



SATHYABAMA

INSTITUTE OF SCIENCE AND TECHNOLOGY

(DEEMED TO BE UNIVERSITY)

Accredited A++ Grade by NAAC | 12B Status by UGC | Approved by AICTE

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SCHOOL OF PHARMACY

1.2.1 Courses having focus on Employability / Entrepreneurship / Skill Development

B. Pharmacy

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BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Limit Test of the following:

- (1) Chloride.
- (2) Sulphate.
- (3) Iron.
- (4) Arsenic.

II Preparation and standardization of

- (1) Sodium hydroxide.
- (2) Sulphuric acid.
- (3) Sodium thiosulfate.
- (4) Potassium permanganate.
- (5) Ceric ammonium sulphate.

III Assay of the following compounds along with Standardization of Titrant:

- (1) Ammonium chloride by acid base titration.
- (2) Ferrous sulphate by Cerimetry.
- (3) Copper sulphate by Iodometry.
- (4) Calcium gluconate by Complexometry.
- (5) Hydrogen peroxide by Permanganatometry.
- (6) Sodium benzoate by non-aqueous titration.
- (7) Sodium Chloride by precipitation titration.

IV Determination of Normality by electro-analytical methods:

- (1) Conductometric titration of strong acid against strong base.
- (2) Conductometric titration of strong acid and weak acid against strong base.
- (3) Potentiometric titration of strong acid against strong base.

Recommended Books: (Latest Editions)

- Vogel's Textbook of Quantitative Chemical Analysis by Mendham J., Denny R.C., Barnes J.D., Thomas M, Jeffery G.H., Pearson Education Asia.
- A Textbook of Pharmaceutical by Connors K.A., Wiley Inter-science.
- Practical Pharmaceutical Chemistry by Beckett A.H., and Stenlake J.B., Vol. I & II. Athlone Press, University of London.
- British Pharmacopoeia, Her Majesty's Stationary Office, University Press, Cambridge.
- Quantitative Analysis by Alexeyev V., CBS Publishers & Distributors, New Delhi.
- The Pharmacopoeia of India, the Controller of Publications, Delhi.
- Bentley and Driver's Textbook of Pharmaceutical Chemistry, Oxford University Press, New Delhi.

Employability

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

Historical background and development of profession of pharmacy: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.

Dosage forms: Introduction to dosage forms, classification and definitions.

Prescription: Definition, Parts of prescription, handling of Prescription and Errors in prescription.

Posology: Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

Unit-II

10 Hours

Pharmaceutical calculations: Weights and measures– Imperial & Metric system, Calculations involving percentage solutions, allegation, proof spirit and isotonic solutions based on freezing point and molecular weight.

Powders: Definition, classification, advantages and disadvantages. Simple & compound powders– official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

Liquid dosage forms: Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques.

Unit-III

10 Hours

Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

Biphasic liquids:

Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

Unit-IV

08 Hours

Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

Pharmaceutical incompatibilities: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

Unit-V

07 Hours

Semisolid dosage forms: Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi-solid dosage forms. Evaluation of semi-solid dosages forms.

Employability

BP109P. PHARMACEUTICS I (Practical)

3 Hours/week

1. Syrups:

- a) Syrup IP'66
- b) Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs:

- a) Piperazine citrate elixir
- b) Paracetamol pediatric elixir.

3. Linctus:

- a) Terpin Hydrate Linctus IP'66
- b) Iodine Throat Paint (Mandles Paint)

4. Solutions:

- a) Strong solution of ammonium acetate
- b) Cresol with soap solution c) Lugol's solution

5. Suspensions:

- a) Calamine lotion
- b) Magnesium Hydroxide mixture
- c) Aluminium Hydroxide gel

6. Emulsions:

- a) Turpentine Liniment
- b) Liquid paraffin emulsion

7. Powders and Granules:

- a) ORS powder (WHO)
- b) Effervescent granules
- c) Dusting powder
- d) Divided powders

8. Suppositories:

- a) Glycero gelatin suppository
- b) Cocoa butter suppository
- c) Zinc Oxide suppository

9. Semisolids:

- a) Sulphur ointment
- b) Non staining-iodine ointment with methyl salicylate
- c) Carbopal gel

10. Gargles and Mouthwashes:

- a) Iodine gargle
- b) Chlorhexidine mouthwash

Employability

BP209P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch).
2. Identification tests for Proteins (Albumin and Casein).
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method).
4. Qualitative analysis of urine for abnormal constituents.
5. Determination of blood creatinine.
6. Determination of blood sugar.
7. Determination of serum total cholesterol.
8. Preparation of buffer solution and measurement of pH.
9. Study of enzymatic hydrolysis of starch.
10. Determination of Salivary amylase activity.
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

 **Employability**

BP304T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Course content

Unit-I

10

Hours

Flow of Fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturi meter, Pitot tube and Rotameter.

Size Reduction: Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.

Size Separation: Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

Unit-II

10

Hours

Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.

Distillation: Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation.

Unit-III

10

Hours

Drying: Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer,

vacuum dryer, freeze dryer.

Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier.

Unit-IV

08

Hours

Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seitz filter.

Centrifugation: Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

Unit-V

07

Hours

Materials of pharmaceutical plant construction, corrosion and its prevention:

Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and their prevention. Ferrous and non-ferrous metals, inorganic and organic non-metals, basic of material handling systems.

Employability

BP307P. PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipment and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid-fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

Employability

BP308P. PHARMACEUTICAL ENGINEERING (Practical)

4
Hours/week

1. Determination of radiation constant of brass, iron, unpainted and painted glass.
2. **Steam distillation** – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient by heat exchanger.
4. Construction of drying curves (for calcium carbonate and starch).
5. **Determination of moisture content and loss on drying.**
6. **Determination of humidity of air** – From wet and dry bulb temperatures- use of Dew point method.
7. **Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, dehumidifier.**
8. **Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.**
9. **Size reduction:** To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond coefficients, power requirement and critical speed of Ball Mill.
10. **Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.**
11. Factors affecting rate of filtration and evaporation (Surface area, Concentration and Thickness/viscosity).
12. To study the effect of time on the rate of crystallization.
13. To calculate the uniformity Index for given sample by using Double Cone Blender.

 **Employability**

BP407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

1. Determination of particle size, particle size distribution using sieving method.
2. Determination of particle size, particle size distribution using Microscopic method.
3. Determination of bulk density, true density and porosity.
4. Determine the angle of repose and influence of lubricant on angle of repose.
5. Determination of viscosity of liquid using Ostwald's viscometer.
6. Determination sedimentation volume with effect of different suspending agent.
7. Determination sedimentation volume with effect of different concentration of single suspending agent.
8. Determination of viscosity of semisolid by using Brookfield viscometer.
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order.
11. Accelerated stability studies.

Employability

BP506P. INDUSTRIAL PHARMACY I (Practical)

4 Hours/week

1. Preformulation studies of Paracetamol/Aspirin/or any other drug.
2. Preparation and evaluation of Paracetamol tablets.
3. Preparation and evaluation of Aspirin tablets.
4. Coating of tablets- film coating of tablets/granules.
5. Preparation and evaluation of Tetracycline capsules.
6. Preparation of Calcium Gluconate injection.
7. Preparation of Ascorbic Acid injection.
8. Quality control test of (as per IP) marketed tablets and capsules.
9. Preparation of Eye drops/ and Eye ointments.
10. Preparation of Creams (cold / vanishing cream).
11. Evaluation of glass containers (as per IP).

Employability

BP508P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of:
Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander.
2. Exercise involving isolation & detection of active principles:
 - a) Caffeine - from tea dust.
 - b) Diosgenin from Dioscorea.
 - c) Atropine from Belladonna.
 - d) Sennosides from Senna.
3. Separation of sugars by Paper chromatography.
4. TLC of herbal extract.
5. Distillation of volatile oils and detection of phytoconstituents by TLC.
6. Analysis of crude drugs by chemical tests:
 - (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh.

Employability

BP605T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Course content:

Unit-I 10

Hours

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. **Enzyme Biotechnology- Methods of enzyme immobilization and applications. Biosensors- Working and applications of biosensors** in Pharmaceutical Industries. Brief introduction to Protein Engineering.

Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. Basic principles of genetic engineering.

Unit-II 10

Hours

Study of cloning vectors, restriction endonucleases and DNA ligase. Recombinant DNA technology. Application of genetic engineering in medicine. **Application of r DNA technology and genetic engineering** in the production of:

- I. Interferon
- II. Vaccines- hepatitis- B
- III. Hormones Insulin.
- IV. Brief introduction to PCR.

Unit-III 10

Hours

Types of immunity- humoral immunity, cellular immunity. Structure of Immunoglobulins.

Structure and Function of MHC. **Hypersensitivity reactions, Immune stimulation and Immune suppressions.** General method of the preparation of bacterial infections, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. Storage conditions and stability of official vaccines. Hybridoma technology- Production, Purification and Applications, Blood products and Plasma Substitutes.

Unit-IV 08

Hours

Immuno-blotting techniques- **ELISA, Western blotting, Southern blotting. Genetic organization of Eukaryotes and Prokaryotes.**

Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. Introduction to Microbial biotransformation and applications. Mutation: Types of mutation/mutants

Unit-V

07

Hours

Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. Large scale production fermenter design and its various controls. Study of the production of - Penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin. Blood Products: Collection, Processing and Storage of whole human blood, dried humanplasma, plasma Substitutes.



Employability

BP606T. PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Course content:

Unit-I

10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP. Total Quality Management (TQM): Definition, elements, philosophies. ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, **ICH stability testing guidelines. Quality by design (QbD):** Definition, overview, elements of QbD program, tools. ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration. NABL accreditation: Principles and procedures.

Unit-II

10 Hours

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

Unit-III

10 Hours

Quality Control: Quality control test for containers, rubber closures and secondary packing materials. **Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, **Protocol for Conduct of a Nonclinical Laboratory Study**, Records and Reports, Disqualification of Testing Facilities.

Unit-IV

08 Hours

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

Unit-V

07 Hours

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, **General principles of Analytical method Validation.** Warehousing: Good warehousing practice, materials management.

Employability

BP705P. INSTRUMENTAL METHODS OF ANALYSIS / NDDS **(Practical)**

4 Hours/Week

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.
2. Estimation of sulphanilamide by colorimetry.
3. Simultaneous estimation of ibuprofen and Paracetamol by UV spectroscopy.
4. Estimation of quinine sulphate by fluorimetry.
5. Study of quenching of fluorescence.
6. Determination of sodium by flame photometry.
7. Determination of potassium by flame photometry.
8. Determination of chlorides and sulphates by nephelo-turbidimetry.
9. Separation of sugars by thin layer chromatography.
10. Separation of plant pigments by column chromatography.
11. Demonstration experiment on HPLC.
12. Demonstration experiment on Gas Chromatography.
13. To perform in-vitro dissolution profile of CR/SR marketed formulation.
14. To prepare sustained release matrix tablets and evaluate by UV spectroscopy.
15. Formulation of nanoparticles and evaluate by HPLC.
16. Formulation and evaluation of liposomes.
17. To prepare buccal dosage form and evaluate by UV spectroscopy.
18. To prepare Paracetamol transdermal patch and evaluate by UV spectroscopy.

Employability

BP805ET. PHARMACOVIGILANCE (Theory)

45 hours

Course Content

Unit-I

10

Hours

Introduction to Pharmacovigilance: History and development of Pharmacovigilance □ Importance of safety monitoring of Medicine, WHO international drug monitoring programme □ Pharmacovigilance Program of India (PvPI).

Introduction to adverse drug reactions

Definitions and classification of ADRs, Detection and reporting, Methods in Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment, Management of adverse drug reactions.

Basic terminologies used in pharmacovigilance

Terminologies of adverse medication related events, Regulatory terminologies.

Unit-II

10

hours

Drug and disease classification

Anatomical, therapeutic and chemical classification of drugs, international classification of diseases, Daily defined doses, International Non-proprietary names for drugs.

Drug dictionaries and coding in pharmacovigilance

WHO adverse reaction terminologies, MedDRA and Standardized MedDRA queries, WHO drug dictionary, EudraVigilance medicinal product dictionary.

Information resources in pharmacovigilance

Basic drug information resources, Specialized resources for ADRs.

Establishing pharmacovigilance programme

Establishing in a hospital, Establishment & operation of drug safety department in industry, Contract Research Organizations (CROs), Establishing a national program.

Unit-III

10 Hours

Vaccine safety surveillance

Vaccine Pharmacovigilance □ Vaccination failure, Adverse events following immunization.

Pharmacovigilance methods

Passive surveillance – Spontaneous reports and case series □ Stimulated reporting □ Active surveillance– Sentinel sites, drug event monitoring and registries □ Comparative observational studies– Cross sectional study, case control study and cohort study. Targeted clinical investigations.

Communication in pharmacovigilance

Effective communication in Pharmacovigilance, Communication in Drug Safety Crisis management, Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media.

Unit-IV

8 Hours

Safety data generation: Pre clinical phase, Clinical phase, Post approval phase (PMS).

ICH Guidelines for Pharmacovigilance: Organization and objectives of ICH, Expedited reporting, Individual case safety reports, Periodic safety update reports, Post approval expedited reporting, Pharmacovigilance planning, Good clinical practice in pharmacovigilance studies

Unit-V

7

Hours

Pharmacogenomics of adverse drug reactions: Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population: Paediatrics, Pregnancy and lactation, Geriatrics.

CIOMS: CIOMS Working Groups CIOMS Form.

CDSCO (India) and Pharmacovigilance: D & C Act and Schedule Y, Differences in Indian and global pharmacovigilance requirements.



Employability

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/weeks

- 1. Study of compound microscope.**
2. Microscopic study of epithelial and connective tissue.
3. Microscopic study of muscular and nervous tissue.
4. Identification of axial bones.
5. Identification of appendicular bones.
6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count.
8. Enumeration of total red blood corpuscles (RBC) count.
- 9. Determination of bleeding time.**
- 10. Determination of clotting time.**
- 11. Estimation of hemoglobin content.**
- 12. Determination of blood group.**
- 13. Determination of erythrocyte sedimentation rate (ESR).**
- 14. Determination of heart rate and pulse rate.**
15. Recording of blood pressure.



Entrepreneurship

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY-I (Practical)

4 Hours / week

A. Systematic qualitative analysis of unknown organic compounds like

1. **Preliminary test:** Color, odor, aliphatic/aromatic compounds, saturation and unsaturation, etc.
2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test.

3. Solubility test.

4. Functional group test like Phenols, Amides/Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.

5. Melting point/Boiling point of organic compounds.

6. Identification of the unknown compound from the literature using melting point/boiling point.

7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
8. Minimum 5 unknown organic compounds to be analyzed systematically.

B. Preparation of suitable solid derivatives from organic compounds.

C. Construction of molecular models.



Entrepreneurship

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools.
4. Creating mailing labels Using Label Wizard, generating label in MS WORD.
5. Create a database in MS Access to store the patient information with the required fields using access.
6. Design a form in MS Access to view, add, delete and modify the patient record in the database.
7. Generating report and printing the report from patient database.
8. Creating invoice table using – MS Access.
9. Drug information storage and retrieval using MS Access.
10. Creating and working with queries in MS Access.
11. Exporting Tables, Queries, Forms and Reports to web pages.
12. Exporting Tables, Queries, Forms and Reports to XML pages.

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

1. Experiments involving laboratory techniques:

- Recrystallization.
- Steam distillation.

2. Determination of following oil values (including standardization of reagents):

- Acid value.
- Saponification value.
- Iodine value.

3. Preparation of compounds

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/Phenol/Aniline by acylation reaction.
- 2,4,6-tribromo aniline/para bromo acetanilide from Aniline.
- Acetanilide by halogenation (Bromination) reaction.
- 5-nitrosalicylic acid/meta di-nitrobenzene from salicylic acid/ nitro benzene by nitration reaction.
- Benzoic acid from benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
- Benzil from benzoin by oxidation reaction.
- Dibenzal acetone from benzaldehyde by Claisen-Schmidt reaction.
- Cinnamic acid from benzaldehyde by Perkin reaction.
- *p*-Iodo benzoic acid from *p*-amino benzoic acid.

BP407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

12. Determination of particle size, particle size distribution using sieving method.
13. Determination of particle size, particle size distribution using Microscopic method.
14. Determination of bulk density, true density and porosity.
15. Determine the angle of repose and influence of lubricant on angle of repose.
16. Determination of viscosity of liquid using Ostwald's viscometer.
17. Determination sedimentation volume with effect of different suspending agent.
18. Determination sedimentation volume with effect of different concentration of single suspending agent.
19. Determination of viscosity of semisolid by using Brookfield viscometer.
20. Determination of reaction rate constant first order.
21. Determination of reaction rate constant second order.
22. Accelerated stability studies.



Entrepreneurship

BP502T. INDUSTRIAL PHARMACY I (Theory)

45 Hours

Course content

Unit-I Hours

07

Pre-formulation Studies: Introduction to pre-formulation, goals and objectives, study of physicochemical characteristics of drug substances.

Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism.

Chemical Properties: Hydrolysis, oxidation, reduction, racemization, polymerization. BCS classification of drugs & its significance.

Application of pre-formulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

Unit-II Hours

10

Tablets: Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipment's and tablet tooling.

Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. **Quality control tests: In process and finished product tests.**

Liquid orals:

Formulation and manufacturing consideration of syrups and elixirs **suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in Pharmacopoeia**

Unit-III Hours

08

Capsules: Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of **formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.**

Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product **quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.**

Pellets: Introduction, formulation requirements, palletization process, and equipment for manufacture of pellets.

Unit-IV

10

Hours

Parenteral Products:

Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity.

Production procedure, production facilities and controls, aseptic processing.

Formulation of injections, sterile powders, large volume parenteral and lyophilized products.

Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids.

Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions, methods of preparation, labeling, containers, evaluation of ophthalmic preparations.

Unit-V

10

Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems, formulation and manufacture of aerosols, Evaluation of aerosols, Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.



Entrepreneurship

BP504T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Course Content

Unit-I 7 Hours

Metabolic pathways in higher plants and their determination

Brief study of basic metabolic pathways and formation of different secondary metabolites

through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway. Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

Unit-II 14 Hours

General introduction, composition, chemistry & chemical classes, bio-sources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium.

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta.

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis.

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander.

Tannins: Catechu, Pterocarpus.

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony.

Glycosides: Senna, Aloes, Bitter Almond.

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, Taxus, carotenoids.

Unit-III 06 Hours

Isolation, Identification and Analysis of Phytoconstituents. Terpenoids: Menthol, Citral, Artemisin.

Glycosides: Glycyrrhetic acid & Rutin. Alkaloids: Atropine, Quinine, Reserpine, Caffeine
Resins: Podophyllotoxin, Curcumin.

Unit-IV 10

Hours

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine.

Unit-V**8****Hours****Basics of Phytochemistry**

Modern methods of extraction, application of latest techniques like Spectroscopy, Chromatography and electrophoresis in the isolation, purification and identification of crude drugs.



Entrepreneurship

BP505T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules.

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

Unit-II

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and restricted license. Offences and penalties.

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules– Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, licensing authorities, controlling authorities, Drugs Inspectors.

Unit-III

10 Hours

Pharmacy Act-1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties.

Medicinal and Toilet Preparation Act-1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation,

opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties.

Unit-IV

08

Hours

Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSE guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.

National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM).

Unit-V

07 Hours

Pharmaceutical Legislations - A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee.

Code of Pharmaceutical ethics - Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)



Entrepreneurship

BP603T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Course content

Unit-I 10

Hours

Herbs as raw materials: Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation, Source of Herbs, Selection, identification and authentication of herbal materials, Processing of herbal raw material.

Biodynamic Agriculture: Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine: Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy. Preparation and standardization of Ayurvedic formulations viz. Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

Unit-II 8

Hours

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfa-alfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina.

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification.

Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

Unit-III 10

Hours

Herbal Cosmetics: Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients: Herbal Excipients – Significance of substances of natural origin as excipients-

colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations: Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes.

Unit-IV

10

Hours

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs. Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products: Definition of the terms:Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy.

Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma& Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

Unit-V

07

Hours

General Introduction to Herbal Industry: Herbal drugs industry: Present scope and future prospects. A brief account of plant-based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine:

Components of GMP (Schedule –T) and its objectives.

Infrastructural requirements working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.



Entrepreneurship

BP609P. HERBAL DRUG TECHNOLOGY (Practical)

4 Hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista.
3. Evaluation of excipients of natural origin.
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias.
7. Determination of Aldehyde content.
8. Determination of Phenol content.
9. Determination of total alkaloids.



Entrepreneurship

BP704T. NOVEL DRUG DELIVERY SYSTEMS (NDDS) (Theory)

45 Hours

Course content

Unit-I

10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design-controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations.

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II

10 Hours

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications.

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion/mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems.

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump.

Unit-III

10 Hours

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of **TDDS, formulation approaches.**

Gastro-retentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS– Floating, high density systems, inflatable and gastro-adhesive systems and their applications.

Naso-pulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers.

Unit-IV

08 Hours

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications.

Unit-V

07 Hours

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome—Preliminary study, ocular formulations and ocuserts.

Intrauterine Drug Delivery Systems: Introduction, advantages and Disadvantages, development of intra uterine devices (IUDs) and applications.



Entrepreneurship

BP105T. COMMUNICATION SKILLS (Theory)

30 Hours

Course content:

Unit-I	07
Hours	
Communication Skills: Introduction, Definition, The Importance of Communication, the communication process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context.	
Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers.	
Perspectives in communication: Introduction, Visual perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment.	
Unit-II	07
Hours	
Elements of communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication.	
Communication styles: Introduction, The Communication Styles Matrix with example for each Direct communication style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style.	
Unit-III	07
Hours	
Basic listening skills: Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in difficult situations.	
Effective written communication: Introduction, When and When Not to Use Written Communication- Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication.	
Writing effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message.	
Unit-IV	05
Hours	
Interview skills: Purpose of an interview, Do's and Don'ts of an interview.	
Giving presentations: Dealing with Fears, planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery.	
Unit-V	04
Hours	
Group discussion: Introduction, Communication skills in group discussion, Do's and Don'ts of group discussion.	

BP111P. COMMUNICATION SKILLS (Practical)

2 Hours / Week

Course content:

The following learning modules are to be conducted using words worth® English language lab software.

Basic communication covering the following topics

- Meeting People.
- Asking Questions.
- Making Friends.
- What did you do?
- Do's and Don'ts.

Pronunciations covering the following topics

- Pronunciation (Consonant Sounds).Pronunciation and Nouns.
- Pronunciation (Vowel Sounds).

Advanced Learning

- Listening Comprehension / Direct and Indirect Speech.Figures of Speech.
- Effective Communication.Writing Skills.
- Effective Writing. InterviewHandling Skills.
- E-Mail etiquette. Presentation Skills.

Skill Development

BP205T. COMPUTER APPLICATIONS IN PHARMACY
(Theory)

30 Hours
(2 Hours/Week)

Course content

Unit-I hours	06
Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division.	
Concept of Information Systems and Software: Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project.	
Unit-II hours	06
Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products.	
Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database.	
Unit-III hours	06
Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring.	
Diagnostic system. Lab-diagnostic System, Patient Monitoring System, Pharma Information System.	
Unit-IV hours	06
Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery.	
Unit-V hours	06
Computers as data analysis in Preclinical development:	
Chromatographic data analysis (CDS), Laboratory Information management System(LIMS) and Text Information Management System (TIMS).	

 **Skill Development**

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools.
4. Creating mailing labels Using Label Wizard, generating label in MS WORD.
5. Create a database in MS Access to store the patient information with the required fields using access.
6. Design a form in MS Access to view, add, delete and modify the patient record in the database.
7. Generating report and printing the report from patient database.
8. Creating invoice table using – MS Access.
9. Drug information storage and retrieval using MS Access.
10. Creating and working with queries in MS Access.
11. Exporting Tables, Queries, Forms and Reports to web pages.
12. Exporting Tables, Queries, Forms and Reports to XML pages.

BP506P. INDUSTRIAL PHARMACY I (Practical)

4 Hours/week

12. Preformulation studies of Paracetamol/Aspirin/or any other drug.
13. Preparation and evaluation of Paracetamol tablets.
14. Preparation and evaluation of Aspirin tablets.
15. Coating of tablets- film coating of tables/granules.
16. Preparation and evaluation of Tetracycline capsules.
17. Preparation of Calcium Gluconate injection.
18. Preparation of Ascorbic Acid injection.
19. Quality control test of (as per IP) marketed tablets and capsules.
20. Preparation of Eye drops/ and Eye ointments.
21. Preparation of Creams (cold / vanishing cream).
22. Evaluation of glass containers (as per IP).

 **Skill Development**

BP705P. INSTRUMENTAL METHODS OF ANALYSIS / NDDS (Practical)

4 Hours/Week

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.
2. Estimation of sulphanilamide by colorimetry.
3. Simultaneous estimation of ibuprofen and Paracetamol by UV spectroscopy.
4. Estimation of quinine sulphate by fluorimetry.
5. Study of quenching of fluorescence.
6. Determination of sodium by flame photometry.
7. Determination of potassium by flame photometry.
8. Determination of chlorides and sulphates by nephelometry-turbidimetry.
9. Separation of sugars by thin layer chromatography.
10. Separation of plant pigments by column chromatography.
11. Demonstration experiment on HPLC.
12. Demonstration experiment on Gas Chromatography.
13. To perform in-vitro dissolution profile of CR/SR marketed formulation.
14. To prepare sustained release matrix tablets and evaluate by UV spectroscopy.
15. Formulation of nanoparticles and evaluate by HPLC.
16. Formulation and evaluation of liposomes.
17. To prepare buccal dosage form and evaluate by UV spectroscopy.
18. To prepare Paracetamol transdermal patch and evaluate by UV spectroscopy.

Skill Development

BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Course content:

Unit-I

10

Hours

Introduction: Statistics, Biostatistics, Frequency distribution.

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples.

Measures of dispersion: Dispersion, Range, standard deviation, pharmaceutical problems.

Correlation: Definition, Karl Pearson's coefficient of correlation, multiple correlation-Pharmaceuticals examples.

Unit-II

10

Hours

Regression: Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$, Multiple regression, standard error of regression– Pharmaceutical examples. **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties– problems.

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples.

Parametric test: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference.

Unit-III

10

Hours

Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test.

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, Plagiarism.

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV

8

Hours

Blocking and confounding system for Two-level factorials.

Regression modeling: Hypothesis testing in Simple and Multiple regression models **Introduction to Practical components of Industrial and Clinical Trials Problems:** Statistical Analysis Using

Excel, SPSS, MINITAB[®], Design of experiment, R- Online Statistical Software's to Industrial and Clinical trial approach.

Unit-V

7

Hours

Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. Advantages of factorial design.

Response Surface methodology: Central composite design, Historical design, Optimization Techniques.





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School of Pharmacy

1.1.3 Courses having focus on Employability / Entrepreneurship / Skill Development

D. Pharmacy

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PHARMACEUTICS – THEORY

Course Code: ER20-11T

75 Hours (3

Hours/week) Scope: This course is designed to impart basic knowledge and skills on the art and science of formulating and dispensing different pharmaceutical dosage forms.

Course Objectives:

This course will discuss the following aspects of pharmaceutical dosage forms

- Basic concepts, types and need
- Advantages and disadvantages, methods of preparation/formulation
- Packaging and labelling requirements
- Basic quality control tests, concepts of quality assurance and good manufacturing practices

Course Outcomes: Upon successful completion of this course, the students will be able to

- Describe about the different dosage forms and their formulation aspects
- Explain the advantages, disadvantages, and quality control tests of different dosage forms
- Discuss the importance of quality assurance and good manufacturing practices

CHAPTER	TOPICS	HOURS
1	• History of the profession of Pharmacy in India in relation to Pharmacy education, industry, pharmacy practice, and various professional associations. • Pharmacy as a career • Pharmacopoeia: Introduction to IP, BP, USP, NF and • Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia	7
2	Packaging materials: Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials	5
3	Pharmaceutical aids: Organo-levigating (Colouring, flavouring, and sweetening) agents Preservatives: Definition, types with examples and uses	3
4	Unit operations: Definition, objectives/applications, principles, construction, and workings of: Size reduction: hammer mill and ball mill Size separation: Classification of powders according to IP, Cyclone separator, Sieves and standards of sieves Mixing: Double cone blender, Turbine mixer, Triple roller mill and Silvester mixer homogenizer Filtration: Theory of filtration, membrane filter and sintered glass filter Drying: working of fluidized bed dryer and process of freeze drying Extraction: Definition, Classification, method, and applications	9

Employability

5	Tablets—coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi-layered, etc.) Capsules—hard and soft gelatin capsules Liquid oral preparations—solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution Topical preparations— ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries Nasal preparations, Ear preparations Powders and granules— Insufflations, dusting powders, effervescent powders, and effervescent granules Sterile formulations—Injectable, eye drops and eye Ointments Immunological products: Sera, vaccines, toxoids, and their manufacturing methods.	8
6	Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants Quality control and quality assurance: Definition and concepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to the concept of calibration and validation	5
7	Novel drug delivery systems: Introduction, Classification with examples, advantages, and challenges	5

Employability

PHARMACOGNOSY – THEORY

Course Code: ER20-13T

75 Hours (3 Hours/week) Scope: T

his course is designed to impart knowledge on the medicinal uses of various drugs of natural origin. Also, the course emphasizes the fundamental concepts in the evaluation of crude drugs, alternative systems of medicine, nutraceuticals, and herbal cosmetics.

Course Objectives: This course will discuss the following aspects of drug substances derived from natural resources.

- Occurrence, distribution, isolation, identification tests of common phytoconstituents
- Therapeutic activity and pharmaceutical application of various natural drug substances and phytoconstituents
- Biological source, chemical constituents of selected crude drugs and their therapeutic efficacy in common diseases and ailments
- Basic concepts in quality control of crude drugs and various systems of medicines
- Application of herbs in health foods and cosmetics

Course Outcomes:

- Upon successful completion of this course, the students will be able to
- Identify the important/common crude drugs of natural origin
- Describe the uses of herbs in nutraceuticals and cosmetics
- Discuss the principles of alternative systems of medicines
- Describe the importance of quality control of drugs of natural origin

CHAPTER	TOPIC	HOURS
1	Definition, history, present status and scope of Pharmacognosy	2
2	Classification of drugs: • Alphabetical • Taxonomical • Morphological • Pharmacological • Chemical • Chemo-taxonomical	4
3	Quality control of crude drugs: • Different methods of adulteration of crude drugs • Evaluation of crude drugs	6
4	Brief outline of occurrence, distribution, isolation, identification tests, therapeutic activity and pharmaceutical applications of alkaloids, terpenoids, glycosides, volatile oils, tannins and resins.	6

Employability

5	Biological source, chemical constituents and therapeutic efficacy of the following categories of crude drugs.		30
	Laxatives	Aloe, Castor oil, Ispaghula, Senna	
	Cardiotonic	Digitalis, Arjuna	
	Carminatives and G.I. regulators	Coriander, Fennel, Cardamom, Ginger, Clove, Black Pepper, Asafetida, Nutmeg, Cinnamon	
	Astringents	Myrobalan, Black Catechu, Pale Catechu	
	Drugs acting on nervous system	Hyoscyamus, Belladonna, Ephedra, Opium, Tea leaves, Coffees, Coca	
	Anti-hypertensive	Rauwolfia	
	Anti-tussive	Vasaka, Tolu Balsam	
	Anti-rheumatics	Colchicum seed	
	Anti-tumour	Vinca, Podophyllum	
	Antidiabetics	Pterocarpus, Gymnema	
	Diuretics	Gokhru, Punarnava	
	Anti-dysenteric	Ipecacuanha	
	Antiseptics and disinfectants	Benzoin, Myrrh, Neem, Turmeric	
	Antimalarials	Cinchona, Artemisia	
	Oxytocic	Ergot	
	Vitamins	Cod liver oil, Shark liver oil	
	Enzymes	Papaya, Diastase, Pancreatin, Yeast	
	Pharmaceutical Aids	Kaolin, Lanolin, Beeswax, Acacia, Tragacanth, Sodium alginate, Agar, Guar gum, Gelatine	
	Miscellaneous	Squill, Galls, Ashwagandha, Tulsi, Guggul	
6	Plant fibres used as surgical dressings: Cotton, silk, wool and regenerated fibres Sutures – Surgical Catgut and Ligatures		3

Employability

7	• Basic principles involved in the traditional systems of medicine like: Ayurveda, Siddha, Unani and Homeopathy • Method of preparation of Ayurvedic formulations like: Arista, Asava, Gutika, Taila, Churna, Lehya and Bhasma	8
8	Role of medicinal and aromatic plants in national economy and their export potential	2
9	Herbs as health food: Brief introduction and therapeutic applications of: Nutraceuticals, Antioxidants, Pro-biotics, Pre-biotics, Dietary fibres, Omega-3-fatty acids, Spirulina, Carotenoids, Soya and Garlic	4
10	Introduction to herbal formulations	4
11	Herbal cosmetics: Sources, chemical constituents, commercial preparations, therapeutic and cosmetic uses of: Aloe vera gel, Almond oil, Lavender oil, Olive oil, Rosemary oil, Sandal Wood oil	4
12	Phytochemical investigation of drugs	2



Employability

SOCIAL PHARMACY – THEORY

Course Code: ER20-15T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge on public health, epidemiology, preventive care, and other social health-related concepts. Also, to emphasize the roles of pharmacists in the public health programs.

Course Objectives: This course will discuss about basic concepts of

1. Public health and national health programs
2. Preventive healthcare
3. Food and nutrition related health issues
4. Health education and health promotion
5. General roles and responsibilities of pharmacists in public health

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Discuss about roles of pharmacists in the various national health programs
2. Describe various sources of health hazards and disease preventive measures
3. Discuss the health care issues associated with food and nutritional substances
4. Describe the general roles and responsibilities of pharmacists in public health

CHAPTER	TOPIC	HOURS
1	Introduction to Social Pharmacy • Definition and Scope. Social Pharmacy as a discipline and its scope in improving the public health. Role of Pharmacists in Public Health. (2) • Concept of Health- WHO Definition, various dimensions, determinants, and health indicators. (3) • National Health Policy – Indian perspective (1) • Public and Private Health System in India, National Health Mission (2) • Introduction to Millennium Development Goals, Sustainable Development Goals, FIP Development Goals (1)	9

Employability

2	Preventive healthcare – Role of Pharmacists in the following • Demography and Family Planning (3) • Mother and child health, importance of breastfeeding, effects of infant milk substitutes and bottle feeding (2) • Overview of Vaccines, types of immunity and immunization (4) • Effect of Environment on Health – Water pollution, importance of safe drinking water, waterborne diseases, air pollution, noise pollution, sewage and solid waste disposal, occupational illnesses, Environmental pollution due to pharmaceuticals (7) • Psychosocial Pharmacy: Drug misuse and abuse – psychotropics, narcotics, alcohol, tobacco products. Social Impact of these habits on social health and productivity and suicidal behaviours (2)	18
3	Nutrition and Health • Basics of nutrition – Macronutrients and Micronutrients (3) • Importance of water and fibres in diet (1) • Balanced diet, Malnutrition, nutrition deficiency diseases, effects of junk foods, calorific and nutritive values of various foods, fortification of food (3) • Introduction to food safety, adulteration of foods, effects of artificial ripening, use of pesticides, genetically modified foods (1) • Dietary supplements, nutraceuticals, food supplements – indications, benefits, Drug-Food Interactions (2)	10
4	Introduction to Microbiology and common microorganisms (3) Epidemiology: Introduction to epidemiology, and its applications. Understanding of terms such as epidemic, pandemic, endemic, mode of transmission, outbreak, quarantine, isolation, incubation period, contact tracing, morbidity, mortality, . (2) Causative agents, epidemiology and clinical presentations and Role of Pharmacists in educating the public in prevention of the following communicable diseases: • Respiratory infections – chickenpox, measles, rubella, mumps, influenza (including Avian-Flu, H1N1, SARS, MERS, COVID-19), diphtheria, whooping cough, meningococcal meningitis, acute respiratory infections, tuberculosis, Ebola (7)	28

Employability

	• Intestinal infections – poliomyelitis, viral hepatitis, cholera, acutediarrheal diseases,typhoid, amebiasis, worm infestations, foodpoisoning(7) • Arthropod-borne infections - dengue, malaria, filariasis and,chikungunya (4) • Surfaceinfections– trachoma,tetanus, leprosy(2) • STDs,HIV/AIDS(3)	
5	Introductiontohealthsystemsandallongoing NationalHealthprograms in India ,their objectives, functioning,outcome, and the roleofpharmacists.	8
6	Pharmacoeconomics – Introduction, basic terminologies,importanceof pharmacoeconomics	2



Employability

PHARMACEUTICS – PRACTICAL

Course Code: ER20-11Ps

75 Hours (3 Hours/week)

Scope: This course is designed to train the students in formulating and dispensing common pharmaceutical dosage forms.

Course Objectives: This course will discuss and train the following aspects of preparing and dispensing various pharmaceutical dosage forms

- Calculation of working formula from the official master formula
- Formulation of dosage forms based on working formula
- Appropriate packaging and labelling requirements
- Methods of basic quality control tests

Course Outcomes:

Upon successful completion of this course, the students will be able to

- Calculate the working formula from the given master formula
- Formulate the dosage form and dispense in an appropriate container
- Design the label with the necessary product and patient information
- Perform the basic quality control tests for the common dosage forms

Practicals

1. Handling and referring the official references: Pharmacopoeias, Formularies, etc. for retrieving formulas, procedures, etc.
2. Formulation of the following dosage forms as per monograph standards and dispensing with appropriate packaging and labelling
 - **Liquid Oral:** Simple syrup, Piperazine citrate elixir, Aqueous Iodine solution
 - **Emulsion:** Castor oil emulsion, Cod liver oil emulsion
 - **Suspension:** Calamine lotion, Magnesium hydroxide mixture
 - **Ointment:** Simple ointment base, Sulphur ointment
 - **Cream:** Cetrimide cream
 - **Gel:** Sodium alginate gel
 - **Liniment:** Turpentine liniment, White liniment BPC
 - **Dry powder:** Effervescent powder granules, Dusting powder
 - **Sterile Injection:** Normal Saline, Calcium gluconate Injection
 - **Hard Gelatine Capsule:** Tetracycline capsules
 - **Tablet:** Paracetamol tablets
3. Formulation of at least five commonly used cosmetic preparations – e.g. cold cream, shampoo, lotion, toothpaste etc
4. Demonstration on various stages of tablet manufacturing processes
5. Appropriate methods of usage and storage of all dosage forms including special dosages such as different types of inhalers, spacers, insulin pens
6. Demonstration of quality control tests and evaluation of common dosage forms viz. tablets, capsules, emulsion, sterile injections as per the monographs

Employability

Assignments

The student shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Various systems of measures commonly used in prescribing, compounding and dispensing practices
2. Market preparations (including Fixed Dose Combinations) of each type of dosage forms, their generic name, minimum three brand names and label contents of the dosage forms mentioned in theory/practical
3. Overview of various machines / equipments / instruments involved in the formulation and quality control of various dosage forms / pharmaceutical formulations.
4. Overview of extemporaneous preparations at community/hospital pharmacy vs. manufacturing of dosage forms at industrial level
5. Basic pharmaceutical calculations: ratios, conversion to percentage fraction, alligation, proof spirit, isotonicity

Field Visit

The student shall be taken for an industrial visit to pharmaceutical industries to witness and understand the various processes of manufacturing of any of the common dosage forms viz. tablets, capsules, liquid orals, injectables, etc. Individual reports from each student on their learning experience from the field visit shall be submitted.



Employability

HOSPITAL AND CLINICAL PHARMACY – THEORY

Course Code: ER20-25T

75 Hours (3 Hours/week)

Scope: This course is designed to impart fundamental knowledge and professional skills required for facilitating various hospital and clinical pharmacy services.

Course Objectives: This course will discuss and train the students in the following

- Hospital and Hospital Pharmacy organization and set-ups
- Basics of hospital pharmacy services including the procurement, supply chain, storage of medicines and medical supplies
- Basics of clinical pharmacy including introduction to comprehensive pharmaceutical care services
- Basic interpretation of common laboratory results used in clinical diagnosis towards optimizing the drug therapy

Course Outcomes: Upon successful completion of this course, the students will be able to

- Explain about the basic concepts of hospital pharmacy administration
- Manage the supply chain and distribution of medicines within the hospital settings
- Assist the other healthcare providers in monitoring drug therapy and address drug-related problems
- Interpret common lab investigation reports for optimizing drug therapy

S.NO.	TOPIC	HOURS
1	Hospital Pharmacy • Definition, scope, national and international scenario • Organisational structure • Professional responsibilities, Qualification and experience requirements, job specifications, work load requirements and interprofessional relationships • Good Pharmacy Practice (GPP) in hospital • Hospital Pharmacy Standards (FIP Basel Statements, AHSP) • Introduction to NAQS guidelines and NABH Accreditation and Role of Pharmacists	6



Employability

2	Different Committees in the Hospital - Pharmacy and Therapeutics Committee - Objectives, Composition, and functions - Hospital Formulary - Definition, procedure for development and use of hospital formulary - Infection Control Committee - Role of Pharmacist in preventing Antimicrobial Resistance	4
4	Supply Chain and Inventory Control - Preparation of Drug lists - High Risk drugs, Emergency drugs, Schedule H1 drugs, NDPS drugs, reserved antibiotics - Procedures of Drug Purchases - Drug selection, short term, long term, and tender/e-tender process, quotations, etc. - Inventory control techniques: Economic Order Quantity, Reorder Quantity Level, Inventory Turnover etc. - Inventory Management of Central Drug Store - Storage conditions, Methods of storage, Distribution, Maintaining Cold Chain, Devices used for cold storage (Refrigerator, ILR, Walk-in-Cold rooms) - FEFO, FIFO methods - Expiry drug removal and handling, and disposal. Disposal of Narcotics, cytotoxic drugs - Documentation - purchase and inventory	14
5	Drug distribution - Drug distribution (in-patients and out-patients) - Definition, advantages and disadvantages of individual prescription order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug Basket Method. - Distribution of drugs to ICCU/ICU/NICU/Emergency wards. - Automated drug dispensing systems and devices - Distribution of Narcotic and Psychotropic substances and their storage	7
6	Compounding in Hospitals. Bulk compounding, IV admixture services and incompatibilities, Total parenteral nutrition	4
7	Radio Pharmaceuticals - Storage, dispensing and disposal of radiopharmaceuticals	2

Employability

8	Application of computers in Hospital Pharmacy Practice, Electronic health records, Software used in hospital pharmacy	2
9	Clinical Pharmacy: Definition, scope, and development - in India and other countries Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Anti-natal Care, Post-natal Care, etc. Daily activities of clinical pharmacists: Definition, goal, and procedure of • Ward round participation • Treatment Chart Review • Adverse drug reaction monitoring • Drug information and poisons information • Medication history • Patient counselling • Interprofessional collaboration Pharmaceutical care: Definition, classification of drug-related problems. Principles and procedure to provide pharmaceutical care Medication Therapy Management, Home Medication Review	12
10	Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results • Haematological, Liver function, Renal function, thyroid function tests • Tests associated with cardiac disorders • Fluid and electrolyte balance • Pulmonary Function Tests	10
11	Poisoning: Types of poisoning; Clinical manifestations and Antidotes Drugs and Poison Information Centre and their services – Definition, Requirements, Information resources with examples, and their advantages and disadvantages	6

Employability

12	Pharmacovigilance • Definition, aim and scope • Overview of Pharmacovigilance	2
13	Medication errors: Definition, types, consequences, and strategies to minimize medication errors, LASA drugs and Tallman lettering as per ISMP Drug Interactions: Definition, types, clinical significance of drug interactions	6



Employability

PHARMACY LAW AND ETHICS – THEORY

Course Code: ER20-26T

75 Hours (3

Hours/week) Scope: This course is designed to impart

basic knowledge on several important legislations related to the profession of pharmacy in India

Course Objectives: This course will discuss the following

- General perspectives, history, evolution of pharmacy law in India
- Act and Rules regulating the profession and practice of pharmacy in India
- Important code of ethical guidelines pertaining to various practice standards
- Brief introduction to the patent laws and their applications in pharmacy

Course Outcomes: Upon successful completion of this course, the students will be able to

- Describe the history and evolution of pharmacy law in India
- Interpret the act and rules regulating the profession and practice of pharmacy in India
- Discuss the various codes of ethics related to practice standards in pharmacy
- Interpret the fundamentals of patent laws from the perspectives of pharmacy

CHAPTER	TOPICS	HOURS
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2
2	Pharmacy Act-1948 and Rules: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties. Pharmacy Practice Regulations 2015	5
3	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and	23

Employability

	analysis, manufacture of new drug, loan license and repackaging license. Study of schedule C and C1, G, H, H1, K, P, M, N, and X. Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in pharmacy Drugs Prohibited for manufacture and sale in India Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.	
4	Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	2
5	Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	2
6	Prevention of Cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA- brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.	2
7	Poisons Act-1919: Introduction, objective, definition, possession, possession for sale and sale of any poison, import of poisons	2
8	FSSAI (Food Safety and Standards Authority of India) Act and Rules: brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements	2

Employability

9	National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)	5
10	Code of Pharmaceutical Ethics: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.	5
11	Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments	2
12	Role of all the government pharmaceutical regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	1
13	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharmaceutical Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices	3
14	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand vs Generic, Tradename concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	7
15	Blood bank – basic requirements and functions	2
16	Clinical Establishment Act and Rules – Aspects related to Pharmacy	2
17	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharmaceutical manufacture to disposal of pharmaceutical / medical waste at homes, pharmacies, and hospitals	2

Employability

18	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	2
19	Introduction to the Consumer Protection Act	1
20	Introduction to the Disaster Management Act	1
21	Medical Devices – Categorization, basic aspects related to manufacture and sale	2

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student) Requirements for Ayurvedic, Homeopathic manufacturing, sale, and licensing requirements

- Layout and contents of official websites of various agencies regulating the profession of pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.
- Licenses required, application processes (online/offline), drug regulatory office website of the respective state
- Case studies – actions taken on violation of any act / rule related to pharmacy
- Schedule H1 drugs and its implementation in India
- Counterfeit/Spurious medicines
- Drug Testing Labs in India
- Overview of Pharma marketing practices
- Generic Medicines

Employability

BIOCHEMISTRY & CLINICAL PATHOLOGY – PRACTICAL

Course Code: ER20-23P

50 Hours (2 Hours/week)

Scope: This course is designed to train the students in the qualitative testing of various biomolecules and testing of biological samples for determination of normal and abnormal constituents

Course Objectives: This course will train and provide hands-on experiences on the following

- Qualitative determination of biomolecules/metabolites in simulated biological samples
- Determination of normal and abnormal constituents of simulated blood and urine samples

Course Outcomes: Upon successful completion of this course, the students will be able to

- Qualitatively determine the biomolecules/metabolites in the given biological samples
- Determine the normal and abnormal constituents in blood and urine samples and interpret the results of such testing

Practical's

- Qualitative analysis of carbohydrates (4 experiments)
- Qualitative analysis of Proteins and amino acids (4 experiments)
- Qualitative analysis of lipids (2 experiments)
- Qualitative analysis of urine for normal and abnormal constituents (4 experiments)
- Determination of constituents of urine (glucose, creatinine, chlorides) (2 experiments)
- Determination of constituents of blood/serum (simulated) (Creatine, glucose, cholesterol, Calcium, Urea, SGOT/SGPT) (5 experiments)
- Study the hydrolysis of starch from acid and salivary amylase enzyme (1 experiment)

Assignments

The students shall be asked to submit written assignments on Various Pathology Lab Reports (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

Employability

COMMUNITY PHARMACY AND MANAGEMENT – THEORY

Course Code: ER20-22T

75 Hours (3 Hours/week)

Scope: The course is designed to impart basic knowledge and skills to provide various pharmaceutical care services to patients and general practitioners in the community setup.

Course Objectives: This course will discuss the following:

- Establishing and running a community pharmacy and its legal requirements
- Professional aspects of handling and filling prescriptions
- Patient counselling on diseases, prescription and or non-prescription medicines
- Scope for performing basic health screening in community pharmacy settings

Course Outcomes: Upon successful completion of this course, the students will be able to

- Describe the establishment, legal requirements, and effective administration of a community pharmacy
- Professionally handle prescriptions and dispense medications
- Counsel patients about the disease, prescription and or non-prescription medicines
- Perform basic health screening on patients and interpret the reports in the community pharmacy settings

Chapter	Topic	Hours
1	Community Pharmacy Practice – Definition, history and development of community pharmacy - International and Indian scenarios	2
2	Professional responsibilities of community pharmacists Introduction to the concept of Good Pharmacy Practice and SOPs.	3
3	Prescription and prescription handling Definition, parts of prescriptions, legality of prescriptions, prescription handling, labelling of dispensed medications (Main label, ancillary label, pictograms), brief instructions on medication usage Dispensing process, Good Dispensing Practices, dispensing errors and strategies to minimize them	7

Entrepreneurship

4	Communications skills Definition, types of communications skills Interactions with professionals and patients Verbal communication skills (one-to-one, over the telephone) Written communications skills Body language Patient interview techniques	6
5	Patient counselling Definition and benefits of patient counselling Stages of patient counselling- Introduction, counselling content, counselling process, and closing the counselling session Barriers to effective counseling - Types and strategies to overcome the barriers Patient counselling points for chronic diseases/disorders - Hypertension, Diabetes, Asthma, Tuberculosis, Chronic obstructive pulmonary disease, and AIDS Patient Package Inserts- Definition, importance and benefits, Scenarios of PPI use in India and other countries Patient Information leaflets- Definition and uses	10
6	Medication Adherence Definition, factors influencing non-adherence, strategies to overcome non-adherence	2
	Health Screening Services in Community Pharmacy Introduction, scope, and importance of various health screening services - for routine monitoring of patients, early detection, and referral of undiagnosed cases	5

Entrepreneurship

9	OverTheCounter(OTC)Medications Definition, need and role of Pharmacists in OTC medicationdispensing OTCmedicationsinIndia,counselingforOTCproducts Self-medicationandroleofpharmacistsinpromotingthesafepracticesduringself-medication Responding to symptoms, minor ailments, and advice forself-care in conditions such as - Pain management, Cough,Cold, Diarrhea, Constipation, Vomiting, Fever, Sore throat,Skin disorders, Oral health (mouth ulcers, dental pain, gumswelling)	15
10	CommunityPharmacyManagement Legalrequirements to setup acommunitypharmacy Siteselectionrequirements Pharmacydesignsandinteriors Vendorselectionandordering Procurement, inventory control methods, and inventorymanagement Financialplanningandmanagement Accountancyincommunitypharmacy–Daybook,Cashbook Introductiontopharmacyoperationsoftwares–usefulnessandavailability CustomerRelationManagement(CRM) AuditsinPharmacies SOPof PharmacyManagement Introduction to DigitalHealth,mHealth and Onlinepharmacies	25

COMMUNITY PHARMACY AND MANAGEMENT – PRACTICAL

Course Code: ER20-22P

75 Hours (3 Hours/week)

Scope: The course is designed to train the students and improve professional skills to provide various pharmaceutical care services in community pharmacy.

Course Objectives: This course will train the students in the following

- Professional handling and filling prescriptions
- Patient counselling on diseases and minor ailments
- Patient counselling on prescription and / or non-prescription medicines
- Preparation of counselling materials such as patient information leaflets
- Performing basic health screening tests

Course Outcomes: Upon successful completion of this course, the students will be able to

- Handle and fill prescriptions in a professional manner
- Counsel patients on various diseases and minor ailments
- Counsel patients on prescription and non-prescription medicines
- Design and prepare patient information leaflets
- Perform basic health screening tests

Practicals

Note: The following practicals shall be carried out in the model community pharmacy with appropriate simulated scenarios and materials. Students shall be trained through role plays wherever necessary. The activities of the students shall be assessed / evaluated using a structured objective assessment form.

- Handling of prescriptions with professional standards, reviewing prescriptions, checking for legal compliance and completeness (minimum 5)
- Identification of drug-drug interactions in the prescription and follow-up actions (minimum 2)
- Preparation of dispensing labels and auxiliary labels for the prescribed medications (minimum 5)
- Providing the following health screening services for monitoring patients / detecting new patients (one experiment for each activity)

Blood Pressure Recording, Capillary Blood Glucose Monitoring, Lung function assessment using Peak Flow Meter and incentive spirometer, recording capillary oxygen level using Pulse Oximeter, BMI measurement

- Providing counselling to simulated patients for the following chronic diseases / disorders including education on the use of devices such as insulin pen, inhalers, spacers, nebulizers, etc. where appropriate (one experiment for each disease)
- Type 2 Diabetes Mellitus, Primary Hypertension, Asthma, Hyperlipidaemia, Rheumatoid Arthritis
- Providing counselling to simulated patients for the following minor ailments (any three)
- Headache, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Worm infestation, Pyrexia, Upper Respiratory Tract infections, Skin infections, Oral and dental disorders.
- Appropriate handling of dummy dosage forms with correct administration techniques - oral liquids with measuring cup/cap/dropper, Eye Drops, Inhalers, Nasal drops, Insulin pen, nebulizers, different types of tablets, patches, enemas, suppositories
- Use of Community Pharmacy Software and digital health tools

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

- SOPs for various activities in Community Pharmacy (as discussed in Theory and Practical)
- List out the various abbreviations, short forms used in prescriptions and their interpretation
- Patient Information Leaflet for a given chronic disease/disorder
- Patient Information Leaflet for prescription/non-prescription medicines
- Preparation of window / shelf display materials for the model community pharmacy
- Overview of Software available for retail pharmacy management including billing, inventory, etc.
- Dosage/Medication Reminder Aids
- Overview on the operations and marketing strategies of various online pharmacies
- Overview on the common fixed dose combinations
- Overview on the medications requiring special storage conditions
- Role of Community Pharmacists in preventing Antimicrobial Resistance
- Jan Aushadhi and other Generic Medicine initiatives in India
- Global Overview of Online Pharmacies
- Community Pharmacy Practice Standards: Global Vs. Indian Scenario
- Overview of pharmacy associations in India

BIOCHEMISTRY & CLINICAL PATHOLOGY – PRACTICAL

Course Code: ER20-23P

50 Hours (2 Hours/week) Scope: This

course is designed to train the students in the qualitative testing of various biomolecules and testing of biological samples for determination of normal and abnormal constituents

Course Objectives: This course will train and provide hands-on experiences on the following

- Qualitative determination of biomolecules/metabolites in simulated biological samples
- Determination of normal and abnormal constituents of simulated blood and urine samples

Course Outcomes: Upon successful completion of this course, the students will be able to

- Qualitatively determine the biomolecules / metabolites in the given biological samples
- Determine the normal and abnormal constituents in blood and urine samples and interpret the results of such testing

Practical's

- Qualitative analysis of carbohydrates (4 experiments)
- Qualitative analysis of Proteins and amino acids (4 experiments)
- Qualitative analysis of lipids (2 experiments)
- Qualitative analysis of urine for normal and abnormal constituents (4 experiments)
- Determination of constituents of urine (glucose, creatinine, chlorides) (2 experiments)
- Determination of constituents of blood/serum (simulated) (Creatine, glucose, cholesterol, Calcium, Urea, SGOT/SGPT) (5 experiments)
- Study the hydrolysis of starch from acid and salivary amylase enzyme (1 experiment)

Assignments

The students shall be asked to submit written assignments on Various Pathology Lab Reports (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student).

Entrepreneurship

PHARMACEUTICS – THEORY

Course Code: ER20-11T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge and skills on the art and science of formulating and dispensing different pharmaceutical dosage forms.

Course Objectives: This course will discuss the following aspects of pharmaceutical dosage forms

- Basic concepts, types and need
- Advantages and disadvantages, methods of preparation / formulation
- Packaging and labelling requirements
- Basic quality control tests, concepts of quality assurance and good
- manufacturing practices

Course Outcomes: Upon successful completion of this course, the students will be

- able to
- Describe about the different dosage forms and their formulation aspects
- Explain the advantages, disadvantages, and quality control tests of different
- dosage forms
- Discuss the importance of quality assurance and good manufacturing practices

CHAPTER	TOPICS	HOURS
1	• History of the profession of Pharmacy in India in relation to Pharmacy education, industry, pharmacy practice, and various professional associations. • Pharmacy as a career • Pharmacopoeia: Introduction to IP, BP, USP, NF and • Extra Pharmacopoeia. Salient features of Indian • Pharmacopoeia	7
2	Packaging materials: Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials	5
3	Pharmaceutical aids: Organoleptic (Colouring, flavouring, and sweetening) agents Preservatives: Definition, types with examples and uses	3

 Skill Development

4	Unit operations: Definition, objectives/applications, principles, construction, and workings of: Size reduction: hammer mill and ball mill Size separation: Classification of powders according to IP, Cyclone separator, Sieves and standards of sieves Mixing: Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer Filtration: Theory of filtration, membrane filter and sintered glass filter Drying: working of fluidized bed dryer and process of freeze drying Extraction: Definition, Classification, method, and applications	9
5	Tablets – coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi-layered, etc.) Capsules - hard and soft gelatine capsules Liquid oral preparations - solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution Topical preparations - ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries Nasal preparations, Ear preparations Powders and granules - Insufflations, dusting powders, effervescent powders, and effervescent granules Sterile formulations – Injectables, eye drops and eye Ointments Immunological products: Sera, vaccines, toxoids, and their manufacturing methods.	8
6	Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants Quality control and quality assurance: Definition and concepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to the concept of calibration and validation	5
7	Novel drug delivery systems: Introduction, Classification with examples, advantages, and challenges	5

Skill Development

PHARMACEUTICAL CHEMISTRY – THEORY

Course Code: ER20-12T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge on the chemical structure, storage conditions and medicinal uses of organic and inorganic chemical substances used as drugs and pharmaceuticals. Also, this course discusses the impurities, quality control aspects of chemical substances used in pharmaceuticals.

Course Objectives: This course will discuss the following aspects of the chemical substances used as drugs and pharmaceuticals for various disease conditions

- Chemical classification, chemical name, chemical structure
- Pharmacological uses, doses, stability and storage conditions
- Different types of formulations / dosage form available and their brand names
- Impurity testing and basic quality control tests

Course Outcomes: Upon successful completion of this course, the students will be able to

- Describe the chemical class, structure and chemical name of the commonly used drugs and pharmaceuticals of both organic and inorganic nature
- Discuss the pharmacological uses, dosage regimen, stability issues and storage conditions of all such chemical substances commonly used as drugs
- Describe the quantitative and qualitative analysis, impurity testing of the chemical substances given in the official monographs. Identify the dosage form & the brand names of the drugs and pharmaceuticals popular in the marketplace

CHAPTER	TOPIC	HOURS
1	Introduction to Pharmaceutical chemistry: Scope and objectives Sources and types of errors: Accuracy, precision, significant figures Impurities in Pharmaceuticals: Source and effect of impurities in Pharmacopoeial substances, importance of limit test, Principle and procedures of Limit tests for chlorides, sulphates, iron, heavy metals and arsenic.	8
2	Volumetric analysis: Fundamentals of volumetric analysis, Acid-base titration, non-aqueous titration, precipitation titration, complexometric titration, redox titration Gravimetric analysis: Principle and method.	8

Skill Development

3	Inorganic Pharmaceuticals: Pharmaceutical formulations, market preparations, storage conditions and uses of • Haematinics: Ferrous sulphate, Ferrous fumarate, Ferric ammonium citrate, Ferrous ascorbate, Carbonyl iron • Gastro-intestinal Agents: Antacids :Aluminium hydroxide gel, Magnesium hydroxide, Magaldrate, Sodium bicarbonate, Calcium Carbonate, Acidifying agents, Adsorbents, Protectives, Cathartics • Topical agents: Silver Nitrate, Ionic Silver, Chlorhexidine Gluconate, Hydrogen peroxide, Boric acid, Bleaching powder, Potassium permanganate • Dental products: Calcium carbonate, Sodium fluoride, Denture cleaners, Denture adhesives, Mouth washes • Medicinal gases: Carbon dioxide, nitrous oxide, oxygen	7
4	Introduction to nomenclature of organic chemical systems with particular reference to heterocyclic compounds containing up to Three rings	2
Study of the following category of medicinal compounds with respect to classification, chemical name, chemical structure (compounds marked with*) uses, stability and storage conditions, different types of formulations and their popular brand names		
5	Drugs Acting on Central Nervous System • Anaesthetics: Thiopental Sodium*, Ketamine Hydrochloride*, Propofol • Sedatives and Hypnotics: Diazepam*, Alprazolam*, Nitrazepam, Phenobarbital* • Antipsychotics: Chlorpromazine Hydrochloride*, Haloperidol*, Risperidone*, Sulpiride*, Olanzapine, Quetiapine, Lurasidone • Anticonvulsants: Phenytoin*, Carbamazepine*, Clonazepam, Valproic Acid*, Gabapentin*, Topiramate, Vigabatrin, Lamotrigine • Anti-Depressants: Amitriptyline Hydrochloride*, Imipramine Hydrochloride*, Fluoxetine*, Venlafaxine, Duloxetine, Sertraline, Citalopram, Escitalopram, Fluvoxamine, Paroxetine	9
6	Drugs Acting on Autonomic Nervous System Sympathomimetic Agents: Direct Acting: Nor- Epinephrine*, Epinephrine, Phenylephrine,	9

Skill Development

	Dopamine*, Terbutaline, Salbutamol (Albuterol), Naphazoline*, Tetrahydrozoline. Indirect Acting Agents: Hydroxy Amphetamine, Pseudoephedrine. Agents With Mixed Mechanism: Ephedrine, Metaraminol • Adrenergic Antagonists: Alpha Adrenergic Blockers: Tolazoline, Phentolamine • Phenoxybenzamine, Prazosin. Beta Adrenergic Blockers: Propranolol*, Atenolol*, Carvedilol • Cholinergic Drugs and Related Agents: Direct Acting Agents: Acetylcholine*, Carbachol, And Pilocarpine. Cholinesterase Inhibitors: Neostigmine*, Edrophonium Chloride, Tacrine Hydrochloride, Pralidoxime Chloride, Echothiophate Iodide • Cholinergic Blocking Agents: Atropine Sulphate*, Ipratropium Bromide Synthetic Cholinergic Blocking Agents: Tropicamide, Cyclopentolate Hydrochloride, Clidinium Bromide, Dicyclomine Hydrochloride*	
7	Drugs Acting on Cardiovascular System • Anti-Arrhythmic Drugs: Quinidine Sulphate, Procainamide Hydrochloride, Verapamil, Phenytoin Sodium*, Lidocaine Hydrochloride, Lorcaïnide Hydrochloride, Amiodarone and Sotalol • Anti-Hypertensive Agents: Propranolol*, Captopril*, Ramipril, Methyldopate Hydrochloride, Clonidine Hydrochloride, Hydralazine Hydrochloride, Nifedipine, • Antianginal Agents: IsosorbideDinitrate	5
8	Diuretics: Acetazolamide, Frusemide*, Bumetanide, Chlorthalidone, Benzthiazide, Metolazone, Xipamide, Spironolactone	2
9	Hypoglycemic Agents: Insulin and Its Preparations, Metformin*, Glibenclamide*, Glimepiride, Pioglitazone, Repaglinide, Gliflozins, Gliptins	3
10	Analgesic And Anti-Inflammatory Agents: Morphine Analogues, Narcotic Antagonists; Nonsteroidal Anti- Inflammatory Agents (NSAIDs) - Aspirin*, Diclofenac, Ibuprofen*, Piroxicam, Celecoxib, Mefenamic Acid, Paracetamol*, Aceclofenac	3
11	Anti-Infective Agents: Antifungal Agents: Amphotericin-B, Griseofulvin, Miconazole, Ketoconazole*, Itraconazole, Fluconazole*, Naftifine Hydrochloride	8

	• Urinary Tract Anti-Infective Agents: Norfloxacin, Ciprofloxacin, Ofloxacin*, Moxifloxacin, • Anti-Tubercular Agents: INH*, Ethambutol, Para Amino Salicylic Acid, Pyrazinamide, Rifampicin, Bedaquiline, Delamanid, Pretomanid* • Antiviral Agents: Amantadine Hydrochloride, Idoxuridine, Acyclovir*, Foscarnet, Zidovudine, Ribavirin, Remdesivir, Favipiravir • Antimalarials: Quinine Sulphate, Chloroquine Phosphate*, Primaquine Phosphate, Mefloquine*, Cycloguanil, Pyrimethamine, Artemisinin • Sulfonamides: Sulfanilamide, Sulfadiazine, Sulfamethoxazole, Sulfacetamide*, Mafenide Acetate, Cotrimoxazole, Dapsone*	
12	Antibiotics: Penicillin G, Amoxicillin*, Cloxacillin, Streptomycin, Tetracyclines: Doxycycline, Minocycline, Macrolides: Erythromycin, Azithromycin, Miscellaneous: Chloramphenicol* Clindamycin	8
13	Anti-Neoplastic Agents: Cyclophosphamide*, Busulfan, Mercaptopurine, Fluorouracil*, Methotrexate, Dactinomycin, Doxorubicin Hydrochloride, Vinblastine Sulphate, Cisplatin*, Dromostanolone Propionate	3

Skill Development

PHARMACEUTICAL CHEMISTRY – PRACTICAL

Course Code: ER20-12P

75Hours(3 Hours/week)

Scope: This course is designed to impart basic training and hands-on experiences to synthesis chemical substances used as drugs and pharmaceuticals. Also, to perform the quality control tests, impurity testing, test for purity and systematic qualitative analysis of chemical substances used as drugs and pharmaceuticals.

Course Objectives: This course will provide the hands-on experience on the following aspects of chemical substances used as drugs and pharmaceuticals

- Limit tests and assays of selected chemical substances as per the monograph
- Volumetric analysis of the chemical substances
- Basics of preparatory chemistry and their analysis
- Systematic qualitative analysis for the identification of the chemical drugs

Course Outcomes: Upon successful completion of this course, the students will be able to

- Perform the limit tests for various inorganic elements and report
- Prepare standard solutions using the principles of volumetric analysis
- Test the purity of the selected inorganic and organic compounds against the monograph standards
- Synthesize the selected chemical substances as per the standard synthetic scheme
- Perform qualitative tests to systematically identify the unknown chemical substances

Practicals

S. NO.	EXPERIMENT
1	Limit test for : Chlorides; sulphate; Iron; heavy metals
2	Identification tests for Anions and Cations as per Indian Pharmacopoeia
3	Fundamentals of Volumetric analysis Preparation of standard solution and standardization of Sodium Hydroxide, Potassium Permanganate
4	Assay of the following compounds • Ferrous sulphate- by redox titration • Calcium gluconate-by complexometric • Sodium chloride-by Modified Volhard's method • Ascorbic acid by iodometry • Ibuprofen by alkalimetry
5	Fundamentals of preparative organic chemistry Determination of Melting point and boiling point of organic compounds
6	Preparation of organic compounds • Benzoic acid from Benzamide • Picric acid from Phenol
7	Identification and test for purity of pharmaceuticals Aspirin, Caffeine, Paracetamol, Sulfanilamide
8	Systematic Qualitative analysis experiments (4 substances)

Skill Development

The students shall be asked to submit the written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

- Different monographs and formularies available and their major contents
- Significance of quality control and quality assurance in pharmaceutical industries
- Overview on Green Chemistry
- Various software programs available for computer aided drug discovery
- Various instrumentations used for characterization and quantification of drug



Skill Development

HUMAN ANATOMY AND PHYSIOLOGY – PRACTICAL

Course Code: ER20-14P

75 Hours (3 Hours/week)

Scope: This course is designed to train the students and instil the skills for carrying out basic physiological monitoring of various systems and functions.

Course Objectives: This course will provide hands-on experience in the following:

- General blood collection techniques and carrying out various haematological assessments and interpreting the results
- Recording and monitoring the vital physiological parameters in human subjects and the basic interpretations of the results
- Microscopic examinations of the various tissues permanently mounted in glass slides
- Discuss the anatomical and physiological characteristics of various organ systems of the body using models, charts, and other teaching aids

Course Outcomes: Upon successful completion of this course, the students will be able to

- Perform the haematological tests in human subjects and interpret the results
- Record, monitor and document the vital physiological parameters of human subjects and interpret the results
- Describe the anatomical features of the important human tissues under the microscopical conditions
- Discuss the significance of various anatomical and physiological characteristics of the human body

Practicals

- Study of compound microscope
- General techniques for the collection of blood
- Microscopic examination of Epithelial tissue, Cardiac muscle, Smooth muscle, Skeletal muscle, Connective tissue, and Nervous tissue of ready / pre-prepared slides.
- Study of Human Skeleton-Axial skeleton and appendicular skeleton
- Determination of
- Blood group, ESR
- Haemoglobin content of blood
- Bleeding time and Clotting time
- Determination of WBC count of blood
- Determination of RBC count of blood
- Determination of Differential count of blood
- Recording of Blood Pressure in various postures, different arms, before and after exertion and interpreting the results
- Recording of Body temperature (using mercury, digital and IR thermometers at various locations), Pulse rate/ Heart rate (at various locations in the body, before and after exertion), Respiratory Rate
- Recording Pulse Oxygen (before and after exertion)
- Recording force of air expelled using Peak Flow Meter
- Measurement of height, weight, and BMI

Skill Development

- Study of various systems and organs with the help of chart, models, and specimens
- Cardiovascular system
- Respiratory system
- Digestive system
- Urinary system
- Endocrine system
- Reproductive system
- Nervous system
- Eye
- Ear
- Skin

Skill Development

SOCIAL PHARMACY – PRACTICAL

Course Code: ER20-15P

75 Hours (3 Hours/week)

Scope: This course is designed to provide simulated experience in various public health and social pharmacy activities.

Course Objectives: This course will train the students on various roles of pharmacists in public health and social pharmacy activities in the following areas:

- National immunization programs
- Reproductive and child health programs
- Food and nutrition related health programs
- Health education and promotion
- General roles and responsibilities of the pharmacists in public health
- First Aid for various emergency conditions including basic life support and cardiopulmonary resuscitation

Course Outcomes: Upon successful completion of this course, the students will be able to

- Describe the roles and responsibilities of pharmacists in various National health programs
- Design promotional materials for public health awareness
- Describe various health hazards including microbial sources
- Advice on preventive measures for various diseases
- Provide first aid for various emergency conditions

Note: Demonstration / Hands-on experience / preparation of charts / models / promotional materials / role plays / enacting / e-brochures / e-flyers / podcasts / video podcasts / any other innovative activities to understand the concept of various elements of social pharmacy listed here. (At least one activity to be carried out for each one of the following):

Practicals

- National immunization schedule for children, adult vaccine schedule, Vaccines which are not included in the National Immunization Program.
- RCH – reproductive and child health – nutritional aspects, relevant national health programmes.
- Family planning devices
- Microscopical observation of different microbes (readymade slides)
- Oral Health and Hygiene
- Personal hygiene and etiquettes – hand washing techniques, Cough and sneeze etiquettes.
- Various types of masks, PPE gear, wearing/using them, and disposal.
- Menstrual hygiene, products used
- First Aid – Theory, basics, demonstration, hands on training, audio-visuals, and practice, BSL (Basic Life Support) Systems [SCA - Sudden Cardiac Arrest, FBAO - Foreign Body Airway Obstruction, CPR, Defibrillation (using AED) (Includes CPR techniques, First Responder)].
- Emergency treatment for all medical emergency cases viz. snake bite, dog bite, insecticide poisoning, fractures, burns, epilepsy etc.
- Role of Pharmacist in Disaster Management.
- Marketed preparations of disinfectants, antiseptics, fumigating agents, antilarval agents, mosquito repellents, etc.

Skill Development

- Health Communication: Audio / Video podcasts, Images, Power Point Slides, Short Films, etc. in regional language(s) for mass communication / education / Awareness on 5 different communicable diseases, their signs and symptoms, and prevention.
- Water purification techniques, use of water testing kit, calculation of Content/percentage of KMnO₄, bleaching powder to be used for wells/tanks
- Counselling children on junk foods, balanced diets – using Information, Education and Communication (IEC), counselling, etc. (Simulation Experiments).
- Preparation of various charts on nutrition, sources of various nutrients from Locally available foods, calculation of caloric needs of different groups (e.g. child, mother, sedentary lifestyle, etc.). Chart of glycemic index of foods.
- Tobacco cessation, counselling, identifying various tobacco containing products through charts/pictures

Assignment

The students shall be asked to submit the written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

- An overview of Women's Health Issues
- Study the labels of various packed foods to understand their nutritional contents
- Breastfeeding counselling, guidance – using Information, Education and Communication (IEC)
- Information about the organizations working on de-addiction services in the region (city / district, etc.)
- Role of a pharmacist in disaster management – A case study
- Overview on the National Tuberculosis Elimination Programme (NTEP)
- Drug disposal systems in the country, at industry level and citizen level
- Various Prebiotics or Probiotics (dietary and market products)
- Prepare poster/presentation for general public on any one of the Health Days. e.g. Day, AIDS Day, Handwashing Day, ORS day, World Diabetes Day, World Heart Day, etc.
- List of home medicines, their storage, safe handling, and disposal of unused medicines
- Responsible Use of Medicines: From Purchase to Disposal
- Collection of newspaper clips (minimum 5) relevant to any one topic and its submission in an organized form with collective summary based on the news items
- Read a minimum of one article relevant to any theory topic, from Pharma
- /Science/ or other Periodicals and prepare summary of it for submission
- Potential roles of pharmacists in rural India

Field Visits : The students shall be taken in groups to visit any THREE of the following facilities to witness and understand the activities of such centres/facilities from the perspectives of the topics discussed in theory and/or practical courses. Individual reports from each student on their learning experience from the field visits shall be submitted.

- Garbage Treatment Plant
- Sewage Treatment Plant
- Bio-medical Waste Treatment Plant
- Effluent Treatment Plant
- Water purification plant
- Orphanage / Elderly-Care-Home / School and or Hostel/Home for persons with disabilities
- Primary health care centre

COMMUNITY PHARMACY AND MANAGEMENT – THEORY

Course Code: ER20-22T

75 Hours (3 Hours/week)

Scope: The course is designed to impart basic knowledge and skills to provide various pharmaceutical care services to patients and general practitioners in the community setup.

Course Objectives: This course will discuss the following:

- Establishing and running a community pharmacy and its legal requirements
- Professional aspects of handling and filling prescriptions
- Patient counselling on diseases, prescription and or non-prescription medicines
- Scope for performing basic health screening in community pharmacy settings

Course Outcomes: Upon successful completion of this course, the students will be able to

- Describe the establishment, legal requirements, and effective administration of a community pharmacy
- Professionally handle prescriptions and dispense medications
- Counsel patients about the disease, prescription and or non-prescription medicines
- Perform basic health screening on patients and interpret the reports in the community pharmacy settings

CHAPTER	TOPIC	HOURS
1	Community Pharmacy Practice – Definition, history and development of community pharmacy - International and Indian scenarios	2
2	Professional responsibilities of community pharmacists Introduction to the concept of Good Pharmacy Practice and SOPs.	3
3	Prescription and prescription handling • Definition, parts of prescriptions, legality of prescriptions, prescription handling, labelling of dispensed medications (Main label, ancillary label, pictograms), brief instructions on medication usage • Dispensing process, Good Dispensing Practices, dispensing errors and strategies to minimize them	7
4	Communication skills • Definition, types of communication skills • Interactions with professionals and patients • Verbal communication skills (one-to-one, over the telephone) • Written communication skills • Body language • Patient interview techniques	6

Skill Development

5	Patient counselling • Definition and benefits of patient counselling • Stages of patient counselling - Introduction, counselling content, counselling process, and closing the counselling session • Barriers to effective counseling - Types and strategies to overcome the barriers • Patient counselling points for chronic diseases/disorders - Hypertension, Diabetes, Asthma, Tuberculosis, Chronic obstructive pulmonary disease, and AIDS • Patient Package Inserts - Definition, importance and benefits, Scenarios of PPI use in India and other countries • Patient Information leaflets - Definition and uses	10
6	Medication Adherence Definition, factors influencing non- adherence, strategies to overcome non-adherence	2
7	Health Screening Services in Community Pharmacy Introduction, scope, and importance of various health screening services - for routine monitoring of patients, early detection, and referral of undiagnosed cases	5
9	Over The Counter (OTC) Medications • Definition, need and role of Pharmacists in OTC medication dispensing • OTC medications in India, counseling for OTC products • Self-medication and role of pharmacists in promoting the safe practices during self-medication • Responding to symptoms, minor ailments, and advice for self-care in conditions such as - Pain management, Cough, Cold, Diarrhea, Constipation, Vomiting, Fever, Sore throat, Skin disorders, Oral health (mouth ulcers, dental pain, gum swelling)	15



Skill Development

10	Community Pharmacy Management • Legal requirements to set up a community pharmacy • Site selection requirements • Pharmacy designs and interiors • Vendor selection and ordering • Procurement, inventory control methods, and inventory management • Financial planning and management • Accountancy in community pharmacy – Day book, Cash book • Introduction to pharmacy operation softwares – usefulness and availability • Customer Relation Management (CRM) • Audits in Pharmacies • SOP of Pharmacy Management • Introduction to Digital Health, mHealth and Online pharmacies	25
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Skill Development

PHARMACY LAW AND ETHICS – THEORY

Course Code: ER20-26T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India

Course Objectives: This course will discuss the following

- General perspectives, history, evolution of pharmacy law in India
- Act and Rules regulating the profession and practice of pharmacy in India
- Important code of ethical guidelines pertaining to various practice standards
- Brief introduction to the patent laws and their applications in pharmacy

Course Outcomes: Upon successful completion of this course, the students will be able to

- Describe the history and evolution of pharmacy law in India
- Interpret the act and rules regulating the profession and practice of pharmacy in India
- Discuss the various codes of ethics related to practice standards in pharmacy
- Interpret the fundamentals of patent laws from the perspectives of pharmacy

CHAPTER	TOPICS	HOURS
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2
2	Pharmacy Act-1948 and Rules: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties. Pharmacy Practice Regulations 2015	5
3	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit.	23

Skill Development

	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. Study of schedule C and C1, G, H, H1, K, P, M, N, and X. Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.	
4	Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	2
5	Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	2
6	Prevention of Cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.	2
7	Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	2
8	FSSAI (Food Safety and Standards Authority of India) Act and Rules: brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements	2
9	National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)	5
10	Code of Pharmaceutical Ethics: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.	5
11	Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments	2

12	Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	1
13	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices	3
14	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	7
15	Blood bank – basic requirements and functions	2
16	Clinical Establishment Act and Rules – Aspects related to Pharmacy	2
17	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals	2
18	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	2
19	Introduction to the Consumer Protection Act	1
20	Introduction to the Disaster Management Act	1
21	Medical Devices – Categorization, basic aspects related to manufacture and sale	2

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

- Requirements for Ayurvedic, Homeopathic manufacturing, sale, and licensing requirements
- Layout and contents of official websites of various agencies regulating the profession of pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.
- Licenses required, application processes (online/offline), drug regulatory office website of the respective state
- Case studies – actions taken on violation of any act / rule related to pharmacy
- Schedule H1 drugs and its implementation in India
- Counterfeit / Spurious medicines
- Drug Testing Labs in India
- Overview of Pharma marketing practices
- Generic Medicines

Skill Development

PHARMACOLOGY – PRACTICAL

Course Code: ER20-21P

50 Hours (2 Hours/week)

Scope: This course provides the basic understanding about the uses, mechanisms of actions, dose dependent responses of drugs in simulated virtual animal models and experimental conditions.

Course Objectives: This course will demonstrate / provide hands-on experience in the virtual platform using appropriate software on the following

- Study of pharmacological effects of drugs like local anaesthetics, mydriatic and mitotic on rabbit eye
- Screening the effects of various drugs acting in the central nervous system
- Study of drug effects on isolated organs / tissues
- Study of pyrogen testing on rabbit

Course Outcomes: Upon successful completion of this course, the students will be able to

- Study and report the local anaesthetic, mydriatic and mitotic effects of the given drug on the rabbit eye
- Choose appropriate animal experiment model to study the effects of the given drugs acting on the central nervous system and submit the report
- Perform the effects of given tissues (simulated) on isolated organs / tissues and interpret the results
- Interpret the dose dependent responses of drugs in various animal experiment models

Practicals : Introduction to the following topics pertaining to the experimental pharmacology have to be discussed and documented in the practical manuals.

- Introduction to experimental pharmacology
- Study of laboratory animals
- Mice; (b) Rats; (c) Guinea pigs; (d) Rabbits
- Commonly used instruments in experimental pharmacology
- Different routes of administration of drugs in animals
- Types of pre-clinical experiments: In-Vivo, In-Vitro, Ex-Vivo, etc.

Experiments

Note: Animals shall not be used for doing / demonstrating any of the experiments given. The given experiments shall be carried- out / demonstrated as the case may be, ONLY with the use of software program(s) such as 'Ex Pharm' or any other suitable software

- Study of local anaesthetics on rabbit eye
- Study of Mydriatic effect on rabbit eye
- Study of Mitotic effect on rabbit eye
- Effect of analgesics using Analgesiometer
- Study of analgesic activity by writhing test
- Screening of anti-convulsant using Electro Convulsimeter
- Screening of Muscle relaxants using Rota-Rod apparatus
- Screening of CNS stimulants and depressants using Actophotometer
- Study of anxiolytic activity using elevated plus maze method
- Study of effect of drugs (any 2) on isolated heart
- Effect of drugs on ciliary motility on frog's buccal cavity
- Pyrogen testing by rabbit method

Skill Development

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

- Introduction to Allergy Testing
- Introduction to Toxicity Studies
- Drug Facts Labels of US FDA
- Pre-clinical studies in new drug development
- Medicines and meals: Before or After food
- Pre-clinical studies in new drug development
- Drugs available as paediatric formulations
- Drug information apps



Skill Development

COMMUNITY PHARMACY AND MANAGEMENT – PRACTICAL

Course Code: ER20-22P

75 Hours (3 Hours/week)

Scope: The course is designed to train the students and improve professional skills to provide various pharmaceutical care services in community pharmacy.

Course Objectives: This course will train the students in the following

- Professional handling and filling prescriptions
- Patient counselling on diseases and minor ailments
- Patient counselling on prescription and / or non-prescription medicines
- Preparation of counselling materials such as patient information leaflets
- Performing basic health screening tests

Course Outcomes: Upon successful completion of this course, the students will be able to

- Handle and fill prescriptions in a professional manner
- Counsel patients on various diseases and minor ailments
- Counsel patients on prescription and or non-prescription medicines
- Design and prepare patient information leaflets
- Perform basic health screening tests

Practicals

Note: The following practicals shall be carried out in the model community pharmacy with appropriate simulated scenarios and materials. Students shall be trained through role plays wherever necessary. The activities of the students shall be assessed / evaluated using a structured objective assessment form.

Handling of prescriptions with professional standards, reviewing prescriptions, checking for legal compliance and completeness (minimum 5)

- Identification of drug-drug interactions in the prescription and follow-up actions (minimum 2)
- Preparation of dispensing labels and auxiliary labels for the prescribed medications (minimum 5)
- Providing the following health screening services for monitoring patients / detecting new patients (one experiment for each activity)

Blood Pressure Recording, Capillary Blood Glucose Monitoring, Lung function assessment using Peak Flow Meter and incentive spirometer, recording capillary oxygen level using Pulse Oximeter, BMI measurement

- Providing counselling to simulated patients for the following chronic diseases / disorders including education on the use of devices such as insulin pen, inhalers, spacers, nebulizers, etc. where appropriate (one experiment for each disease)
- Type 2 Diabetes Mellitus, Primary Hypertension, Asthma, Hyperlipidaemia, Rheumatoid Arthritis
- Providing counselling to simulated patients for the following minor ailments (any three)
- Headache, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Worm infestations, Pyrexia, Upper Respiratory Tract infections, Skin infections, Oral and dental disorders.
- Appropriate handling of dummy dosage forms with correct administration techniques - oral liquids with measuring cup/cap/dropper, Eye Drops, Inhalers, Nasal drops, Insulin pen, nebulizers, different types of tablets, patches, enemas, suppositories
- Use of Community Pharmacy Software and digital health tools

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

- SOPs for various activities in Community Pharmacy (as discussed in Theory and Practical)
- List out the various abbreviations, short forms used in prescriptions and their interpretation
- Patient Information Leaflet for a given chronic disease / disorder
- Patient Information Leaflet for prescription / non-prescription medicines
- Preparation of window / shelf display materials for the model community pharmacy
- Overview of Software available for retail pharmacy management including billing, inventory, etc.
- Dosage / Medication Reminder Aids
- Overview on the operations and marketing strategies of various online pharmacies
- Overview on the common fixed dose combinations
- Overview on the medications requiring special storage conditions
- Role of Community Pharmacists in preventing Antimicrobial Resistance
- Jan Aushadhi and other Generic Medicine initiatives in India
- Global Overview of Online Pharmacies
- Community Pharmacy Practice Standards: Global Vs. Indian Scenario
- Overview of pharmacy associations in India



Skill Development



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School of Pharmacy

1.1.3 Courses having focus on Employability / Entrepreneurship / Skill Development

Pharm.D (Doctor of Pharmacy)

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PH 101P	HUMAN ANATOMY AND PHYSIOLOGY-LAB	Total Marks
		100

General Requirements:

Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments

- Study of tissues of human body
 - Epithelial tissue.
 - Muscular tissue.
- Study of tissues of human body**
 - Connective tissue.
 - Nervous tissue.
- Study of appliances used in hematological experiments.
- Determination of W.B.C. count of blood.**
- Determination of R.B.C. count of blood.**
- Determination of differential count of blood.
- Determination of
 - Erythrocyte Sedimentation Rate.
 - Hemoglobin content of Blood.
 - Bleeding time & Clotting time.
- Determination of
 - Blood Pressure.
 - Blood group.
- Study of various systems with the help of charts, models & specimens**
 - Skeleton system part I-axial skeleton.
 - Skeleton system part II- appendicular skeleton.
 - Cardiovascular system.
 - Respiratory system.
 - Digestive system.
 - Urinary system.
 - Nervous system.
 - Special senses.
 - Reproductive system.
- Study of different family planning appliances.
- To perform pregnancy diagnosis test.**
- Study of appliances used in experimental physiology.**
- To record simple muscle curve using gastrocnemius sciatic nerve preparation.
- To record simple summation curve using gastrocnemius sciatic nerve preparation.

15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

Contents	Sessional	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is **30** (**20** for practical sessional plus **10** marks for regularity, promptness, viva-voce and record maintenance).

Employability

PH 102	PHARMACEUTICS	L	T	P	Total Marks
		2	1	3	100

Scope and objectives: This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

Outcomes; upon the completion of the course the student should be able to:

- know the formulation aspects of different dosage forms;
- do different pharmaceutical calculation involved in formulation;
- formulate different types of dosage forms; and
- appreciate the importance of good formulation for effectiveness.

UNIT: 1.

- Introduction to dosage forms - classification and definitions
- Prescription:** definition, parts and handling
- Posology:** Definition, Factors affecting dose selection. Calculation of children and infant doses.
- Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.

UNIT: 2

- Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- Weights and measures,** Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.

UNIT: 3

- Powders and Granules:** Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- Monophasic Dosage forms:** Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavors with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

UNIT: 4

- Biphasic dosage forms:** Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- Suppositories and pessaries:** Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation
- Galenicals:** Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

UNIT: 5

- Pharmaceutical calculations.**
- Surgical aids:** Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- Incompatibilities:** Introduction, classification and methods to overcome the incompatibilities.

Employability

PH 103	MEDICINAL BIOCHEMISTRY	L	T	P	Total Marks
		3	1	3	100

Scope:

Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases

Objectives of the Subject (Know, do, appreciate):

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. *Upon completion of the subject student shall be able to –*

- understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- know the metabolic process of biomolecules in health and illness (metabolic disorders);
- understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- do the qualitative analysis and determination of biomolecules in the body fluids.

UNIT.1:

a. Introduction to biochemistry: Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.

b. Enzymes: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.

UNIT.2:

i) Carbohydrate metabolism: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

ii) Lipid metabolism: Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).

UNIT.3:

i) Biological oxidation: Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

iii) Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

iv) Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

UNIT.4:

Introduction to clinical chemistry: Cell; composition; malfunction; Role of the clinical chemistry laboratory.

The kidney function tests: Role of kidney; Laboratory tests for normal function includes-

- Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)

b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)

c) Urine concentration test

d) Urinary tract calculi. (stones)

Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

a) Test for hepatic dysfunction-Bile pigments metabolism.

b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.

c) Dye tests of excretory function.

d) Tests based upon abnormalities of serum proteins. Selected enzyme tests.

UNIT.5:

i) **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

ii) **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.

Radio Immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

iii) **Electrolytes:** Body water, compartments, water balance and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

Text books (Theory)

a) Harpers review of biochemistry - Martin

b) Text book of biochemistry – D.Satyanarayana

c) Text book of clinical chemistry- Alex kaplan&LaverveL.Szabo

Reference books (Theory)

a) Principles of biochemistry -- Lehninger

b) Text book of biochemistry – Ramarao

c) Practical Biochemistry-David T.Plummer.

Employability

PH 102	PHARMACEUTICS	L	T	P	Total Marks
		2	1	3	100

Scope and objectives: This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

Outcomes; *upon the completion of the course the student should be able to:*

- e) know the formulation aspects of different dosage forms;
- f) do different pharmaceutical calculation involved in formulation;
- g) formulate different types of dosage forms; and
- h) appreciate the importance of good formulation for effectiveness.

UNIT: 1.

- e) Introduction to dosage forms - classification and definitions
- f) **Prescription:** definition, parts and handling
- g) **Posology:** Definition, Factors affecting dose selection. Calculation of children and infant doses.
- h) Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.

UNIT: 2

- c) Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- d) **Weights and measures,** Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.

UNIT: 3

- c) **Powders and Granules:** Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- d) **Monophasic Dosage forms:** Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavors with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

UNIT: 4

- d) **Biphasic dosage forms:** Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- e) **Suppositories and pessaries:** Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation
- f) **Galenicals:** Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

UNIT: 5

- d) **Pharmaceutical calculations.**

e) **Surgical aids:** Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.

- f) **Incompatibilities:** Introduction, classification and methods to overcome the incompatibilities.

PH 103P	MEDICINAL BIOCHEMISTRY -LAB	Total Marks
		100

Title of the Experiment:

1. Qualitative analysis of normal constituents of urine.*
 2. Qualitative analysis of abnormal constituents of urine.*
 3. Quantitative estimation of urine sugar by Benedict's reagent method.**
 4. Quantitative estimation of urine chlorides by Volhard's method.**
 5. Quantitative estimation of urine creatinine by Jaffe's method.**
 6. Quantitative estimation of urine calcium by precipitation method.**
 7. Quantitative estimation of serum cholesterol by LibermannBurchard's method.**
 8. Preparation of Folin Wu filtrate from blood.*
 9. Quantitative estimation of blood creatinine.**
 10. Quantitative estimation of blood sugar Folin- Wu tube method.**
 11. Estimation of SGOT in serum.**
 12. Estimation of SGPT in serum.**
 13. Estimation of Urea in Serum.**
 14. Estimation of Proteins in Serum.**
 15. Determination of serum bilirubin**
 16. Determination of Glucose by means of Glucoseoxidase.**
 17. Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
 18. Study of factors affecting Enzyme activity. (pH& Temp.)**
 19. Preparation of standard buffer solutions and its pH measurements (any two)*
 20. Experiment on lipid profile tests**
 21. Determination of sodium,calcium and potassium in serum.**
- ** indicate major experiments & * indicate minor experiments

Assignments: Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Entrepreneurship

PH 104	PHARMACEUTICAL ORGANIC CHEMISTRY	L	T	P	Total Marks
		3	1	3	100

Scope and objectives: This course is designed to impart a very good knowledge about

- IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
- Some important physical properties of organic compounds;
- Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
- Some named organic reactions with mechanisms; and
- Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

UNIT.1:

i) Structures and Physical properties:

- Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
- Acids and bases, Lowry bronsted and Lewis theories
- Isomerism

ii) Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.

iii) Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability

iv) Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

UNIT.2:

i) Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN 2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

ii) Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

iii) Electrophilic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

iv) Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

UNIT.3:

i) **Theory of resonance:** Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allylcation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allylcation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinyliccation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

ii) **Electrophilic aromatic substitution:** Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, Friedel-Craft alkylation, Friedel-Craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.

UNIT.4:

i) **Nucleophilic addition reaction:** Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

ii) **Mechanism of aldol condensation,** Claisen condensation, Cannizzaro reaction, crossed aldol condensation, crossed Cannizzaro reaction, benzoin condensation, Perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

iii) **Hoffman rearrangement:** Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer-Tiemann's reactions.

UNIT.5:

i) **Nucleophilic aromatic substitution:** Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

ii) **Oxidation reduction reaction.**

iii) **Study of the following official compounds-** preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glycerol trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

REFERENCES

- a. T.R. Morrison and R. Boyd - Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L. Finer- Organic chemistry, the fundamentals of chemistry
- d. Organic chemistry – J.M. Cram and D.J. Cram
- e. Organic chemistry- Brown
- f. Advanced organic chemistry- Jerry March, Wiley
- g. Organic chemistry- Cram and Hammond, Pine-Hendrickson

PH 105	PHARMACEUTICAL INORGANIC CHEMISTRY	L	T	P	Total Marks
		3	1	3	100

Scope and objectives: This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

Upon completion of the course student shall be able to:

- understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
- know the analysis of the inorganic pharmaceuticals their applications; and
- appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

UNIT.1:

- Errors
- Volumetric analysis
- Acid-base titrations
- Redox titrations

UNIT.2:

- Non aqueous titrations
- Precipitation titrations
- Complexometric titrations
- Theory of indicators

UNIT.3:

- Gravimetry
- Limit tests
- Medicinal gases
- Acidifiers

UNIT.4:

- Antacids
- Cathartics
- Electrolyte replenishers
- Essential Trace elements

UNIT.5:

- Antimicrobials
- Pharmaceutical aids
- Dental Products
- Miscellaneous compounds
- Radio Pharmaceuticals

REFERENCES

- A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
- Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao
- Inorganic Pharmaceutical Chemistry by Anand&Chetwal

Entrepreneurship

PH 101	HUMAN ANATOMY AND PHYSIOLOGY	L	T	P	Total Marks
		3	1	3	100

Scope:

This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

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

- describe the structure (gross and histology) and functions of various organs of the human body;
- describe the various homeostatic mechanisms and the imbalances of various systems;
- identify the various tissues and organs of the different systems of the human body;
- perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
- appreciate coordinated working pattern of different organs of each system; and
- appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

UNIT: 1

- Scope of anatomy and physiology**, basic terminologies used in this subject (Description of the body as such planes and terminologies)
- Structure of cell** – its components and their functions. Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
 - Osseous system - structure, composition and functions of the Skeleton
 - Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

UNIT: 2

i) Haemopoetic System

- Composition and functions of blood
- Haemopoiesis and disorders of blood components
- Blood groups
- Clotting factors and mechanism
- Platelets and disorders of coagulation

ii) Lymph

- Lymph and lymphatic system, composition, formation and circulation.
- Spleen: structure and functions, Disorders
- Disorders of lymphatic system (definition only)

iii) Cardiovascular system

- Anatomy and functions of heart
- Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
- Electrocardiogram (ECG)
- Cardiac cycle and heart sounds
- Blood pressure – its maintenance and regulation
- Definition of the following disorders:** Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

UNIT-3

i) Respiratory system

- a) Anatomy of respiratory organs and functions
- b) Mechanism / physiology of respiration and regulation of respiration
- c) Transport of respiratory gases
- d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

ii) Digestive system

- a) Anatomy and physiology of GIT
- b) Anatomy and functions of accessory glands of GIT
- c) Digestion and absorption
- d) Disorders of GIT (definitions only)

iii) Nervous system

- a) Definition and classification of nervous system
- b) Anatomy, physiology and functional areas of cerebrum
- c) Anatomy and physiology of cerebellum
- d) Anatomy and physiology of mid brain
- e) Thalamus, hypothalamus and Basal Ganglia
- f) Spinal cord: Structure & reflexes – mono-poly-planter
- g) Cranial nerves – names and functions
- h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

UNIT: 4

i) Urinary system

- a) Anatomy and physiology of urinary system
- b) Formation of urine
- c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
- d) Clearance tests and micturition

ii) Endocrine system

- a) Pituitary gland
- b) Adrenal gland
- c) Thyroid and Parathyroid glands
- d) Pancreas and gonads

iii) Reproductive system

- a) Male and female reproductive system
- b) Their hormones – Physiology of menstruation
- c) Spermatogenesis & Oogenesis
- d) Sex determination (genetic basis)
- e) Pregnancy and maintenance and parturition
- f) Contraceptive devices

UNIT: 5

i) Sense organs

- a) Eye
- b) Ear

- c) Skin
- d) Tongue & Nose

ii) Skeletal muscles

- a) Histology
- b) Physiology of Muscle contraction
- c) Physiological properties of skeletal muscle and their disorders (definitions)

iii) Sports physiology

- a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
- b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
- c) Drugs and athletics

TEXT BOOKS

- a) Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins College New York.
- b) Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburgh.

REFERENCE BOOKS

- a) Guyton Arthur, C. *Physiology of human body*. Publisher: Holt Saunders.
- b) Chatterjee, C.C. *Human physiology*. Volume 1 & 11. Publisher: medical allied agency, Calcutta.
- c) Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H. *Gray's anatomy* Publisher: Churchill Livingstone, London

Skill Development

PH 102P	PHARMACEUTICS-LAB	Total Marks
		100

List of Experiments

1. Syrups

- a) Simple Syrup I.P
- b) Syrup of Ephedrine Hcl NF
- c) Syrup Vasaka IP
- d) Syrup of ferrous Phosphate IP
- e) Orange Syrup

2. Elixir

- a) Piperizine citrate elixir BP
- b) Cascara elixir BPC
- c) Paracetamol elixir BPC

3. Linctus

- a) Simple Linctus BPC
- b) Pediatric simple Linctus BPC

4. Solutions

- a) Solution of cresol with soap IP
- b) Strong solution of ferric chloride BPC
- c) Aqueous Iodine Solution IP
- d) Strong solution of Iodine IP
- e) Strong solution of ammonium acetate IP

5. Liniments

- a) Liniment of turpentine IP*
- b) Liniment of camphor IP

6. Suspensions*

- a) Calamine lotion
- b) Magnesium Hydroxide mixture BP

7. Emulsions*

- a) Cod liver oil emulsion
- b) Liquid paraffin emulsion

8. Powders*

- a) Eutectic powder
- b) Explosive powder
- c) Dusting powder
- d) Insufflations

9. Suppositories*

- a) Boric acid suppositories
- b) Chloral suppositories

10. Incompatibilities

- a) Mixtures with Physical
- b) Chemical & Therapeutic incompatibilities

Skill Development

PH 103P	MEDICINAL BIOCHEMISTRY -LAB	Total Marks
		100

Title of the Experiment:

1. Qualitative analysis of normal constituents of urine.*
2. Qualitative analysis of abnormal constituents of urine.*
3. Quantitative estimation of urine sugar by Benedict's reagent method.**
4. Quantitative estimation of urine chlorides by Volhard's method.**
5. Quantitative estimation of urine creatinine by Jaffe's method.**
6. Quantitative estimation of urine calcium by precipitation method.**
7. Quantitative estimation of serum cholesterol by LibermannBurchard's method.**
8. Preparation of Folin Wu filtrate from blood.*
9. Quantitative estimation of blood creatinine.**
10. Quantitative estimation of blood sugar Folin- Wu tube method.**
11. Estimation of SGOT in serum.**
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13. Estimation of Urea in Serum.**
14. Estimation of Proteins in Serum.**
15. Determination of serum bilirubin**
16. Determination of Glucose by means of Glucoseoxidase.**
17. Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18. Study of factors affecting Enzyme activity. (pH& Temp.)**
19. Preparation of standard buffer solutions and its pH measurements (any two)*
20. Experiment on lipid profile tests**
21. Determination of sodium,calcium and potassium in serum.**

a. ** indicate major experiments & * indicate minor experiments

Assignments: Format of the assignment

7. Minimum & Maximum number of pages.
8. It shall be computer draft copy.
9. Reference(s) shall be included at the end.
10. Name and signature of the student.
11. Assignment can be a combined presentation at the end of the academic year.
12. Time allocated for presentation may be 8+2 Min.

Skill Development

PH 104	PHARMACEUTICAL ORGANIC CHEMISTRY	L	T	P	Total Marks
		3	1	3	100

Scope and objectives: This course is designed to impart a very good knowledge about

- IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
- Some important physical properties of organic compounds;
- Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
- Some named organic reactions with mechanisms; and
- Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

UNIT.1:

i) Structures and Physical properties:

- Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
- Acids and bases, Lowry bronsted and Lewis theories
- Isomerism

ii) Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.

iii) Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability

iv) Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

UNIT.2:

i) Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN 2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

ii) Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

iii) Electrophilic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

iv) Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

UNIT.3:

i) Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allylcation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allylcation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

ii) Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, Friedel-Craft alkylation, Friedel-Craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.

UNIT.4:

i) Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

ii) Mechanism of aldol condensation, Claisen condensation, Cannizzaro reaction, crossed aldol condensation, crossed Cannizzaro reaction, benzoin condensation, Perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

iii) Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer-Tiemann's reactions.

UNIT.5:

i) Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

ii) Oxidation reduction reaction.

iii) Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

REFERENCES

- T.R. Morrison and R. Boyd - Organic chemistry,
- Bentley and Driver-Text book of Pharmaceutical chemistry
- I.L. Finer- Organic chemistry, the fundamentals of chemistry
- Organic chemistry – J.M. Cram and D.J. Cram
- Organic chemistry- Brown
- Advanced organic chemistry- Jerry March, Wiley
- Organic chemistry- Cram and Hammond, Pine Hendrickson

Skill Development

PH 104P	PHARMACEUTICAL ORGANIC CHEMISTRY - LAB	Total Marks
		100

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Benzanilide / Phenyl benzoate (Benzoylation)
2. Acetanilide / aspirin (Acetylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenoneoxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Skill Development

PH 105P	PHARMACEUTICAL INORGANIC CHEMISTRY -LAB	Total Marks
		100

1. Limit test (6 exercises)

- a) Limit test for chlorides
- b) Limit test for sulphates
- c) Limit test for iron
- d) Limit test for heavy metals
- e) Limit test for arsenic
- f) Modified limit tests for chlorides and sulphates

2. Assays (10 exercises)

- a) Ammonium chloride- Acid-base titration
- b) b.Ferrous sulphate- Cerimetry
- c) c.Coppersulphahte- Iodometry
- d) d.Calcilugluconate- Complexometry
- e) e.Hydrogen peroxide – Permanganometry
- f) f.Sodium benzoate – Nonaqueous titration
- g) g.Sodium chloride – Modified volhard's method
- h) h.Assay of KI – KIO₃ titration
- i) i.Gravimetric estimation of barium as barium sulphate
- j) j.Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

- a) Sodium hydroxide and sodium carbonate
- b) Boric acid and Borax
- c) Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

- a) Sodium bicarbonate
- b) Barium sulphate
- c) Ferrous sulphate
- d) Potassium chloride

5. Test for purity (Any two exercises)

- a) Swelling power in Bentonite

- b) Acid neutralising capacity in aluminium hydroxide gel
- c) Ammonium salts in potash alum
- d) Adsorption power heavy Kaolin
- e) Presence of Iodates in KI

6. Preparations (Any two exercises)

- a) Boric acids
- b) Potash alum
- c) Calcium lactate
- d) Magnesium sulphate



Skill Development



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School of Pharmacy

1.1.3 Courses having focus on Employability / Entrepreneurship / Skill Development

M.Pharm (Pharmaceutics)

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MPH101T	Modern Pharmaceutical Analytical Techniques (Theory)	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Objectives: After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

60 Hours

Unit: I

11 hrs

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit: II

11 hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

Unit: III

11 Hours

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI. Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

Unit: IV

12 Hours

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography
d) Column chromatography e) Gas chromatography
f) High Performance Liquid chromatography g) Affinity chromatography

Unit: V

15 Hours

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
- b. X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.
- c. Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

MPH102T	DRUG DELIVERY SYSTEMS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

THEORY

60 Hours

Unit: I

11 Hrs

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic Concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bio electronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.

Unit: II

11 Hrs

Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

Unit: III

11 Hrs

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Unit: IV

12 Hrs

a) Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

b) Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Unit: V

15 Hrs

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Inter science Publication, John Wiley and Sons, Inc, New York! Chichester / Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable



Employability

MPH103T	MODERN PHARMACEUTICS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

- Upon completion of the course, student shall be able to understand
- The elements of Preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY

60 Hours

Unit: I

12 Hrs

a) Preformulation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

b). Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

Unit: II

12 Hrs

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

Unit: III

12 Hrs

C GMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

Unit: IV

12 Hrs

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

Unit: V

12 Hrs

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckle plots, Similarity factors – f2 and f1, Higuchi and Peppas

plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean &A.H.Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.



Employability

MPH104T	REGULATORY AFFAIRS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings indifferent countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies indifferent countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ e CTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

60Hours

Unit: I

12 Hrs

Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERALREGULATION) ,drug product performance, in-vitro, AND A regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

Unit: II

12 Hrs

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

Unit: III

12 Hrs

CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

Unit: IV

12 Hrs

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Unit: V

12 Hrs

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and

procedures. HIPAA- new, requirement to clinical study process, Pharmacovigilance safety monitoring in clinical trials.

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R.Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>

MPH201T	Molecular Pharmaceutics (Nano Technology & Targeted DDS) (NTDS)	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY

60 Hours

Unit: I

12 Hrs

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

Unit: II

12 Hrs

Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposome's: Types, preparation and evaluation.

Unit: III

12 Hrs

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

Unit: IV

12 Hrs

Pulmonary Drug Delivery Systems: Aerosols, propellants, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit: V

12 Hrs

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non viral gene transfer). Liposomal gene delivery systems. Bio distribution and Pharmacokinetics. Knowledge of therapeutic anti sense molecules and aptamers as drugs of future.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery- concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

Employability

MPH103T	MODERN PHARMACEUTICS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

- Upon completion of the course, student shall be able to understand
- The elements of Preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY

60 Hours

Unit: I

12 Hrs

a) Preformulation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

b). Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

Unit: II

12 Hrs

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH& WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

Unit: III

12 Hrs

C GMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

Unit: IV

12 Hrs

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

Unit: V

12 Hrs

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckle plots, Similarity factors – f2 and f1, Higuchi and Peppas

plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.

REFERENCES

18. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
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20. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
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25. Physical Pharmacy; By Alfred martin
26. Bentley's Textbook of Pharmaceutics – by Rawlins.
27. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
28. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
29. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
30. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
31. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
32. Pharmaceutical Preformulations; By J.J. Wells.
33. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
34. Encyclopaedia of Pharmaceutical technology, Vol I – III.

MPH104T	REGULATORY AFFAIRS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings indifferent countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies indifferent countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ e CTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

60Hours

Unit: I

12 Hrs

Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERALREGULATION) ,drug product performance, in-vitro, AND A regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

Unit: II

12 Hrs

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

Unit: III

12 Hrs

CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

Unit: IV

12 Hrs

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Unit: V

12 Hrs

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and

procedures. HIPAA- new, requirement to clinical study process, Pharmacovigilance safety monitoring in clinical trials.

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12. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R.Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
13. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
14. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons.Inc.
15. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
16. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
17. www.ich.org/
18. www.fda.gov/
19. europa.eu/index_en.htm
20. <https://www.tga.gov.au/tga-basics>

Entrepreneurship

MPH201T	Molecular Pharmaceutics (Nano Technology & Targeted DDS) (NTDS)	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY

60 Hours

Unit: I

12 Hrs

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

Unit: II

12 Hrs

Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposome's: Types, preparation and evaluation.

Unit: III

12 Hrs

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

Unit: IV

12 Hrs

Pulmonary Drug Delivery Systems: Aerosols, propellants, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit: V

12 Hrs

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non viral gene transfer). Liposomal gene delivery systems. Bio distribution and Pharmacokinetics. Knowledge of therapeutic anti sense molecules and aptamers as drugs of future.

REFERENCES

4. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery- concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
6. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY

60 Hours

Unit: I

12 Hrs

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of In vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Micro climate Intracellular pH Environment, Tight-Junction Complex.

Unit: II

12 Hrs

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution Testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

Unit: III

12 Hour

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction,

the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

Unit: IV

12 Hrs

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (bio similar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

Unit: V

12 Hrs

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

MPH203T	COMPUTER AIDED DRUG DEVELOPMENT	L	T	P	Credits	Total Marks
		4	0	0		

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY

60 Hours

Unit: I

12 Hrs

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

Unit: II

12 Hrs

Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT,OATP, BBB-Choline Transporter.

Unit: III

12 Hrs

Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

Unit: IV

12 Hrs

A) Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations.

B) Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction,
Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

C) Computers in Clinical Development: Clinical Data Collection and Management,
Regulation of Computer Systems

Unit: V

12 Hrs

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview,
Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages.
Current Challenges and Future Directions.

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.



Entrepreneurship

MPH205P	PHARMACEUTICS PRACTICALS-II	L	T	P	Credits	Total Marks
		0	0	12	6	150

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes /niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Entrepreneurship

MPH102T	DRUG DELIVERY SYSTEMS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

THEORY

60 Hours

Unit: I

11 Hrs

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic Concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bio electronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.

Unit: II

11 Hrs

Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

Unit: III

11 Hrs

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Unit: IV

12 Hrs

a) Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

b) Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Unit: V

15 Hrs

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

REFERENCES

6. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
7. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
8. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Inter science Publication, John Wiley and Sons, Inc, New York! Chichester / Weinheim
9. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

10. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.

JOURNALS

5. Indian Journal of Pharmaceutical Sciences (IPA)
6. Indian drugs (IDMA)
7. Journal of controlled release (Elsevier Sciences) desirable
8. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable



Skill Development

MPH105P	PHARMACEUTICS PRACTICALS-I	L	T	P	Credits	Total Marks
		0	0	12	6	150

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometer
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out Preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

Skill Development

MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY

60 Hours

Unit: I

12 Hrs

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of In vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Micro climate Intracellular pH Environment, Tight-Junction Complex.

Unit: II

12 Hrs

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution Testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

Unit: III

12 Hour

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction,

the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

Unit: IV

12 Hrs

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (bio similar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

Unit: V

12 Hrs

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

14. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
15. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
16. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
17. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
18. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
19. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
20. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
21. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
22. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
23. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
24. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
25. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
26. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

Skill Development

MPH203T	COMPUTER AIDED DRUG DEVELOPMENT	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY

60 Hours

Unit: I

12 Hrs

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

Unit: II

12 Hrs

Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

Unit: III

12 Hrs

Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

Unit: IV

12 Hrs

A) Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity

analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations.

B) Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

C) Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

Unit: V

12 Hrs

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

REFERENCES

4. Computer Applications in Pharmaceutical Research and Development, SeanEkins, 2006, John Wiley & Sons.
5. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris, Woodhead Publishing
6. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

Skill Development

MPH204T	COSMETICS AND COSMECEUTICALS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge and skills necessary For the fundamental need for cosmetic and cosmeceutical products.

Objectives

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

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

THEORY

60 Hours

Unit: I

12 Hrs

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

Unit: II

12 Hrs

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

Unit: III

12 Hrs

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants –Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndic bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

Unit: IV

12 Hrs

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

Unit: V**12 Hrs**

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

REFERENCES

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

 Skill Development