<table>
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<th>Pharmaceutical Regulatory Affairs</th>
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</table>
Course Objective: This subject will impart knowledge about physiological structure of skin, hair, nail and eye. This gives the information about rheological properties of different cosmetic properties. It will teach the students on preparation and evaluation of different cosmetic products and their excipients. It will teach the students in developing cosmetic safety and new technology in developing cosmetics.

Course Outcome: Upon completion of the course, the student shall be able to,
- Explain the physiological structures of skin, hair, nail and eye.
- It gives the knowledge about rheological property determination
- Explain the evaluation process, safety use of cosmetics and new technology development.
- Explain the principles involved in liposomes, multiple emulsions and creams.

UNIT I
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) Evaluation of cosmetics: Performance, physicochemical, microbiological and psychometric evaluation of cosmetics.

UNIT III
5) Clinical safety testing: Irritation, sensitization, photoirritation, photoallergy ocular irritation and protocols for the same.
6) Herbal cosmetics: Formulation development

UNIT IV
7) Packaging: Package development and design for cosmetics including aerosol packs
8) Regulatory requirements: Manufacturing and sale of cosmetics

UNIT V
9) Advances in cosmetics: Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.
10) Manufacturing techniques: cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.

RECOMMENDED BOOKS:
1. J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
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 V.C. 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.
PHARMACEUTICAL ADMINISTRATION (Open Elective)

Course Objective: This subject will provide principles of pharmaceutical industrial management, forms of business organization, plant location and layout. It will teach the students on workman safety, export and import of drugs and pharmaceuticals and briefly on industrial accounting.

Course Outcome: Upon completion of the course, the student shall be able to, □ Explain the Indian pharmaceutical industry development, knowledge about Pharmaxil and its involvement □ Explain the books of accounting, journals, ledger, cashbook and balance sheet.

UNIT I

UNIT II

UNIT III
Indian pharmaceutical industry: Pharmaceutical industry in India, milestones in the development of pharmaceutical industry, current status and its role in national economy and national health. Structure of the industry, organized sector, small sector, manufacture of pharmaceuticals in public sector. Progress in the manufacture of basic drugs – synthetic and drugs of vegetable origin.

UNIT IV

UNIT V

RECOMMENDED BOOKS:
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.
- Forest resources
- Water resources
- Mineral resources
- Energy resources
- 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
RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380013, India,
Course Objective: This subject will provide introduction of project life cycle, its duties, planning for project life cycle leaders and their involvement project management. It will teach the students on role of project managers, clients, customers etc. This subject also focuses on project planning process, executing and heading the project team and responsibilities.

Course Outcome: Upon completion of the course, the student shall be able to, □ Explain the project management and its life cycle □ involves in different duties as project manager, clients and customers □ Explain the responsibilities of key players involved in project management □ Execute project as project leaders and team responsibilities.

UNIT I
Introduction & Project Life Cycle:
The difference between a project manager and a project engineer / project leader, duties of a project engineer /project leader, relationship between scope/schedule/budget/resources and how it relates to all project activities
Project Life Cycle and how it relates to project definition and control, feasibilities and feasibility study, key elements of working in a group and group dynamics.

UNIT II
Pre-Planning for Project Management:
Importance of project management, organizing for project management, Role of project manager, Role of clients, customers and others, setting up planning and control system.

UNIT III
Project Planning Process:
Defining project, creating work breakdown structure, estimating activities, sequencing activities, calculating the critical path, scheduling project, resources planning, preparing planning budgets, approval of projects, setting up a monitoring and control process.

UNIT IV
Executing the Project:
Initiating the project, controlling project objectives, reporting on project objectives, controlling changes in the project, conducting project evaluations, managing risks in project management, Closing the project.

UNIT V
Heading the Project Team:
Developing project teams, managing conflicts, communicating effectively, holding effective meetings, making team decisions, using sources of power wisely, making changes, managing performance.

RECOMMENDED BOOKS:
1. Project management; step by step By Larry Richman Publisher: Prentice-Hall of India Pvt. Ltd Year of publication 2008
3. Rethinking project management By Erling S. Andersen Publisher: Prentice- Hall Year of publication 2008
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

RECOMMENDED BOOKS:
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 Rabbits 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:

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.
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

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

UNIT IV

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

RECOMMENDED BOOKS:
Course Objectives: These topics are designed to impart 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-phylene 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 tewl, 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:
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.

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UNIT V
RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
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

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

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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.

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

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

UNIT IV
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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:

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.
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

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

UNIT IV

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

RECOMMENDED BOOKS:
Course Objectives: These topics are designed to impart 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.

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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.
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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 perspants and Deodrants: Actives and MOA.
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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
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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 tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

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

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
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UNIT V
RECOMMENDED BOOKS:
1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380013, India,
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;
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UNIT II
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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

RECOMMENDED BOOKS:
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
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UNIT I

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

UNIT IV

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

RECOMMENDED BOOKS:
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.
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- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
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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.

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UNIT IV

UNIT V
RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
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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
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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

RECOMMENDED BOOKS:
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)

PHARMACEUTICAL VALIDATION (Open Elective)

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
- Validate the manufacturing facilities

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


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

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

RECOMMENDED BOOKS:
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.


9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam
NUTRACEUTICALS (Open Elective)

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 Outcome: 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, Gingko, Flaxseeds

UNIT II
Phytochemicals as Neutraceuticals: 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: Reservetrol
d) Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics: Fructo oligosaccharides, Lacto bacillus
f) Phytoestrogens: Isoflavones, daidzein, Geebustin, 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
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.


RECOMMENDED 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.
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:

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.
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)

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

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

UNIT IV

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

RECOMMENDED BOOKS:
**Course Objectives:** These topics are designed to 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-ylene 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 tewl, 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:

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**
RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
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

RECOMMENDED BOOKS:
ENTREPRENEURSHIP MANAGEMENT (Open Elective)

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

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

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

UNIT IV

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

TEXT AND REFERENCE BOOKS:
Course Objective: These topics are designed to impart specialized knowledge on various cosmetics, their preparation, properties, MOA, uses, etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcome: 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 problems 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-phylene di amine-based hair dye.
Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth, teeth whitening, mouthwash.

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 toothpaste.

UNIT IV
Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tewl, 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:
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 Outcome: 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, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II
Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following
  b. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, Lutein
  c. Sulfides: Diallysulfides, Allyltrisulfide.
  d. Polyphenolics: Reservetrol
  e. Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
  f. Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
  g. Phytoestrogens, Isoflavones, daidzein, Geebustin, lignans
  h. 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.

UNIT IV
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin
c. 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

RECOMMENDED 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.
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, transferasomes, 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

RECOMMENDED 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: Nanoplatforms in Drug Delivery, Jose L. Arias, CRC press
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
JAWAHRLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Open Elective)

Course Objective: This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health careregimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:
- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT - I
Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT - II
Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds’ ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT - III

UNIT - IV
Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT - V
Definition, Steps involved, Applications, Advantages and disadvantages of the following: Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree,
Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

**RECOMMENDED BOOKS:**
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
10. Relevant review articles from recent medical and pharmaceutical literature
Course Objective: This subject will impart knowledge about physiological structure of skin, hair, nail and eye. This gives the information about rheological properties of different cosmetic properties. It will teach the students on preparation and evaluation of different cosmetic products and their excipients. It will teach the students in developing cosmetic safety and new technology in developing cosmetics.

Course Outcome: Upon completion of the course, the student shall be able to,
- Explain the physiological structures of skin, hair, nail and eye.
- It gives the knowledge about rheological property determination
- Explain the evaluation process, safety use of cosmetics and new technology development.
- Explain the principles involved in liposomes, multiple emulsions and creams.

UNIT I
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) Evaluation of cosmetics: Performance, physicochemical, microbiological and psychometric evaluation of cosmetics.

UNIT III
5) Clinical safety testing: Irritation, sensitization, photoirritation, photoallergy ocular irritation and protocols for the same.
6) Herbal cosmetics: Formulation development

UNIT IV
7) Packaging: Package development and design for cosmetics including aerosol packs
8) Regulatory requirements: Manufacturing and sale of cosmetics

UNIT V
9) Advances in cosmetics: Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.
10) Manufacturing techniques: cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.

RECOMMENDED BOOKS:
1. J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
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 V.C. 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.
PHARMACEUTICAL ADMINISTRATION (Open Elective)

Course Objective: This subject will provide principles of pharmaceutical industrial management, forms of business organization, plant location and layout. It will teach the students on workman safety, export and import of drugs and pharmaceuticals and briefly on industrial accounting.

Course Outcome: Upon completion of the course, the student shall be able to, □ Explain the Indian pharmaceutical industry development, knowledge about Pharmaxil and its involvement □ Explain the books of accounting, journals, ledger, cashbook and balance sheet.

UNIT I

UNIT II

UNIT III
Indian pharmaceutical industry: Pharmaceutical industry in India, milestones in the development of pharmaceutical industry, current status and its role in national economy and national health. Structure of the industry, organized sector, small sector, manufacture of pharmaceuticals in public sector. Progress in the manufacture of basic drugs – synthetic and drugs of vegetable origin.

UNIT IV

UNIT V

RECOMMENDED BOOKS:
Course Objective: 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 Outcome:
- 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 Cosmmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API’s, Manufacturing Contract and Loan licence manufacturing.

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

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

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

UNIT V
Governing Regulatory Bodies across the globe.
Country Authority Submission
- U.S Food & Drug Administration USDMF
- Canada Therapeutic Product Directorate DMF
- European
  1) European Medicines Agency (EMEA/ National Authorities) EDMF
  2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
  3) MHRA – Medicines and Health Care Products Regulatory Agency
- Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

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

RECOMMENDED BOOKS:
1. Original laws published by Govt. of India.
3. Laws of Drugs in India by Hussain.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013
PROJECT MANAGEMENT (Open Elective)

Course Objective: This subject will provide introduction of project life cycle, its duties, planning for project life cycle leaders and their involvement project management. It will teach the students on role of project managers, clients, customers etc. This subject also focuses on project planning process, executing and heading the project team and responsibilities.

Course Outcome: Upon completion of the course, the student shall be able to,
- Explain the project management and its life cycle
- Involves in different duties as project manager, clients and customers
- Explain the responsibilities of key players involved in project management
- Execute project as project leaders and team responsibilities.

UNIT I
Introduction & Project Life Cycle
The difference between a project manager and a project engineer / project leader, duties of a project engineer / project leader, relationship between scope/schedule/budget/resources and how it relates to all project activities
Project Life Cycle and how it relates to project definition and control, feasibilities and feasibility study, key elements of working in a group and group dynamics.

UNIT II
Pre-Planning for Project Management:
Importance of project management, organizing for project management, Role of project manager, Role of clients, customers and others, setting up planning and control system.

UNIT III
Project Planning Process:
Defining project, creating work breakdown structure, estimating activities, sequencing activities, calculating the critical path, scheduling project, resources planning, preparing planning budgets, approval of projects, setting up a monitoring and control process.

UNIT IV
Executing the Project
Initiating the project, controlling project objectives, reporting on project objectives, controlling changes in the project, conducting project evaluations, managing risks in project management, Closing the project.

UNIT V
Heading the Project Team
Developing project teams, managing conflicts, communicating effectively, holding effective meetings, making team decisions, using sources of power wisely, making changes, managing performance

RECOMMENDED BOOKS:
1. Project management; step by step By Larry Richman Publisher: Prentice-Hall of India Pvt. Ltd Year of publication 2008
3. Rethinking project management By Erling S. Andersen Publisher: Prentice- Hall Year of publication 2008
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

RECOMMENDED BOOKS:
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:

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.
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

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

UNIT IV

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

RECOMMENDED BOOKS:

Course Objectives: These topics are designed to impart 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 perspents 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-phylene 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 tewl, 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:

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
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
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380013, India,
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)

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 Outcome: 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

RECOMMENDED BOOKS: