physiological consideration: skin, hair, nail and eye - in relation to cosmetic application.

2) Rheology of cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.

UNIT II

3) Manufacturing techniques: cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.

4) Evaluation of cosmetics: Performance, physicochemical, microbiological and psychometric evaluation of cosmetics. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and antiaging products.

UNIT III

5) Clinical safety testing: Irritation, sensitization, photoirritation, photoallergy ocular irritation and protocols for the same.

6) Advances in cosmetics: Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.

7) Herbal cosmetics: Formulation development

UNIT IV

8) Packaging: Package development and design for cosmetics including aerosol packs

9) -Regulatory requirements: Manufacturing and sale of cosmetics

Recommended Books:

1) J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
2) J.B.Wilkinson and R.J. Moore; Harry's cosmetology; Longman Science and Technical.
3) S.N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
4) E.G.Thomssen; Modern cosmetics; Universal Publishing Corporation.
5) M.S.Balsam and E. Sagarin ; Cosmetics, science and technology; John Wiley and Sons.
6) R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox
7) H.R.Moskowitz; Cosmetic Product Testing; Marcel Dekker.
8) W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.
9) C.G.Gebelein, T.C.Cheng and VC. Yang ; Cosmetic and pharmaceutical applications of polymers; Plenum.
10) L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
11) w.A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3, Chapman and Hall
12) Dr. Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

SEMESTER-I

(M. 1. 1) Advanced Analytical Techniques
(M. 1.2) Advanced Analytical Techniques (Practical)
(M.1.3) Research Methodology
(M.1.4) Advanced Pharmaceutics
(M.1.5) Advanced Pharmaceutics (Practical)
(M.1.6) Advanced Pharmaceutical Chemistry
(M.1.7) Advanced Pharmaceutical Chemistry (Practical)
(M.1.8) Advance Pharmacology (Preclinical Evaluation of Drugs)
(M.1.9) Advance Pharmacology (Preclinical Evaluation of Drugs) (Practical)
(M.1.10) Advanced Pharmacognosy
(M.1.11) Advanced Pharmacognosy (Practical)
(M.1.12) Advanced Quality Assurance Techniques (cGMP & Documentation)
(M.1.13) Advanced Quality Assurance Techniques (cGMP & Documentation) (Practical)

SEMESTER-II

(M.2.1) Drug Regulatory Affairs
(M.2.2) Formulations & Development
(M.2.3) Formulations & Development (Practical)
(M.2.4) Novel Drug Delivery Systems
(M.2.5) Advanced Medicinal Chemistry
(M.2.6) Advanced Medicinal Chemistry (Practical)
(M.2.7) Drug Design
(M.2.8) Clinical Pharmacology
(M.2.9) Clinical Pharmacology (Practical)
(M.2.10) Molecular Pharmacology
(M.2.11) Phytochemistry & Phytopharmaceuticals
(M.2.12) Phytochemistry & Phytopharmaceuticals (Practical)
(M.2.13) Industrial Pharmacognosy
(M.2.14) Pharmaceutical Validation
(M.2.15) Pharmaceutical Validation (Practical)
(M.2.16) Quality Planning And Analysis

ELECTIVE SUBJECTS OF ALL SEMESTERS

(E.1.1) Quality Control & Assurance of Pharmaceuticals
(E.1.2) Pharmaceutical Plant Design and Operations
(E.1.3) Biopharmaceutics and Pharmacokinetics
(E.1.4) Sterile Products Formulation & Technology
(E.1.5) Active Pharmaceutical Ingredients (APIs) Manufacturing Technology
(E.1.6) Chemistry of Medicinal Natural Products

(E.1.7) Traditional Systems of Medicine & Ayurvedic Formulations
(E.1.8) Medicinal Plant Biotechnology
(E.1.9) Natural Products Management
(E.1.10) Quality Assurance Techniques In Herbal Products
(E.1.11) Toxicology
(E.1.12) Safety Pharmacology
(E.1.13) Clinical Trials
(E.1.14) Clinical Pharmacokinetics and Pharmacodynamics
(E.1.15) Clinical Immunology and Enzymology
(E.1.16) Industrial Pharmacy And Production Management
(E.1.17) Fermentation Technology
(E.1.18) Project Management
(E.1.19) Pharmaceutical Administration
(E.1.20) Cosmeticology