MASTER OF PHARMACY
SEMESTER I: Pharmaceutics

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and Clinical Evaluation	4
PHA-PG-103T	Biopharmaceutics & Pharmacokinetics	4
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-103P	Biopharmaceutics & Pharmacokinetics	2
22		

SEMESTER I: Pharmaceutical Chemistry

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and Clinical Evaluation	4
PHA-PG-104T	Pharmaceutical Chemistry-I (Organic)	4
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-104P	Pharmaceutical Chemistry-I (Organic)	2
22		

SEMESTER I: Pharmacognosy

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and Clinical Evaluation	4
PHA-PG-105T	Advanced Pharmacognosy and	4

	Phytochemistry	
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-105P	Advanced Pharmacognosy and Phytochemistry	2
22		

SEMESTER I: Pharmacology

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and Clinical Evaluation	4
PHA-PG-106T	Pharmacology & Toxicology	4
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-106P	Pharmacology & Toxicology	2
22		

SEMESTER I: Pharmaceutical Analysis & Quality Assurance

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and Clinical Evaluation	4
PHA-PG-107T	Applied Pharmaceutical Analysis	4
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-107P	Applied Pharmaceutical Analysis	2
22		

SEMESTER I: Pharmacy Practice

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and Clinical Evaluation	4
PHA-PG-108T	Hospital & Clinical Pharmacy	4
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-108P	Hospital & Clinical Pharmacy	2
22		

SEMESTER I: Pharmaceutical Biotechnology

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and Clinical Evaluation	4
PHA-PG-109T	Pharmaceutical Biotechnology	4
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-109P	Pharmaceutical Biotechnology	2
22		

SEMESTER I: Pharmaceutical Management

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and	4

	Clinical Evaluation	
PHA-PG-110T	Pharmaceutical Marketing	4
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-110P	Pharmaceutical Marketing	2
22		

SEMESTER I: Drug Development and Clinical Research

Code	Paper	Credit
PHA-PG-101T	Modern Pharmaceutical Analytical Techniques	4
PHA-PG-102T	Pharmacological Screening Methods and Clinical Evaluation	4
PHA-PG-111T	New Drug Development	4
PHA-PG-112T	Biodiversity in Eastern Himalayas	4
PHA-PG-101P	Modern Pharmaceutical Analytical Techniques	2
PHA-PG-102P	Pharmacological Screening Methods and Clinical Evaluation	2
PHA-PG-111P	New Drug Development	2
22		

SEMESTER II: Pharmaceutics

Code	Paper	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-202T	Preformulation and Production Management	4
PHA-PG-203T	Advances in Drug Delivery Systems	4
PHA-PG-220T	Research Methodology	4
PHA-PG-201P	Quality Assurance	2
PHA-PG-202P	Preformulation and Production Management	2
PHA-PG-203P	Advances in Drug Delivery Systems	2
22		

SEMESTER II: Pharmaceutical Chemistry

Code	Paper	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-204T	Pharmaceutical Chemistry-II (Drug Design)	4
PHA-PG-205T	Pharmaceutical Chemistry-III (Natural Products)	4
PHA-PG-220T	Research Methodology	4
PHA-PG-201P	Quality Assurance	2
PHA-PG-204P	Pharmaceutical Chemistry-II (Drug Design)	2
PHA-PG-205P	Pharmaceutical Chemistry-III (Natural Products)	2
22		

SEMESTER II: Pharmacognosy

Code	Paper	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-206T	Herbal Drug Technology	4
PHA-PG-207T	Medicinal Plant Biotechnology	4
PHA-PG-220T	Research Methodology	4
PHA-PG-201P	Quality Assurance	2
PHA-PG-206P	Herbal Drug Technology	2
PHA-PG-207P	Medicinal Plant Biotechnology	2
2 **2**		

SEMESTER II: Pharmacology

Code	Paper	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-208T	Biological Standardization and Screening Methods	4
PHA-PG-209T	Molecular Pharmacology & Drug Design	4
PHA-PG-220T	Research Methodology	4

PHA-PG-201P	Quality Assurance	2
PHA-PG-208P	Biological Standardization and Screening Methods	2
PHA-PG-209P	Molecular Pharmacology & Drug Design	2
22		

SEMESTER II: Pharmaceutical Analysis and Quality Assurance

Code	Paper	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-210T	Formulation Technology & Validation	4
PHA-PG-211T	Chemical & Biological Evaluation	4
PHA-PG-220T	Research Methodology	4
PHA-PG-201P	Quality Assurance	2
PHA-PG-210P	Formulation Technology & Validation	2
PHA-PG-211P	Chemical & Biological Evaluation	2
22		

SEMESTER II: Pharmacy Practice

Subject Code	Subject	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-212T	Pharmacotherapeutics-I	4
PHA-PG-213T	Pharmacotherapeutics-II	4
PHA-PG-220T	Research Methodology	4
PHA-PG-201P	Quality Assurance	2
PHA-PG-212P	Pharmacotherapeutics-I	2
PHA-PG-213P	Pharmacotherapeutics-II	2
22		

SEMESTER II: Drug Development and Clinical Research

Code	Paper	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-214T	Drug Discovery Process	4

PHA-PG-215T	Drug Delivery Approaches	4
PHA-PG-220T	Research Methodology	4
PHA-PG-201P	Quality Assurance	2
PHA-PG-214P	Drug Discovery Process	2
PHA-PG-215P	Drug Delivery Approaches	2
22		

SEMESTER II: Pharmaceutical Biotechnology

Code	Paper	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-216T	Bioprocess Technology	4
PHA-PG-217T	Pharmaceutical Biotechnology-II	4
PHA-PG-220T	Research Methodology	4
PHA-PG-201P	Quality Assurance	2
PHA-PG-216P	Bioprocess Technology	2
PHA-PG-217P	Pharmaceutical Biotechnology-II	2
22		

SEMESTER II: Pharmaceutical Management

Code	Paper	Credit
PHA-PG-201T	Quality Assurance	4
PHA-PG-218T	Pharmaceutical Management	4
PHA-PG-219T	Formulation Production Management	4
PHA-PG-220T	Research Methodology	4
PHA-PG-201P	Quality Assurance	2
PHA-PG-218P	Pharmaceutical Management	2
PHA-PG-219P	Formulation Production Management	2
22		

SEMESTER III: All Branches

Code	Paper	Project maximum marks	**Grand total**	Passing minimum marks	**Credit**

PHA-PG-301	Mid Semester Dissertation Report	200	**200**	100	

SEMESTER IV: All Branches

Code	Paper	Project maximum marks	**Grand total**	Passing minimum marks	**Credit**
PHA-PG-401	Final Dissertation Report	200	**200**	100	

PHA-PG-101:
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Common to all Branches)

Theory

1. UV-VISUAL SPECTROSCOPY: Brief review of electromagnetic spectrum, UV-Visual range, energy, wavelength and color relationships. Interaction of electromagnetic radiation (UV-Visible) with matter and its effects. Chromophores and their interaction with E.M.R. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs. Shifts and their interpretation (including solvent effects). Empirical correlation of structure with absorption phenomena (Woodward's rules etc) Quantitative estimations, Modern instrumentation.

2. INFRARED SPECTROSCOPY: Nature of Infra-red radiation. Interaction of I.R. radiation with organic molecules and effects on bonds. Molecular Infrared spectra. Brief outline of classical I.R. instrumentation and practical details of obtaining spectra, including sample preparation for spectroscopy, qualitative interpretation of I.R. spectroscopy including FT-IR, ATR.

3. OPTICAL ROTATORY DISPERSION: Fundamental principles of ORD. Cotton effect curves, their characteristics and interpretation. Octant rule and its application with examples. Circular dichroism and its relation to ORD.

4. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY: Fundamental principles of MNR (Magnetic properties of nuclei; applied field and precession; absorption and transition; frequency). Chemical shifts concept: Isotopic nuclei, Reference standards: Proton Magnetic spectra, their characteristics, presentation terms used in describing spectra and their interpretation (Signal No., Position and Intensity). Signal multiplicity phenomenon in higher resolution PMR. Spin-spin coupling. Application of Signal Split and coupling constant data to interpretation of spectra. Decoupling and shift reagent methods. Brief outline of principles of

FT-NMR with reference to 13CNMR: Spin- spin and spin-lattice relaxation phenomenon.

5. MASS SPECTROMETRY: Basic Principle and brief outline of Instrumentation. Ion formation and types; molecular ion, meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Chemical ionization Mass spectrometry. GC-MS, other recent advances in MS. Fast atom bombardment mass spectrometry.

6. CHROMATOGRAPHIC TECHNIQUES: Classification of chromatographic methods based on mechanism of separation. Paper chromatography; techniques and applications. Thin Layer chromatography, comparison to paper chromatography and HPLC, adsorbents TLC. Preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC detection methods, quantitative methods in TLC. Programmed multiple development techniques.

7. GAS CHROMATOGRAPHY: Instrumentation packed and open tabular column, Column efficiency parameters, the Vandeemeter equation, Resolution, liquid stationary phases, derivatization methods of GC including acylation, perfluoroacylation, alkylation and esterification. Detectors; FID, ECD, TCD, NPDA critical comparison of sensitivity and field of applications of these detectors, Examples of GC applications in pharmaceutical analysis.

8. LIQUID CHROMATOGRAPHY: Comparison of GC and HPCL, instrumentation in HPLC, Analytical, preparative and micro bore columns, normal and reserved-phase packing materials, Reserves phase HPLC refractive index, Photometric and electrochemical. Comparison of sensitivity and field of applications of these detectors. HPLC- instrumentation and applications.

9. ELECTROPHORESIS: Moving boundary electrophoresis, zone electrophoresis, Isotachophoresis, Isoelectric focusing and immunoelectrophores, continuous electrophoresis (preparative) application.

10. X-RAY DIFRACTION METHODS: Introduction, Generation of X- ray, Elementary crystallography, Miller Indices, X- ray diffraction, Bragg's law, X- ray powder diffraction, X-ray powder diffractometer, obtaining and interpretation of X- ray powder diffraction data.

Practical

Simultaneous estimation of Paracetamol and Ibuprofen; Aspirin and Caffeine; Rifampicin and Isoniazid or other combination formulation (4 expts).

U.V. Visible spectrum scanning of certain organic compounds- absorption and correlation of structures. Comparison e.g, Chloramphenicol, Analgin, Sulphadiazine, Ibuprofen

Comparison of three different analytical methods for Salbutamol or other drugs.

Experiments based on HPLC and G.C. (2 expt).

Workshop on spectroscopy structural elucidation of at least 5 unknown compounds.

IR, NMR and Mass spectroscopy (1 compound each)

Case studies on quality control lab planning and analytical reporting of materials, In-process and finished goods. Minor Experiments.

1. Effect of pH and solvent on U.V. Spectrum of certain drugs.
2. Two dimensional paper chromatography and TLC (Minor expt.)
3. Gradient elution and other techniques in column chromatography (Minor expt.)
4. Separation by electrophoresis.

5. Any other relevant exercises based on theory.

Books Recommended:

1. Spectrophotometric identification of organic compounds, Silverstein et.al (7th Edition, 1981).
2. Gupta S.C. and Kapoor C. K. Fundamentals of applied statistics
3. Indian Pharmacopoeia (Vol. I & II). 1996, 2007. New Delhi: Controller of Publication.
4. Clive, W. 1987. X- Ray methods. John Wiley and Sons.
5. Statistics by Gofeti Radhakrishna.
6. Bio Statistics by Sarkar.
7. Skoog, D.A., West, D.M. Fundamentals of Analytical Chemistry (6th Edition): West and James Holler.
8. Instrumental methods of analysis- Modern methods part- B, vol- 2 pages 11 to 154. Editor- James W. Munson, Drug and Pharm. Sciences Marcel Dekker.

PHA-PG-101(A): PHARMA DISEASE MANAGEMENT

Theory

1. Cell cycle, structure and functions of cell membrane, Communication between cells and their environment, Cell ageing, Gene expression and gene based therapy.

2. Drug-Receptor binding, ion channels and G-Protein coupled receptors, second messenger systems, receptor expression and regulation. Pharmacokinetics: The dynamics of drug absorption, distribution metabolism and elimination

3. Basic principles and mechanisms involved in:

Inflammation and anti-inflammatory agents

4. Etiopathogenesis and drug therapy in the management of:

a. CNS disorders: Anxiety disorders, mood disorders, schizophrenia
b. Degenerative disorders: Parkinsonism and Alzheimer's
c. CVS disorders: Anemia, Coagulation disorders, cardiac arrhythmias, hypertension,
d. CHF, angina pectoris, acute myocardial infarction, atherosclerosis
e. GIT disorders: Peptic ulcer and GERD
f. Endrocrine disorders: Diabetes
g. Respiratory disorders: Asthama and COPD
h. Musculoskeletal disorders: RA, gout, osteoporosis and osteoarthritis, ankylosing spondilitis

5. Chemotherapy of

STDs (HIV), Leprosy, Tuberculosis, Malaria, Amoebiasis, UTI, Neoplastic diseases

6. Drug discovery process

Principles, techniques and strategies used in new drug discovery

7. Pharmacy Ethics

Practical

Students shall carry out a project and submit a journal consisting of a write-up on project suggested for the year, which may include:

- Suggestion of disease management details for the suggested disease. Clinical case presentation.
- Survey of hospital to collect information regarding management of a given disease or disorder
- Survey to find presence of banned drugs in the retail outlet.
- Perception of doctors/nurses/chemists/patients towards a drug/disease/therapy, etc.
- Group Discussions and case studies based on theory.
- Solving Pharmacokinetic problems.

Books Recommended:

1. Pharmacology, 3rd edition, Rand H.P., Dale M. Mand Ritter J.M 1995 Churchill Livingstone
2. Basic and clinical pharmacology, 5th edition, Katzung B.G (Editor), 1992 McGraw Hill
3. Modern Pharmacology, 4th edition, Craig C.R and Stitzel R.E .editor, 1994 Little, Brown and
4. Company; New York and London.
5. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 9th edition. Hardman J.D
6. and Limbird L.E (editors-in chief), 1996 McGraw-Hill (medical publishing Division)
7. Text book of therapeutics, Drug and Disease Management, 6th edition. Herfindal E.T and
8. Gourley D.R Editors, 1996 Williams and Wilkins.
9. Principles of Pharmacology, Basic concepts and Clinical applications, Munson P.L(editor-in chief), 1995 Chapman and Hall (an International Thomson Publishing Company)

PHA-PG-102:
PHARMACOLOGICAL SCREENING METHODS AND CLINICAL EVALUATION
(Common to all branches)

Theory

1. Study of laboratory animals, Regulation and ethics requirements:
Transgenic animals and other genetically prone animal models (nude mice, SH rats).
Bioassay, basic & its principle, experimental models and statistical design employed in biological standardization.

2. Preclinical models employed in the screening of new drugs belonging to following categories :
Antipsychotic agents, Antianxiety agents, Nootropic agents, Anti-depressant drugs, analgesics, antiepileptic, models for status epilepticus , Anti-inflammatory agents, antiulcer drugs, anti-diarrhoeals, emetics, anti-emetics, antiathereosclerotic drugs, anti-diabetics, anti-hyperlipidemic, anti-obesity and hepatoprotective agents.

3. Drug developmental process;
Clinical trials, safety evaluation, preparation of IND/NDAs, statistical design in clinical trials.
International guidelines (ICH recommendation) GLP including GCP, ICMR guidelines.

4. Importance of alternatives experimental models-its advantages and disadvantages.

Practical

Bioassay of Acetylcholine/histamine using guinea pig ileum preparation.
Screening of anxiolytic drugs.
Screening of CNS Stimulants & depressant.

Screening of antiulcer drugs.
Screening of Anticonvulsants.
Experiments on Analgesic and Anti-inflammatory drugs.
Experiment on local anesthetics.
General screening methods for the anti-ulcer activity, intestinal motility, and anti-diarrheal activity.

Books Recommended:

1. Gerhard, H.G. 2008. Drug Discovery and Evaluation-Pharmacological Assays. Springer.
2. Ghosh, M.N. 2008. Fundamentals of Experimental Pharmacology. Kolkata: Hilton and Company.
3. Rowland, M. and Tozer, T.M. 2007. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, Lippincott Williams and Wilkins.
4. McLeod, L.J. 1970. Pharmacological Experiments in Intact preparations. Edinburgh University: Churchill Livingstone.
5. Kulkarni, S.K. 2011. HandBook of Experimental Pharmacology 3rd Edition. Pune: Vallabh Prakashan.
6. Turner, R.A. 1965. Screening Methods in Pharmacology. New York: Academic Press Inc.

PHA-PG-103:
BIOPHARMACEUTICS AND PHARMACOKINETICS

Theory

1 Bio-Pharmaceutics and pharmacokinetics: Introduction, General Principle & Application.
2 Absorption: Rate of drug absorption after administration, drug concentration in blood, biological factors in drug absorption, physicochemical factors, dosage form consideration for gastrointestinal absorption
3 Distribution: Factors affecting, protein binding, kinetics of protein binding
4 Excretion: Renal and non renal excretion, concept of clearance
5 Bioavailability and bio-equivalency testing: Definitions, dosage forms, dissolution rate and bio-equivalency testing.
6 Pharmacokinetics: Compartment models, a brief study of parameters like biological half-life, apparent volume of distribution, renal clearance, total body clearance, absorption, elimination rate constant and significance of the data.
7 Non-linear Pharmacokinetics: Causes of non-linearity, Michaelis-Menten equation, estimation of Km and Vmax

Practical

Bioavailability testing and other experiments to illustrate topics mentioned in theory.

Books Recommended:

1. Gibaldi, M. 1991. Biopharmaceutics and Clinical Pharmacokinetics. Philadelphia: Lea and Febiger.
2. Shargel, L and Yu, A.B.C. 1985. Applied Biopharmaceutics and Pharmacokinetics. Connecticut: Appleton Century Crofts.

3. Swarbrick, J. 1970.Current Concepts in Pharmaceutical Sciences: Biopharmaceutics. Philadephia: Lea and Febiger.
4. Rowland, M and Tozen, TM. 1995. Cilincal Pharmacokinetics, Concepts and Applications. Philadelphia: Lea and Febreger.
5. Abdou H.M. 1989. Dissolution, Bioavailability and Bioequivalence. Pennsylvania. Mack Publishing Company.

PHA-PG-104: PHARMACEUTICAL CHEMISTRY - I (Organic)

Theory

1. Mechanisms and Methods for Determination

Thermodynamic requirements for reaction, kinetics requirements forreaction, basic mechanistic concepts: Kinetics versus thermodynamic control.

Methods for determining mechanisms

i. Non Kinetic: Identification of products, determination of the presence of intermediate, isolation of an intermediate, detection of an intermediate, trapping of an intermediate and addition of suspected intermediate. Study of catalysis: isotopic labeling stereochemical evidences, crossover experiments.

ii. Kinetic studies: First order reactions, second order reactions, thirdorder reactions, determination of the order of reaction, reversible reactions.

2. STEREO CHEMISTRY

Elements of symmetry, plane of symmetry, centre of symmetry, alternating axis of symmetry, simple axis of symmetry, Kinds of molecule displaying optical activity, compound with chiral carbon atom, compounds with other quadrivalent chiral atoms, Compounds with tervalent chiral atoms suitably substituted adamantanes. Optical isomerism in compounds containing no chiral atom, Bipheneyl, allenes, compounds with exocylic double bonds, spiranes, chirality due to helical shape chirality caused by restricted rotation of other types. Cis-trans isomerism: resulting from double bonds, monocyclic compounds, fused ring systems, out-in isomerism. Enantiotropic and diastereotopic atoms and groups and faces, stereospecific and steroselective synthesis.

3. REACTIVE INTERMEDIATES IN ORGANIC SYNTHESIS:

a. Carbocation: formation, structure, stability, reactions involving
carbocations, rearrangement reactions like, Wagner-Meerwein, Pinacol-pinacolone and trans-annular rearrangements.

b. Carbanions: formation structure, stability, reactions involving
carbanions, Perkin, Claisen, Benzoin, Aldol condensation, Cannizzaro reaction and Favorskii rearrangement.

c. Free radicals: formation,structure, stability, detection, reactions
involving free radicals, addition to carbon-carbon multiple bonds.

d. Carbenes: formation structure, stability, reactions involving carbenes,
Reimer – Tiemen reaction, Wolff rearrangement, ring expansion reactions, conversion of pyrrole to pyridine.

4. AROMATIC NUCLEOPHILIC REACTIONS

Cyclohexadienyl anions and benzene mechanism (cine substitution)

5. CATALYSIS

a. Introduction, homogenous, heterogenenous catalysis enzyme catalysed reactions in the manufacture of drugs.

b. Phase transfer catalysis in anhydride, epoxide, ester, nitrile and sulfide formation in ester hydrolysis and reduction reactions

6. ELEMENTERY STUDY OF PERICYCLIC REACTIONS

Conversation of molecular orbital symmetry, electrocyclic reaction, cyclo addition reactions like, Diel's Alder reaction, Sigmatropic rearrangements (Frointier Molecular orbital method) Sommelet- Hauser, Cope rearrangements.

7. AN INTRODUCTION TO COMBINATORIAL CHEMISTRY:

i) Introduction to combinatorial Libraries. Concepts and terms

ii) Parallel Organic Synthesis Technology:

iii) Polymer-Supported Synthesis of Organic Compounds and Libraries.

iv) Macro Beads in New Solid-Phase Synthesis.

v) Combinatorial Libraries in Solution.

vi) Solid-Phase Methods in Combinatorial Chemistry.

Practical

1. Preparation of benzanilide from benzophenone (Beckmann rearrangement) Benzophenone → Benzophenoneoxime → Benzanilide.
2. Preparation of 2-Phenyl indole from accetophenone (Fischer indolisation) Actophenone → Acetophenonephenylhydrazine → 2- Phenylindole.
3. Preparation of Antipyrine from ethylactoacetateEthylacetoacetate → 3-Methyl-1-phenylpyrazol-5- one → 2, 3-Dimethyl-1 phenylphyrazol-5-one.
4. Preparation of dibromocinnamic acid from benzaldehyde (Perkin's reaction) Benzaldehyde → Cinnamic acid → Dibromocinnamic acid.
5. Preparation of 2, 5-dihydroxy acetophenone from acetophenone from hydroquinone (Fries rearrangement) Hydroquinone → Hydroquinone di acetate → 2,5-Dihydroxy acetophenone.
6. Preparation of Diethyl fumarate from maleic acid (conversion of cis isomer to trans isomer) Maleic acid → Fumaric acid → Diethyl fumarate.
7. Preparation of 2,2 –dihydroxy -1, 1-binapthyl from 2-naphthol (oxidation of 2-naphthol and free radical coupling)
8. Preparation of Benzilic acid from Benzil (Benzilic acid rearrangement)

Books Recommended:

1. Finar, I.L. 1973. Organic chemistry-the fundamental principle (6th ed.). New York: Addison-Wesley.
2. March, J. Advanced Organic Chemistry- Reactions, Mechanism and Structure. New York: Wiley Interscience Publication.
3. Mukherjee S. Singh S.P. Reaction Mechanisms in Organic Chemistry. (3rd ed.). New Delhi: McMillan India Ltd.
4. Sykes, P. A Guide Book to Mechanisms in Organic Chemistry. New Delhi: Orient Longman.
5. Physical Organic Chemistry – Jack Hine
6. Vogel's Text Book of practical organic Chemistry 4th ed. London: ELBS, Longman.
7. Wilson S.R. Czarnik, A. W. Combinatorial Chemistry- Synthesis and Applications. USA:Jhon Wiley.

8. Lednicher. Organic Chemistry of Synthic Drugs. New York: Wiley, Inter Science Publications.

PHA-PG-105:
ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY

Theory

1. Plant drug cultivation

Factor involved in production of crude drug: Exogenous, Edaphic factors, Mineral supplements, Nutrients, Growth regulators and inhibitors. Disease management of medicinal and aromatic plants**.** Profile for commercial cultivation technology and post harvest care of following medicinal plants-Ashwagandha, Periwinkle, Guggul, Senna, Digitalis. Technology for commercial scale cultivation and processing of following aromatic plants- Lemon grass, Geranium, Basil, Vetiver, Patchouli.

2. Detailed phytochemical study of following class of phytoconstitutes, including important drugs.

Terpenes and terpenoids, Resins and related compounds, Alkaloids, Glyocosides. Steroids.

3. Study of information retrieval methods of natural plants and herbal databases.

Screening and review of literature for the following activities: Anti-hepatoxics, Anti-microcials and Anti-Virals, Anti-cancer agents, Hypolipidaemics, Anti-diabetics, Cardiovascular agents.

4. Chemotaxonomy

Definition, Signification, types. Chemotaxonomic significance of flavonoids and alkaloids.

5. Biosynthetic studies

Shikkimic acid pathway-Atropine & Morphine. Acetate pathway-Cardiac glycosides & Anthraquinone glycosides.

6. Structural elucidation of important phytoconstituents belonging to different groups.

a. Alkaloids- Nicotine, Atropine, Morphine, Cafeine.
b. Glycosides- Amygdalin, Strophanthidin.
c. Steroids- Cholesterol
d. Terpenes- Citral.

7. Marine Pharmacognosy

Definition, present status, classification of important bioactive agents including their uses.

Practical

1. Phytochemical screening of plants extracts and Drugs.
2. Isolation, separation, purification, and identification of important phytoconstitutents belonging to different classes:

a. Starch, amylase and amylopectin.
b. Myristicin and trimyristicin from nutmeg.
c. Eugenol from clove
d. Stigmasterol from soyabean.
e. Lycopene from tomato.
f. Curcumin from turmeric.
g. Sennosides from senna.

h. Glycyrrhizin from glycyrrhiza.
i. Strychine and Brucine or quinine or caffeine or nicotine or piperine or hesperidine.
3. Antimicrobial screening of plants extracts and drugs.
4. Screening of drugs for the presence of enteric organisms.
5. Screening of drugs for their antimicrobial property.

3. DRUG ABSORPTION: Gastrointestinal, percutaneous and rectal pharmacokinetics. Factors affecting drug absorption.

Books Recommended:

1. Mukherjee, P.K. 2002. Quality Control on Herbal Drugs. New Delhi: Eastern Publishers (Business Horizons).
2. Mukherjee, P.K. & Houghton, P.J. 2009. Evaluation of Herbal Medicinal Products - Perspectives of Quality, Safety and Efficacy. Pharmaceutical Press, Royal Pharmaceutical Society of Great Britain.
3. Mukherjee, P.K & Verpoorte R. 2003. GMP in Herbal Drugs. New Delhi: Eastern Publishers (Business Horizons).
4. Jean Brunton, J. 1995. Pharmacognosy and Phytochemistry of medicinal plants. Lavoise: Techniques and documentation.
5. C.K. Kokate, C.K. & Purohit, Gokhlae. 1996. Text book of pharmacognosy. New Delhi: Nirali Prakashan.
6. Farooqui, A.A & Sreeramu, B.S. 2001. Cultivation of medicinal and aromatic crops. University Press.

PHA-PG-106: PHARMACOLOGY AND TOXICOLOGY

Theory/Practical

Common Laboratory Animals: breeding, maintenance, handling and CPCSEA regulation.

1. Evaluation of antidepressants and anxiolytics.
2. Analgesic, anti-inflammatory and anti-pyretic activity of drugs using suitable animal model.
3. Evaluation of local anesthetic effect of drugs.
4. Anticonvulsant activity of drugs.
5. Virtual /stimulated/computer-based experiments.
6. Effect of various drugs on rat/rabbit thoracic aorta (with or without endothelium).
7. Effect of various autonomic drugs on rat phrenic nerve diaphragm preparation.
8. Anti-arrhythmic activity in rats using ECG.
9. Monitoring of drug concentration in urine and blood.
10. Action of CNS stimulants and depressant using suitable experimental models.

Books Recommended:

1. Tripathi, K.D. 2014. Essentials of Medical Pharmacology 7TH Edition. New Delhi: Jaypee Publication.
2. Kulkarni, S.K. 2011. Hand Book of Experimental Pharmacology 3rd Edition. Pune: Vallabh Prakashan.
3. Brahmankar, D.M. and Jaiswal, S.B. 2012. Biopharmaceutics and Pharmacokinetics– A Treatise. New Delhi: Vallabh Prakashan.

4. Goodman, G. and Gilman, E. 2013. The Pharmacological Basis of Therapeutics 12th Edition. London: McGraw-Hill.
5. Katzung, B.G. 2012. Basic and Clinical Pharmacology 12th Edition. London: Lange.
6. Lippincotts, W. 2012. Illustrated Pharmacology 4th Edition. London: Lange.
7. Longo, D.; Fauci, A.; Kasper, D.; Hauser, S.; Jameson, J. and Loscalzo, J. 2011. Harrison's Principles of Internal Medicine. New York: McGraw-Hill.

PHA-PG-107: APPLIED PHARMACEUTICAL ANALYSIS

Theory

1. Application of instrumental methods: Application of instrumental methods in the development and use of medicines Introduction, product characterization for drug development, product development, production and Pharmacopoeial controls, concept of analytical method development.

2. Analysis of drugs and excipients: Analysis of drugs and excipients in the solid state Introduction, particle size analysis, importance of particle size in various dosage forms, methods of particle size analysis, x-ray power diffraction.

3. Light scattering methods in quantitative analysis: Turbidometry, Nephelometry

4. Light emission methods in quantitative analysis: Fluorimetry, b. Flame photometry

5. A detailed study of principles and procedures involved in various physico-chemical methods of analysis including instrumental methods of analysis of pharmaceutical dosage forms containing the following classes of drug: Sulphonamides, Barbiturates, Antitubercular drugs, Diuretics, Antimalarials, Analgesics and antipyretics.

6. Elemental analysis :

a. Elemental analysis – non-metals and metals

b. Principles and procedures involved in the quantitative determination of the following groups.

Carboxylic acid, Hydroxyl, Aldehyde, Amine

7. Principles and procedures involved in the pharmaceutical preparations and dosage forms containing the following groups of substances: Alkaloids, Glycosides, Vitamins, Antibiotics, Steroid hormones

8. Principles and procedures involved in the use of the following reagents in pharmaceutical Analysis:

MBTH (3-methyl-2-benzothiazone) reagent, FC (folin ciocalteu) reagent, 2,6-dichloroquinine monoamine reagent

1,2-naptha quinine-4-sulfonate reagent, Ninhydrine reagent, Bratton-Marshal reagent.

9.Analytical method validation Parameters: Spectrophotometric, HPLC and GC methods, statistical analysis and significance in analytical methods.

10. Quality control of radiopharmaceuticals and radiochemical methods in analysis.

Practical

1. Determination of chloride and sulphate in calcium gluconate by Nepheloturbidimetric analysis.
2. Estimation of drugs by fluorimetry
3. Study of quenching effect in fluorimetry – eg. Quenching of quinine fluorescence by Iodide ions.
4. Depermination of sodium/potassium by flame photometry.

5. Colourimetric estimation of sulphadiazine/sulphacetamide using N-(I-naphthyl) ethylene diamine di HCI.
6. Quantitative analysis of drug in multicomponent dosage forms.
7. Quantitative determination of the following groups: Hydroxyl, Carboxyl, Amine, Aldehydes
8. Quantitative colourimetric determination of any drug by using MBTH reagent.
9. Colourimetric estimation of Ferrous ions using 1, 10 –Phenanthroline.
10. Assay of paracetamol tablets, IP 1996.
11. Assay of Alprazolam tablets, IP 1996.
12. Identification and verification of standards for a sample of castor oil, IP 1996.
13. Identification and verification of standards for a sample of cetyl alcohol, IP 1996.
14. Identification of drugs using IR spectra.

Books Recommended:

1. A.I. Vogel: Textbook of Inorganic chemistry 4th edition, ELBS, Publications, London.
2. Becket and Stanlake: Pharmaceutical Chemistry, 3rd edition, Vol-I and II, CBS Publishers, New Delhi.
3. K.A. Connors: Text Book of Pharmaceutical Analysis, 3rd edition, Wiley-inter Science Publication, New York.
4. Sidney, Siggia: Quantitative organic analysis, 4th edition, Wiley interscience Publication, New York, Toronto.
5. P.D. Sethi: Quantitative analysis of drug in Pharmaceutical formulations, 2nd edition, CBS Publisher, New Delhi.
6. S.C. Gupta, V.K. Kapoor: Fundamentals of Applied Statistics.
7. Jhon.H.kennedy: Principles of analytical chemistry, 2nd edition, Saunders College Publishing, New York.
8. Jorg Augstin, Barbara P.Klien, Deborah Becker, Paul B: Methods of vitamin assay, 4th edition, Wiley interscience publications, John Wiley and Sons, New York.
9. David. G. Watson: Phermaceutical Analysis, Churchill Livingstone, Edinburg.
10. Indian Pharmacopoeia, 1996, The Controller of Publications, Govt. of India.

PHA-PG-108: HOSPITAL AND CLINICAL PHARMACY

Theory

1. Definition, development and scope of clinical pharmacy

2. Introduction to daily activities of a clinical pharmacist : Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions), Ward round participation, Adverse drug reaction management, Drug information and poisons information, Medication history, Patient counseling, Pharmaceutical care, Drug utilization evaluation (DUE) and review (DUR), Quality assurance of clinical pharmacy services.

3. Patient data analysis: The patient's cash history, its structure and use in evaluation of drug therapy and Understanding common medical abbreviations and terminologies used in clinical practices, Communication skills, including patient counseling techniques, medication history interview, presentation of cases. Teaching skills, Clinical laboratory tests used in the evaluation of disease states, and

interpretation of test results, Hematological, Liver function, renal function, thyroid function tests, Tests associated with cardiac disorders, Fluid and electrolyte balance, Microbiological culture sensitivity tests, Pulmonary Function Tests.

4. Drug and Poison information: Introduction to drug information resources available, Systematic approach in answering DI queries, Critical evaluation of drug information and literature, Preparation of writing and verbal report, Establishing a Drug Information Centre, Poison information- organization and information resources.

5. Clinical Pharmacokinetics: Clinical Pharmacokinetic models, Physiological determinants of drug clearance and volumes of distribution, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses, Doses adjustment in renal failure, hepatic dysfunction, geriatric and pediatric patients, Therapeutic Drug Monitoring (General aspects)

6. Clinical Application of Statistical Analysis: Basic concepts of biomedical statistics, Descriptive and Differential statistics, Statistical tests- Parametric and Non-parametric, Sample size calculation, Confidence intervals, Test of significance.

7. Research Design and Conduct of Clinical Trials: Research support including planning and execution of clinical trials, Guidelines for good clinical research practice and ethical requirements, Various Phases of clinical trials, Categories of Phase- IV studies, Monitoring and Auditing of Clinical Trials.

8.Hospital Pharmacy

8.1. The role of the hospital pharmacy and its department and its relationship to other hospital departments and staff.

8.2. Hospital drug policy Drug Committee, Formulary and guidelines, other hospital committees such as Infection Control Committee and Research and Ethics Committee.

8.3. Hospital Pharmacy management Staff (professional and non-professional), Materials (drugs, consumables), Financial (drug budget, cost center, sources of revenue, revenue collection), Policy and planning, Infrastructure requirements (building, furniture and fitting, specialized equipment, maintenance and repairs), Workload statistics.

8.4. Organism of hospital pharmacy services

8.4.1 Drug distribution

Purchasing, Warehousing (storage condition, expiry date control, recycling of drugs, stocktaking, drug recalls), Drug distribution methods (ward stock, individual patient dispensing, unit dose), Specific requirements for inpatients, outpatients, Casualty/Emergency, Operation Theatres, ICU/CCU, Drugs of departmendence, Hospital waste management.

8.4.2 Manufacturing

Sterile and non-sterile production, including total parenteral nutrition, Cytotoxis Radiopharmaceuticals, IV additive service, Prepackaging and labeling, Quality control.

8.4.3 Education and Training

Training of technical staff, Traning and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and the therapeutics news letter.

Ethical Issues in Biomedical Research-Principles of ethicsin biomedical research, good clinical practice [ICH GCP guidelines], Ethical committee [institutional review board], its constitution and functions, Ethics of publication.

Practical

Patient medication history interview, answering drug information questions, patient medication counseling, participation in ward rounds, Case studies related to laboratory investigations covering the topics dealt in theory class.

1. Answering drugs information questions (4) Queries related to Dosage, administration, Contraindications, Adverse drug reactions, drug use in pregnancy and lactation, drug profile, efficacy and safety).
2. Case studies related to laboratory investigations (4) LFT, Hematology, Thyroids, Renal, Cardiac enzymes) Patient medication history interview (2) Medication order review (2) Detection and assessment of adverse drug reaction and their documentation (3).

Books Recommended:

1. Scott, L.T. 2012.Basic skills in interpreting laboratory data. New Jersey. American Society of Health System Pharmacist. Inc.
2. Rowland, M and Tozer, T.2014. Clinical Pharmacokinetics. London. Williams and Wilkins Publication.
3. Hassan, W.E .2013.Hospital Pharmacy. Soudi Arabia. Lec and Fibiger publication.
4. Allwood, M.C and Fell, J.T.1999.Text book of hospital pharmacy. London. Blackwell Scientific Publications
5. Trevor, M and Nicolas, H.G.1997.Avery's Drug Treatment, 4th Edn. Adis International Limited.
6. David, B. T and Paul, B.2013.Remington pharmaceutical Sciences 21st Edition. London. Williams and Wilkins Publication.
7. Relevant review articles from recent medical and pharmaceutical literature.

PHA-PG-109: PHARMACEUTICAL BIOTECHNOLOGY – I

Theory

1. Structure and Chemistry of microbial cell.

2. Virus:

Structure, chemistry and replication, their importance in fermentation industry.

3. Classification of microbes:

Species concept, Principles of microbial taxonomy, numerical taxonomy, new approach to taxonomy-comparison of bacterial genotypes by genetic analysis.

4. Bacteria, Actinomycetes, Yeasts and Fungi:

Occurrence and distribution in nature, morphological, cultural, physiological and reproductive features, methods for isolation, cultivation and maintenance, selective isolation techniques; nomenclature and general classification systems; identification of industrially important genera.

5. Nutrition of microorganisms:

a. General considerations, substrate entry in to the cell, translocation.

b. Growth and death of microorganisms: General considerations; Physical and Chemical environment for microbial growth; batch and continuous culture, synchronous growth, growth cycle, growth stability and degeneration of microbial cultures on repeated transfer.

6.Metabolism:

Chemical links between energy yielding metabolism and biosynthesis, model of energy yielding metabolism, biochemistry of fermentations; aerobic respiration and anaerobic respiration, storage of energy, secondary metabolism- its importance in fermentation industry.

7.Genetics of industrial microorganism:

Bacteria, Streptomycetes and fungi, Mutation and selection in train improvement. Mechanisms of antibiotic resistance and the role of plasmids and actinophages.

8. Screening techniques:

Stock cultures, fermentation media, detection and assays of fermentation products.

9. Detailed critical study of the process technology of the following industriaiy important microbial metabolites:

a. Organic solvents (Alcohol, acctone, butanol)
b. Organic acids(Citric, lactic and gluconicacids) wine and beer.
c. Penicillin, Streptomycin, Tetracyclines, Erythromycin,*Griseofulvin, Neomycin, Cephalosporins*, Hcl*, Rafampicin.
d. Antitumour, antiviral and semi-synthetic antibiotics, Ergot alkaloids
e. Vitamins(Vitamin C, Vitamin B12 and riboflavin)
f. Alminoacids (Glutamic acid and Lysine)
g. Nucleotides (Cyclic AMP, GMP)
h. Microbial transformation of steroids, alkaloids and terpenes.
i. Ephendrine; L –Dopa
j. Dextrose from starch and cellulose substrates, prostagiandins, Microbial poly saccharides and surfactants.

10. Mixed culture fermentations:

Production of single biochemicals by plant and animal cell cultures, applications of animal cell culture.

11. Yeasts and its uses, production of single cell proteins, detailed considerations of following microbiological assays:

Streptomycin, vitamin B12 and Iysine. Fermentation and pharmaceutical effluents; treatment and legal requirements.

12. Introduction to patents and Secret Processes.

Practical

1. Study of Morphological features of bacteria, fungi, yeasts and actinomycetes.
2. Determination of cell-wall composition.
3. Determination of yield constant.
4. Replica plating
5. Isolation of microorganisms from soil and study of their biochemical properties.
6. Chromatographic identification of amino acids and sugars.
7. Production of ethyl-alcohol
8. Production of penicillin
9. Production of streptomicn
10. Production of gultamic acid
11. Production of wine
12. UV-Survival curve of micro organisms.
13. Test for coliform bacteria in water and milk
14. Antibiotic assay by cup-plate method.

Books Recommended:

1. Frobisher et al. 1999. Fundamental of Microbiology. Cambridge. Cambridge University Press.
2. Cook, A.H. 2010. Chemistry and Biology of Yeasts. London. Academic Press.
3. Sermonti, G. 2010. Genetics of Antibiotics producing micro-organisms. New York. Academic Press,
4. Rhodes, A and Fletcher, D.L.1997. Principle of Industrial Microbiology. Oxford. Pergamon Press.
5. Koflu, T and Hickey, L. 1997. Industrial Chemical Fermentations. New York. Publishing Co. Inc.
6. Sebek, O.K. and Laskin, A.I. 2001. Genetivs of industrial microorganisms. Sydney. International Symposium.
7. Solomons, G.L.1997. Materials and Methods in Fermentations. Oxford. Pergamon Press.
8. Perlman, D.2001. Fermentation Advances. Oxford. Black Well Scientific Publications.

PHA-PG-110: PHARMACEUTICAL MARKETING

Theory

1. Marketing concept: Role of marketing in today's organization, Specificities of pharmaceutical marketing, Identifying and classifying market, Understanding market behavior / consumer behavior, Task of marketing and planning, Marketing strategy at the portfolio level, Translating the portfolio strategy to the product level, Pharmaceutical market in India, Pharmaceutical industry scenario

2. Analyzing marketing opportunities: Market measurement and forecasting, Market Information System- analysis and interpretation of marketing data, application and uses.

3. Marketing strategy: Strategy statement, Target audience specification, Promotional concept, Promotional plan, Material preparation, Distribution strategy, Product distribution plan

4. Market Segmentation, Targeting and Positioning

Market Segmentation: Definition and approaches to segmenting a market, Base for segmenting a pharmaceutical market, Advantage and drawbacks of segmentation

Market Targeting: Evaluation the Market Segments, Target Market Selection

Product Positioning: Definition, types of Positioning, Positioning Strategies

5. Understanding the product and its market: Market definition, Market size, volumes, Patent and other laws applicable to product, Drugs and magic remedies act, Other ethical aspects of promotion and advertisements, Product life cycle, SWOT analysis, Product strategy

6. Launching product: Creating hype about launch, Launching with a bang, Monitoring launch, Analyzing launch plan vs. actual field working, Feedback at various levels on launching

7. Planning marketing tactics: Product, brand, packing and service decisions, Pricing decisions – DPCO, National Drug policy, Financial implications of marketing

8. Marketing channel decisions and perspective of distribution function: Role of distribution manager in pharmaceutical marketing efforts, Inventory control, cash control and debtor control, Physical distribution and logistic support, Management of distribution- stockists, wholesalers and retailers, Role of computers in distribution control system, Management of institutional business of Govt. /Private large hospital.

9. Communication and Promotion –Mix Decisions

a. Marketing communication and the communication process
b. Barriers and gateways to communication in marketing of Pharmaceuticals
c. Sources of marketing communications
d. Understanding promotional decisions
e. Elements of promotional mix and deciding on the promotional mix
f. Principles of medical advertising
g. Pharmaceutical promotional materials

10. Competitor analysis: Competitive structure of the pharmaceutical industry, Process of competitive analysis, Competitive pricing analysis, pricing structure, Promotional activity New product launch

11. Product performance objectives: Company's objectives, Marketing objectives, Sales objectives

12. Pharmaceutical Market Research: Preparation of Questionnaire, Methodology, Field research with doctors, chemists, wholesalers and hospitals. Desk research and its sources

13. Global marketing management: Deciding whether to go abroad, Deciding which markets to enter, Deciding how to enter the market, Deciding on the Marketing programme, Deciding on the marketing organization

14. Writing marketing plan

15. Organization of Marketing and Sales Department

a. Organization structure of Pharmaceutical Marketing and sales department
b. Job responsibilities and job description of each person
c. Training and its importance, different types of training, evaluation methods
d. Visual aid preparation, Product manual preparation, detailing story preparation.
e. Detailing of pharmaceutical products, SOP's of detailing, do's and don'ts', innovative approaches
f. Objection handling of doctors and chemists by pharma marketing personnel
g. Prescription audit

16. Industrial Marketing

a. What is organizational buying?
b. Institutional and Government markets

Practical

Case studies (15) and group discussions (10) and 2 role Plays

1. Preparation and presentation of visual-aids
2. Preparation and presentation of campaigns
3. Training in the Pharmaceutical Marketing and sales department of a Pharmaceutical Industry

Schedule for each class:

1 case study
1 group discussion based on concepts outlined in theory.

Books Recommended:

1. Kotler, P. 2003. Marketing Management Millennium Edition. Lisbon. Published by Prentice-Hall Pvt Ltd.
2. Subba, R.R 1998. Handbook of Pharmaceutical Marketing in India (Second impression). New Delhi.
Panther Publishers
3. Mickey, C.S. 2000. Pharmaceutical Marketing in the 21st Century. New Delhi. Viva

Books Pvt Ltd.
4. Harrison, T.1997. The Product Manager's Hand book. London. Paperback Edition.
5. Smarta, R. B. 1999. Revitalizing the pharmaceutical business, Innovative Marketing Approaches, 1st Edition. New Delhi. Sage Publications.
6. Smarta, R. 2002. Strategies in Pharmaceutical Marketing by 3rd Edition. New Delhi. C.B.S Publisher and distributor.
7. Richard, S.H. The 1989. Product Management Handbook. McGraw-Hill Book Company.

PHA-PG-111: NEW DRUG DEVELOPMENT

Theory

1. Modern Analytical Techniques for characterization: NMR (C-13 and Proton), XRD, Thermal, Mass Spectroscopy.

2. Discovery and isolation of active molecule from natural sources: Preparation of plant material for biological evaluation (various methods of extraction, solvent choices, dose preparation and mode of administration); bioactivity directed fractionation; applications, advantages and limitations of various separation techniques (column chromatography, centrifugally accelerated chromatography, HPLC and MPLC) for isolation of lead molecules.

3. Combinatorial Chemistry and HTS including solid state synthesis, Parallel synthesis and liquid phase synthesis Identification of hits and concept of deconvolation.

4. Process Development.

5. Synthetic Strategies Protection and deprotection of various groups. Synthetic methodologies for obtaining drugs: Disconnection approach, synthesis for carbon- carbon bond formation, dysfunctional compounds, selective functional group interconversions (FGI), retrosynthetic analysis, synthetic approaches for attaching hetrocyclic ring systems in drug molecules having five-membered and six-membered hetroaromatic rings, Fused ring systems.

6. Receptors: Drug receptor interaction, G-protein coupled receptors, ion channel linked receptors. Ligand gated ion channels (LGICs). Ligand- receptor theories: Clark Occupancy theory, Rate theory, Induced fit theory, Macromolecular perturbation theory and activation aggregation theory.

7. Genetic engineering

8. Prodrug Approach: A) Enzyme activation of drugs: a. Utility of prodrugs: 1. Solubility, 2. Absorption and distribution 3. Site specificity 4. Instability 5. Prolonged release 6. Toxicity 7. Poor patient acceptability 8. Formulation problems.

b. Types of prodrugs.

c. Mechanisms of prodrug activation: a) Carrier linked prodrugs:

1. Carrier linkages for various functional groups 2. Examples of carrier linked Bipartate prodrugs 3. Macromolecular drug carrier systems 4. Tripartate prodrugs 5. Mutual prodrugs. b) Bioprecursor prodrugs: 1. Origins 2. Oxidative activation 3. Reductive activation 4. Nucleotide activation 5. Phosphorylation activation 6. Decarboxylation activation.

9. Polymorphism in Drug Molecules: a) Forces responsible for crystal packing b) Types of polymorphs c) Determination of structure of polymorphs d) Importance of studying the structure of polymorphs

Practical

Draft a proposal for clinical trial Phase I, Phase II, Phase III

1. Classify the ADR found in the regular visit of a patient along with disease code for ADR reporting
2. Calculate the pharmacokinetic parameters and apply statistics on the data received from analytical department for bioequivalence submission
3. Prepare a model clinical audit report
4. Prepare IND and NDD application for regulatory submission

Books Recommended:

1. Wolff, M.E.1989. Burger's Medicinal Chemistry and Drug Discovery. New York. John Wiley and Sons.
2. Silverman, R.B. 2011. The organic Chemistry of drug design and drug action. New York. John Wiley and Sons.
3. Nogrady, T. 2012. Medicinal Chemistry, A Biochemical Approach. Oxford. Oxford University Press.
4. Monographs and relevant review articles appearing in various Periodicals and Journals.
5. Yan, Z.G and Caldwell, G.W. 2004. Optimization in Drug Discovery: In Vitro Methods. New Delhi. Yamuna Press.
6. Silverstein, R. M and Webster. X. 1998.Spectrometric Identification of Organic Compounds, 6th Ed. New York. John Wiley and Sons.
7. James, W.D and Kenneth, T.2000. Analytical Chemistry by Open Learning: Thermal Methods, New York .John Wiley and Sons.
8. Abraham, R. J; Fisher, J; Bftus, P .2001.Introduction to NMR Spectroscopy. New York. John Wiley and Sons.

PHA-PG-112: BIODIVERSITY OF THE EASTERN HIMALAYAS

Theory

1. Drug discovery and development from natural resources, issues in medicinal plant research, Role of natural products for development of modern medicine – integrated approaches, Limitations of traditional experience.
2. Traditional alternative and complementary medicinal system (TACM) practiced throughout the globe including Indian system of traditional medicine, Traditional Chinese Medicine (TCM), Tibetian medicine, Kampo medicine etc. used in therapeutics
3. Historical overview on traditional system of Medicine practiced in India with special reference to Eastern Himalayas
4. Development of Traditional system of medicine in Himalayas and its prospects. Ethnobotany, ethnographic profile of Eastern Himalayas – their impact in traditional medicine. Anthropology, ethnomedicine in drug development with special emphasis on North East India, Disseminating knowledge of traditional medicine.
5. Biodiversity of Eastern Himalayas – Local food plants and nutraceuticals, role in primary health care, herbal drug development. Indian biodiversity rules and guidelines, Green chemistry for sustainable development

6. The extent of plant kingdom in medicine – Role of medicinal and aromatic plants in Indian health industry, export potential of medicinal and aromatic plants from India, Role of Eastern Himalayan biodiversity in traditional beliefs and folk practices

Scheme of Examination

Mid Semester Examination	20 marks
Project Report	40 marks
Seminar and Viva voce	20 +20 marks
TOTAL	**80 marks**

Books Recommended:

1. Mukherjee, P.K. 2002. Quality Control of Herbal Drugs by, 1st edition. New Delhi. Business Horizons Pharmaceutical Publisher.
2. Michael, J; Barnes, S; Gibbons, E.M. 2004. Fundamentals of Pharmacognosy and Phytotherapy. New York. Charchill Livingstone.
3. Patwardhan, B.2007. Drug discovery and development a Traditional medicine and ethno pharmacology. New Delhi. India Publishing Agency.
4. Srivastava, M .M and Sanghi, R.2005. Chemistry for greener environment. New Delhi. Narosa Publishing House Private Limited. .
5. Trease, and Evans, W.C.2013. Pharmacognosy. London. Churchill Livingstone.
6. Sharma, T and Arora, L. 2006. Herbal drugs: 21st century perspective. JAYPEE Publishers.

PHA-PG-201: QUALITY ASSURANCE
(Common to all Branches)

Practical

Planning, design and plan layouts, Purchasing of equipments and other inventories.

Concepts of TQM, philosophy of GMP, GLP, ISO 9000

2 Organization and personnel

3 Premises: Location, design, plan and layout, construction, maintenance and sanitation, environmental control, sterile areas, control of contamination.

4 Equipment: Selection, purchase specification, maintenance, clean in place , sterile in place

5 Raw material: Purchase specification, maintenance of stores, selection of vendors

6 Manufacture of and controls on dosage forms: Manufacturing documents, master formula recors, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities

7 In process quality control: For various doasage forms –sterile & non sterile, SOP for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilsation, membrane filtration.

8 Packaging and labeling controls: Packaging materials and line clearance

9 Quality control laboratory responsibilities: GLP protocols on clinical testing, controls on animal hous, data generation and storage, quality control, documentation, retention of sample records, audits of quality control

10 Finished product release: Quality review, quality audits, batch release document

11 Ware housing: Good ware housing practice, materials management

12 Distribution: Distribution records, handling of returned goods recovered materials and reprocessing

13 Complaints and recalls: Evaluation of complaints, recall procedure, documentation

14 Waste and scrap disposal: Disposal procedures and records

15 Loan license and contract manufacture

16 Recent amendments: Drugs and cosmetics act and other relevant rules

17 WHO certification, globalization of drug industry, introduction to EXIM policy

18 Present status and scope of pharmaceutical industry in India

19 Patent regime

1. Validation of analytical instruments, Validation of pharmaceutical manufacturing machinery, Validation of analytical methods, Validation of pharmaceutical manufacturing process
2. Calibration of volumetric glassware
3. Documentation of master formula records, Documentation of batch formula records, Batch release documentation, Maintenance of documentation, Recall procedure- documentation
4. Quality control records
5. Standard operating procedures-for analytical instrumentation, Standard operating procedures-for operating pharmaceutical machinery, Standard operating procedures-cleaning process
6. Monograph analysis & Quality audits.
7. Application for licensing of new drugs
8. Patenting procedures

Books Recommended:

1. Maitra K., Ghosh, S.K. A guide to TQM. Calcutta: Oxford Publishing House.
2. Mehara, M.L. GMP 1st edition. Allahabad: University book agency,
3. Ghosh S.K. 1994. Introduction to ISO 9000 and TQM (1st Ed.). Calcutta: Oxford Publishing House.

4. Patant A. The Drug and Cosmetics Act 1940. Lucknow: Eastern Book Company.
5. Shah, D.H. SOP guidelines (1st ed.). New Delhi: Business horizons.
6. Iyer, R.S. Schedule M & Beyond good manufacturing practices. Mumbai: Indian Drug Manufactuters Association.
7. Shah, D.H. 2000. QA manual (1st ed.) India: Business horizons.
8. The international pharmacopoeia vol.1,2,3,4; 3rdedn, general methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms-CBS publishers and distributors, New Delhi
9. WHO expert committee on specifications for pharmaceutical preparations 13th, 22nd, 23rd, 24th and 34th reports.

PHA-PG-202: PREFORMULATION AND PRODUCTION MANAGEMENT

Theory

1. **Preformulation:** Introduction, organolepic properties, purity, particle size, shape & surface area. Effects of particle size & surface area, temperature, pH, co-solvency, surfactants, molecular inclusion & solid dispersion on solubility. Crystal properties & polymorphism, stability studies & shelf life.
2. **Compaction & compression:** Introduction, Effect of particle size, moisture content, lubrication etc on strength of tablets. Formulation, evaluation & processing problems of tablets including sublingual, buccal, chewable tablets & medicated lozenges. Tablet coating & its defects. Process validation: mixing, granulation, drying & compression.
3. **Capsules:** Introduction, preparation, filling, sealing, polishing & evaluation of hard & soft gelatine capsules, Base adsorption, microencapsulation.
4. **Parenterals:** Preformulation factors, vehicles, isotonicity & its adjustment, pyrogenicity, selection of containers, prefilling treatment of closures and containers, preparation of solution, suspension & lyophilized powder, filling &sealing, evaluation, aseptic techniques. Validation of sterilization methods.
5. **Pilot plant scale up techniques:** Introduction, Significance of pilot plant scale up, pilot study of tablets, injections & liquid per oral delivery system.
6. **Statistical applications in Pharmaceutical sciences:** Normal distribution, Test of hypothesis, t-test, F-test, ANOVA, Chi-square test, Sign test, run test, Latin square design, Factorial design, Replication, Randomization and local control.

Practical

1. Preformulation study of tablets.	2 experiments
2. Study of effect of excipients on the properties of tablets.	3 experiments
3. Preparation and comparative evaluation with marketed products (tablets & capsules).	3 experiments
4. Preparation and comparative evaluation with marketed products for antacid efficiency.	2 experiments
5. Solid dispersion formulation and evaluation.	2 experiments
6. Test of glass containers.	1 experiment
7. Preparation and evaluation of sterile water for injection.	1 experiment
8. Preparation and evaluation of microcapsules.	1 experiment

9. Statistical interpretation of experimental data. 3 experiments

Books Recommended:

1. Banker and Rhodes. 1990. Modern Pharmaceutics. New York: Marcel Dekker, Inc.
2. Leon Lachman, Lieberman, Kanig J.L. 1987. Theory and Practice of Industrial Pharmacy. Bombay: Varghese Publishing House.
3. Martin, Swarbrick, Cammarata. 2010. Physical Pharmacy. Bombay: Varghese Publishing House.
4. Lieberman, Lachman, Schwartz. Pharmaceutical Dosage Forms- Tablets. New York: Marcel Dekker, Inc.
5. Avis, Lachman, Lieberman. Pharmaceutical Dosage Forms – Parenteral Medications. M. New York: Marcel Dekker, Inc.

PHA-PG-203: ADVANCES IN DRUG DELIVERY SYSTEMS

Theory

1. Sustained Release: Introduction, concept, advantages and disadvantages, physicochemical and biological properties of drugs relevant to sustained release.
2. Concept and System Design for Rate Controlled Drug Delivery in Cluding Oral Drug Delivery Systems: Classification, rate-preprogrammed, activation-modulated, feedback regulated systems
3. Mucoadhesive Drug Delivery Systems: Buccal drug delivery systems, concept, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, permeability enhancers, evaluation, nasal and pulmonary drug delivery systems.
4. Ocular Drug Delivery Systems: Ophthalmic inserts, formulation and evaluation, pilocarpine delivery system
5. Transdermal Drug Delivery Systems: Permeation through skin, various designs and basic components of TDDS, evaluation.
6. Bone Drug Delivery: Bone, various diseases that demand local drug delivery, blood flow and drug availability, carrier systems preparation, factors influencing drug release and evaluation
7. Targeted And Submicron Drug Delivery Systems: Spheres, capsules, emulsions, suspensions that involve submicron ingredients, vesicular drug delivery systems (Liposomes, niosomes)

Practical

Practical experiments to practice knowledge gained in theory.

Books Recommended:

1. Chien, Y.W. 1992. Novel Drug Delivery Systems. New York: Marcel Dekker, Inc.
2. Robinson, J.R., Lee V.H.L.1992. Controlled Drug Delivery Systems. New York: Marcel Dekker, Inc.
3. Mathiowitz, E. 1999. Encyclopedia of controlled delivery. New York/ Chichester/ Weinheim: Wiley Interscience Publication, John Wiley and Sons, Inc,.
4. Banker and Rhodes. 1990. Modern Pharmaceutics. New York: Marcel Dekker, Inc.

5. Lachman, Lieberman, Kanig J.L. 1987. Theory and Practice of Industrial Pharmacy. Bombay: Varghese Publishing House.

PHA-PG-204: PHARMACEUTICAL CHEMISTRY-II (DRUG DESIGN)

Theory

1. Theoretical aspects of drug action and concept on drug design.

2. Prodrug design: Various aspects governing prodrug design including ADEPT.

3.Quantitative structure activity relationships

a. History and development of QSAR

b. Drug receptor interactions

c. How should original lead be used in the design of analogs

. Bioisosteric replacements

i. Rigid analogs

ii. Ring size, alkyl chains, branching, ring position isomers etc.

v. Alterations of stereochemistry and design of stereo and geometric isomers.

d. Physical properties related to potency

e. Calculation, measurement and meaning of partition coefficients

f. Theoretical compartment model for relationship between physical properties and biological activity (Hammet, Taft)

g. Mathematical methods for the analysis of QSAR

Diagnosis of mechanism

Prediction of activity

Optimization

Refinement of synthetic targets

i) Application of Hansch Analysis

j) Application of Freewilson analysis.

4. Molecular modelling in drug design: Molecular mechanics, Quantum mechanics, Modelling of known and unknown receptor sites, Computer aided drug design

5. Approaches to rational design of drugs including

Enzyme inhibitors [COX-II, ACE, HMG-coA inhibitors, DHFR etc]

Gastric acid secretion and inhibition

The immune response and immunosuppressive agents

Practical

Synthesis, purification and identification of at least five of the following compounds employing micro TLC and qualitative analysis

a. INH
b. Methaqualone
c. Chloramine-T and DicloromineT
d. Saccharin Sodium
e. 7-Nitrohydroxy-4-methyl coumarin
f. Dapsone
g. Phenytoin from Benzaldehyde
h. Benzaldehyde
i. Benzophenoneoxime
j. Sulfanilamide
k. Phenothiazine
l. 2,3 Diphenylquinoxaline
m. Benzimidazole
n. Phenyl urea and Diphenyl urea
o. Benzofuran
p. Uramil

The following demonstration experiments to be arranged

1. Solving problems based on QSAR.
2. Molecular modeling.

Books Recommended:

1. Burger's Medicinal Chemistry (6^{th} Ed.). Vol-I & II. The Basis of Medicinal Chemistry. John Wiley
2. Block, J.H., Beale, J.M. 2004. Wilson & Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry (11^{th} Ed.). Lippincott Williams & Wilkins
3. Foye, W.A. Medicinal Chemistry.
4. Nogrady T. Biochemical Basis-Medicinal Chemistry.
5. Martin, Y.C. Introduction to Quantitative Drug Design
6. Corwin and Hansch, Comprehensive Medicinal Chemistry. New York: Pergamon Press.

PHA-PG-205: PHARMACEUTICAL CHEMISTRY – III (NATURAL PRODUCTS)

Theory

1. Natural Products:

Introduction, sources (Plant, animal, microbial, marine), classification on chemical basis. Role of natural products in development of medicinal chemistry, providing "leads". Selected example taken from Antimalarials, Local anaesthetics and Anticholinergics

2. Medicinal agents obtained by chemical modification of natural products

Selected examples from the categories of antineoplastic agent (palcitaxel and its derivative) podophyllotoxin and its derivative like etoposide and tenoposide.

3. Structure elucidation of the following compounds based on chemical degradation, synthesis and spectral data.

Morphine alkaloids like Morphine. Pepavarine, Cardiac glycosides and lanatoside C, Quaban, Reserpine, Vinblastine, Emetine

4. Blood Glucose Regulator: Introduction, diabetes mellitus, insulin preparation, human insulin, storage and release of insulin, Active constituents of crude drugs like, Gymnemesylvestere, salacia reticulate, Pterocarpusmarsupium, Swertiachirata, Trogonellafoenum-graeceum used in antidiabetic therapy in indigenous system of medicine

5. Hormones: Female and male sex hormones-development of antifertility agents, Adrenal cortex hormones and their derivatives, Steriods/ Trierpenoids –classification of plants steroids and triterpenoids.

6. Antibiotics: Penicillins and cephalosporins. AmidoPenicilins, Betallactamase stable cephalosporins, Antipsuedomonalpenicilins and cephalosporins. New oral compounds and future prospects. Other betalactam agents

h. Norcadins and monobactams, Clavulanic acid analog. Carbapenams. Other fused Betalactam systems

7. Purine and Pyrimidines: Themetebolism of purines and pyrimidines, allopurinol and xanthine Oxidase, Antineoplastic agentsmAntiparasitic purine and pyrimidines related agents, Antifungal agents

Practical

1-15 Isolation and Characterization using Co-IR, Co-TLC methods

1. Eugenol from Clove

2. Curcumin from Turmeric
3. Sennosides from Senna
4. Hesperidine from Orange peel
5. Embelin from Embeliaribes
6. Glycyrrhizin from Glycyrrhizaglabra
7. Plumbagin from Plumbagorosec
8. Solanine from potatoes
9. Naringen from Grapes Fruit Peel
10. Trimyristin and Myristin from Nutmeg
11. Azylic acid from Castor Oil
12. Pectin from Orange Peel
13. Lycopene from Tomato Peel
14. Epicatechin from Cashew Kernel outer covering
15. Piperine from Black pepper Degradation reaction of following natural products and the identification of the degraded intermediates by micro TLC and qualitative tests. Atropine, Caffeine, Ephedrine, Saponification of Trimyristin.

Books Recommended:

1. Evaluation of Herbal Medicinal Products - Perspectives of Quality, Safety and Efficacy" Pulok K. Mukherjee, Peter J. Houghton, Pharmaceutical Press, Royal Pharmaceutical Society of Great Britain, 2009.
2. Quality Control on Herbal Drugs- Pulok K. Mukherjee, Eastern Publishers (Business Horizons Ltd.) New Delhi 2002.
3. Peech and Tracey, Modern Methods of Plant Analysis.
4. Miller, Jan Nostrant Rein Hold. Pytochemistry Vol-I and II
5. Recent Advances in Pytochemistry – Vol-I-Iv Scikel Runeckles
6. Chemistry of Natural Products Vol-I onwards IWPAC
7. Nakanishi, G., Natural Products Chemistry

PHA-PG-206: HERBAL DRUG TECHNOLOGY

Theory

1. General methods of isolation, purification and estimation of phytoconstituents.

2. Isolation and estimation of phytopharmaceuticals.

Different Methods (Including industrial) for isolation and estimation of phytoconstitutents from the flowing drugs (with special emphasis on HPLC and HPTLC): Acourus calamus –Asarone, Aloe barbadensis- Aloin, Adhatoda vasica- Vasicine, Andrographis paniculata- Andrographolides, Bacopa monnieri- Bacosides, Berberis aristata- Berberine, Curcuma longa- Circumin, Phyllanthus amarus- Phyllanthin, Piper nigrum/longum- Piperine, Withania somnifera- Withanolides

3. Commerce and quality control of drugs

a. Indian and International trade in medicinal and aromatic plants

b. Quality control methods for medicinal plants materials.

i. Factors affecting herb quality

ii. Development of standardization parameters according to WHO guidelines for assessment of crude drugs.

Evaluation of identity, purity and quality of crude drugs, Determination of pesticide residue,

Determination of arsenic and heavy metals, Determination of micro-organisms.

4. Herbal based industries: Types, forms, scope and applications, Study of infrastructure for different types of industries involved in making standardized extracts and various dosage forms including traditional Ayurvedic dosage forms and modern dosage forms, Research: Needs, areas and current on going research, analytical methods and clinical evaluation techniques.

5. Patents: Indian and International patent laws, proposed amendments as applicable to herbal/ natural products and processes; important points to be kept in mind while drafting and filling a patent, Plants breeders' rights.

6. Study of Herbal Extracts: Processing, Equipment and analytical profiles of extracts of drugs listed in Sec (2) of the course content.

7. Study of herbal formulation and their standardization: Study of traditional formulation as per Ayurvedic Formulary of Indian and few dosage form (modern) in market, Self life study, protocols to study stabilization of herbal based products. Approaches for both physical physico-chimical and chemical parameters of assessment at different stage.

8. Herbal cosmetics: Raw materials of herbal origin uses in cosmetics : oil, waxes, gums, hydrophilic colloids, perfumes, protective agents, bleaching agents, preservation, anti oxidant and other ancillary agents, Formulation aspect incorporation herbal extract in various preparations like skin care cream, deodorants, anti-perspirants, and hair care preparation, Detailed methods of preparation of few representative preparations and standardization of above categories.

Practical

Thin layer chromatography, Paper chromatography and HPLC.

1. Pharmacognostic evaluation of crude drugs:
2. Extractive value determination, Moisture content determination, Ash value determination, Volatile oil content determination, Determination of heavy metals.
3. Spectroscopic analysis of isolated compounds.
4. Evaluation and standardization of extracts based on WHO guidelines.
5. Preparation of two herbal medicinal and cosmetic formulations and their evaluation.

Books Recommended:

1. Mukherjee, P.K. 2002. Quality Control on Herbal Drugs. New Delhi: Eastern Publishers (Business Horizons).
2. Mukherjee, P.K. & Houghton, P.J. 2009. Evaluation of Herbal Medicinal Products - Perspectives of Quality, Safety and Efficacy. Pharmaceutical Press, Royal Pharmaceutical Society of Great Britain.
3. Mukherjee, P.K & Verpoorte R. 2003. GMP in Herbal Drugs. New Delhi: Eastern Publishers (Business Horizons).
4. Jean Brunton, J. 1995. Pharmacognosy and Phytochemistry of medicinal plants. Lavoise: Techniques and documentation.
5. C.K. Kokate, C.K. & Purohit, Gokhlae. 1996. Text book of pharmacognosy. New Dehli: Nirali Prakashan.

6. Farooqui, A.A & Sreeramu, B.S. 2001. Cultivation of medicinal and aromatic crops. University Press.
7. Choudary, R.D. 1996. Herbal Drugs Industry. New Delhi: Eastern Publisher.
8. V. Rajpal, V. 2002. Standarisation of Botanicals. New Delhi: Eastern Publishers.

PHA-PG-207: MEDICINAL PLANTS BIOTECHNOLOGY

Theory

1. **Introduction to genetics and molecular biology:** Genetic materials- DNA, RNA, Protein, Replication,
   Genetic Code.
2. **Methods of improving quality of crops and their application:** Chemodems, Hybridization, Mutation, Polyploidy
3. **Tissue Culture:** Types, Techniques and Application of Callus, Suspension, Haploid, Embryo, and organ culture, Hairy root culture and their application, Protoplast culture and Protoplast fusion.
4. **Germplasm conservation:** In situ conservation. In vitro methods of conservation.
5. **Gene transfer in plants:**

a) i. Using vectors of Agrobacterium.
ii. DNA mediate gene transfer: Electoporation, Microprojectile, Microinjection, Liposomes and Chemical mediated gene transfer.
b) Localization of transferred gene in genetically modified plants:
i. Nuclic acid hybridization.
ii. Use of Radioisotopes and Molecular Makers.
iii. Auto radiography.
iv. Electrophoresis.

6. Application of Transgenic plants.

a) Resistance to Herbicide.
b) Tesistance to insect, fungus and virus.
c) Production of Phytopharmaceutical.
d) Edible vaccine.

7. **Gene mapping and molecular maps of plants genome:**

a) Uses of PCR in gene mapping.
b) Molecular maps- Rapid Fragment Length Polymorphism (RFLP) and Randam Amplified Polymorfic DNA. (RAPD)

Practical

1. Initiation of callus.
2. Growth determination- Cell counts, Cell staining, Mitotic index, Media analysis.
3. Chromosomal analysis by onion root tip culture.
4. Isolation of DNA and RNA from plant sources.
5. Estimation of DNA and RNA.
6. Isolation of enzymes.
7. Isolation and fusion of protoplast.
8. Isolation of Plasmids.

9. Isolation of Chloroplast
10. Transformation of bacteria

Books Recommended:

1. David R. Murray, D.R. 1991. Advanced methods in plant breeding and biotechnology. CAB International Panima Book distributors.
2. Dixon. 1985. Plant tissue culture. Washington DC: IRL Press Oxford.
3. Khan, I.A. & Khanum, A. 1998. Role of Biotechnology in Medicinal and Aromatic Plants. Ukaoz Publications.
4. Sharma, A & Sharma, Archana. 1999. Plant Chromosome analysis, manipulation and engineering. Harwood Academic Publishers.
5. Murray Moo-Young, M.M. 1985. Comprehensive Biotechnology. Pergamon Press Ltd.
6. Transgenic Plants by R Ranjan Agrobotanica. 1999
7. Vyas, S.P & Dixit, V.K. 2001. Pharmaceutical biotechnology. CBS Publishers and distributors, 2001

PHA-PG-208: BIOLOGICAL STANDARDIZATION OF DRUGS AND SCREENING METHODS

Theory

1 Immunoassay:
Basic concept on immunology, General principal of immunoassay.
Heterogeneous Immunoassay system & homogeneous immunoassay system.
Evaluation of immunoassay methods.

2 Introduction To New Approaches In Drug Discoveries:
Combinatorial chemistry, Pharmacogenomics, Proteomics, Lipidomics, Data Mining, and Array Technology.

3 Pharmacological screening of new drug substance with emphasis on evaluation, using in vivo, in vitro, ex vivo, in situ, Insilco and other possible animal alternative models.
Cardiovascular pharmacology –antihypertensive, anti-arrhythmic, diuretics.
Respiratory pharmacology-anti-asthmatics, drugs used for COPD.
Reproductive pharmacology-models for sexual dysfunction and anti-fertility agents.
Anti-cancer agents.
Screening of free radical scavenging activity.

Practical

Biological Standardization of drugs like Histamine, Acetylcholine and 5-HT.

1. Experiments on CVS - General screening procedure of anti-arrhythmic agents and anti-hypertensive, anti-ischemic drugs.
2. Experiments on diuretics-General methods for evaluating diuretic activity
3. PA2 values of various antagonist using suitable isolated tissue preparation.
4. Monitoring of concentration of drugs in blood.
5. General screening methods of evaluating the Antimicrobial activities of chemotherapeutic agents.

6. Experiments on toxicology-Oral & skin acute toxicity tests.
7. Estimation of biochemical & free radical scavengers.

Books Recommended:

1. Goodman, G. and Gilman, E. 2013. The Pharmacological Basis of Therapeutics. London: McGraw-Hill.
2. Ballantyer, B.; Marrs, T.C. and Syversen, T. 2009. General and Applied Toxicology. London: Wiley.
3. Longo, D.; Fauci, A.; Kasper, D.; Hauser, S.; Jameson, J. and Loscalzo, J. 2011. Harrison's Principles of Internal Medicine. New York: McGraw-Hill.
4. Liebler, D.C. 2002. Introduction to Proteomics: Tools for the New Biology. NJ: Humana press.
5. Uppu, R.M.; Murthy, S.N.; Pryor, W.A. and Parinandi N.L. 2010. Methods in molecular biology- Free radical and antioxidant protocol. NJ: Humana press.

PHA-PG-209: SYSTEMIC AND MOLECULAR PHARMACOLOGY

Theory

1 Drug receptor theory:
Concept of receptor theory and drug-receptor interaction forces involved in drug receptor complex. Receptor polymorphism & dimerization and its importance in drug design.

2 Physiochemical properties in relation to biological action and drug design:
Rational drug design.

3 Molecular pharmacology :
Application of molecular pharmacology to drug design.
Cell signaling, organization of signal transduction pathway and biosensors.
Protein structure prediction and molecular modeling.

4 Gene expression, regulation, gene mapping and drug targets from human genome, identification of biological targets for drug development.

5 Recombinant DNA technology: Principal, process and its application.

6 Gene therapy:
Types of gene therapy, in-vivo and ex-vivo methods, and steps involved in gene therapy, gene transfer technologies (viral & non-viral vectors).
Clinical application of gene therapy. Advantages, disadvantages and ethical considerations.

7 Pharmacodynamics, pharmacokinetics of peptide and protein drugs:
Immunogenicity of protein therapeutics and other regulations for safety.

Practical

Preparation of buffers and overview of calculations used in biological experiments.

1. Estimation of proteins in serum and tissues.
2. Isolation of protein by gel electrophoresis method.
3. Virtual/simulated/computer-based experiments.
4. Evaluation of antimicrobial activity.

5. Experiments on physiochemical properties of drugs and their biological effects including partition coefficient on laboratory animals.
6. Free radical scavenging activity.
7. Evaluation of hemolytic activity.
8. DNA isolation, sequencing and PCR techniques.
9. Isolation of RNA from yeast.

Books Recommended:

1. Crommelin, D.J.A. and Sindelar, R.D. 1997. Pharmaceutical Biotechnology. Harward Academic Publishers.
2. Alberts, B. et.al. 1994. Molecular Biology of the Cell. New York: Garlound Publishing Inc.
3. Tripathi, K.D. 2014. Essentials of Medical Pharmacology 7TH Edition. New Delhi: Jaypee Publication
4. Watson, J.D.; Gilman, M.; Witowski, J.; and Zoller, M. 1996. Recombinant DNA. New York: Scientific American Books.
5. Abraham, D.J. 2003. Burger's Medicinal Chemistry and Drug Discovery Vol. 1-Drug Discovery. NJ: John Wiley and Sons.
6. Goodman, G. and Gilman, E. 2013. The Pharmacological Basis of Therapeutics 12th Edition. London: McGraw-Hill.
7. Lemke, T.L.; Roche, V.F.; Williams, D.A. and Zito, S.W. 2008. Foye's Principles of Medicinal Chemistry. New Delhi: Wolters Kluwer (India) Pvt. Ltd.
8. Karp, G. 2008. Cell and Molecular Biology. NJ: NJ: John Wiley and Sons.
9. Meibohm, B. 2006. Pharmacokinetics and Pharmacodynamics of Biotech Drugs: Principles and Case Studies in Drug Development. Weinheim: WILEY-VCH Verlag GmbH & Co.

PHA-PG-210: FORMULATION TECHNOLOGY AND VALIDATION

Theory

1. Preformulation studies: Pka and solubility, Partition coefficient, Crystal morphology, Polymorphism, powder flow, Dissolution, Compatibility studies, Protocol for preformulation studies.

2. Solubilization techniques: Determination of solubility parameters, Methods of solublization including the addition of co-solventsurfactants, Complexation, Dielectric constant, Hydrotrophy.

3. Drug stability: Solution stability, Solid-state stability, Parameters for physical stability testing, Protocol for physical stabilitytesting program, Accelerated stability studies and shelf life assignment.

4. Formulation, evaluation and sterilization concepts: Tablets, Capsules, Liquid dosage forms, Parenterals preparation, Transdermal products, Suppositories and Controlled release products.

5. Container caps, closures and packaging products: Types, Performance, Quality control testing, Plastic containers for Parenterals. Flexible packaging , Compatibility studies.

6. Raw materials for cosmetic preparations: Formulation, Production evaluation and Quality Control of Hair care products, skin care products, colour cosmetics. Baby care products, dental products, personal and hygiene products.

7. Quality, safety and legislation for cosmetic products

8. Validation: Validation and calibration of equipments, Validation of process: mixing, granulation, drying,compression, filtration, filling, Validation of sterilization methods and equipmentsdry heat sterilization, autoclaving, membrane filtration, Validation of analytical procedures, Validation of air

handling equipments and facilities insterile and non sterile areas, Validation of water supply systems (Demineralised,Distilled and Water for Injection), Validation of security measures for electronic dataprocessing.

Practical

1. Solublisation of solid using co-solvents
2. Pilot plant experiments on tablet formulation and coating of solid dosage forms
3. Formulation of medication for transdermal drug delivery
4. Quality control testing for pharmaceutical containers.
5. Pilot scale preparation of sustained for parenterals (including sealing)
6. Preparation of sustained release formulation
7. Shelf life study of formulations
8. Preparation protocols on various validation requirements
9. Formulation and evaluation of gels, dispersible tablets, chewable tablets
12. Comparative study of marketed products (dosage forms)
13. Formulation of and evaluation of hair care products &skin care products.

Books Recommended:

1. Lachman, L., Herbert, A. Liberman, Schwartz, J. B. 1989. Tablets Vol-I, II, III 2nd ed. New York: Marcel Dekker Inc.
2. Gibaldi, M. Text book of Bio-Pharmaceutics and clinical Pharmacokinetics (3rd ed.) Philadelphia: Lea and Febriger.
3. Berry, I.R., Robert, A. 1993. Pharmaceutical process validation (Drugs and Pharmaceuticals Series) (2nd ed) NewYork: Marcel Dekker Inc.
4. Gilbert R. and Banker 1990. Modern Pharmaceuticals (2nd ed.), NewYork: Marcel Dekker Inc.
5. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing Company, Eastern Pennsylvania.
6. Remington's Pharmaceutical Sciences, by Alfonso and Gennaro, 19th edition 1995 Lippingcott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
7. Indian Pharmacopoeia, 1996, The Controller of Publications, Govt. of India.
8. Goran, Alderborn, Christer Nystrom, 1996. Pharmaceutical power compaction technology, Marcel Dekker Inc, New York.
9. Kohil, D.P.S and Shah, D.H. 1998. Drug formulation Manual (1st ed.) New Delhi: Eastern publishers.
10. Wilkinson, J.B., Moore, R.J. Harry's cosmeticology (7thed.) Singapore: Longman Scientific and Technical Publishers.

PHA-PG-211: CHEMICAL AND BIOLOGICAL EVALUATION

Theory

1. **Validation:** Method validation, cleaning validation, personnel validation.
2. **Development of drug information profiles.**
3. **Enzyme immune assay. Concepts and methodology.**
4. **Sterility testing-methodology and interpretation.**

5. Test for effectiveness of antimicrobial preservative.

6. Detailed study of principles and procedures involved in the biological assays of the following:

a. Diphtheria antitoxin.
b. Heparin sodium.
c. Japanease encephalitis vaccine
d. Rabies vaccine
e. Streptokinase.
f. Tetanus antitoxin.
g. Tuberculin purified protein derivative.

7. Pyrogens:

Production, chemistry and properties of bacterial pyrogens and endotoxins. Pyrogens testing: IP, BP and USP methods. Interpretation of data comparison with other official pyrogen tests.

8. Microbial assays of antibiotic and vitamins.

Practical

1. Planning, design and plant layouts.
2. Purchasing of equipments and other inventories.
3. Validation of analytical instruments, pharmaceutical manufacturing machinery
5. Validation of analytical methods, pharmaceutical manufacturing process
7. Calibration of volumetric glassware
8. Documentation of master formula records, batch records
10. Quality control records
11. SOP for analytical instrumentation, pharmaceutical machinery, cleaning process, monograph analysis
15. Assay of Amikacinsulphate injection, IP 1996, Bacitracin zinc, IP 1996, Gentamycin sulphate injection, IP 1996, Tertracyline HCI, IP 1996, Neomycin sulphate eye drops, IP 1996
20. Test for absence and abnormal toxicity

Books Recommended:

1. Maitra, K. and Ghosh, S. K. A guide to total quality management. Calcutta: Oxford Publishing House.
2. Mehra, M.L. GMP, 1st edition. Allahabad: University book agency.
3. Sharma, P.P. How to practice GMPs, Agra: Vandana Publications.
4. Ghosh S.K. Introduction to ISO 9000 and Total quality management. Calcutta: Oxford Publishing House.
5. Patani A. The drug and cosmetics act 1940, Lucknow: Eastern book Company.
6. Malik V. The drug and cosmetic acy 1940, Lucknow: Eastern book Company.
7. Shah,D.H. SOP guidelines, 1st edition, New Delhi: Business horizons.
8. Shah, D.H. QA Manual, 1st edition, 2000, Business Horizones.
9. Controller of Publications, Govt. of India: Indian Pharmacopoeia 1996., Vol-I and II,
10. Burn, Fininey and Godwin. Biological standardsation, 2nd edition, London: Oxford University Press.
11. The international pharmacopoeia Vol-1.2.3.4; 3rd edition, General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
12. Quality assurance of pharmaceuticals – A compendium of guidelines and related

materials Vol- 1 (WHO publications).

PHA-PG-212: PHARMACOTHERAPEUTICS-I

Theory

1. Pathophysiology and pharmacotherapy of diseases associated with following systems/ diseases

1.1 Cardiovascular system: Hypertension, Congestive cardiac failure, Ischemic heart disease, Myocardial infarction, Arrhythmias, Hyperlipidaemia.

1.2 Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

1.3 Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders.

1.4 Rheumatic disease: Rheumatoid arthritis, Osteoarthritis, Gout, Systemic Lupus erythematosus.

1.5 Gastrointestinal system: Peptic ulcer diseases, Reflux oesophagitis, Inflammatory, Inflammatory bowel diseases, Hepatitis, Jaundice and Cirrhosis, Diarrhea and constipation, Drug- induce liver disease.

1.6 Skin and sexually transmitted diseases: Psoriasis, Eczema and scabies, Syphilis and Gonorrhea, Drug related skin reactions.

1.7 Pain management: Pain pathways, Analgesics and NSAIDs, Neuralgias including post herpetic, trigeminal and glossopharyngeal neuralgia, Palliative care.

1.8 Immunology: Autoimmunity- Definition, Classification, Mechanism of Autoimmune disease, pathogenesis of Autoimmunity, Immunoglobulin's.

2. General prescribing guidelines for: Paediatric patients, Geriatric patients, Pregnancy and breast feeding

3. Introduction to rational drug use: Definition, Essential drug concept, Rational drug formulations, Role of pharmacist.

Practical

Hospital postings in the various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of case presented and the same should be submitted at the end of the course for evaluation. A minimum of 10 cases should be presented and recorded covering most common diseases. The list of clinical cases should include follow up of the clinical case mentioned below from the day of admission till discharge. The same cases should be entered in their practical records following SOAP (Subjective, Objective, Assessment, and Plan technique).

1. Hypertension
2. Heart Failure
3. Myocardial Infarction
4. Coronary Heart Disease
5. Asthma
6. Chronic Obstruction
7. Anemia
8. Osteoarthritis
9. Rheumatoid arthritis
10. Gout
11. Peptic Ulcer
12. Gastro esophageal reflux disease
13. Hyperlipidaemia Pulmonary Disease
14. Neuralgias
15. Psoriasis
16. Hepatitis

Books Recommended:

1. Roger, R and Walker. L. 2011. Clinical Pharmacy and Therapeutics. London.

Churchill Livingstone publication.
2. Joseph, T.D.2006. Pharmacotherapy: A Pathophysiology approach. London. Appleton and Large.
3. Robins, S.L.2009. Pathologic basis of disease. W.B. Saunders publication.
4. Herfindal, E.T. 2001.Clinical Pharmacy and Therapeutics. New York. Williams and Wilkins Publication.
5. Trevor, M and Nicolas, H.G.1997.Avery's Drug Treatment, 4th Edn. Synney. Adis International Limited.
6. Parthasarathy, G.2011. Text book of Clinical Pharmacy. Chennai. Orient Longman Publishers.
Relevant review articles from recent medical and pharmaceutical literature.

PHA-PG-213: PHARMACOTHERAPEUTICS - II

Theory

1. Pathophysiology and pharmacotherapy of diseases associated with following systems/ diseases

1.1 Renal system

- Acute renal failure, Chronic renal failure, Renal dialysis and transplantation, Drug induced renal diseases

1.2 Endocrine system

- Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.

1.3 Nervous system

- Epilepsy, Parkinson's disease, stroke and transient ischaemic attacks, Headache.

1.5 Ophatalmology

- Glaucoma, Eye infections

1.6 Infectious diseases

- General guidelines for the rational use of antibiotics, Meningitis, Respiratory tract infections. Gastroenteritis, Bacterial endocarditis, Septicaemia, Otitis media, Urinary tract infections, Tuberculosis, Leprosy, Malaria, helmenthiasis, HIV and opportunistic infections, Fungal infection, Rheumatic fever.

1.7 Oncology

- General principles of cancer chemotherapy, commonly used sytotoxic drugs, Chemotherapy of lungs cancer, hematological malignancies, Management of nausea and vomiting.

Practical

Hospital posting in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 15 cases should be presented and recorded covering most common diseases. The list of clinical cases should include follow up of the clinical cases

mentioned below from the day of admission till discharge; the same case should be entered in their practical records following SOAP [Subjective, Objective, Assessment and Plan technique.

1. Diabetes type 1
2. Diabetes type 2
3. Hypothyroidism
4. Hyperthyroidism.
5. Acute renal failure
6. Chronic renal failure
7. Schizophrenia
8. Depression
9. Anxiety
10. Epilepsy
11. Parkinson's disease
12. Stroke
13. Infectious diseases [any five]

Books Recommended:

1. Roger, R and Walker.L.2011.Clinical Pharmacy and Therapeutics. London. Churchill Livingstone publication.
2. Joseph, T.D.2006. Pharmacotherapy: A Pathophysiology approach. London. Appleton and Large.
3. Robins, S.L.2009. Pathologic basis of disease .W.B. Saunders publication.
4. Herfindal, E.T. 2001.Clinical Pharmacy and Therapeutics. New York. Williams and Wilkins Publication.
5. Trevor, M and Nicolas, H.G.1997.Avery's Drug Treatment, 4th Edn. Synney. Adis International Limited.
6. Parthasarathy, G.2011. Text book of Clinical Pharmacy. Chennai. Orient Longman Publishers.
7. Relevant review articles from recent medical and pharmaceutical literature.

PHA-PG-214: DRUG DISCOVERY PROCESSES

Theory

1. Introduction to drug discovery: History and definition of drug discovery, sources of drugs: plants, animals, microorganisms, drugs from organic synthesis. Existing drugs as a source of new drug discovery, using disease models as screen for new drug leads, physiological mechanisms: rationale approach to drug design, pro-drug approach, lead optimization.

2 . Model approaches of drug discovery from natural sources: Lepinsky rule and strengths of natural products in drug discovery; different approaches to drug discovery- rational (sense), irrational (non-sense) and antisense approach; selection of natural sources for drug development based on phytoconstituents, chemotaxonomy, ethnopharmacological records and random approach; synergy principle in herbal drugs; secondary metabolites and discovery of new drug templates from natural products; recent development in natural products.

3. Three dimensional structure-aided drug design: Introduction, the structure drug design process, Methods to derive three dimensional structure

4. Drug Discovery: Drug discovery without a lead, lead discovery, random screening, Non-random Screening, Drug metabolism studies, clinical observation, rational approach to lead discovery, lead modification, lead optimization.

5. Conventional methods of drug design, discovery a lead, lead optimization, objective of lead optimization, Pharmacophoric identification and Analog approach of drug designing. Various

approaches in QSAR: objectives of QSAR, Hansch approach, Free- Wilson model, statistical methods, noncomputer assisted search operations like topless decision tree Simplex method, Fibonacci search technique. Parameterization of groups/ molecules, Introduction to Molecular Modeling.

6. Molecular Modeling in drug design: Introduction, background and methods, molecular mechanics, quantum mechanics, known receptors, unknown receptors

7. Preclinical studies and drug development: Stages of drug discovery, stages of pre-clinical and safety evaluation, acute, sub-acute, chronic studies, in-vivo and in-vitro studies (behavioral, biochemical, neurochemical models), special studies including carcinogenicity, mutagenicity, teratogenicity studies.

8. Novel Drug targets for drug discovery: Enzymes as targets of drug design, receptors as targets for drug design, cytokine and genes as targets of drug design, other targets (transporters etc) for drug design. Receptor, GPCR, neurotransmitters (dopamine, serotonin, glutamate, GABA etc), messenger molecules, drug action and its concept, brief dynamics and kinetic, receptor ligand studies.

9. Emerging tools and technique in drug discovery: High throughput screening (HTS), PK-PD modeling, enzyme kinetics, Ultra HTS, combinational chemistry, pharmacogenomics, proteomics, Cell line/Stem cells, gene-based personalized drug therapy, transgenic and knockout animals, alternative to animal studies, animal ethics, role of Institutional animal ethical committee, CPSCS guidelines, biodegradable waste and its management.

10. Animal house and its management: Experimental animals, strain, genetic animals, breeding of animals, storage of experimental and large animals, lighting and water conditions, temperature control

11.Biostatistics: General concepts, one-tailed, two-tailed Student's test and paired Student's t-test, independent sample t-test, Wilcoxon rank-sum test, Mann-Whitney test, ANOVA, Kruskal-Wallis test, Multiple comparision procedures in ANOVA: Fisher's LSD test, Tukey's test and Dunnett's test.

Practical

Preparation of drugs through synthetic process:

1. Preparation of benzanilide from benzophenone (Beckmann rearrangement) Benzophenone —→ Benzophenone oxime —→ Benzanilide.
2. Preparation of 2-Phenyl indole from accetophenone (Fischer indolisation) Actophenone -—→ Acetophenone phenylhydrazine —→ 2- Phenylindole.
3. Preparation of Antipyrine from ethylactoacetate Ethylacetoacetate —→ 3-Methyl-1-phenylpyrazol-5- one —→ 2, 3-Dimethyl-1 phenylphyrazol-5-one.
4. Preparation of dibromocinnamic acid from benzaldehyde (Perkin's reaction) Benzaldehyde —→ Cinnamic acid —→ Dibromo cinnamic acid.
5. Preparation of 2,5-dihydroxy acetophenone from acetophenone from hydroquinone (Fries rearrangement) Hydroquinone —→ Hydroquinone di acetate —→ 2,5-Dihydroxy acetophenone.

The following demonstration experiments to be arranged:

1. Solving problems based on QSAR
2. Molecular modeling

Lead molecule identification and Isolation from natural products and

Characterization using Co-IR, Co-TLC methods:

1. Eugenol from Clove
2. Curcumin from Turmeric
3. Sennosides from Senna
4. Hesperidine from Orange peel
5. Embelin from Embelia ribes

Preparation and in vitro evaluation of buccal mucoadhesives - 2 experiments
Preparation and evaluation of transdermal films - 2 experiments
Preparation and evaluation of hydrodynamically balanced tablets - 1 experiments
Study of *in vitro* dissolution of various sustained release formulation of marketed products.

Books Recommended:

1. Wolff, M.E.1989. Burger's Medicinal Chemistry and Drug Discovery. New York. John Wiley and Sons.
2. Silverman, R.B. 2011. The organic Chemistry of drug design and drug action. New York. John Wiley and Sons.
3. Nogrady, T. 2012. Medicinal Chemistry, A Biochemical Approach. Oxford. Oxford University Press.
4. Pramanik A.2004. Ligand- receptor interactions in live cells by fluorescence correlation spectroscopy, Current Pharmaceutical Biotechnology.5 (2): 205-212.
5. Tickle, I; Sharff, A; Vinkovic; Yon J. 2004. High throughput protein crystallography and drug discovery. London. Chemical Society Reviews, 33 (8): 558- 565.
6. Hillisch,A, A and Hilgenfeld, R. 2003. Modern Methods in Drug Discovery. New York. Springer.
7. Mukherjee, S. and Singh, S.P. 2010. Reaction Mechanisms in Organic Chemistry. New Delhi. McMilan India Ltd.

PHA-PG-215: DRUG DELIVERY APPROACHES

Theory

(A) Development, Validation and Optimization of Dosage Forms

Preformulation Studies: Introduction; goals of pre-formulation, physico-chemical properties, criteria for selection of drug and excipients, compatibility tests.

Drug Solubility Improvement: Vital techniques including solid state manipulations, inclusion complexes, Cyclodextrins, classification and pharmaceutical applications.

Stability Testing: Stress testing of drug substances, stability testing protocols, shelf-life determination, photostability testing, post-approval changes, packaging influence on stability. ICH guidelines.

Validation of Pharmaceutical Dosage Forms:

(a) Pharmaceutical process validation: Pilot scale-up and process validation

(b) Validation of solid dosage forms: definition and control of process variables, guidelines for process validation of solid dosage forms.

(B) Drug Delivery Systems

Oral Controlled Release (CR) Systems: Rationale of CR delivery, pharmacokinetic/ pharmacodynamic basis, regulatory requirements, Strategies and design of oral CR delivery systems. Gastroretentive

systems.
Implantable Therapeutic Systems: Polymers and approaches.
Closed Bilayer Systems: Structural aspects, preparation, characterization, evaluation and pharmaceutical applications, specialized liposomes in drug targeting, niosomes, erythrosomes, pharmacosomes, aquasomes and solid lipid Nanoparticles.
Nanoparticles and Microspheres: preparation, characterization, evaluation and pharmaceutical applications
Self-emulsifying Drug Delivery Systems (SEDDS) and Microemulsions: Structure, formulation, transport properties and pharmaceutical applications.
Transdermal Therapeutic Systems (TTS): Basic components of TTS (patch, gel, etc.), Varied approaches and evaluation.
Novel Ocular Drug Delivery Systems: Ocular inserts, implants and other novel delivery systems like vesicular systems, microemulsions, SLNs, etc. for ocular use
Protein and Peptide Drug Delivery: Problems associated with delivery of proteins and peptides, delivery systems, toxicity aspects, recent trends in vaccine and vaccine delivery systems.
Monoclonal Antibodies: Production, diagnostic, therapeutic and analytical applications. Introduction to their role in drug targeting.
Gene therapy: An introduction to genetic disorders, approaches, viral and non viral mediated gene therapy, safety and ethical considerations.

(C) Pharmacokinetic and Biopharmaceutical Precepts:

Review of Pharmacokinetic Rudiments: Single-dose and multi-dose compartmental pharmacokinetics, Review of biopharmaceutical considerations.
Bioavailability/ Bioequivalence: Basic concepts, Design and evaluation of Bioequivalence trials, Federal (US FDA and DCGI) guidelines for oral drug delivery systems: immediate release and extended release formulations.
Biopharmaceutical Classification Scheme (BCS) and IVIVC: In vitro and in vivo correlations (IVIVC): Concepts, In vitro Dissolution as a surrogate to In vivo bioavailability, varied IVIVC/IVIVR approaches in the light of BCS, applications and limitations, Federal perspectives.
Recent Advances in Pharmacokinetics and Biopharmaceutics: Fundamentals of noncompartmental pharmacokinetics, PBPK modeling, PK/PD modeling, toxicokinetics, chronopharmacokinetics, etc.

Practical

1. Preparation and evaluation of albumin microspheres.
2. Preparation and evaluation of microcapsules by different microencapsulation technique.
3. Study on diffusion of drug through various polymeric membranes.
4. Preparation and in vitro evaluation of buccal mucoadhesives.
5. Preparation and evaluation of transdermal films.
6. Preparation and evaluation of hydrodynamically balanced tablets.
7. Study of in vitro dissolution of various sustained release formulation of marketed products.
8. Improvement of dissolution characteristics of slightly soluble drugs by various Solid dispersion techniques and solvent deposition systems.
9. Comparison of dissolution of two different marketed products/brands.
10. Influence of polymorphism on solubility and dissolution.
11. Calculation of Ka, Ke, $t_{1/2}$, C_{max} and T_{max} for two sets of data.

12. Calculation of AUC and bioequivalence from the given data for two drugs.

Books Recommended:

1. David, B. T and Paul, B. 2013. Remington pharmaceutical Sciences 21st Edition. London. Williams and Wilkins Publication
2. www.fda.gov/guidelines: USFDA guidelines for bioavailability/bioequivalence, Stability, IVIVC, etc.
3. Shargel, L .1993. Applied Bio pharmaceutics and Pharmacokinetics. Berlin. Appleton and Large.
4. Robinson, R. and Lee, H. L. 1987. Controlled drug delivery, fundamentals and applications, Vol. 29 and vol. 31, 2nd edition. New York. Williams & Wilkins publication.
5. Wells, J.J.1998. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances, London. Ellis Horwood, Chiechester.

PHA-PG-216: BIO-PROCESS TECHNOLOGY

Theory

1.Detailed study: Of the design and operation of different types of fermenters, ancillary fittings like sampling point, aseptic transfer of spore suspension, transfer of inoculums from seed tank to fermenter etc. impeller design and agitator powder requirements, measurement and control of dissolved oxygen, CO2, temperature, pH and foam.

2. Aeration, agitation: And mass transfer in fermentation equipment, effects of aeration and agitation, oxygen requirements of micro organisms, mass transfer theories and diffusional resistance to oxygen transfer, measurement of mass transfer coefficients and factors affecting them.

3. Supply of air: Air compression, cleaning and sterilization of air, plnum ventilation, number of air charges, physiological effects of air movements, sterile areas of biological factories, sampling of air, required standards of air purity, methods of providing air, air compression, air sterilization methods, sterilization of air by filtration through fibrous filters, theory and practice, modern commercial filters, laminar flow stations, granular carbon filters.

4. Rheology of fermentation systems and its importance in fermenter operation.

5. Fermentation process kinetics: Reaction kinetics: Types of reaction, order of reaction, michaelis-menten constant, effect of temperature on reaction rate, activated complexes, catalysed reactions, thermal death of microorganisms. Enzyme inhibition. Fermentation kinetics: continuous fermentation, advantages and limitations, theory of single and two stage continuous fermentation systems applications.

6. Scale up of fermentation process: Principles, theoretical considerations and techniques used.

7. Isolation and purification of fermentation and biological products (theory, equipment, design, operation and applications): Filtration, solvent extraction, adsorption, partition, paper, gas, thin, layer ion analysis and cell yield determinations, metabolic response assays, enzymatic assays, bioautographic technique, disintegration of cells for product recovery.

8. Thermal death times inactivation of bacterial spores, theoretical justification for: HTST (High Temperature Short Time) sterilization and its practical limits, industrial scale batch and continuous liquid sterilization techniques.

9. General fermentation process economics.

Practical

1. Study of oxygen transfer rates in plain and indented flasks by shake-flask method, Kal

method, Kal determination.
2. Determination of respiratory quotient of microbial cells by Warbug-respirometer.
3. Sampling of microorganisms from air by air samples.
4. Bio-autographic technique for the identification of active metabolites.
5. Study and operation of a laboratory fermenter.
6. Determination of thermal death time.
7. Measurement of bacterial growth rate by turbidmetric method.
8. Effect of temperature and pH on enzyme production.
9. Scale of fermentation process of any one antibiotic.
10. Effect of varying substrate concentrations and metal ion concentration on enzyme production.

Books Recommended:

1. Webb, F.C. 2011. Biochemical Engineering. New York. McGraw Hill.
2. Steel, R.2012. Biochemical Engineering. New York. Chemical Publishing Co. Inc.
3. Bailey and Ollis. 2010. Biochemical Engineering. Fundamentals by McGraw Hill, New York.
4. Humphrey, A. S. and Milli, A.E Biochemical Engineering. New York. Academic Press.
5. Paulin, M.D. 2003. Bioprocess Engineering Principles. London. Academic Press.
6. Relevant articles published in Biotechnology and Bioengineering from time to time.

PHA-PG-217: PHARMACEUTICAL BIOTECHNOLOGY – II

Theory

1. Enzyme technology: Sources of enzymes; productions; isolation and purification of enzymes, applications of enzymes in pharmaceutical industry, in therapeutics and in clinical analysis. Production of amyloglucosidase, glocuse isomerase, amylase, cellulose, takadiastase, trypsin, streptokinase and urokinase.

2. Immobilize enzyme engineering: Different techniques of immobilization of enzymes, kinetics of immobilized enzyme, design and operation of immobilized enzyme reactors, multi step immobilized enzyme systems, applications and future of enzyme engineering.

3. Computer control of fermentation process: Optimization of fermentation parameters.

4. Biosynthesis of microbial metabolites: General consideration of metabolic pathways, biosynthesis of alcohol, critic acid, antibiotics(Penicillin, Strepomycin, Tetracycline and Erythromycin), ergot alkaloids, riboflavin, vitamin B 12 and Gultamic acid.

6. Monoclonal antibodies and: Other Immunoreactive products of permanent Immunoclones. Production and application of monoclonal antibodies.

7. Current developments in immunotechnology-diagonstic kits for identifying infection agents: HIV, malaria, tuberculosis, VDRL and pregnancy test. Current status of development of vaccines for HIV.

8. Bussiness management and economic importance: Biotech products such as antibiotics, enzymes and vaccines in developing countries.

9. Plant tissue culture: Phytochemicals from plant cell cultures.

10. Bio-informatics: Information theory and biology, redundancy networking, Network access, Internet and E-mail services, use of data bases in biology, sequence data bases for comparisons.

Practical

1. Production, isolation and purification of an enzyme.
2. Estimation of DNA and RNA.
3. Plant tissue culture technique.
4. Determination of A,B,O and Rh blood groups in human beings.
5. Handling of mice and rats.
6. Enzyme Linked Immunosorbent Assay (ELISA)
7. Dissection and indentification of thymus, spleen and lymph nodes.
8. Diagnostic test for typhoid fever
9. VDRL test.
10. Pregnancy test.
11. Qualitative analysis of proteins and estimation of molecular weight of proteins.

Books Recommended:

1. Old, R.W and Primrose, S.B. 2010. Principles of Gene Manipulation – An introduction to Genetic Engineering. Oxford. Blackwell Scientific Publications.
2. Banot, S.T. 2011. Text book of Immunology. Cambridge. Cambridge University Press.
3. Murashige, T and Skoog. F. 1012. Physiology of Plants. Oxford. Pergamum Press.
4. Rainbow, C. and Rose, A.H. 2010. Biochemistry of Industrial Microorganisms by for Biosynthesis. London. Academic Press.
5. Chapter 1, 2, 7 in Advances in Applied Microbiology Vol-15,1972 on Enzymes, Immobilized Enzymes and Animal and Plant Cell Culture. Academic Press, London.
6. Recombination DNA by Watson et al. (McGraw-Hill, New York)
7. Dodds, J.H. and Roberts, LW. 2003. Experiments in Plant Tissue Culture. Oxford. Pergamon Press.

PHA-PG-218: PHARMACEUTICAL MANAGEMENT

Theory

1. Introduction to management aspects: Concept, nature and purpose of management, Professional managers- tasks, responsibilities and skills needed. Leadership styles, Decision making- Types, procedures, evaluation and selection of alternatives, decision making under various situations, CEO's roles of responsibilities corporate governance and methods to increase the shareholder's value, corporate governance

2. Understanding organizations: Meaning process, types of organization structure and map, Hospital pharmacy as one model of organization and its study. Pharmaceutical company as a model, organizational culture.

Role of a marketing person in different organizations namely, CRO's, manufacturing units with bulk drugs and formulations, contract manufacturing units, R and D units. Globalization aspects in the pharma industry and its impact.

3. Human resource management (HRM): Human resource planning, recruitment and interviewing, human skills evaluation through various instruments. Job description, job evaluation, role clarity,

performance appraisal methods, career planning. Motivational techniques, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, management of conflict.

4. Communication skills: Significance of communication, its process, measures for effective communication (oral and written), barriers of communication.

5. Management of industrial relations: Industrial disputes, settlement of disputes through various routes as bargaining.

6. Quantitative aptitude skills, basic concepts and their relevance to financial management.

Introduction to statistical methods: Probability distribution (Binomial, Poisson and Normal distribution), regression analysis.

Financial Management: Study of the balance sheet of a pharma company, Profit and Loss , Preparing and Monitoring budget and Budgeting controls

7. Operational Research Management ORM

Operation research techniques: Linear programming by graphical method, transportation models, assignment models. Project evaluation techniques by PERT and CPM. Network diagrams and determination of critical path, determination of float. Evaluation of investment decisions by payback period, accounting rate of return, net present value methods. Break-even analysis.

Productivity and operations Management: Productivity concepts, problems, tools and techniques for improvement.

Supply Chain management(SCM), Logistics, planning

8. Systems Management: Management information system (MIS), Database Management system (DBMS), Management Resource Planning (MRP), Enterprise Resource Planning (ERP)

Practical

Student shall submit a journal consisting a write-up on Job description of different levels of employees each from different function and give employee evaluation controls (e.g. one for distribution dept, one for finance dept, one in administration, and one in marketing and production dept.).

Student shall also submit a journal consisting a write-up on case studies and their analysis covering the various principles outlined in theory.

1 Case studies- 15 Cases shall be analyzed based on topics of Principles of Management, Organizational behavior and HRM, globalization- Mergers and acquisitions

2 Group discussions -10 based on problem –solving areas

3 2 role plays , movie presentations, video clips

4 Problem solving to decide upon project choices and investment decisions

One case study, one group discussion, presentation on any development in the field of Pharmacy management.

Books Recommended:

1. Heinz, K and Harold, K. 1994. Management - A Global Perspective. New York. McGraw-Hill International.
2. Peter, F.B. 1998. Management, Tasks, Responsibilities, Practices, Published. Allied Publishers Ltd. Reprinted
3. James, A and Brien, O'.1999. Management Information Systems. Galgotia Publishers Pvt. Ltd.
4. Subba Rao, R.V. 1997. Human Resource Management and Industrial Relations. 1997.

Himalaya Publishing House.

PHA-PG-219: FORMULATION PRODUCTION MANAGEMENT

Theory

1. Pilot plant scale- up techniques: Pharmaceutical pilot plant, pilot plant design, case studies for tablets, capsules, aerosols, liquid orals, parenterals, controlled and sustained release preparations and semi solid preparations.

Basic requirements -design of product, facility, equipment selection and personnel.

2. Quality assurance and validation: Validation: Basics of validation, General principles of Equipment and Process validation case studies related to solid dosage forms. GMP considerations, cGMP standards, quality assurance and Process control, Total Quality Management and Productivity. ISO 9000 series- Salient features. Salient features of Intellectual property Rights and Intellectual property Management, Patents ICH guidelines with respect to Stability testing of New drug substance and products.

3. Optimization techniques in pharmaceutical formulations and processing: Introduction, optimization parameters, classical optimization, statistical design, applied optimization methods like EVOP, Simplex, application of factorial Design in Formulation Development.

4.Production planning, scheduling and forecasting: Production planning and inventory control management, purchasing (vendor development), assessment of production rate changes, costing of products and cost controls

5. Drugs and Cosmetics Act with reference to manufacture, packing, labeling and sale of Drugs and Cosmetics, recent amendments.

6. Formulation production management: Plant site selection and layout. Material handling for various pharmaceutical products, service facilities and preventive maintenance in pharmaceutical companies. Group and individual replacement.

7. Safety: Industrial hazards due to fire, accident, mechanical, electrical equipment, monitoring and preventive system (safety measures including insurance)

8. Effluent testing treatment and waste management

9. Drug Approval Process in different countries – Relate Regulatory Bodies

Practical

1. Preformulation - drug - excipient interactions at different temperatures
2. Preformulation - drug - excipient interactions at different Relative Humidities
3. Comparative evaluation of marketed preparations of solid dosage forms (Major)
4. Comparative evaluation of marketed preparations of liquid dosage forms (Major)
5. Comparative evaluation of marketed preparations of semi-solid dosage forms (Major)
6. Solubilization of drugs by using surfactants and evaluation (Major), by preparing solid dispersions and evaluation (Major), by complexation and evaluation (Major)
9. Effect of surfactant on dissolution of tablets containing sparingly soluble drugs. (Minor)
12. Evaluation of rubber as packing materials (Minor), glass as packing materials (Minor), of plastic as packing materials (Minor)
15. Formulation of semisolid dosage forms and evaluation of excipients used in its formulation (Major)
16. Formulation of solid dosage forms and evaluation of excipients used in its formulation (Major)

17. Formulation of liquid dosage forms and evaluation of excipients used in its formulation (Major)

Books Recommended:

1. Lachman, L and Lieberman, A. 1987. The Theory and Practice of Industrial Pharmacy. Bombay. Varghese Publishing House.
2. Ansel, H.C and Nicholas, G.1990. Pharmaceutical Dosage Forms & Drug Delivery System Fifth Edition. Philadelphia. Lea and Fibiger.
3. Malik, V. 1999.Drugs and Cosmetics Act. Eastern Publishers.
4. Udtipa, N. 1992. Selected Topics in Industrial Pharmacy. Bombay. Varghese Publishing House.
5. Gilbert, S. and Christopher, T.1990. Modern Pharmaceutics, Second Edition. New York. Banker Publications.

PHA-PG-220: RESEARCH METHODOLOGY

Theory

Part A: Research methodology

A1. Research Methodology: An Introduction: Meaning of research; Objectives of research; Motivation of research ; Types of research; Research approaches; Significance of research; Research methods versus methodology; Research and scientific methods; Importance of knowing how research is done; Research process; Criteria of good research; Problems encountered by researchers in India

A2. Defining a research problem, What is research problem?, Selecting the problem, Necessity of defining the problem, Technique involved in defining a problem

A3. Research design: Meaning of research design; Need for research design; Features of good design; Important concepts relating to research design; Different research designs; Basic principles of experimental design; Conclusion; Appendix; Developing a research plan

A4. Sampling design: Census and sample survey, Implications of a sample design, Characteristics of a good sample design

A5. Measurement and scaling techniques: Measurement scales, Sources of error in measurement, Meaning of scaling, Scale classification bases, Important scaling techniques

A6. Methods of data collection, Processing and analysis of data: Collection of primary data, Processing operations

Statistics in research, Measures of central tendency, Measures of dispersion, Measures of asymmetry (skewness), Multiple correlation and regression, Partial correlation

A7. Sampling fundamentals: Need for sampling, Some fundamental definitions, Important sampling distributions

Concept of standard error

A8. Testing of hypothesis -I (Parametric or standard test hypothesis)

What is hypothesis?, Basic concepts concerning testing of hypothesis, Hypothesis testing for comparing two related samples, Hypothesis testing of proportions, Hypothesis testing for difference between proportions, Chi-square tests

Analysis of Variance and covariance, Testing of hypothesis –II

A9. Interpretation and report writing; Meaning of interpretation,Why interpretation, Technique of

interpretation
Precaution in interpretation, Significance of report writing, Different steps in writing report, Layout of the research report, Oral presentation, Mechanics of writing a research project, Precautions for writing research project, Conclusion

A10. The computer: Its role in research: Introduction, The computer and computer technology, The computer system, Important characteristics, Computer applications, Computer and research, Appendix-selected statistical tables

Part B-Scientific Writing Skills

B1. Structuring scientific papers and technical reports: The overall structure, Choosing the title, the abstract of a scientific paper, the executive summary of a technical report, the introduction (or background), Methods, Results (or findings), Discussion, Conclusions, Recommendations, Acknowledgements, References, Appendices.

B2. General strategies for clearer writing; Use analogies and context, Personal pronouns in scientific writing , Emotion

B3. Plain English: What is it? Use one word, not several, Avoid pompous, pretentious writing , Eliminate buzzwords and unnecessary jargon, Use short sentences, Use short paragraphs, Use the active voice, Tone: personal pronouns and contractions, Latin has to go: avoiding i.e. and e.g.

B4. Referencing: Why reference? Different referencing styles, Simple references, Page and volume numbers, Initials, Multiple references, Multiple authors, No stated author, Unpublished material, Ambiguously dated works, The reference list or bibliography, General principles References to books, References to periodicals, References to newspapers, References to web pages

B5. Captions and tables, Writing numbers, Units of measurement: Captions, Formatting tables, Writing large numbers, Writing spans, Writing dates, Writing times, Writing numbers as words, Writing units of measurement , Metric units , Metric prefixes , Case sensitivity, Bibliography

Scheme of Examination

Mid Semester Examination	20 marks
Project Report	40 marks
Seminar and Viva voce	20 +20 marks
TOTAL	**80 marks**

Books Recommended:

1. Kothari, C.R.2005. Research methodology: Methods and Techniques. New Delhi. New Age International publishers.
2. Belmont, L.1993. An Introduction to statistical methods and data analysis. New Delhi. Wadsworth publication Inc.
3. Wayne, C and Gregory, G. 2003.Williams The craft of research, Booth, 2nd Ed. Chicago: University of Chicago Press.
4. Huth, E.J. 1999. Writing and publishing in Medicine. 3rd Ed. Baltimore. Lippincott, Williams and Wilkins.
5. Day, R.A. 2006. How to Write and Publish a Scientific Paper 6th Ed. Westport. Greenwood Press.
6. Sheen, A. P. 1982. Breathing life into medical writing: A Handbook. St. Louis, MO international publication.

7. Amanda, L. 2007. Scientific Writing Skills. Stellenbosch. Sun Press African Sun Media Pvt Ltd.
8. Michael, F.W; Pfaller W.et.al .2001.Guidelines for the design and statistical analysis of experiments in papers. Alta. Sage Publication.
9. Jacquelyn, E; Moorhead, P; V. Rao. 1994. Guidelines for experimental studies. Baltimore. Oriental express publications.