BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

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.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterjee ,Academic Publishers Kolkata

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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 Permanganometry
- (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)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

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, alligation, 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 **08 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 ofEmulsion, 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.

UNIV – 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

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BP109P. PHARMACEUTICSI (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) Aluminimum 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)Divded powders

8. Suppositories

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

8. Semisolids

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopal gel

9. Gargles and Mouthwashes

a) Iodine gargle

b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

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1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

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BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

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 Dont's 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 Dont's of group discussion

BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

Thefollowing learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

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

Interview Handling Skills

E-Mail etiquette

Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1st Edition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5th Edition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2nd Edition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1st Edition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1st Edition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4th Edition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999

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BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

1. Introduction to experiments in biology
   a) Study of Microscope
   b) Section cutting techniques
   c) Mounting and staining
   d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

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UNIT V **07 Hours**

- **Enzymes**

  Introduction, properties, nomenclature and IUB classification of enzymes

  Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

  Enzyme inhibitors with examples

  Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

  Therapeutic and diagnostic applications of enzymes and isoenzymes

  Coenzymes –Structure and biochemical functions

BP 209 P. 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.

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Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes.This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:

Unit I **10Hours**

- **Basic principles of Cell injury and Adaptation:**
  Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury,Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage),Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia),Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis &Alkalosis,Electrolyte imbalance

- **Basic mechanism involved in the process of inflammation and repair:**
  Introduction, Clinical signs of inflammation, Different types of Inflammation,Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's,Mediators of inflammation,Basic principles of wound healing in the skin,Pathophysiology of Atherosclerosis

Unit II **10Hours**

- **Cardiovascular System:**
  Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial infarction, atherosclerosis and arteriosclerosis)
- **Respiratory system:**Asthma, Chronic obstructive airways diseases.
- **Renal system:**Acute and chronic renal failure

Unit II **10Hours**

- **Haematological Diseases:**
  Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia
- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- **Gastrointestinal system:** Peptic Ulcer
-

Unit IV **8 Hours**

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout
- **Principles of cancer:** classification, etiology and pathogenesis of cancer
- **Diseases of bones and joints:**Rheumatoid Arthritis, Osteoporosis,Gout

- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V **7 Hours**

- **Infectious diseases:**Meningitis,Typhoid, Leprosy, Tuberculosis

Urinary tract infections

- **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

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

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

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BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

I Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

II Determination of following oil values (including standardization of reagents)

- Acid value
- Saponification value
- Iodine value

III **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-Nitro salicylic acid/Meta di nitro benzene 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-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

- Study of all categories of microorganisms especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc..

Objectives: Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterilization in pharmaceutical processing and industry
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

Unit I **10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.
Introduction to Prokaryotes and Eukaryotes
Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).
Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

Unit II **10 Hours**

Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous,radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III **10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV **08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.
Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.
Assessment of a new antibiotic.

Unit V **07Hours**

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

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BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipments 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.

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

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BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

I. Determination of radiation constant of brass, iron, unpainted and painted glass.
II. Steam distillation – To calculate the efficiency of steam distillation.
III. To determine the overall heat transfer coefficient by heat exchanger.
IV. Construction of drying curves (for calcium carbonate and starch).
V. Determination of moisture content and loss on drying.
VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic andlogarithmic probability plots.
IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
XII. To study the effect of time on the Rate of Crystallization.
XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

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BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I	**Preparation of drugs/ intermediates**
1	1,3-pyrazole
2	1,3-oxazole
3	Benzimidazole
4	Benztriazole
5	2,3- diphenyl quinoxaline
6	Benzocaine
7	Phenytoin
8	Phenothiazine
9	Barbiturate
II	**Assay of drugs**
1	Chlorpromazine
2	Phenobarbitone
3	Atropine
4	Ibuprofen
5	Aspirin
6	Furosemide
III	**Determination of Partition coefficient for any two drugs**

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

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BP 502 T. Industrial Pharmacyl (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

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

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

3 hours/ week

UNIT-I **07 Hours**

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicoehemical characteristics of drug substances.

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

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

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

UNIT-II **10 Hours**

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. 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 **08 Hours**

Capsules:

a. ***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.

b. ***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, pelletization process, equipments for manufacture of pellets

UNIT-IV **10 Hours**

Parenteral Products:

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

b. Production procedure, production facilities and controls,
aseptic processing

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

d. 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.

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BP 506 P. Industrial Pharmacyl (Practical)

4 Hours/week

1. Preformulation studies on paracetamol/asparin/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 tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity 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)

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5th edition, 2005
9. Drug stability - Principles and practice by Carteusen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

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BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition,emphasis on the basic concepts of bioassay.

Objectives: Upon completion of this course the student should be able to

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

Course Content:

UNIT-I **10hours**

1. Pharmacology of drugs acting on cardio vascular system

a. Introduction to hemodynamic and electrophysiology of heart.
b. Drugs used in congestive heart failure
c. Anti-hypertensive drugs.
d. Anti-anginal drugs.
e. Anti-arrhythmic drugs.
f. Anti-hyperlipidemic drugs.

UNIT-II **10hours**

1. Pharmacology of drugs acting on cardio vascular system

a. Drug used in the therapy of shock.
b. Hematinics, coagulants and anticoagulants.
c. Fibrinolytics and anti-platelet drugs
d. Plasma volume expanders

2. Pharmacology of drugs acting on urinary system

a. Diuretics
b. Anti-diuretics.

UNIT-III **10hours**

3. Autocoids and related drugs

a. Introduction to autacoids and classification
b. Histamine, 5-HT and their antagonists.
c. Prostaglandins, Thromboxanes and Leukotrienes.
d. Angiotensin, Bradykinin and Substance P.
e. Non-steroidal anti-inflammatory agents
f. Anti-gout drugs
g. Antirheumatic drugs

UNIT-IV **08hours**

5. Pharmacology of drugs acting on endocrine system

a. Basic concepts in endocrine pharmacology.
b. Anterior Pituitary hormones- analogues and their inhibitors.
c. Thyroid hormones- analogues and their inhibitors.
d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
d. Insulin, Oral Hypoglycemic agents and glucagon.
e. ACTH and corticosteroids.

UNIT-V **07hours**

5. Pharmacology of drugs acting on endocrine system

a. Androgens and Anabolic steroids.
b. Estrogens, progesterone and oral contraceptives.
c. Drugs acting on the uterus.

6. Bioassay

a. Principles and applications of bioassay.
b.Types of bioassay
c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamine and 5-HT

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BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

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BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives: Upon completion of the course, the student shall be able

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I **7 Hours**

Metabolic pathways in higher plants and their determination

a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II **14 Hours**

General introduction, composition, chemistry & chemical classes, biosources, 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

a) Terpenoids: Menthol, Citral, Artemisin
b) Glycosides: Glycyrhetinic acid & Rutin
c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine
d) Resins: Podophyllotoxin, Curcumin

UNIT-IV **10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Semnoside, 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.

BP 508 P. 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 phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

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BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

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

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT – I **10 Hours**

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II **10 Hours**

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding. Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV **08 Hours**

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V **07 Hours**

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

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BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

1 Sulphanilamide

2 7-Hydroxy, 4-methyl coumarin

3 Chlorobutanol

4 Triphenyl imidazole

5 Tolbutamide

6 Hexamine

II Assay of drugs

1 Isonicotinic acid hydrazide

2 Chloroquine

3 Metronidazole

4 Dapsone

5 Chlorpheniramine maleate

6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition,emphasis on the principles of toxicology and chronopharmacology.

Objectives: Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisoningsand
3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hours**

1. Pharmacology of drugs acting on Respiratory system

a. Anti -asthmatic drugs
b. Drugs used in the management of COPD
c. Expectorants and antitussives
d. Nasal decongestants
e. Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

a. Antiulcer agents.
b. Drugs for constipation and diarrhoea.
c. Appetite stimulants and suppressants.
d. Digestants and carminatives.
e. Emetics and anti-emetics.

UNIT-II **10hours**

3. Chemotherapy

a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III **10hours**

3. Chemotherapy

a. Antitubercular agents

b. Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08hours**

3. Chemotherapy

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V **07hours**

5. Principles of toxicology

a. Definition and basic knowledge of acute, subacute and chronic toxicity.

b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

c. General principles of treatment of poisoning

d. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

6. Chronopharmacology

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

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BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

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BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I **11 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

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

UNIT-II **7 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: Alfaalfa, 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: Hypericum, 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:
a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
b) 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.

BP 609 P. 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

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

PHARMACY - GIET

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BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

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

- understand the cGMP aspects in a pharmaceutical industry
- appreciate the importance of documentation
- understand the scope of quality certifications applicable to pharmaceutical industries
- understand the responsibilities of QA & QC departments

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

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopocia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

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BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT –II **10 Hours**

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III **10 Hours**

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT –IV **08 Hours**

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

UNIT –V **07 Hours**

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

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BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2. Estimation of dextrose by colorimetry
3. Estimation of sulfanilamide by colorimetry
4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5. Assay of paracetamol by UV- Spectrophotometry
6. Estimation of quinine sulfate by fluorimetry
7. Study of quenching of fluorescence
8. Determination of sodium by flame photometry
9. Determination of potassium by flame photometry
10. Determination of chlorides and sulphates by nephelo turbidometry
11. Separation of amino acids by paper chromatography
12. Separation of sugars by thin layer chromatography
13. Separation of plant pigments by column chromatography
14. Demonstration experiment on HPLC
15. Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

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

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I **10 Hours**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

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BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

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 implantsand 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

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary 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

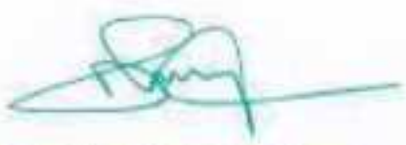
Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

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. Eneyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience 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, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)



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BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

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

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

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

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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 regressionmodels

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V **7Hours**

Design and Analysis of experiments:

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

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

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit I **10 Hours**

Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.

Unit II **10 Hours**

Product decision:

Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III **10 Hours**

Promotion:

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations; online promotional techniques for OTC Products.

Unit IV **10 Hours**

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V **10 Hours**

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

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BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

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

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- 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 Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

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

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

Unit II **10 hours**

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08 hours**

Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

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BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course Content:

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT-II **10 Hours**

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III **10 Hours**

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

UNIT-IV **08 Hours**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V **07 Hours**

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics.Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro Ikovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

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BP809ET. COSMETIC SCIENCE(Theory)

45Hours

UNIT I **10Hours**

Classification of cosmetic and cosmeceutical products

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

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

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II **10 Hours**

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages.Application of these products in formulation of cosmecuticals.

Antiperspants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner,anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

UNIT IV **08 Hours.**

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps,and syndet bars. Evolution and skin benfits.

UNIT V **07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

References

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

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

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and researchmethodology
- Design and execute a research hypothesis independently

Unit –I	**08 Hours**
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	**10 Hours**
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. **Study of screening animal models for** Diuretics, nootropics, anti-Parkinson's,antiasthmatics, **Preclinical screening models:** for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

Unit –III **Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	
Unit –IV **Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data	**05 Hours**

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

PHARMACY - GIET SCHOOL OF

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BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

Course Content:

UNIT-I **10 Hours**

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II **10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, structural elucidation and applications.

UNIT-III **10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV **08 Hours**

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V **07 Hours**

Hyphenated techniques- LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

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INDUSTRIAL PHARMACY (MIP)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP 101T)

(Note: Common Paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and 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, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

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. **10 Hours**

Unit 3:

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. **10 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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 methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

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d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 102T)

(Common paper for MPH and MIP specializations)

Unit 1:

Drug absorption from the gastrointestinal tract and other routes of administration: Mechanisms and factors affecting drug absorption from different routes, influence of pH–partition theory on drug absorption. Factors affecting dissolution rate and its process, Noyes-Whitney equation. dissolution testing methods for solids - tablets, capsules and for suspensions. Correlation of in vivo and in vitro dissolution data. **12 Hours**

Unit 2:

Biopharmaceutical considerations in drug product design and in vitro drug product performance. Introduction - biopharmaceutical factors affecting bioavailability, rate limiting steps in drug absorption, physicochemical nature of drug, formulation factors affecting drug product performance. In vitro dissolution and drug release testing, dissolution test apparatus and methods as per IP and USP for different types of drug delivery systems, design of dissolution testing for conventional and controlled release products. Data handling and correction factor, bio relevant media, similarity and dissimilarity factors f_1 & f_2, alternative methods of dissolution testing, problems of variable control in dissolution testing performance of drug products. Drug product stability during dissolution testing, in vitro evaluation of drug release from different dosage forms. **12 Hours**

Unit 3:

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model - IV bolus, IV infusion, extra-vascular. Multi compartment models in brief, calculation of parameters in two compartment models. Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of k_m and V_{max}. Concept of clearance and its applications. Problems related to the above. **12 Hours**

Unit 4:

Drug Product Performance: Bioavailability and bioequivalence, drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods, protocol design for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, biocquivalence

example, study submission and drug review process. In vitro - in vivo correlations in protocol design, levels of correlation, biopharmaceutical classification system, methods. Permeability: Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

Unit 5:

Application of pharmacokinetics: Modified-release drug products, targeted drug delivery systems and biotechnological products. Significance of pharmacokinetic and pharmacodynamic drug interactions in the design of the modified release products. **12 Hours**

REFERENCES

1. Pharmacokinetics - Milo Gibaldi. 2nd ed.
2. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel. 5th ed.
3. Biopharmaceutics and Clinical Pharmacokinetics - Robert E. Notari. 4th ed.
4. Modern Pharmaceutics - Gilbert S. Banker, Christopher T. Rhodes. 4th ed.
5. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
6. Drug Disposition and Pharmacokinetics - Stephen H Curry. 3rd ed.
7. Current Concepts in the Pharmaceutical Sciences:Biopharmaceutics - James Swarbrick
8. Current Concepts in the Pharmaceutical Sciences:Dosage Form Design and Bioavailability - James Swarbrick.

NOVEL DRUG DELIVERY SYSTEMS (MIP 103T)

Unit 1:

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for drug delivery: Polymers/co-polymers, introduction, classification, characterization, polymerization techniques, application in CDDS/NDDS, biodegradable & natural polymers. **12 Hours**

Unit 2:

Study of various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, mucoadhesive DDS (buccal, nasal, pulmonary) pulsatile, colon specific, liquid sustained release systems, ocular delivery systems

Transdermal drug delivery systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. **12 Hours**

Unit 3:

Targeted drug delivery systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions. **12 Hours**

Unit 4:

Protein/peptide drug delivery systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

Biotechnology in drug delivery systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy. **12 Hours**

tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control. **12 Hours**

Unit 5:

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, their. monitoring & prevention systems. Industrial effluent testing and treatment. Control of environmental pollution. **12 Hours**

REFERENCES

1. Pharmaceutical Process Validation - Fra R. Berry & Robert A. Nash. Vol 57. 2nd ed. Marcel Dekker, NY.
2. Pharmaceutical Production Facilities, Design and Applications – G.C. Cole. Taylor and Francis.
3. Pharmaceutical Project Management - T.Kennedy. Vol 86, Marcel Dekker, NY.
4. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A Lieberman & Joseph L Karig, Varghese Publishing House, Bombay.
5. Tablet Machine Instruments in Pharmaceuticals – P.R. Watt. John Wiley & Sons.
6. Pharmaceutical Dosage Forms: Tablets - Herbert A Lieberman & Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
7. Pharmaceutical Dosage Forms : Disperse Systems - Herbert A Lieberman, Martin M Rieger & Gilbert S Banker, Vol 1 – 3. Informa Healthcare.
8. Pharmaceutical Dosage Forms : Parenteral Medication – Sandeep Nema & John Ludwig, Vol 1 – 3. 3rd ed. Informa Healthcare.
9. Pharmaceutical Production and Management – C.V.S. Subrahmanyam. Vallabh Prakashan, Dehli, 2007.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP 202T)

Unit 1:

Improved tablet production: Tablet production process, unit operation improvements, granulation and pelletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered. **12 Hours**

Unit 2:

Parenteral production: Area planning and environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. **12 Hours**

Unit 3:

Lyophilization and spray drying technology: Principles, process, freeze-drying and spray drying equipment. **12 Hours**

Unit 4:

Capsule production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Disperse systems production: Production processes, applications of mixers, mills, disperse equipment including fine solids dispersion, problems encountered. **12 Hours**

Packaging technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms. **12 Hours**

methods, Joint venture, co-ordination and feasibility study. **12 Hours**

Unit 5:

Preparing project proposal to start on new enterprise project work – feasibility report. Planning, resource mobilization and implementation. **12 Hours**

REFERENCES

1. Entrepreneurship for Women in India - M.M.P. Akhauri. NIESBUD, New Delhi, 1990.
2. The Women Entrepreneurs - R.D. Hisrich, & C.G. Brush. D.C. Health & Co., Toranto, 1996.
3. Entrepreneurship: Starting, Developing and Managing a New Enterprise – Robert A Hisrich & Michael P Peters. 4th ed. McGraw Hill Education, 1997.
4. Practice of Entrepreneurship – G.G. Meredith, Robert E Nelson & Philip A Neck. ILO, Geneva, 1982.
5. Women Entrepreneurship – Developing New Entrepreneurs - V.C. Patel. Entrepreneurship Development Institute of India, Ahmedabad, 1987.

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 204T)

Unit 1:

Preformulation studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination. **12 Hours**

Unit 2:

Formulation additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development. **12 Hours**

Unit 3:

Solubility: Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. **12 Hours**

Unit 4:

Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in vitro and in vivo correlations, levels of correlations. **12 Hours**

Unit 5:

Product stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines. **12 Hours**

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A Lieberman & Joseph L Karig. Varghese Publishing House, Bombay.
2. Martin's Physical Pharmacy and Pharmaceutical Sciences - Patrick J Sinko. 6th ed. BI Publications Pvt. Ltd.

3. Pharmaceutical Dosage Forms: Tablets - Herbert A Lieberman & Leon Lachman. Volume 1 - 3. Marcel Dekker, Inc.
4. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances - Ellis Horwood Ltd., England, 1998.
5. Techniques of Solubilization of Drugs – S.H. Yalkowsky. Vol - 12. Marcel Dekker Inc., New York, 1981.
6. Pharmaceutical Dissolution Testing – J. Dressman & J. Kramer. Saurah Printers Pvt. Ltd., New Delhi, 2005.
7. Drug Stability Principles and Practices – J.T. Carstensen & C.T. Rhodes. CBS Publishers, New Delhi, 2005.
8. Stability of Drugs and Dosage Forms – S. Yoshioka & V.J. Stella. Springer (India) Pvt. Ltd., New Delhi, 2006.
9. Modern Pharmaceutics - Gilbert S. Banker, Christopher T Rhodes. 4th ed.
10. Stability Testing of Drug Products - W. Grimm.
11. International Stability Testing – D.J. Mazzo. Eastern Press Pvt. Ltd., Bangalore,
12. Indian Pharmacopoeia-2018. Controller of Publication. Delhi.
13. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2017.
14. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2019.
17. Encyclopedia of Pharmaceutical Technology – James Swarbrick. Vol 1-3.
18. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances - J. I. Wells. Ellis Horwood Ltd. England, 1988.

INDUSTRIAL PHARMACY PRACTICAL - III (MIP 205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of paracetamol (Animal)
5. Pharmacokinetic and IVIVC data analysis by WinNolin® software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension
12. Formulation and evaluation of enteric coating tablets
13. Preparation and evaluation of a freeze dried formulation
14. Preparation and evaluation of a spray formulation

Study of ICH Q8. Quality by design and process development report.

Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools (FMEA, fish bone diagram), HACCP, risk ranking and filtering according to ICH Q9 guidelines. **12 Hours**

Unit 5:

Statistical process control (SPC): a) Definition and importance of SPC. Quality measurement in manufacturing, statistical control charts - concepts and general aspects, Advantages of statistical control, process capability, estimating inherent or potential capability from a control chart analysis, measuring process control and quality improvement, pursuit of decreased process variability. b) regulatory compliance through quality management and development of quality culture benchmarking: Definition of benchmarking, reasons for benchmarking, types of benchmarking, benchmarking process, advantages of bench marking, limitations of benchmarking. **12 Hours**

REFERENCES

1. Juran's Quality Handbook - Joseph M Juran & Joseph A De Feo. 6th ed. ASQ Publications.
2. Implementing Juran's Road Map for Quality Leadership and Results - Al Endres. John Wiley & Sons.
3. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases - Jiju Antony. David Preece, Routledge, 2002.
4. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report - Edward E Lawler, Susan Albers Mohrman & George Benson. Jossey-Bass, 2001.
5. Corporate Culture and the Quality Organization - James W Fairfield-Sonn.
6. The Quality Management Sourcebook: An International Guide to Materials and Resources - Christine Avery & Diane Zabel. Routledge, 1997.
7. The Quality Toolbox - Nancy R. Tague. 2nd ed. ASQ Publications.
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action - Duke Okes. ASQ Publications, 2009.
9. Pharmaceutical QA and Management - Quality Management System for APIs – K.P. Bhusari.

PHARMACEUTICAL VALIDATION (MQA 103T)

(Note: Common paper for MPA and MQA specializations)

Unit 1:

Introduction to validation: Definition of calibration, qualification and validation, scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of validation, scope of validation, organization for validation, validation master plan, types of validation, streamlining of qualification & validation process and validation master plan.

Qualification: User requirement specification, design qualification, factory acceptance test (FAT)/site acceptance test (SAT), installation qualification, operational qualification, performance qualification, re-qualification (Maintaining status-calibration preventive maintenance, change management). **12 Hours**

Unit 2:

Qualification of analytical instruments/Equipment: Training & qualification of analyst. qualification of UV-visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, and dissolution test apparatus. **10 Hours**

Unit 3:

Validation of utility systems: Pharmaceutical water system, HVAC system, compressed air and nitrogen. Facility qualification, AHU validation, clean room validation.

Cleaning validation: Cleaning method development, sampling techniques, validation of analytical method used in cleaning. Cleaning of equipment, cleaning of facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5, LIMS, audit trail and data integrity. **12 Hours**

Unit 4:

Process validation: Concept, process and documentation of process validation. Prospective, concurrent & retrospective validation, re validation criteria, process validation of various formulations (coated tablets, capsules, ointment/creams, liquid orals and aerosols).

Aseptic filling: Media fill validation, USFDA guidelines on process validation- A life cycle approach.

Analytical method validation: General principles, validation of analytical method as per ICH guidelines (Q2A) and USP. Preparation & qualification of working standards and reference standards. **12 Hours**

Unit 5:

General principles of intellectual property: Concepts of intellectual property (IP), intellectual property protection (IPP), intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property – patents, copyright, trademark; factors affecting choice of IP protection; penalties for violation; role of IP in pharmaceutical industry; global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types of patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; rights and responsibilities of a patentee; practical aspects regarding maintaining of a patent file; patent infringement meaning and scope. Significance of transfer of technology (TOT), IP and ethics-positive and negative aspects of IPP; societal responsibility, avoiding unethical practices. **14 Hours**

REFERENCES

1. Pharmaceutical Process Validation - B. T. Loftus & R. A. Nash. Drugs and Pharm Sci. Series, Vol. 129, 3rd ed. Marcel Dekker.
2. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A Lieberman & Joseph L Kanig, Varghese Publishing House, Bombay.
3. Validation of Aseptic Pharmaceutical Processes - Carleton & Agalloco. 2nd ed. Marcel Dekker.
4. Pharmaceutical Process Scale-Up - Michael Levin, Drugs and Pharm. Sci. Series, Vol. 157, 2nd ed. Marcel Dekker.
5. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider.
6. Validation of Pharmaceutical Processes: Sterile Products - Frederick J Carlton and James Agalloco. 2nd ed. Marcel Dekker.
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A Cloud, Interpharm Press.
8. Analytical Method Validation and Instrument Performance Verification - Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang. Wiley Inter Science.

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8. The process of New Drug Discovery and Development - Charles G Smith, James T & O. Donnell. CRC Press.
9. Pharmaceutical Product Development - Vandana V Patrevale, John I Disouza & Maharukh T Rustomji. CRC Press.
10. Dissolution, Bioavailability and Bio-Equivalence - H.M. Abdou. Mack Publishing.
11. Guide Book for Drug Regulatory Submissions - Sandy Weinberg.

PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – I (MQA 105P)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV- Vis spectrophotometer.
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry.
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 or AAS
7. Case studies on
   - Total Quality Management
   - Six Sigma
   - Change Management/ Change control. Deviations,
   - Out of Specifications (OOS)
   - Out of Trend (OOT)
   - Corrective & Preventive Actions (CAPA)
   - Deviations
8. Development of Stability study protocol
9. Estimation of process capability.

PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL -II (MQA 106P)

1. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
2. Assay of raw materials as per official monographs
3. Testing of related and foreign substances in drugs and raw materials
4. To carry out pre-formulation study for tablets, parenterals (2 experiments).
5. To study the effect of pH on the solubility of drugs, (1 experiment)
6. Quality control tests for Primary and secondary packaging materials
7. Accelerated stability studies (1 experiment)
8. Improved solubility of drugs using surfactant systems (1 experiment)
9. Improved solubility of drugs using co-solvency method (1 experiment)
10. Determination of pKa and Log p of drugs.

Second Semester

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)

Unit 1:

Multidisciplinary nature of environmental studies: Natural resources, renewable and non-renewable resources, natural resources and associated problems: a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources

parenterals, ophthalmic and surgical products. Quality control test for containers, closures and secondary packing materials. **12 Hours**

Unit 4:

Documentation in pharmaceutical industry: Three tier documentation, policy, procedures and work instructions, and records (Formats), basic principles - how to maintain, retention and retrieval etc. Standard operating procedures (how to write), Master Formula Record, Batch Manufacturing Record, quality audit plan and reports. Specification and test procedures, protocols and reports, distribution records, Electronic data handling, Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). **12 Hours**

Unit 5:

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. **12 Hours**

REFERENCES

1. Quality Assurance Guide by Organization of Pharmaceutical Procedures of India. 3rd Revised ed. Vol I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations - Sandy Weinberg Vol 69. 2nd ed. Marcel Dekker.
3. Quality Assurance of Pharmaceuticals - A Compedium of Guidelines and Related Materials. Vol 1 & 2. 2nd ed. WHO Publications, 1999.
4. How to Practice GMP's – P.P. Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excipients and Dosage forms. Vol 1-5. 3rd ed. WHO, Geneva, 2005.
6. Good Laboratory Practice Regulations – Allen F. Hirsch. Vol 38, Marcel Dekker.
7. ICH guidelines
8. ISO 9000 and Total Quality Management
9. The Drugs and Cosmetics Act 1940 – Deshpande & Nilesh Gandhi. 4th ed. Susmit Publishers.
10. QA Manual – D.H. Shah. 1st ed. Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals; A Plan for Total Quality Control – Sidney H Willig. Vol. 52. 3rd ed. Marcel Dekker.
12. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers - Steinborn L. Vol 1 - With Checklists and Software Package. 6th ed. Taylor & Francis.
13. Quality Systems and Controls for Pharmaceuticals – D.K. Sarker. John Wiley & Sons, 2008.

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

Unit 1:

Pharmaceutical industry developments: Legal requirements and licenses for API and formulation industry. Plant location and plant layout, factors influencing. Special provisions, storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost,

process planning, routing, loading, scheduling, dispatching of records, production control.

12 Hours

Unit 2:

Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for dosage forms: Ointment, suspension and emulsion, dry powder, solutions, sterile dosage forms (small volume & large volume).

Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Process automation in pharmaceutical industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP),

Monitoring of parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), prefilled syringe, powdered jet, needle free injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment **12 Hours**

Unit 3:

Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in-process-quality control tests for non-sterile solid dosage forms: Tablets (compressed & coated), capsules (hard & soft).

Advanced non-sterile solid product manufacturing technology: Process automation in pharmaceutical industry with specific reference to manufacturing of tablets and coated products.

Improved tablet production: Tablet production process, granulation and palletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered. **12 Hours**

Unit 4:

Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil /plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material. **12 Hours**

Unit 5:

Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, advantages, elements of QbD, terminology: QTPP, CMA, CQA, CPP, RLD, design space, design of experiments, risk assessment and mitigation /minimization. Quality by Design, formulations by design, QbD for drug products, QbD for drug substances, QbD for excipients, analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

12 Hours

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A.
11

Lieberman & Joseph L Karig, Varghese Publishing House, Bombay.
2. Martin's Physical Pharmacy and Pharmaceutical Sciences - Patrick J Sinko. 6th ed. BI Publications Pvt. Ltd.
3. Pharmaceutical Dosage Forms : Tablets - Herbert A Lieberman & Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
4. Modern Pharmaceutics - Gilbert S Banker & Christopher T. Rhodes. 4th ed.
5. Good Manufacturing of Pharmaceuticals (A Plan for Total Quality Control) - Sidney H Willig, M. Murray, Tuckerman & Williams Hitchings IV. 3rd ed. Bhalani Publishing House, Mumbai.
6. Indian Pharmacopoeia-2018. Controller of Publication. Delhi.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2017.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2019.
9. Pharmaceutical Packaging Technology – D.A. Dean, E.R. Evans & I.H. Hall. 1st ed. Taylor & Francis, London.
10. Pharmaceutical Packaging Handbook - Edward J Bauer. Informa Health Care USA Inc., 2009.
11. Pharmaceutical Manufacturing Handbook - Shaybe Cox Gad. John Willey and Sons.

PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – III (MQA 205P)

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO_2 using Colorimetric method
7. Qualification of following Pharma equipment
   - Autoclave
   - Hot air oven
   - Powder Mixer (Dry)
   - Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

3. Oxford Textbook of Clinical Pharmacology - Graham Smith.
4. Avery Drug Treatment - Trevor M Speight & Nicholas H G Holford.
5. Dipiro Pharmacology, Pathophysiological approach.
6. Robbins & Cortan Pathologic Basis of Disease. 9th ed. (Robbins Pathology)
7. Essentials of Medical Pharmacology – K.D. Tripathi.
8. Modern Pharmacology with Clinical Applications - R. Craig Charles & E. Stitzel Robert. Lippincott.
9. Modern Pharmacology – C.R. Craig & R.E. Stitzel. Little Brown & Company.
10. Green Pathophysiology for Pharmacists.
11. A Complete Text Book of Medical Pharmacology - S.K. Srivastava. APC Avichal Publishing.

PHARMACOKINETICS AND DRUG METABOLISM (MPL 103T)

Unit 1:

ADME: Transfer of drugs through biological membranes (BBB, placental barrier), role of P-glycoprotein in drug absorption. Gastrointestinal, percutaneous and rectal absorption, factors affecting drug absorption, absorption kinetics, distribution kinetics (plasma protein binding, tissue binding). **12 Hours**

Unit 2:

Drug metabolism: Microsomal and non-microsomal biotransformation of drugs (liver, kidney and intestine), human cytochrome P450 enzymes, substrates, inducers and inhibitors. In vitro drug metabolism (liver microsomes, liver S9 fraction and hepatocytes). Physiological, pathological and genetic factors affecting drug metabolism. **12 Hours**

Unit 3:

Routes of drug excretion, factors affecting drug excretion, enterohepatic recirculation, significance of elimination rate constant, elimination half-life. **12 Hours**

Unit 4:

Clinical pharmacokinetics, population pharmacokinetic, PK-PD modeling, therapeutic drug monitoring (TDM), and dug-drug interactions, drug food and predictions of drug-drug interactions. **12 Hours**

Unit 5:

Toxicokinetics: Toxicokinetic evaluation in pre-clinical studies, importance and applications of toxicokinetic studies, alternative methods to animal toxicity studies. **12 Hours**

REFERENCES

1. Biopharmaceutics and Pharmacokinetics - An Introduction - Robert E Notari.
2. Drug metabolism - Bernard Testa & Peter Jenner.
3. Selected Chapters from: Principles of Drug Action - Gldstein, Aranow & Kalman.
4. Drug Interaction - D.G. Grahme Smith
5. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.
6. Goodman and Gillman's The Pharmacological Basis of Therapeutics. 10th ed.
7. Hand book of Clinical Pharmacokinetics - Gibaldi and Prescott.
8. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel & Andrew B C Yu.
9. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
10. Applied Biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug Delivery.

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12. Basic Cell Culture (Practical Approach) - J. M. Davis.
13. Animal Cell Culture: A Practical Approach - John R Masters.
14. Current Protocols in Molecular Biology - Frederick M. Ausuvel et al. Vol 1 to 6.

PHARMACOLOGY PRACTICAL – I (MPL 105P)

1. Enzyme based in vitro assays (MPO, AChEs, α amylase, α glucosidase)
2. Handling of laboratory animals
3. Various routes of drug administration.
4. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software
5. Enzyme inhibition and induction activity
6. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
7. Extraction of drug from various biological samples and estimation of drug in biological fluids using different analytical techniques (HPLC)
8. Predictions of drug - drug interactions using software

PHARMACOLOGY PRACTICAL – II (MPL 106P)

1. Functional observation battery tests (modified Irwin test).
2. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
3. Evaluation of analgesic & anti-inflammatory.
4. Evaluation of local anesthetic, mydriatic and miotic activity.
5. Evaluation of diuretic activity.
6. Evaluation of antiulcer activity models
7. Estimation of glucose and lipid parameters in blood samples.
8. Estimation of lipid levels in tissues.
9. Oral glucose tolerance test, oral fat tolerance test.

Second Semester

ADVANCED PHARMACOLOGY – II (MPL 201T)

Unit 1:

Chemotherapy: Basic concepts of chemotherapy, pharmacology of antibacterial resistance, pharmacology of antibacterial agents – β – lactams, aminoglycosides, tetracyclins, chloramphenicol, macrolide antibiotics, fluoroquinolines, antitubercular, antileprotic, antiprotozoal (antimalarial, asntiamoebics., etc.) and anthelmintics. **12 Hours**

Unit 2:

Antiviral, antifungal, anticancer drugs: Drugs acting on immune disorders (rhematoid arthritis, asthma, COPD), immunosupressants. **12 Hours**

Unit 3:

Endocrine pharmacology: Pharmacology of hormones (hormones of hypothalamic pituitary axis), pancreatic hormones, pharmacology of antithyroid drugs, oral contraceptives, oral hypoglycemic drugs, corticosteroids, drugs affecting calcium regulation. **12 Hours**

Unit 4:

GIT pharmacology: Antiulcer drugs, antiemetics, antidiarrhoeals, drugs used for intestinal bowel disorders (IBD) and constipation.

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Respiratory Pharmacology: Antiasthmatics, cough suppressants, expectorants and drugs used in COPD. **12 Hours**

Unit 5:

Autacoid pharmacology: Physiological and pathological role of histamines, serotonin, prostaglandins, kinins, interleukins, substance P, neuropeptides, NFkβ. Pharmacology of antihistamines, 5 HT antagonists. Concept of chronopharmacology, circadian rhythm and its applications. **12 Hours**

REFERENCES

1. Goodman and Gillman's The Pharmacological Basis of Therapeutics. 10th ed.
2. Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy - David E Golan, Armen H Tashjian Jr, Ehrin J Armstrong & April W Armstrong. Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology - B.G. Katzung
4. Rang and Dale's Pharmacology - James Ritter, Rod Flower, Graeme Henderson, Yoon Kong Loke, David MacEwan & Humphrey Rang
5. Text book of Therapeutics, Drug and Disease Management - E T. Herfindal & Gourley.
6. Robbins & Cortan Pathologic Basis of Disease, 9th ed. (Robbins Pathology)
7. A Complete Text Book of Medical Pharmacology - S.K. Srivastava. APC Avichal Publishing.
8. Essentials of Medical Pharmacology - K.D. Tripathi.
9. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy - David E Golan, H. Armen, Tashjian Jr, J. Ehrin, Armstrong, W. April & Armstrong. Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
10. Relevant Research and Review articles

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS (MPL 202T)

Unit 1:

Laboratory animals/Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications. Anesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA, OECD, ICH, EPA guidelines to conduct experiments on animals. Good laboratory practice. Bioassay - Principles, scope and limitations and methods of Immunoassays. **12 Hours**

Unit 2:

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. **12 Hours**

CNS Pharmacology: Behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis. Screening of drugs acting on Autonomic Nervous System

Unit 3:

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Respiratory pharmacology: Anti-asthmatics, drugs for COPD and anti-allergics. **Reproductive pharmacology:** Aphrodisiacs and antifertility agents. Analgesics, anti-

inflammatory and antipyretic agents.

Gastrointestinal drugs: Anti-ulcer, anti-emetic, anti-diarrheals and laxative. **12 Hours**

Unit 4: Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Cardiovascular pharmacology: Antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods. **12 Hours**

Unit 5:

Toxicity studies (acute, sub acute and chronic) oral, inhalation and dermal toxicity studies. Reproductive toxicity – Teratogenicity, genotoxicity (Ames test, in vitro, in vivo micronucleus, chromosomal aberrations) carcinogenicity. Introduction to IND Studies.

12 Hours

REFERENCES

1. Biological Standardization - J.H. Burn, D.J. Finney & I.G. Goodwin.
2. Screening Methods in Pharmacology - A. Robert Turner.
3. Evaluation of Drugs Activities - Laurence & Bachrach.
4. Fundamentals of Experimental Pharmacology - M.N. Ghosh.
5. Pharmacological Experiments on Intact Preparations - Churchill Livingstone
6. Drug Discovery and Evaluation – H.G. Vogel.
7. Experimental Pharmacology - R.K. Goyal.
8. Handbook of Experimental Pharmacology – S.K. Kulkarni
9. Practical Pharmacology and Clinical Pharmacy - S.K. Kulkarni, 3rd ed.
10. Screening Methods in Pharmacology - Robert A Turner.
11. Rodents for Pharmacological Experiments - Tapan Kumar Chatterjee.
12. Practical Manual of Experimental and Clinical Pharmacology - Bikash Medhi & Ajay Prakash.
13. Methods in Pharmacology - Arnold Schwartz.
14. Preclinical Evaluation of New Drugs - S.K. Guta.
15. Animal Models in Cardiovascular Research - David R Gross, 2nd ed. Kluwer Academic Publishing.
16. OECD Test Guidelines.
17. Relevant Research and Review articles and guidelines

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Unit 1:

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation. **12 Hours**

Unit 2:

Role of Genomics, proteomics and bioinformatics. Role of nucleic acid microarrays, protein microarrays, antisense technologies, siRNAs, antisense oligonucleotides, zinc finger proteins. Role of transgenic animals in target validation. Lead identification - combinatorial chemistry & high throughput screening, in silico lead discovery techniques. Assay development for hit identification. **12 Hours**

Unit 3:

Rational drug design - Traditional vs. rational drug design. Methods followed in traditional drug design. High throughput screening, Concepts of rational drug design. **12 Hours**

Unit 4:

Rational drug design methods: Structure and pharmacophore based approaches. Molecular docking - rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of structure activity relationship. **12 Hours**

Unit 5:

Prodrug design: Basic concept, prodrugs to improve patient acceptability. Drug solubility, drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design. **12 Hours**

REFERENCES

1. Target Discovery and Validation Reviews and Protocols - Emerging Molecular Targets and Treatment Options - Mouldy Sioud. Vol 2. Humana Press Inc., 2007.
2. Silico Technologies in Drug Target Identification and Validation - Darryl León. Scott Markel In., 2006. Taylor and Francis Group, LLC.
3. Disease Gene Identification: Methods and Protocols - Johanna K DiStefano. Springer New York Dordrecht Heidelberg, London.
4. QSAR: Hansch Analysis and Related Approaches: Methods and Principles in Medicinal Chemistry - Hugo Kubiny. Wiley-VCH.
5. Structure - Based Ligand Design: Methods and Principles in Medicinal Chemistry - Klaus Gubernator & Hans-Joachim Böhm. Wiley-VCH.
6. Rational Drug Design: Novel Methodology and Practical Applications - Abby L Parrill. M. Rami Reddy. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. New Drug Development Design, Methodology and Analysis - J. Rick Turner. John Wiley & Sons, Inc., New Jersey.
8. Relevant Research and Review articles and guidelines

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Unit 1:

Regulatory perspectives of clinical trials: Origin and principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.

Ethical committee: Institutional Review Board, ethical guidelines for biomedical research and human participant - Schedule Y. ICMR informed consent process: structure and content of an informed consent process, ethical principles governing informed consent process.

12 Hours

Unit 2:

Clinical trials: Types and design of experimental study- RCT and non RCT.

Observation study: Cohort, case control, cross sectional clinical trial study - Team roles and responsibilities of clinical trial personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management. **12 Hours**

Unit 3:

Clinical trial documentation: Guidelines to the preparation of documents, preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report.

Clinical trial monitoring - Safety monitoring in clinical trial adverse drug reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions;

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Terminologies of ADR. **12 Hours**

Unit 4:

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance. Significance of safety monitoring. Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance, guidelines for ADR reporting, Argus, Aris G Pharmacovigilance, Vigi Flow. Statistical methods for evaluating medication safety data. Methods, ADR reporting and tools used in pharmacovigilance. **12 Hours**

Unit 5:

Pharmacoepidimology and pharmacoeconomics: Definition and scope, measurement of outcomes, Pharmacoepidimology methods, Definition evaluation and applications of pharmacoeconomic methods. **12 Hours**

REFERENCES

1. Central Drugs Standard Control Organization - Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health, 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials - David Machin, Simon Day & Sylvan Green. John Wiley and Sons, March 2005.
5. Clinical Data Management – R.K. Rondels, S.A. Varley & C.F. Webbs. 2nd ed. Wiley Publications. Jan 2000.
6. Handbook of Clinical Research - Julia Lloyd & Ann Raven. Churchill Livingstone.
7. Principles of Clinical Research - Giovanna di Ignazio & Di Giovannaand Haynes.
8. Relevant Research and Review articles and guidelines

PHARMACOLOGY PRACTICAL – III (MPL 205P)

1. Recording of rat BP, heart rate and ECG
2. Recording of rat ECG
3. Drug absorption studies by averted rat ileum preparation
4. Acute oral toxicity studies as per OECD guidelines
5. Acute dermal toxicity studies as per OECD guidelines
6. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies
8. Protocol design for clinical trial.(3 Nos.)
9. To record the DRC of agonist using suitable isolated tissues preparation
10. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation
11. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation
12. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation

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design, levels of correlation, biopharmaceutical classification system, methods. Permeability: Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

Unit 5:

Application of pharmacokinetics: Modified-release drug products, targeted drug delivery systems and biotechnological products. Significance of pharmacokinetic and pharmacodynamic drug interactions in the design of the modified release products. **12 Hours**

REFERENCES

1. Pharmacokinetics - Milo Gibaldi. 2nd ed.
2. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel. 5th ed.
3. Biopharmaceutics and Clinical Pharmacokinetics - Robert E Notari. 4th ed.
4. Modern Pharmaceutics - Gilbert S. Banker, Christopher T Rhodes. 4th ed.
5. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
6. Drug Disposition and Pharmacokinetics - Stephen H Curry. 3rd ed.
7. Current Concepts in the Pharmaceutical Sciences : Biopharmaceutics - James Swarbrick
8. Current Concepts in the Pharmaceutical Sciences:Dosage Form Design and Bioavailability - James Swarbrick.

MODERN PHARMACEUTICS (MPH 103T)

Unit 1:

Preformulation Concepts – Drug excipient interactions-different methods, kinetics of stability, stability testing. Theories of dispersion and pharmaceutical dispersion (emulsions and suspensions, SMEDDS) preparation and stability. Large and small volume parenterals – physiological and formulation consideration, manufacturing and evaluation.

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. **12 Hours**

Unit 2:

Validation: Introduction to pharmaceutical validation, scope & merits of validation. Validation and calibration of master plan, ICH & WHO guidelines for calibration and validation of equipment, validation of specific dosage form, types of validation. Government regulations, manufacturing process model, user requirement specifications (URS), design qualification (DQ), installation qualification (IQ), operational qualification (OQ) & performance qualification (PQ) of facilities. **12 Hours**

Unit 3:

cGMP & industrial management: Objectives and policies of current good manufacturing practices (cGMP), layout of buildings, services, equipment 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 (TQM). **12 Hours**

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Unit 4:

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

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. **12 Hours**

Unit 5:

General principles of intellectual property rights (IPR): IP protection, economic importance, mechanism of protection. Patents, criteria, types of patent application-steps, trademarks and copy rights. **12 Hours**

REFERENCES

1. The Theory and Practice of Industrial Pharmacy - Leon Lachman, H.A. Lieberman & Joseph L Kanig. 3rd ed. Varghese Publishing, 1991.
2. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy - Roop K Khar, S.P. Vyas, Farhan J Ahmad & Gaurav K Jain. 4th ed. CBS Publishers, New Delhi.
3. Quality Assurance of Pharmaceuticals – WHO. Vol. 1 & 2. Pharma Book Syndicate.
4. Pharmaceutical Product development - N.K. Jain. CBS Publishers, New Delhi.
5. Law relating to Drugs & Cosmetics - Vijay Malik. Eastern Book Company.

PHARMACEUTICS PRACTICAL - I (MPH 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV - Visible spectrophotometer.
2. Colorimetric analysis of aspirin.
3. Kinetic studies of aspirin degradation.
4. Molecular weight determination of polymers by viscosity method.
5. Preparation of granules, drying by conventional dryer and fluidized bed dryer and comparing the granules by their flow property.
6. HPLC analysis of any one drug.
7. GMP audit requirements as per CDSCO.
8. Preparation of check-lists for registration of IND as per ICH CTD format.
9. Preparation of check-lists for registration of NDA as per ICH CTD format.
10. Preparation of check-lists for registration of ANDA as per ICH CTD format.
11. To carry out pre formulation studies of tablets.
12. To study the effect of Compression force on tablets disintegration time.

PHARMACEUTICS PRACTICAL - II (MPH 106P)

1. Improvement of dissolution of drugs by solid dispersions, cyclo dextrin complexation etc.
2. Effect of ointment base on drug diffusion using agar plate method and diffusion membrane.
3. To study the effect of particle size on dissolution of a tablet.
4. To study the effect of binders on dissolution of a tablet.
5. To plot Heckel plot, Higuchi and Peppas plot and determine similarity factors.
6. Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.
7. Protein binding studies of a highly protein bound drug and poorly protein bound drug.

8. Absorption kinetics of paracetamol in goat intestine (ex vivo study)
9. Pharmacokinetic and IVIVC data analysis by WinNonlin® Software (Demo).
10. In vitro cell studies for permeability and metabolism (Demo).
11. Effect of surfactant on drug dissolution using BCS II drugs.

Second Semester

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (MPH 201T)

Unit 1:

Targeted drug delivery systems: Concepts, events and biological process involved in drug targeting. Tumor targeting and brain specific delivery. **12 Hours**

Unit 2:

Targeting Methods: Introduction, preparation, evaluation and application of nano particles & liposomes. **12 Hours**

Unit 3:

Micro capsules/micro spheres: Types, preparation, evaluation and applications of monoclonal antibodies, niosomes, aquasomes, phytosomes, electrosomes. **12 Hours**

Unit 4:

Pulmonary drug delivery systems: Aerosols, metered dose inhalers, dry powder inhalers, propellants, containers, types, preparation and evaluation. Intra nasal route delivery systems; types, preparation and evaluation. **12 Hours**

Unit 5:

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 antisense molecules and aptamers as drugs of future. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems – Y.W. Chien. 2nd ed. (Revised and expanded). Marcel Dekker.
2. Controlled Drug Delivery: Concepts and Advances - S.P. Vyas & R.K. Khar. 1st ed. Vallabh Prakashan, New Delhi.
3. Controlled and Novel Drug Delivery - N.K. Jain. 1st ed. CBS Publishers, New Delhi, 1997.

DRUG DELIVERY SYSTEMS (MPH 202T)

Unit 1:

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, bioelectronic medicines, 3D printing of pharmaceuticals, tele pharmacy. **12 Hours**

Unit 2:

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;

Unit 4:

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

Computer simulations in pharmacokinetics and pharmacodynamics: Introduction. Computer simulation: Whole organism, isolated tissues, organs, cell, proteins and genes.

12 Hours

Unit 5:

Artificial intelligence (AI): Concepts and applications, robotics. Computational fluid dynamics: General overview and applications. Pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. Current challenges and future directions.

12 Hours

REFERENCES

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

PHARMACEUTICAL AND COSMETIC PRODUCT DEVELOPMENT (MPH 204T)

Unit 1:

Preformulation studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies by TLC, DTA, DSC and TGA spectral studies, formulation additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. **12 Hours**

Unit 2:

Solubility: Importance, experimental determination, phase solubility analysis, pH-solubility profile, techniques to improve solubility of drugs and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy, methods of characterization. **12 Hours**

Unit 3:

Product stability: Mechanisms of degradation and protection, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf-life assignment. Stability protocols, reports and ICH guidelines. **12 Hours**

Unit 4:

Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. **12 Hours**

Unit 5:

Cosmetics: Formulation, manufacturing and quality control methods of following cosmetic products. Hair care products - Shampoos, hair dyes, shaving products and depilatories. Dental hygiene products: Tooth paste, mouth washes. Skin care products: Hand cream, cleansing

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Unit 2:

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles - stationary phases and mobile phases.

Gas chromatography: Derivatization, head space sampling, analytical method development and quantification. **12 Hours**

Unit 3:

Super critical fluid chromatography: Principle, instrumentation, pharmaceutical applications.

Capillary electrophoresis: General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation & its applications.

12 Hours

Unit 4:

Mass spectrometry: LC-MS hyphenation and DART MS analysis. Mass analyzers (Quadrupole, Time of flight, FT-ICR, Ion Trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap. **12 Hours**

Unit 5:

NMR spectroscopy:

Brief outline of principles of NMR &FT-NMR. Spin-spin and spin-lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, interpretation and qualitative and quantitative applications of NMR spectroscopy. LC-NMR hyphenations. ICP-MS, ICP-OES, PES, TOC Analysis, KF titration, melting point determination using advanced instrumentation. **12 Hours**

REFERENCES

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
5. Quantitative Analysis of Pharmaceutical Formulations by HPTLC – P.D. Sethi. CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern Methods – Part B – J.W. Munson. Vol 11, Marcel Dekker Series.
8. Organic Spectroscopy - Donald L Paviya. 5th ed.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Unit 1:

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the bioanalytical methods such as protein precipitation, liquid - liquid extraction and solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines. **12 Hours**

Unit 2:

Biopharmaceutical consideration: Introduction, in vitro: dissolution and drug release

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. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs

PHARMACEUTICAL ANALYSIS PRACTICAL - II (MPA 106P)

1. Calibration of glassware
2. Calibration of pH meter
3. Calibration of UV-Visible spectrophotometer
4. Calibration of FTIR spectrophotometer
5. Calibration of GC instrument
6. Calibration of HPLC instrument
7. Cleaning validation of any one equipment
8. Determination of total reducing sugar
9. Determination of proteins
10. Determination of saponification value, iodine value, peroxide value, acid value in food products
11. Determination of fat content and rancidity in food products
12. Analysis of natural and synthetic colors in food
13. Determination of preservatives in food
14. Determination of pesticide residue in food products
15. Analysis of vitamin content in food products
16. Determination of density and specific gravity of foods
17. Determination of food additives.
18. Analysis of vanillin content in foods
19. Analysis of oxalate content in guava fruit
20. ELISA & CLIA – demonstration
21. IMVIC test - Indole test, methyl red test, Voges-Proskauer test, citrate utilization test

Second Semester

ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Unit 1:

HPLC: Principle, analytical method development, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, new developments in HPLC-role and principles of ultra, nano liquid chromatography, and preparative HPLC in pharmaceutical analysis. Advancement in enantiomeric separations, Immobilized polysaccharide CSP's and HILIC approaches.

cream, foundation creams. **12 Hours**

REFERENCES

1. Harry's Cosmeticology. 8th ed.
2. Poucher's Perfumes, Cosmetics & Soaps – Hilda Butler. 10th ed. Kluwer Academic Publishers.
3. Cosmetics - Formulation, Manufacture and Quality Control – P.P. Sharma. 4th ed.
4. Hand Book of Cosmetic Science and Technology - A.O. Barel, M. Paye & H.I. Maibach. 3rd ed.
5. Cosmetic and Toiletries Recent Suppliers' Catalogue.
6. CTFA Directory.

PHARMACEUTICS PRACTICAL – III (MPH 205P)

1. To perform in vitro dissolution profile of Controlled release or Sustained release marketed formulation.
2. Formulation and evaluation of sustained release matrix tablets.
3. Formulation and evaluation of osmotically controlled DDS.
4. Preparation and evaluation of Floating DDS- Hydro dynamically balanced DDS.
5. Formulation and evaluation of Muco-adhesive tablets.
6. Formulation and evaluation of transdermal patches.
7. To study the effect of temperature change, non solvent addition, incompatible polymer addition in micro capsule preparation.
8. Formulation and evaluation of microspheres.
9. Formulation and evaluation of liposomes or niosomes.
10. Demonstration statistical designing in formulation development through QBD approach.
11. Development and evaluation of Creams.
12. Development and evaluation of Shampoo and Tooth paste.
13. Effect of surfactant on the solubility of drugs.
14. Effect of pH on the solubility of drugs.
15. Stability testing of drugs in dosage forms at 25°C/60% RH and 40°C/75% RH and determine the shelf life.
16. Compatibility evaluation of drugs and excipients (DSC & FTIR).

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9. Validation Master Plan - Terveeks or Deeks. Davis Harwood International Publishing.

FOOD ANALYSIS (MPA 104T)

Unit 1:

Carbohydrates: Classification and properties of food carbohydrates, general methods of analysis of food carbohydrates, changes in food carbohydrates during processing, digestion, absorption and metabolism of carbohydrates. Dietary fiber, crude fiber and application of food carbohydrates.

Proteins: Chemistry and classification of amino acids and proteins, physico-chemical properties of protein and their structure, general methods of analysis of proteins and amino acids. **12 Hours**

Unit 2:

Lipids: Classification, general methods of analysis, determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: Classification of vitamins, principle & microbial assays of vitamin-B_1, B_2 & B_{12}. **12 Hours**

Unit 3:

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, non-permitted synthetic dyes used by industries, method of detection of natural, permitted and non-permitted dyes. **12 Hours**

Unit 4: General analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar. **12 Hours**

Unit 5:

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA. FSSAI guidelines-special emphasis on mycotoxins, microbiology, antibiotic residues in foods. HACCP (Biological, Physical & Chemical hazards), Regulatory aspects of CODEX Alimentarius. **12 Hours**

REFERENCES

1. The Chemical Analysis of Foods – David Pearson. 7th ed. Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical Analysis of Foods – S. Nielsen. Jones & Bartlett Publishers, Boston, London, 1994.
3. Official Methods of Analysis of AOAC International. 6th ed. Volume 1 & 2. 1997.
4. Analysis of Food Constituents – Multon. John Wiley & Sons.
5. Official methods of analysis of AOAC International - Dr. William Horwitz. 18th ed. 2005.

PHARMACEUTICAL ANALYSIS PRACTICAL - I (MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV-Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

9. The Drugs and Cosmetics Act 1940 – Deshpande & Nilesh Gandhi. 4th ed. Susmit Publishers.
10. QA Manual – D.H. Shah 1st ed. Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals; A Plan for Total Quality Control – Sidney H. Willig. Vol. 52. 3rd ed. Marcel Dekker.
12. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers - Steinborn L (Volume 1 - With Checklists and Software Package). 6th ed. Taylor & Francis.
13. Quality Systems and Controls for Pharmaceuticals – D.K. Sarker. John Wiley & Sons, 2008.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Unit 1:

Herbal remedies: Toxicity and regulations: Herbals vs. conventional drugs, Efficacy of herbal medicine products, validation of herbal therapies, pharmacodynamics and pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol. **12 Hours**

Unit 2:

Adulteration and deterioration: Introduction, types of adulteration/substitution of herbal drugs, causes and measure of adulteration, sampling procedures, determination of foreign matter, DNA finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

12 Hours

Unit 3:

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, adulterant screening using modern analytical instruments, stability testing of natural products, protocol. Monographs of herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American Herbal Pharmacopoeia, British Herbal Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

12 Hours

Unit 4:

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. **12 Hours**

Unit 5:

Evaluation of cosmetic products: Determination of moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Schedule S: Standards for cosmetics. Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards. **12 Hours**

REFERENCES

1. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy - Kokate, Purohit & Gokhale.
3. Quality Control Methods for Medicinal Plant, WHO, Geneva.
4. Pharmacognosy & Pharmacobiotechnology - Ashutosh Kar.
5. Essential of Pharmacognosy - S.H.Ansari.
6. Cosmetics – Formulation, Manufacturing and Quality Control - P.P. Sharma. 4th ed. Vandana Publications Pvt. Ltd., Delhi.
7. Indian Standard Specification for Raw Materials, BIS, New Delhi.
8. Indian Standard Specification for 28 Finished Cosmetics BIS, New Delhi.
9. Harry's Cosmeticology. 8th ed.
10. Suppliers Catalogue on Specialized Cosmetic Excipients.
11. Poucher's Perfumes, Cosmetics & Soaps – Hilda Butler. 10th ed. Kluwer Academic Publishers.
12. Handbook of Cosmetic Science and Technology. 3rd ed.

PHARMACEUTICAL ANALYSIS PRACTICAL - III (MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward - Fiesure rule
2. Interpretation of organic compounds by FTIR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FTIR, NMR, CNMR and mass spectra
7. In process and finished product quality control tests for tablets, capsules, parenterals and creams
8. Quality control tests for primary and secondary packing materials
9. Assay of raw materials as per official monographs
10. Bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by gel electrophoresis.
11. Bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by HPLC techniques
12. Isolation of analgesics from biological fluids (blood, serum and urine)
13. Protocol preparation and performance of analytical/bio analytical method validation
14. Protocol preparation for the conduct of BA/BE studies according to guidelines
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record
17. Preparation of Batch Manufacturing Record
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and developer in hair dye
20. Determination of foam height and SLS content of shampoo
21. Determination of total fatty matter in creams (soap, skin and hair creams)
22. Determination of acid value and saponification value
23. Determination of calcium thioglycolate in depilatories

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

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:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.
8. Determination of
   (a) Blood Pressure.
   (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardiovascular system.
   (d) Respiratory system.

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(e) Digestive system.
(f) Urinary system.
(g) Nervous system.
(h) Special senses.
(i) Reproductive system.

10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastroenemius sciatic nerve preparation.
14. To record simple summation curve using gastroenemius sciatic nerve preparation.
15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.
17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	**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).

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1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. **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.

2. **Upon the completion of the course the student should be able to:**
   a. know the formulation aspects of different dosage forms;
   b. do different pharmaceutical calculation involved in formulation;
   c. formulate different types of dosage forms; and
   d. appreciate the importance of good formulation for effectiveness.

3. **Course materials:**

   Text books
   a. Cooper and Gunns Dispensing for pharmacy students.
   b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

   Reference books
   a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
   b. Remington's Pharmaceutical Sciences.
   c. Register of General Pharmacy by Cooper and Gunn.
   d. General Pharmacy by M.L.Schroff.

4. **Lecture wise programme:**

   Topics

   1 a. Introduction to dosage forms - classification and definitions
   b. Prescription: definition, parts and handling
   c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
   2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
   3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
   4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
   5 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.
   6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

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7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
10 Pharmaceutical calculations.
11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

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

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