

**JODHPUR NATIONAL UNIVERSITY
JODHPUR**

Faculty of Pharmaceutical Sciences

M.Pharm.

Session 2009-2010

Plan and scheme of Examination for M. Pharm. Semester - I								
Subject Code	Subjects	T	P	Semester Exam.		Sessional Exam.		Total
				Theory	Practical	Theory	Practical	
0011	Advance Analytical Tech. – I (Compulsory)*	4	4	80	80	20	20	200
0021	Bio-Statistics And Computer Applications	4	4	80	80	20	20	200
0031	Professional practice (Compulsory)	3	-	-	-	-	-	50
Branch:- Pharmaceutics (Branch Code:- 01)								
0111	Biopharmaceutics & Pharmacokinetics**	4	4	80	80	20	20	200
0121	Advances in drug delivery system	4	4	80	80	20	20	200
Branch:- Pharmaceutical Chemistry (Branch Code:- 02)								
0211	Advance Organic Chemistry	4	4	80	80	20	20	200
0221	Advanced Medicinal Chemistry – I (Drug Discovery & Development)	4	-	80		20		100
Branch:- Pharmacology (Branch Code:- 03)								
0311	Basic principles of drug therapy and clinical pharmacology	4	4	80	80	20	20	200
0321	Bio pharmaceutics and Pharmacokinetics	4	4	80	80	20	20	200
Branch:- Pharmacognosy (Branch Code:- 04)								
0411	Photochemistry & Medicinal Plant Biotechnology	4	4	80	80	20	20	200
0421	Advance Pharmacognosy	4	4	80	80	20	20	200
Branch:- Quality Assurance(Branch Code:- 05)								
0511	Quality Assurance - I	4	4	80	80	20	20	200
0521	Total Quality Management - I	4	-	80	-	20	-	100
Branch:- Clinical Pharmacy (Branch Code:- 06)								
0611	Applied Pharmacotherapeutics - I	4	4	80	80	20	20	200
0621	Clinical & Hospital Pharmacy - I	4	4	80	80	20	20	200
Branch:- Industrial Pharmacy (Branch Code:- 07)								
0711	Cosmeticology	4	4	80	80	20	20	200
0721	Advances in drug delivery system	4	4	80	80	20	20	200
Branch:- Pharmaceutical Biotechnology (Branch Code:- 08)								
0811	Pharmaceutical Aspects of Microbiology	4	4	80	80	20	20	200
0821	Advances In Pharmaceutical Biotechnology – I	4	4	80	80	20	20	200

*Not Compulsory for Clinical Pharmacy (Branch Code: - 06)

** Compulsory for Clinical Pharmacy (Branch Code: - 06)

Plan and scheme of Examination for M. Pharm. Semester - II								
Subject Code	Subject	T	P	Semester Exam.		Sessional Exam.		Total
				Theory	Practical	Theory	Practical	
0012	Intellectual Property Rights & Drug Regulatory Affairs (Compulsory)*	4	-	80	-	20	-	100
0022	Advance Analytical Tech.- II (Compulsory)	4	4	80	80	20	20	200
0032	Professional practice (Compulsory)	3	-	-	-	-	-	50
Branch:- Pharmaceutics (Branch Code:- 01)								
0112	Novel Drug Delivery System	4	4	80	80	20	20	200
0122	Product Development & Packaging Technology	4	4	80	80	20	20	200
Branch:- Pharmaceutical Chemistry (Branch Code:- 02)								
0212	Advance Medicinal Chemistry- II (Chemistry of Synthetic Drugs)	4	4	80	80	20	20	200
0222	Natural Chemistry (Chem. of Natural Product)	4	4	80	80	20	20	200
Branch:- Pharmacology (Branch Code:- 03)								
0312	Recent advances and emerging trends in pharmacology science	4	4	80	80	20	20	200
0322	Pharmacological methods and toxicology	4	4	80	80	20	20	200
Branch:- Pharmacognosy (Branch Code:- 04)								
0412	Biogenesis & Chemistry of Natural Product	4	4	80	80	20	20	200
0422	Industrial Pharmacognosy	4	4	80	80	20	20	200
Branch:- Quality Assurance(Branch Code:- 05)								
0512	Quality Assurance - II	4	4	80	80	20	20	200
0522	Total Quality Management - II	4		80		20		100
Branch:- Clinical Pharmacy (Branch Code:- 06)								
0612	Applied Pharmacotherapeutics - II	4	4	80	80	20	20	200
0622	Clinical & Hospital Pharmacy – II	4	4	80	80	20	20	200
0623	Drug Discovery development & Clinical Research	4		80	80		20	100
Branch:- Industrial Pharmacy (Branch Code:- 07)								
0712	Novel Drug Delivery System	4	4	80	80	20	20	200
0722	Industrial pharmacy and production management	4	4	80	80	20	20	200
Branch:- Pharmaceutical Biotechnology (Branch Code:-08)								
0812	Bioprocess Technology	4	4	80	80	20	20	200
0822	Advances In Pharmaceutical Biotechnology – II	4	4	80	80	20	20	200

*Not Compulsory for Clinical Pharmacy (Branch Code: - 06)

Plan and scheme of Examination for M. Pharm. Semester – III

Subject	External Exam.	Internal Exam.	Total
Dissertation	200	100	300

Plan and scheme of Examination for M. Pharm. Semester – IV

Subject	External Exam.	Internal Exam.	Total
Dissertation	200	100	300

M.PHARM. SEMESTER-I

ADVANCE ANALYTICAL TECHNIQUE-I (Compulsory)

THEORY

Subject code -0011T

Hours- (04/week)

1. UV-Visible Spectroscopy: Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, choice of solvent and solvent effects, modern instrumentation – design and working principle. Applications of UV-Visible spectroscopy (qualitative and quantitative analysis), Woodward –Fischer rules for calculating absorption maximum.
2. Infrared Spectrophotometry: Introduction, basic principles, vibrational frequency and factors influencing vibrational frequency, instrumentation and sampling techniques, interpretation of spectra and applications in Pharmacy. FT-IR-theory and applications, Attenuated Total Reflectance (ATR).
3. Nuclear Magnetic Resonance Spectroscopy: Fundamental Principles and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, FT-NMR, 2D -NMR, NMDR, NOE, NOESY, COSY and applications in Pharmacy, interpretation of spectra, C¹³ NMR-Introduction, Natural abundance, C¹³ NMR Spectra and its structural applications.
4. Mass Spectroscopy : Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS

- (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), GC-MS, interpretation of spectra and applications in Pharmacy.
5. Thermal Methods of Analysis: Theory, principles, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).
 6. X-Ray Diffraction Methods: Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray crystallography, X-ray powder diffraction, Miller indices, interpretation of diffraction patterns and applications.
 7. Optical Rotary Dispersion: Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.
 8. Application of Instrumental methods in the development of medicines, concept of Analytical methods development.

PRACTICALS

1. Use of Spectro photometer for analysis for Pharmacopoeial compounds and their formulations.
2. Quantitative Colorimetric determination of suitable drugs using following reagents:
 - a) Paradimethyl Amino Cinnamaldehyde
 - b) MBTH
 - c) FC reagent
 - d) 2, 6 dichloro quinine chlorimide
 - e) Ninhydrin
3. Simultaneous estimation of combination formulations (Ibuprofen and Paracetamol tablet, Paracetamol and Nimesulide tablet, Ciprofloxacin and Tinidazole tablet.).
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. I.R. of certain compound possessing following functional groups.....
 - a) –OH
 - b) carbonyl
 - c)Amine
 - d) Aromatic nucleus
6. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (at least for 4 compounds each).
7. Assay of following official formulations:
 - a) Frusemide tablet IP
 - b) Metformine tablet IP
 - c) Chloramphenicol Capsule IP
 - d) Digoxin Tablet IP

BOOKS RECOMMENDED:

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al,7th Edition, 1981.

2. Principles of Instrumental Analysis by Douglas A. Skoog, James, J. Leary, 4th Edition.
3. Text book of Biopharmaceutic Analysis- Robert Smith and James Stewart.
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.
5. Vogel's Text Book of Quantitative Chemical Analysis, 6th Edition, 2004.
6. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition.
7. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
8. Instrumental Methods of Analysis – Hobert H. Willard, 7th Edition.
9. Spectroscopy of Organic Compounds by P. S. Kalsi.
10. Text book of pharmaceutical analysis-K.A. Connors.
11. Pharmaceutical analysis-Hiquchi, Bechmann, Hassan.
12. Methods of Drug analysis- Gearian, Graboski.
13. Quantitative analysis of Drugs- Garrot.
14. Quantitative analysis of Drugs in Pharmaceutical formulations- P.D. Sethi.
15. Instrumental Methods of Chemical Analysis – Y.R. Sharma.
16. IP/ BP/ USP.

BIO-STATISTICS AND COMPUTER APPLICATIONS (Compulsory)

THEORY

Subject code -0021T

Hours– (04/week)

1. Introduction of samples, random sampling, sampling procedures – stratified, systematic and cluster sampling, sampling in quality control measurement of spread of data coding, precision, accuracy.
2. Statistical Inference Statistical estimation (confidence of intervals), statistical hypothesis testing composition of variances in independent samples, test of equality, population mean, variance in case of two population, large sample tests.
3. Linear regression and correlation. Introduction, analysis of standard curves in Drug analysis-application of linear regression, assumption of tests in hypothesis in linear regression, variance of sample estimates of the parameters, a Drug stability study – an example of the application

- of linear regression, confidence intervals in regression coefficients, nonlinear regression.
4. Analysis of variance Linear models One-way analysis of variance, planned versus a Posteriori (Unplanned) comparisons in ANOVA, example of one-way analysis of variance-unequal sample size and fixed and random models, two-way analysis of variance (Randomized blocks). Analysis of covariance, ANOVA for pooling regression lines as related to stability data.
 5. Quality control Introduction, control charts, acceptance sampling and operating characteristic curves, statistical procedures in Assay. Department establishing in-house limits, some statistical aspects of quality and the “Barr Decision”.
 6. Research Methodology and literature sources, thesis writing and presentation of the work, citation of references. Computer fundamentals, MS-Excel, SPSS/SYSTAT

PRACTICALS:

1. Computer basics like MS-Office
2. Chem-Sketch, ISIS draw
3. Statistical software SPSS/Instat/Systat
4. Data handling
5. Some software of Medicinal Chemistry

BOOKS RECOMMENDED:

1. Pharmaceutical Statistics Marcel Dekker
2. Practical and clinical applications 3rd Edn by Sanford Bolton, 1997 Marcel, Dekker.
3. Fundamental of Applied Statistics: S.C. Gupta and C.K. Kapoor
4. Biostatistics- Sadaker
5. Statistics- Gofeti Radhakrishnan
6. Biostatistics - Zar wiley Publication
7. Statistical methods in clinical trial by Woolson

PROFESSIONAL PRACTICE

THEORY (Compulsory)

Subject code -0031

Hours – (03/week)

Professional Practice: A student shall undergo professional training to assist in practical classes and in theory lectures to diploma and degree

classes assign to him/her under the supervision of subject incharge. He/She has to submit a report on the work assign to him/her. His/Her evaluation will be on the basis of performance and report submitted by him/her.

M. Pharm. Branch: - Pharmaceutics (Branch Code: - 01)

BIOPHARMACEUTICS AND PHARMACOKINETICS

THEORY

Subject code - 0111

Hours – (04/week)

1. Absorption of drugs: Definition, Structure of cell membrane and composition, Gastrointestinal absorption – Mechanism, Factors affecting drug absorption: Biological, Physiological, Physico-Chemical and Pharmaceutical dosage form factors; Methods of determining absorption: In-vitro and In-vivo methods; Absorption of drugs from non-oral route.
2. Distribution of drugs: Definition, Distribution in blood and other fluids: cellular distribution, drug penetration to CNS, placental transfer of drugs and blood flow; Volume of distribution, Plasma protein binding: Drug distribution and drug effects, Drug binding in tissues.
3. Excretion of drugs: Definition, Renal and non- renal excretion.
4. Pharmacokinetics:
Definitions, Basic considerations - zero order and first order kinetics.
 - a. A detailed study of open one compartment model and open two compartment model.
 - b. Non-compartmental methods-Area under first movement curve (AUMC),
 - c. Drug clearance, apparent volume of distribution, mean residence time (MRT) and its significance.
 - d. Concept of clearance- Organ clearance, Total clearance, Hepatic clearance and Renal clearance.
 - e. Non- linear Pharmacokinetics: Cause of non-linearity, Michaelis-menten equation, Estimation of Km and Vmax.
6. Pharmacodynamics:
 - a. General aspects of receptor pharmacology.

- b. Structural and functional aspects of receptors.
 - c. Regulation of receptors.
 - d. Classification of receptors.
7. Bioavailability: Definition, Estimating absorption rate of drugs; Preabsorptive hydrolysis and metabolism; Presystemic metabolism: Hepatic metabolism and Gut wall metabolism; Bioavailability of some specific drugs namely Acetazolamide, Ampicillin, Carbamazepine, Diazepam, Furosemide, Nitrofurantoin, Tolbutamide; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Methods of Enhancing Bioavailability of Drugs: Solubilisation, Prodrugs, Enhancement of dissolution characteristics, Inclusion of bioavailability enhancers.
 8. Dosage Regimen: Multiple dosing with respect to IV and oral route, concept of loading dose, maintenance dose and accumulation index.
 9. Bioequivalence Studies: Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.
 10. Pharmacokinetic Variability: Body weight, Age, Sex, Genetic factors, Pharmacokinetic variability's in disease, states of Renal, Liver, Cardiovascular, Thyroid and Dosage adjustment in the above conditions.

PRACTICALS:

In vitro release / dissolution study of a dosage form, plasma protein binding, bioavailability studies using urinary excretion data analysis method and blood serum concentration estimation method, In vitro bioequivalence study, in vivo release studies, estimation of pharmacokinetics, drug-food interaction.

BOOKS RECOMMENDED:

1. Biopharmaceutics and Clinical pharmacokinetics-M. Gibaldi
2. Biopharmaceutics and Clinical pharmacokinetics-Notari
3. Biopharmaceutics and relevant pharmacokinetics-T. G. Wagner
4. Biopharmaceutics and Drug interactions-Cadwallader
5. Pharmacokinetics-M. Gibaldi and D. Perrier

ADVANCES IN DRUG DELIVERY SYSTEM

THEORY

Subject code - 0121

Hours– (04/week)

1. Preformulation Studies: on various dosage forms such as tablets, capsules, suspension, creams, emulsion, injectables, ophthalmic and aerosols etc.
2. Advances in Solid dosages forms: Physics of table's compression, direct compression, recent advances in tablet coating, micro-encapsulation and uses of newer encapsulating agents and techniques. Particle size enlargement – various methods and application.
3. Advances in liquid dosages forms: Theoretical and particle aspects in the manufacture of liquid dosage forms such as suspension, emulsion. Solubilization, formulation of parenteral suspension and emulsion. Techniques and principles involved in the formulation of multiphase and micro-emulsion. Mechanism of droplet stabilization. Stability of multiphase and micro-emulsion. Destabilization kinetics.
4. Parenteral dosage forms: Processing of small and large volume parenteral raw materials, principle and technique. Stability evaluation environment, personnel and management factors in control and quality assurance.
5. Stability studies and kinetics: stability and stabilization of Pharmaceuticals, Stability calculation, rate equation, activation energy calculation, interpretation of kinetic data, stability data in product development. Accelerated stability testing. Factors to responsible for destabilization of pharmaceutical product and techniques and means to improve stability. Mathematical treatment of stability test data. Calculation shelf life, Calculation of Q. 10 value and application Q. 10 value in stability testing.
6. Polymer Sciences: Pharmaceutical applications of polymer, properties of polymers.

PRACTICALS:

Preformulation studies of different dosage forms and also see the effect of variables that can effect the formulation of dosage forms. Such as Tablets, Suspensions, Emulsions, Aerosols, Ophthalmic preparations etc. Preparation and evaluation of microcapsules/ microspheres, coating of tablets, microemulsions, multiple emulsions, suspension/ disperse system,

small volume parenterals, Accelerated stability study of prepared dosage form.

BOOKS RECOMMENDED:

1. Remington's Pharmaceutical application of polymers, properties of polymers. Thermodynamics of polymer solution, phase separation, coacervation and Micro-encapsulation. Polymer in solid state.
2. Theory and practice of Industrial Pharmacy Leon Lachman, Herbert A Lieberman and Joseph L. Kaning. Varghese Publishing House, Bombay
3. Essential of Physical Chemistry and pharmacy Arnikar, Kadam, Gujar, Orient Longman.
4. Quality Control in The pharmaceutical Industry: Volumes 1,2 and 3, Murraray
5. S. Copper Academic Press, New York and academic Press London.
6. Good Manufacturing Practices for pharmaceuticals – A plan for total Quality Control. S. H. Willing, M. M. Tuckerman, S. Hitchings, Marcel Dekker, Inc. New York.
7. Pharmaceutical Preformulation by J. I. Wells, John wiley & sons, N.Y.
8. Chemical Stability of Pharmaceutics – A Handbook for Pharmacists – Kenneth A Connors, Gordon L. Amidon. Voluation J. Stelle, John Wiley & Sons, New York.
9. Pharmaceutical Dosage Forms: Parenteral Medications Volumes 1, 2 and 3. Kenneth E. Vavis, Loan Lachman and Herbert A. Lichman. Marcel Dokker New York.
10. Pharmaceutical Dosage Forms: Dispersed System Vol. 1 & 2 Edited by as 13.
11. Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3.
12. Sterile Dosage Forms, Salvatore Turbo and Rebest E. King Lea and Febiger, Philadelphia.
13. Pharmaceutics – The Sciences of Dosage Form Design Michael E. Aulton, Churchill Livingstone, New York.
14. Advances in Pharmaceutical Sciences, Edited by Bean, Bockett and Carless, Academic Press, New York. Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
15. Physical Pharmacy: A. N. Martine, James Swarbrick and Commarate (Lea & Febiger, Philadelphia.

Branch: - Pharmaceutical Chemistry (Branch Code: - 02)
ADVANCED ORGANIC CHEMISTRY

THEORY

Subject code - 0211

Hours– (04/week)

1. Stereo chemistry
 - a) Stereo isomerism, Geometrical Isomers and optical isomers, basic concept of optical activity and chirality structural features necessary for optical activity.
 - b) Configuration and a specification, correlation of configuration, absolute configuration, methods of determining configurations, racemic modification, resolution and optical purity.
 - c) Stereo chemistry of olefins- cis-trans, stereo chemistry of ring systems-including fused ring and bridge rings.
 - d) Confirmation and reactivity in a cyclic compounds- conformational analysis.
 - e) Confirmation in open chain. Six member rings and other rings having heteroatoms.
2. Detail study on aliphatic nucleophilic substitution (S_N1 & S_N2) and aliphatic electrophilic substitution, electrophilic and nucleophilic substitution in aromatic systems, E1, E2 mechanisms, Hofmann and Saytzeff elimination, competition between elimination and substitution, intermolecular elimination, addition reaction, Markownikove's rule, nucleophilic addition, hydride transfer reactions and Cram's rule with reference important reaction and pharmaceutical preparations, organometallic compounds and ylides of phosphorus, sulphur & nitrogen.
3. Pericyclic reactions: Mechanism, Types of pericyclic reactions – cyclic addition, electrocyclic reaction, Sigmatropic rearrangement.
4. Mechanism consideration in detail for the following organic reactions:- Claisen condensation, Enolization, Hofmann rearrangements, Free radicals displacement, Addition and rearrangement of free radicals, Beckmann rearrangements, Transannular rearrangements, Pinacol rearrangements, Curtius rearrangement, Schmidt rearrangement, Fries rearrangement, Benzidine rearrangement, Benzilic rearrangement, Allylic rearrangement, Dimoth rearrangement, Wittig reaction, Reimer-Tiemann's reaction, Buchner method of ring enlargement, Carrol reaction, Diels-Alder reaction, Pinner reaction, Reformatsky

reaction, Robinson reaction, Annulation reaction, Cannizzarro's reaction, Oppeneaur oxidation, Birch's reduction and Clemmensen's reduction.

PRACTIACLS:

The reaction and mechanism involved in theory as applied to drugs and drug intermediates are synthesized (at least two steps).

BOOKS RECOMMENDED:

1. Stereochemistry of Carbon Compounds by Eliel.
2. Conformational analysis by E. L. Eliel.
3. Advanced Organic Chemistry, Reaction Mechanism and Structure by J. March.
4. A Guidebook to Mechanism in Organic Chemistry by Sykes.
5. Mechanism and Structure in Organic Chemistry by Gould.
6. Principles of Ionic Organic Reactions by Alexander.
7. Reactions in Organic Chemistry by Surrey.
8. Organic Chemistry, Vol.-I by Finar.
9. Organic Chemistry, Vol.-II., The Fundamentals and Principles by Finar.
10. Unit Processes in Organic Synthesis by Groggins.
11. Mechanism and theory of Organic Chemistry, Lowry and Richardson, Harper
12. Stuart Warren: Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
13. Mann and Saunters, Practical Organic Chemistry (Orient Longman)

ADVANCED MEDICINAL CHEMISTRY-I (Drug Discovery & Development)

THEORY

Subject code-0221

Hours – (04/week)

1. Drug Design- Definition, Historical development approach to drug discovery, Parameters involved in drug design- Importance of physicochemical & steric properties (including isosteric modifications) in new drug discovery, Tailor-made drugs, Specific and non-specific protein binding, Tissue depots, Influence of formulations on bioavailability. Various approaches used in drug design, electronic aspects of design, molecular size, shape, molecular orbital approach.

2. Metabolism- Definition, general introduction, different phases, metabolic pathways, importance in drug design.
3. Quantitative Structure Activity Relationship(QSAR)- Introduction, methods of QSAR, aims, object, limitations, applications, Hansch's LFER model, various physicochemical parameters used in drug design and their practical determination, free Wilson mathematical model.
Molecular Modeling- structure based drug design-3 D-QSAR, Computer aided drug design.
4. Pharmacokinetic Studies in New Drug Discovery- Introduction, relation of drug metabolism to drug design structure, absorption-distribution relationship-significance for drug design.
5. Design and Application of Prodrugs- Prodrug concept, Prodrugs of various functional groups like carbonyl, hydroxyl, amides, amines; Application of Prodrug approaches to- Improvement of bioavailability, Prevent first pass metabolism, Reduction of side effects, Prolong duration of action, Site specific delivery.
6. Approaches to the rational design of enzyme inhibitors- Enzyme inhibitors in medicines, Enzyme inhibitors in basic research, rational design of non-covalently & covalently binding enzyme inhibitors.

BOOKS RECOMMENDED:

1. Introduction to the Principles of Drug Design by Smith & Williams.
2. Drug Design, Vol. VII by Ariens.
3. Progress in Pharmaceutical Research by Woodridge.
4. Annual Reports in Medicinal Chemistry, Academic Press Inc.
5. Comprehensive Medicinal Chemistry, Vol. 4.
6. Burger's Medicinal Chemistry, Vol. 1
7. Manfred E. Wolff and Burger's, Medicinal Chemistry and Drug Discovery- Vol. I-VI, Principles and Practice, Vth Ed., John Wiley & Sons.
8. Receptor based drug design, by P. Leff, Marcel Dakker, New York, 1998. 6. Paul's charifron – Practical application of computer Aided drug design – Marcel Dakker – 1997.
9. The Organic Chemistry of Drug design and Drug Action - R. B. Silverman – Academic Press –1992.
10. Exploring QSAR – Fundamental and applications in Chemistry and Biology by Carowari Hansch and Albert Leo, ACS, Washington DC – 1995.
11. Advanced in drug discovery techniques by Alan L. Harney.
12. Metabolic Pathways by Greenbury.

Branch: - Pharmacology (Branch Code: - 03)

**BASIC PRINCIPLES OF DRUG THERAPY
&
CLINICAL PHARMACOLOGY**

THEORY

Subject code - 0311

Hours – (04/week)

1. Definition, scope, organization and growth of clinical pharmacology, Cellular transduction mechanisms. Clinic pharmacokinetic, monitoring of drug therapy. Adverse drug reactions, patient compliance. Pharmacogenetic, paediatric and geriatric pharmacology. Drug interaction, drug therapy during pregnancy and lactation.
2. Drugs acting on the autonomic nervous system
Neurotransmission Autonomic and Somatic motor nervous system.
Muscarinic receptor agonists and antagonists.
Anticholinestrage agents
Agents acting at the neuromuscular junction and automatic ganglia
Catecholamine, sympathomimetic drugs and adrenergic receptor antagonists, 14o0c0.ular pharmacology.
5-Hydroxy tryptamine (Serotonin)
3. Drugs acting on the Central Nervous System
Neurotransmission and the Central Nervous System (CNS)
History and principles of anaesthesiology
General anesthetics
Local anesthetics.
Hypnotics, sedatives and ethanol
Drugs and the treatment of psychiatric disorder. Psychosis, anxiety, depression and mania
Drugs effective in the therapy of epilepsy
Drugs effective in the therapy of migraine
Treatment of central nervous system degenerative disorders
Opioid analgesics and antagonists
Drugs addiction and drugs abuse
4. Autocoids: Drug Therapy of Inflammation
Histamine, bradykinin and their antagonists
Lipid- derived autocoids: Eicosanoids and platelets activating factor
Analgesic, antipyretic and anti- inflammatory agents and drugs employed in the treatment of gout
Drugs used in the treatment of asthma.
5. Drugs effecting renal, blood and cardiovascular function

- a. Diuretic
- b. Drugs used in the treatment of Myocardial Ischemia (MI)
- c. Antihypertensive agents and the drug therapy of hypertension
- d. Pharmacological treatment of heart failure
- e. Anti-arrhythmic drugs
- f. Drugs used in the treatments of hyperlipoproteinemias
- g. Hematopoietic Agent: Growth factors, minerals and vitamins
- h. Anti coagulant, thrombolytic and anti-platelets drugs.

PRACTICALS:

Pharmacological techniques employed in the studies of various drugs.

BOOKS RECOMMENDED:

1. C. R. Craig and R. E. Stitzel, Modern Pharmacology.
2. Goodman and Gilman's: The Pharmacological Basis of Therapeutics; Edited by: Alfred Goodman; Theodore W. Rall, Alan S. Nies and Palmar Taylor.
3. D. R. Laurence and P. N. Bennett; Clinical Pharmacology.
4. F.S.K. Brar; Essentials of Pharmacotherapeutics.
5. H. P. Rang and M. M. Dale; Pharmacology.
6. James Crossland; Lewis's Pharmacology (Revised).
7. D. G. Grahame-Smith and J. K. Aronson; Oxford Textbook of Clinical Pharmacology and Drug Therapy.
8. S. Singh; Essentials of Pharmacology; Academia Publishers.

BIOPHARMACEUTICS AND PHARMACOKINETICS

THEORY

Subject code - 0321

Hours – (04/week)

1. Absorption of drugs: Definition, Structure of cell membrane and composition, Gastrointestinal absorption – Mechanism, Factors affecting drug absorption: Biological, Physiological, Physico-Chemical and Pharmaceutical dosage form factors; Methods of determining absorption: Invitro and Invivo methods; Absorption of drugs from non-oral route.
2. Distribution of drugs: Definition, Distribution in blood and other fluids: cellular distribution, drug penetration to CNS, placental transfer of drugs and blood flow; Volume of distribution, Plasma protein binding: Drug distribution and drug effects, Drug binding in tissues.
3. Biotransformation of drugs: Definition, Phase I and Phase II reactions and Factors affecting biotransformation.
4. Excretion of drugs: Definition, Renal and non- renal excretion.
5. Pharmacokinetics:
 - a. Definitions, Basic considerations - zero order and first order kinetics.
 - b. A detailed study of open one compartment model and open two compartment model.
 - c. Non-compartmental methods-Area under first movement curve (AUMC),
 - d. Drug clearance, apparent volume of distribution, mean residence time (MRT) and its significance.
 - e. Concept of clearance- Organ clearance, Total clearance, Hepatic clearance and Renal clearance.
 - f. Non- linear Pharmacokinetics: Cause of non-linearity, Michaelis-menten equation, Estimation of K_m and V_{max} .
6. Pharmacodynamics :
 - a. General aspects of receptor pharmacology.
 - b. Structural and functional aspects of receptors.
 - c. Regulation of receptors.
 - d. Classification of receptors.
7. Bioavailability: Definition, Estimating absorption rate of drugs; Preabsorptive hydrolysis and metabolism; Presystemic metabolism: Hepatic metabolism and Gut wall metabolism; Bioavailability of some specific drugs namely Acetazolamide, Ampicillin, Carbamazepine,

- Diazepam, Furosemide, Nitrofurantoin, Tolbutamide; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Methods of Enhancing Bioavailability of Drugs : Solubilisation, Prodrugs, Enhancement of dissolution characteristics, Inclusion of bioavailability enhancers.
8. Dosage Regimen: Multiple dosing with respect to IV and oral route, concept of loading dose, maintenance dose and accumulation index.
 9. Bioequivalence Studies: Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.
 10. Pharmacokinetic Variability: Body weight, Age, Sex, Genetic factors, Pharmacokinetic variability's in disease, states of Renal, Liver, Cardiovascular, Thyroid and Dosage adjustment in the above conditions.

PRACTICALS:

In vitro release / dissolution study of a dosage form, plasma protein binding, bioavailability studies using urinary excretion data analysis method and blood serum concentration estimation method, In vitro bioequivalence study, in vivo release studies, estimation of pharmacokinetics, drug-food interaction

BOOKS RECOMMENDED:

1. Biopharmaceutics and Clinical pharmacokinetics-M. Gibaldi
2. Biopharmaceutics and Clinical pharmacokinetics-Notari
3. Biopharmaceutics and relevant pharmacokinetics-T. G. Wagner
4. Biopharmaceutics and Drug interactions-Cadwallader
5. Pharmacokinetics-M. Gibaldi and D. Perrier

Branch: - Pharmacogonosy (Branch Code: - 04)

**PHYTOCHEMISTRY AND MEDICINAL PLANT
BIOTECHNOLOGY**

THEORY

Subject code-0411

Hours– (04/week)

1. Phytochemical studies of following classes of drugs including basic chemistry, chemical or phytochemical properties (excluding synthesis) of herbal medicine. Studies includes Carbohydrates, Glycosides, Alkaloids, Flavonoids, Tannins, Terpines, Coumarin and other Phenolic compounds, Essential or Volatile oil, Resin.
2. Review on chemistry, bioactivity and mechanism of action of insecticides and pesticides of natural and synthetic origin.
3. An over view on hallucinogenic, teratogenic, poisonous plants and mushroom.
4. Influence of mutation, polyploidy, hybridization on phytoconstituents.
5. Historical perspectives and applications of plant biotechnology in pharmacy and allied fields.
6. Types, techniques, nutritional requirements and growth of plant tissue cultures. Organogenesis and embryogenesis. Protoplast fusion and cultures. Biotechnology of micro propagation of medicinal plants.
7. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Procedures and elicitors on production of Biomolecules Immobilization techniques and its application on secondary metabolites production.
8. Biotransformation, bioreactors, for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture.
9. Hairy roots and multiple shoots culture and their application.

PRACTICALS

1. Preliminary phytochemical screening and detection of various plant constituents such as Carbohydrates, Alkaloids, Anthraquinones, Flavonoids, Polyphenolic compounds, Lipids, Proteins and Amino acids.
2. Preparation of extracts enriched with active principles and studying their Stability.
3. Phytochemical analysis of isolated plant constituents by UV, HPLC and HPTLC.
4. UV analysis of some crude drugs and phytochemicals for identification and detection.

5. Fumigation of aseptic area and air sampling.
6. Methods of preservation of culture.
7. Qualitative analysis of potable water.
8. Estimation of microbial load in pharmaceutical excipients and raw materials as per official pharmacopoeia.
9. Preparation and maintenance of primary cell culture and cell lines.
10. Animal immunization – inoculation, bleeding and antigen- antibody reactions by haemagglutination – inhibition, neutralization and precipitin reactions.
11. Standardization of inoculum and estimation of MIC by serial dilution and gradient plate technique.
12. Qualitative and quantitative analysis of anti- microbial agents by ditch – plate method and extinction methods (RWC test).
13. Microbial sensitivity of some human pathogenic isolates against various
14. Antibiotics.

BOOKS RECOMMENDED:

1. Text book of Pharmacognosy – Trease and Evans.
2. Medicinal Natural Products IInd Edition (A biosynthetic approach) – Paul M. Dewier.
3. Pharmacognosy, Phytochemistry, Medicinal Plants IInd Edition – Jean Bructon.
4. Herbal Medicine – Manuchair Ebadi.
5. Plant tissue Culture – Bhagwani Vol 5. (Elsevier)
6. Plant Cell and Tissue Culture (Lab. Manual) – J.R.M.M. Yeoman.
7. Medicinal Natural roducts IInd Edn. (A biosynthetic Approach) Paul M. Dewick.
8. Pharmacognosy, Phytochemistry Medicinal Plants IInd Edn. Jean Bruneton.
9. Elements of Biotechnology – P.K. Gupta. Kalyani Publication.
10. Plant Tissue Culture an alternative for production of useful metabolites. Masanaru Misawa.
11. Chemistry of Alkaloids by S.W. Pelletier
12. A Hand Book of Common remedies in Siddha system of medicine- CCRIMH
13. Alkaloids by Manske. 3. Plant Physiology by Dieter Hess.
14. Steroids by Fieser and Fieser.
15. Organic Chemistry by I.L. Finar Vol. II.
16. Chemistry of Natural Products by K.W. Bentley.

17. Biosynthesis of Aromatic Compounds by Ulrich Weiss & J. Michael Edwards.
18. Essential oils and waxes: H.F. Linskens & J.F. Jackson.
19. The Ayurveda Encyclopedia – Swami Sada Shiva Tirtha.
20. Encyclopedia of Natural medicine – Michael Murray & Joseph. Pizzorno
21. Toxic plants and other Natural toxicants – Tom Garland & Catharine Barr.
22. Alternate medicine – Dr. K.B. Nangia
23. Ayurvedic Medicines – H. Panda.
24. Pharmacognosy and Pharmacobiotechnology – Ashutoshkar.

ADVANCED PHARMACOGNOSY

THEORY

Subject code - 0421

Hours– (04/week)

1. Classification of herbal drugs with special reference to sero-taxonomical classification.
2. Biomedicinals of recent discovery. Current status of plants in alternative system of medicine
3. Basic principal of treatment in different system of medicine (Ayurvedic, Unani, Sidhha, Chinese, Kempo).
4. Recent advances in Pharmacognosy. Modern method of extraction, isolation, drying & purification of phytoconstituents with their merits and demerits
5. Review on plant bitters, sweeteners, dyes, pigments & preservatives, endangered medicinal plants including classification.
6. Extraction, Isolation, purification & analytical interpretation of phytoconstituents-alkaloids, terpens, glycosides, tannin, resin, flavonoids, volatile oils, carbohydrates, coumarine & other phenolics compounds, fats & fixed oils etc.
7. A review of marine drugs including collection, storage & therapeutic activities
8. General method of screening of natural products for the following biological activities -
9. Anti-inflammatory, Anti-malarial, Diuretics, Antidiabetic, Hepatoprotective, Anti-fertility, Immunomodulators, Analgesic, Antipyretic, Anti oxidants, Anti obesity, Anticancer, Anti viral, Anti bacterial.

10. A review on herbs as insecticides, pesticides, cosmetics, functional food and nutraceutical.
11. Use of microtome in the preparation of histological slides.

PRACTICALS

1. Pharmacognostic study of medicinal plants and animals of pharmacognostical importance. Microtome section cutting.
2. Extraction, isolation and characterization of the isolated phytoconstituents.
3. Quantitative estimation of phytoconstituents using various separation and spectral techniques.
4. Screening of natural products as per WHO/ICH guideline.
5. Evaluation of marketed formulation.

BOOKS RECOMMENDED:

1. Pharmacognosy by G.E. Trease, W.C. Evans, ELBS.
2. Pharmacognosy by Varro E. Tyler, Lynn. R. Brady, James E. Robbers.
3. Text Book of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
4. Introduction to flavonoids: Bruce A. Bohm, Harwood Academic Publishers, 1998.
5. Herbal Drug Industry: R. D. Chudhary, Eastern Publishers, New Delhi 1996.
6. Wealth of India, CSIR, New Delhi (Related Volumes)
7. Cultivation & Utilization of medicinal plants: Atal & Kapoor, PRL, Jammu.
8. Cultivation & Utilization of aromatic plants: Atal & Kapoor, PRL, Jammu.
9. Various journals related to medicinal plants.
10. Pharmacognosy: Trease W.C. Evans G. E. Bailliere & Tindall, London, 14th edn.
11. Pharmacognosy: Kokate, Purohit, Gokhale, 15th edition, Nirali Prakashan, Pune
12. British Herbal Pharmacopoeia, (vol. I, II, & III) Her Majesty's Services, U. K.
13. Phytochemical methods: J. B. Harborne
14. Various Research Journals on Medicinal natural products.
15. Modern Toxicology vol. II by P.K. Gupta, D.K. Salunkhe
16. Clinical applications of the Ayurvedic remedies.
17. Baidyanth Book of Ayurvedic Knowledge.

Branch: - Quality Assurance (Branch Code: - 05)

QUALITY ASSURANCE -I

THEORY

Subject code -0511

Hours – (04/week)

1. Microbiological assay of antibiotics and vitamins. Immunological assays: - ELISA, immunoblotting, immunofluorescence, immunoaffinity including Radio immuno assay.
2. In process quality control testing of pharmaceuticals like tablets, capsules and liquid dosage forms, parenteral preparations, transdermal products, suppositories and controlled release products.
3. Containers, closures and packaging materials for pharmaceuticals: Types, performance, quality control tests; assuring quality of glass; types of plastics used, permeation, leaching, sorption, chemical reaction, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment.
4. An approach to the development of analytical methods including recovery studies for drugs in bulk and in formulations,
5. Theoretical aspect of analysis of drugs in biological fluids like urine, blood etc.
6. Stability studies of various formulations as per ICH guidelines.
7. Sterility testing including Pyrogen testing.
8. Quality control testing of Herbals and screening of plant extracts as per WHO guidelines.
9. Quality control testing of Cosmetics as per BIS.

PRACTICALS

Practical based on theory.

BOOKS RECOMMENDED:

1. IP, BP & USP
2. Enzymes – Biochemistry, Biotechnology, Clinical Chemistry
3. Michael E. Swartz, Analytical method development & validation.

TOTAL QUALITY MANAGEMENT-I

THEORY

Subject code -0521

Hours – (04/week)

1. Concepts and philosophy of TQM, GLP, GMP (orange guide).
2. Good manufacturing practices.
3. Organization and personnel, responsibilities, training, hygiene.
4. Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination.
5. Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP).
6. Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms.
7. Warehousing design, construction, maintenance and sanitation, good warehousing practice, materials management.
8. Standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.
9. Standard test procedures.
10. Quality control laboratory: Responsibilities, good laboratory practices, routine control instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house.

BOOKS RECOMMENDED

1. Guideline for Developing National Drug Polices- WHO Publication, 1998.
2. Quality Assurance of Pharmaceuticals- A Compendia of Guidelines and Related Materials, Vol.-1, WHO publication.
3. A Guide of Total Quality Management- kaushik maitra and sedhan k. Ghosh.
4. GMP- Mehra.
5. ISO 9000 and Total Quality Management- Sedhan k. Ghosh.
6. How To Practice Gmp- P.P. Sharma.
7. Good Manufacturing Practice for Pharmaceutical- A Plan For Total Quality Control-Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol.78,Marcel Dekker Inc.
8. OPPI- Quality Assurance.
9. USP.

Branch: - Clinical Pharmacy (Branch Code: - 06)

APPLIED PHARMACOTHERAPEUTICS – I

THEORY

Subject code -0611

Hours – (04/week)

1. A brief pathophysiology and pharmacotherapy of diseases associated with the following systems with special emphasis on the drug of choice.
2. Cardiovascular system: Hypertension, congestive cardiac failure, ischemic heart disease, arrhythmias, hyperlipidemia, shock.
3. Renal system: Acute and chronic renal failure, drug induced renal disorders, Renal Dialysis and transplantation, dosage adjustment in renal failure
4. Respiratory system: Asthma, chronic obstructive pulmonary disease, drug induced pulmonary disorders
5. Haematological system: Anaemias, venous thromboembolism, drug induced blood disorders
6. Nervous system:
7. Neurology: Epilepsy, Parkinsonism, stroke, pain management, headache disorders.
8. Psychiatry: Schizophrenia, bipolar disorders, anxiety disorders, sleep disorders, Alzheimer's disease.
9. Endocrinology: Diabetes mellitus, thyroid disorders.
10. Rheumatology: Rheumatoid arthritis, Osteoarthritis.

PRACTICALS

1. Ward round participation: Students will be posted in various medicine departments and have to attend morning ward rounds everyday other than their OPDs (Out patient department). Students have to follow up patients from the day of admission till the day of discharge. They also have to actively take part in various clinical pharmacy services/activities like providing drug and poison information, patient counseling, ADR monitoring and reporting and other related activities.
2. Case presentation: Case presentation has be done based on respective theory topics, which are followed during ward rounds. The cases have to be presented according to SOAP format or pharmaceutical case plan. Case presentations should also include respective patient counseling aspects along with counseling AIDS like insulin syringe, inhalers.

BOOKS RECOMMENDED:

1. Clinical Pharmacy and Therapeutics: Roger Walker and Clive Edwards. 3rd Edn. Churchill Livingstone, Edinburgh, 2003.
2. Textbook of therapeutics, Drug and disease management: Eric T Herfindal. 7th Edn. Williams & Wilkins Publications 2003.
3. Pharmacotherapy, A Pathophysiologic Approach: Joseph T Dipiro. 5th Edn. McGraw-Hill Medical publishing division 2002.
4. Applied therapeutics: Mary Anne Koda-Kimble, Lloyd Yee Young et al, 8th Edn. Lippincott Williams and Wilkins publications 2005.
5. Avery's Drug Treatment: Trevor M Speight, Nicholas HG et al, 4th Edn. Adis International Ltd. 1997.
6. American Hospital Formulary Services: GK Mc Evoy, Published by American Society of Hospital Pharmacists, 2004.
7. Davidsons Principles and Practice of Medicine: Christopher Haslett, et al, and 19th Edn. Churchill Living stone Publicatios, 2002.
8. Principles of Internal Medicine: Harrisons: Braunwald et al, 16th Edn. Mc Graw Hill Publications, 2005.

CLINICAL AND HOSPITAL PHARMACY-I

THEORY

Subject code - 0621

Hours – (04/week)

Section A: Clinical Pharmacy

1. Introduction Definition, history and scope of clinical pharmacy
2. Professional activities of a clinical pharmacist
 - a. Ward round participation
 - b. Medication history interview
 - c. Drug therapy monitoring
 - d. Medication order review
 - e. Adverse drug reaction management: Definitions, classification, epidemiology, predisposing factors, mechanism of ADRs, monitoring, reporting and evaluation of ADRs.
 - f. Clinical review
 - g. Therapeutic drug monitoring
 - h. Selection of drug therapy
 - i. Drug interactions: Definition, mechanism of kinetic and dynamic drug interaction. Prevention, assessment and management of drug interactions
 - j. Provision of drug information: Introduction, definition, approaches for answering queries, requirements to establish a drug information center, quality assurance of drug information services
 - k. Provision of medication counseling: patient counseling and education, communication skills.
 - l. Liaison with community services
 - m. Pharmaceutical care
3.
 - a. Interpretation of clinical lab data: Hematological, Hepatic, Pulmonary, Renal including electrolytes, Cardiac & Thyroid function tests
 - b. Tests to diagnose specific infectious disorders- CSF analysis, urine analysis, faeces and sputum tests.

Section B: Hospital Pharmacy.

1. Introduction: Hospital- classification and organization
 - a. Hospital pharmacy and its relationship with other departments regarding the practice of pharmacy.

2. Hospital Pharmacy: Location, layout, personnel, objectives, functions, organization of modern hospital pharmacy services.
3. Hospital Drug Policy: General consideration, pharmacy and therapeutic committee, hospital formulary, pharmacy communications

Section C: Community Pharmacy

1. Introduction: Concept, activities and professional goals.
2. Organisation and structure of retail and wholesale pharmacy: Location, legal requirements and maintenance of records.
3. Prescription
4. Posology
5. Patient information leaflets: Uses, guidelines for preparations.
6. Patient medication adherence.

PRACTICALS

1. Drug information: Students are supposed to answer to drug information queries on their OPD days which have to be documented on respective forms.
2. Patient Counseling: counseling of OP and IP.

BOOKS RECOMMENDED:

1. A textbook of clinical pharmacy practice- Essential concepts and skills. G Parthasarathi et al, 1st Edn. Orient longman publications, 2004.
2. Basic skills in interpreting lab data: Scott L Traub, 2nd Edn. Published by American Society of Health System Pharmacist 1996.
3. Hospital pharmacy: William & Hassan JR, 5th Edn, 1986.
4. Practice standards and definition - The Society of Hospital Pharmacist of Australia 1996.
5. Pharmacotherapy - A pathophysiologic Approach: Joseph T Dipiro, 5th Edn published by Mc Graw-Hill medical publication, 2002.
6. Comprehensive Pharmacy Review: Leon Shargel, 5th Edn. Published by Lippincott Williams & Wilkins 2004.

Branch: - Industrial Pharmacy (Branch Code:- 07)

COSMETICOLOGY

THEORY

Subject code - 0711

Hours– (04/week)

1. Physiological consideration: Skin, hair, nail and eye – in relation to cosmetic application.
2. Rheology of cosmetic: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.
3. Manufacturing techniques: cosmetics cream, powders, compacts, sticks, liquids, foam and aerosol cosmetics.
4. Evaluation of cosmetics: Performance, physicochemical, microbiological and Psychometric evaluation of cosmetics. Design and assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen', anti-aging products. and other cosmetics.
5. Clinical safety testing: Clinical safety testing and protocols for Irritation, sensitization, photo-irritation, photo-allergy, and ocular irritation.
6. Regulatory requirements: Manufacturing and sale of cosmetics
7. Herbal cosmetics: Formulation development and their stability studies.
8. Packaging: Package development and design for cosmetics
9. Advances in cosmetics: Liposome, multiple and micro-emulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.

PRACTICALS:

1. Performance, physicochemical & microbiological evaluation of various cosmetics such as: lotions, creams, hair products, deodorants, antiperspirants, nail products.
2. Effect of rheology and rheological additives in cosmetics such as: Antiperspirants, Deodorants, Creams, Nail products, Hair products etc.
3. Preparation and evaluation dosage forms using herbal drug/ drug from natural origin.
4. Assessment of role and quantity of preservatives in stability of cosmetics,
5. Use of liposomes, multiple emulsions in cosmetics.

BOOKS RECOMMENDED:

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

ADVANCES IN DRUG DELIVERY SYSTEM

THEORY

Subject code - 0721

Hours– (04/week)

1. Preformulation Studies: on various dosage forms such as tablets, capsules, suspension, creams, emulsion, injectables, ophthalmics, and aerosols etc.
2. Advances in Solid dosages forms: Physics of tables compression, direct compression, recent advances in tablet coating, micro-encapsulation and uses of newer encapsulating agents and techniques. Particle size enlargement – various methods and application.
3. Advances in liquid dosages forms: Theoretical and particle aspects in the manufacture of liquid dosage forms such as suspension, emulsion. Solublization, formulation of parenteral suspension and emulsion. Techniques and principles involved in the formulation of multiphase

- and micro-emulsion. Mechanism of droplet stabilization. Stability of multiphase and micro-emulsion. Destabilization kinetics.
4. Parenteral dosage forms: Processing of small and large volume parenteral raw materials, principle and technique. Stability evaluation environment, personnel and management factors in control and quality assurance.
 5. Stability studies and kinetics: stability and stabilization of Pharmaceuticals, Stability calculation, rate equation, activation energy calculation, interpretation of kinetic data, stability data in product development. Accelerated stability testing. Factors responsible for destabilization of pharmaceutical product and techniques and means to improve stability. Mathematical treatment of stability test data. Calculation shelf life, Calculation of Q_{10} value and application Q_{10} value in stability testing.
 6. Polymer Sciences: Pharmaceutical applications of polymer, properties of polymers.

PRACTICALS:

Preformulation studies of different dosage forms and also see the effect of variables that can effect the formulation of dosage forms. Such as Tablets, Suspensions, Emulsions, Aerosols, Ophthalmic preparations etc. Preparation and evaluation of microcapsules/ microspheres, coating of tablets, microemulsions, multiple emulsions, suspension/ disperse system, small volume parenterals, Accelerated stability study of prepared dosage form.

BOOKS RECOMMENDED:

1. Remington's Pharmaceutical application of polymers, properties of polymers. Thermodynamics of polymer solution, phase separation, coacervation and Micro-encapsulation. Polymer in solid state.
2. Theory and practice of Industrial Pharmacy Leon Lachman, Herbert A Lieberman and Joseph L. Kanig. Varghese Publishing House, Bombay
3. Essential of Physical Chemistry and pharmacy Arnikar, Kadam, Gujar, Orient Longman.
4. Quality Control in The pharmaceutical Industry: Volumes 1,2 and 3, Murraray
5. S. Copper Academic Press, New York and academic Press London.
6. Good Manufacturing Practices for pharmaceuticals – A plan for total Quality Control. S. H. Willing, M. M. Tuckerman, S. Hitchings, Marcel Dekker, Inc. New York.

7. Pharmaceutical Preformulation by J. I. Wells, John Wiley & Sons, N.Y.
8. Chemical Stability of Pharmaceuticals – A Handbook for Pharmacists – Kenneth A Connors, Gordon L. Amidon. Voluation J. Stelle, John Wiley & Sons, New York.
9. Pharmaceutical Dosage Forms: Parenteral Medications Volumes 1, 2 and 3. Kenneth E. Vavis, Loan Lachman and Herbert A. Lichman. Marcel Dekker New York.
10. Pharmaceutical Dosage Forms: Dispersed System Vol. 1 & 2 Edited by as 13.
11. Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3.
12. Sterile Dosage Forms, Salvatore Turbo and Rebest E. King Lea and Febiger, Philadelphia.
13. Pharmaceuticals – The Sciences of Dosage Form Design Michael E. Aulton, Churchill Livingstone, New York.
14. Advances in Pharmaceutical Sciences, Edited by Bean, Bockett and Carless, Academic Press, New York. Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
15. Physical Pharmacy: A. N. Martine, James Swarbrick and Commarate (Lea & Febiger, Philadelphia.

Branch:- Pharmaceutical Biotechnology (Branch Code:- 08)

PHARMACEUTICAL ASPECTS OF MICROBIOLOGY

THEORY

Subject code - 0811

Hours--(04 /Week)

1. Bacteria, Fungi and Viruses:
Structure, Chemistry and Morphology, Cultural, Physiological and Reproductive features, Methods of isolation, Cultivation and Maintenance, Nomenclature, General classification, Molecular and Genotypic taxonomy. Industrially important micro organisms including Actinomycetes and important fermentation products. Methods of microbiology including pure culture techniques and microscopy.
2. Manipulating Microorganisms in Culture
Media formulation, Principles of microbial nutrition, Construction of culture media. Growth of micro organisms in cultures pertaining to Bacteria, Principles of microbial nutrition, Physical and chemical environment for microbial growth, Batch, continuous and synchronous cultures, Stability and degeneration of microbial cultures.
3. Cell Regulation and Metabolism:
 - a. Basic aspects of cell regulation.
 - b. Bio-energetics and Metabolism – biochemical mechanisms of generating ATP,
Fuelling reactions of aerobic and anaerobic organisms.
 - c. Secondary metabolism and its applications.
4. Nucleic Acids, the Genetic Code and Protein Synthesis:
Structure of DNA and arrangement of genes on chromosomes, RNA syntheses and processing, Plasmids, Transposable elements, TY Elements and repetitive sequences, Synthesis of DNA – polymerization of nucleotides into DNA (DNA replication), Role of DNA in protein synthesis. Synthesis of proteins: the role of RNA in Translation, different classes of RNA (m RNA, t RNA and r RNA) and their functions, Ribosome and its enzymes, Protein expression in Prokaryotes and Eukaryotes.
5. Microbial Genetics:
 - a. Genetic organization of Prokaryotic and Eukaryotic cells, Mutagenesis and repair mechanisms, Types of mutants, Application of mutagenesis in strain improvement, Gene mapping of Plasmids – their Types, purification, transfer and applications.

- b. Transformation, Conjugation, Transduction.
 - c. Structure and Classification of Viruses, Replication of Viruses including gene organisation, Phage mutation and Lysogeny. Bacteriophages and Animal Viruses.
6. Immunology :
Cellular and humoral basis for immune response, Immunity to viruses, bacteria and fungi, Hypersensitivity reactions and auto- immune diseases. Immunisation schedules, Active and Passive immunity.
7. Microbial Pathology and Chemotherapy:
Identifying features of pathogenic bacteria, viruses and fungi, mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases, currently recommended therapies for common bacterial, fungal and viral infection, mechanism of action of anti- microbial agents and possible sites for chemotherapy.

PRACTICALS

1. Fumigation of aseptic area and air sampling.
2. Morphological study, isolation and characterization of some bacteria and fungi.
3. Methods of preservation of culture.
4. Isolation and primary screening of Streptomyces.
5. Qualitative analysis of potable water.
6. Estimation of microbial load in pharmaceutical excipients and raw materials as per official pharmacopoeia.
7. Construction of UV survival curve and demonstration of dark repair mechanism.
8. Preparation and maintenance of primary cell culture and cell lines.
9. Enumeration of viruses by titration and plaque assay.
10. Determination of cytotoxicity and screening for anti- viral activity of some natural and synthetic products.
11. Induction of mutation, isolation of antibiotic resistant and auxotrophic mutants adopting replica plating technique.
12. Isolation of specialized transducing phage.
13. Animal immunization – inoculation, bleeding and antigen- antibody reactions by haemagglutination – inhibition, neutralization and precipitin reactions.
14. Standardization of inoculum and estimation of MIC by serial dilution and gradient Plate technique.
15. Qualitative and quantitative analysis of anti- microbial agents by ditch – plate method and extinction methods (RWC test).

16. Microbial sensitivity of some human pathogenic isolates against various antibiotics.

REFERENCES

1. General Microbiology: R.Y. Stanier.
2. Essentials and applications of microbiology : Judy Kandal.
3. Microbiology: Pelczar, Reid and Chan.
4. Genetics of Antibiotic producing Microorganisms : G. Sermonti.
5. Microbial Genetics : David Freifelder.
6. Topley & Wilson : Volumes I to IV.
7. Genes V and VI : Lewin Benjamin.
8. Virology : Fields.
9. Animal cell culture : Ian Freshney.
10. Immunology : Weir.
11. Immunology : Ivan Roitt, Johnathan Bronstoff, David Male.
12. Medical Microbiology: Mackie and McCartney.
13. The Actinomycetes : Waksman SA

ADVANCES IN PHARMACEUTICAL BIOTECHNOLOGY – I

THEORY

Subject code - 0821

Hours–(04 /Week)

1. Enzyme Technology:
 - a. Classification, General properties of Enzymes, Enzyme Kinetics, Dynamics of Enzymatic activity, Sources of enzymes, Extraction and purification, Applications: Pharmaceutical, Therapeutic and Clinical, Production of Amyloglucosidase, Glucose Isomerase, Amylase and Trypsin.
 - b. Techniques of Immobilisation of Enzymes, Kinetics of immobilized enzymes and their applications in the Industry. Reactors for Immobilized systems and perspective of enzyme engineering.
2. Genetic Engineering:
 - a. Techniques of gene manipulation, Cloning strategies, Procedures, Coning vectors, Expression vectors, Recombinant selection and screening, Expression in E.coli and Yeast.
 - b. Gene library and c DNA.

- c. Applications of the above technique in the production of:
 - i) Regulatory proteins Interferon, Interleukins etc.
 - ii) Blood products – Erythropoietin.
 - iii) Vaccines – Hepatitis – B,
 - iv) Hormones – Insulin.
 - d. Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.
 - e. Production of useful proteins in transgenic animals.
 - f. Signal transduction, oncogenes and their proteins.
 - g. The human genome project and stem cell research – a brief study.
 - h. Gene therapy (Basic principle and introduction).
3. Microbial Biotechnology:
- Biotransformation for the synthesis of Chiral drugs and sterols.
 Biodegradation of Xenobiotics, Chemical and Industrial wastes.
 Production of Single-cell protein.
4. Biotechnology and Intellectual Property:
- Study of published U.S. patents related to biotechnology and its products, trade secrets, IPR related to plant genetic resources; Patents for higher plants, higher animals, transgenic organisms, isolated genes and DNA sequences; plant breeder's/ farmer's rights.
5. Immuno Biotechnology:
- a. Hybridoma technology – fusion methods for Myeloma cells and B - lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their application in clinical diagnosis, immunotherapy and pharmaceutical research.
 - b. Immune-diagnosis of infectious diseases.
 - c. Vaccine technology – Immune-potential, adjuvant, living and non-living antigens, newer delivery systems and naked DNA vaccines. New and improved vaccines against Hepatitis-A, Malaria, Typhoid and HIV-1.
 - d. Transplantation of bone marrow & artificial skin
 - e. Antenatal diagnosis.
6. Bioinformatics:
- Information theory and biology, redundancy. Networking: Network access, internet and E-mail servers, use of Databases in biology sequence databases for comparisons.

PRACTICALS

1. Production of extra-cellular enzymes from microbial sources and downstream processing.
 - a. Ammonium sulphate precipitation.
 - b. Dialysis.

- c. Size exclusion chromatography.
- d. Affinity chromatography.
- 2. Estimation of some microbial enzymes and quantification in terms of total protein by Lowry method.
- 3. Isolation of Plasmid DNA – Mini – prep and estimation of DNA.
- 4. Isolation of RNA from microbial sources and its estimation.
- 5. DNA cloning with different expression vectors and Agarose electrophoretic analysis.
- 6. Transformation techniques with different antibiotic resistance markers.
- 7. Southern blotting with radioactive and non-radioactive probes.
- 8. Northern blotting technique.
- 9. Qualitative analysis of proteins & Estimation of molecular weight of proteins by PAGE techniques.
- 10. Enzyme-linked immunosorbant assay and western blotting techniques.
- 11. Hybridoma techniques: Fusion of myeloma and lymphocytes, screening methods and raising Monoclonal antibodies and purification.
- 12. Development of suitable delivery system for anti-tumour agents, newer vaccines and therapeutic proteins and peptides for site-specific delivery.
- 13. Estimation of enzyme activity using Michelis Menten equation and Line Weaver Burk Plot

REFERENCES

- 1. Biotechnology – The biological principles: MD Trevan, S Boffey, KH Goulding and P. Stanbury.
- 2. Immobilisation of cells and enzymes: Hosevear kennady Cabral & Bicker staff.
- 3. Principles of Gene Manipulating: RW Old and S.B. Primrose.
- 4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S. Lawrence Zipursky, Paul Matsudaira, James Darnell.
- 5. Therapeutic Peptides and Proteins; Formulation, processing and delivery systems: Ajay K Banga.
- 6. Modern Biotechnology : S.B Primrose.
- 7. Industrial biotechnology : Vedpal S Malik and Padma Sridhar.
- 8. Immunology : Ivan Roitt, Jonathan Brostoff and David Male.
- 9. Gene transfer and expression protocols – methods in Molecular Biology, Vol. VII, Edit E.T. Murray.
- 10. Current protocols in Molecular Biology, Vol.I & II : F.M. Asubel, John Wiley Publishers.
- 11. Current protocols in cellular biology, Vol.I & II, John Wiley Publishers.
- 12. Cell Biology, Vol.I, II & III Edited by Julio E Celis.

M.PHARM. SEMESTER-II

Intellectual Property Rights & Drug Regulatory Affairs (Compulsory)

THEORY

Subject code - 0012

Hours– (04/week)

1. Introduction to Intellectual Property Rights; Copy Right Act, Trade Mark Act, Patent Act and Industrial design Act, WTO, TRIPS and TRIMS. Introduction to Drug regulatory and accrediting agencies of the world (USFDA, MHRA, TGA, ICH, WHO, ISO etc.).
2. Regulatory Considerations for Pre-clinical and Clinical Evaluation: Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratogenicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism.
3. Globalization of drug industry, present status and scope of pharmaceutical industry in India & U.S.
4. Regulatory aspects of pharmaceutical industry and bulk drug purchasing, manufacture, regulatory drug analysis.
5. New Chemical Entity (NCE). Approval of New Drug: Investigational new drug (IND) submission, format and content of IND, content of investigator brochure, clinical research protocols, objective and protocol design. FDA guidelines for clinical trials, reviews and approval of a clinical study. General consideration, content, format and approval of NDA & Abbreviated New Drug Application (ANDA).
6. Procedure of exporting and importing Pharmaceutical drugs & products. Study of tax aspects, marketing aspects, labor aspects and economic integration. BOP analysis, foreign exchange control and governmental policies.
7. Introduction to patent, Indian Patent Law: Introduction to Indian Patents Office. Provisional application. PCT route to filling of patents. Examination & oppositions of patent application. Fee structure of patent, renewal fee requirement in the United States, Europe and India. Introduction to Patent infringement – literal infringement and doctrine of equivalents. Patent search engines, keywords and databases.

PRACTICALS

1. Written Analysis of Case studies related to Drug regulatory affairs.
2. Patent searching for U.S., U.K. & ROW (with special emphasis of Indian patents).
3. Searching of Innovator's patent for pharmaceutical products.

BOOKS RECOMMENDED:

1. Willing, S. H. "Good Manufacturing Practices for Pharmaceuticals" Marcel Dekker, Inc. New York
2. Drugs and Cosmetics Acts and Rules.
3. Bharathi, Drugs and Pharmacy Laws in India.
4. Nash R. A. and Wachter, A. H. "Pharmaceutical Process Validation" Marcel Dekker, Inc, New York.
5. Banker, G. S. and Rhodes, C. T. "Modern Pharmaceutics", Marcel Dekker, incc, New York
6. OPPI, Quality Assurance
7. Garfield, Quality Assurance Principles of Analytical Laboratories.

ADVANCE ANALYTICAL TECH: - II (COMPULSORY)

THEORY

Subject code - 0022

Hours – (04/week)

1. Flame Emission Spectroscopy and Atomic Absorption Spectroscopy: Principle, instrumentation, interferences and applications in Pharmacy.
2. Spectrofluorimetry and Phosphometry: Theory, instrumentation, advantages, relationship of chemical structure to fluorescence spectra, solvent effect, effect of acids and bases on fluorescence spectra, concentration effects, factors affecting fluorescence intensity, comparison of fluorescence and UV-Visible absorption methods and applications. Principle, instrumentation and application of Chemiluminiscence.
3. Electron Spin Resonance Spectroscopy: Theory and Principle, Limitations of ESR, choice of solvent, g-values, hyperfine splitting, instrumentation, difference between ESR & NMR and applications.
4. Chromatographic Techniques:
 - a. Classification of chromatographic methods based on mechanism of separation: paper chromatography, thin layer chromatography, ion exchange chromatography, size exclusion /gel permeation

- chromatography, column chromatography and affinity chromatography –techniques and applications.
- b. Gas Chromatography (GC): Theory and principle, column operation, instrumentation, derivatisation methods and applications in Pharmacy.
 - c. High Performance Liquid Chromatography (HPLC): Principle, instrumentation, solvents used, elution techniques, NP-HPLC, RP-HPLC, LC-MS and applications in Pharmacy.
 - d. HPTLC and Super Critical Fluid Chromatography (SFC): Theory and Principle, instrumentation, elution techniques and pharmaceutical applications.
5. Electrophoresis : Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.
 6. Radio Chemical Assays: Sodium iodide, Cynocobalamine and quality control of Radio Pharmaceuticals.
 7. AC pulse polarography and square wave polarography.
 8. Enzyme Analysis: Pepsin, papain, hyaluronidase.
 9. Analysis of drugs obtained from Genetic Engineering: Vaccines, sera and toxoids.
 10. Basic principles, classifications, instrumentation and application of LASER.
 11. Reference standards: Source, preparation, characterization, usage, storage and records.

PRACTICALS

1. Experiments by using Electrophoresis such as
 - a) Separation of Indicators.
 - b) Separation of Amino acids.
2. Experiments of Chromatography.
 - a) Thin Layer Chromatography.
 - b) Paper Chromatography.
 - i. Ascending Technique.
 - ii. Descending Technique.
 - iii. Circular Technique.
3. Two dimensional Paper Chromatography and TLC.
4. Experiments based on HPLC & GC.
5. Use of fluorimeter for analysis of Pharmacopoeial compounds.
6. Calibration and Validation of official compounds by Fluorimetry:
 - a) Quinine
 - b) Codeine
 - c) Thiamine
 - d) Riboflavin
7. Study of Quenching effect in fluorimetry: quenching of Quinine by potassium iodide.

8. Determination of Sodium in Sodium chloride injection by flame photometry.
9. Any other relevant exercises based on theory.

BOOKS RECOMMENDED:

1. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
2. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
3. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
4. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
5. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
6. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd edition.

PROFESSIONAL PRACTICE (Compulsory)

THEORY

Subject code -0032

Hours– (03/week)

Professional Practice:

A student shall undergo professional training to assist in practical classes and in theory lectures to diploma and degree classes assign to him/her under the supervision of subject incharge. He/She has to submit a report on the work assign to him/her. His/Her evaluation will be on the basis of performance and report submitted by him/her.

Branch: - Pharmaceutics (Branch Code: - 01)

NOVEL DRUG DELIVERY SYSTEMS

THEORY

Subject code-0112

Hours– (04/week)

1. Basic considerations of novel drug delivery systems:
Biopharmaceutical aspects and technology transfer of controlled release dosage forms.
2. Oral drug delivery systems:
Based on different control mechanism such as Dissolution controlled, Diffusion controlled, Osmotic pressure, Membrane controlled pH, Ion-exchange, Gastrointestinal transit etc.
3. Mucosal drug delivery: Physiological, biopharmaceutical consideration formation and models used.
 - a. Buccal: Physiology and permeability of oral mucosa, penetration enhancement, drug delivery systems and in-vitro and in-vivo techniques.
 - b. Nasal: Anatomy and physiology of nasal mucosa, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation.
 - c. Pulmonary: Structure and function of pulmonary system, factors affecting deposition in lungs. Dosage forms: Nebulizers, pressurized inhalation aerosols, aerosol powder devices.
 - d. Rectal: Physiology, advantages, dosage forms and evaluation models.
Intrauterine and intravaginal drug delivery devices.
4. Implantable therapeutic system, introductory part of Intrauterine, Intravaginal, and Ocular drug delivery devices.
5. Transdermal drug delivery:
Permeation through skin, permeation enhancers, approaches to development and evaluation of Transdermal drug delivery.
6. Micro-encapsulation:
Various techniques, parameters affecting microcapsules, microcapsule stability, mechanisms, manufacturing equipments.
7. Advances in drug delivery: Pulsatile, colon specific, intra-arterial, noncorneal drug delivery and systemic delivery of ophthalmic diseases.
8. Miscellaneous:
 - (a) Liposoms, Niosoms, Aquasoms, Nanoparticles, Microsphere.
 - (b) Microchip as drug delivery, Nanotubes, Dendimers, Resealed erythrocytes.

PRACTICALS:

Preparation and evaluation of oral, nasal, pulmonary, ocular, transdermal drug delivery system, Mucoadhesive drug delivery system, targeted drug delivery system, micro encapsulation etc

BOOKS RECOMMENDED:

1. P. Tyle; Drug Delivery Devices, fundamental and applications; Marcel Dekker.
2. Morton Rosoff; Controlled release of drugs; VCH Publishers.
3. Osborne, and Amann; Topical drug delivery formulations; Marcel Dekker.
4. P. Tyle; Drug delivery devices: Marcel Dekker.
5. Barry; Dermatological formulation; Marcel Dekker
6. Robinson; Novel Drug Delivery systems; Marcel Dekker
7. N.K. Jain; controlled and novel drug delivery; CBS Publication, New Delhi
8. P. Johnson and J. G. Lloyd – Jones; Drug delivery systems; VCH Publisher
9. P. Tyle and B. P. Ram; Targeted therapeutics systems; Marcel Dekker.
10. C.G. Wilson & N. Washington; Physiological Pharmaceutics; Ellis Horwood Limited.
11. H.S. Bean, A.H. Beckett, and J.E. Carless; Advances in Pharmaceutical Sciences; Vol. 5, Academic Press.
12. R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivery; Marcel Dekker
13. T.J. Roseman and S.Z. Mansdorf; Controlled release delivery systems; Marcel Dekker
14. A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology; Marcel Dekker.
15. J. Kreuter; Controlled drug delivery system; Marcel Dekker
16. P.B. Deasy; Microencapsulation and related drug processes; Marcel Dekker.

PRODUCT DEVELOPMENT AND PACKAGING TECHNOLOGY

THEORY

Subject code-0122

Hours – (04/week)

1. Packaging - Introduction, components of packaging, brand consciousness and packaging, bioactive packaging.
2. Adhesives in packaging, types, evaluation in terms of viscosity adhesion strength, rheology hygroscopicity, stability, compatibility etc.
3. Containers and closures: Types of material, evaluation method as per IP, BP, USP and EP.
4. Labeling, Package inserts, (Specific requirements, indications and usage, pregnancy category specifications, drug abuse dependence, over dosage), dosage administrations.
5. G M P Guidelines for the Pharmaceutical Packaging Materials
6. Validation of Packaging Process and Future Trends in Packaging, Intelligent packaging (Oxygen scavenging, time temperature history, microbial growth indicators, physical shock indicator),
7. Introduction, non clinical requirements of IND and NDA, waivers, principals of IND submission, format and contents of IND, Investigator's Brochure and CFR's descriptions.
8. N D A Definitions, general requirements, N D A regulations in U S, N D A.
9. Specific requirements, contents and format of N D A, NDA Review guide.
10. Brief introduction to Abbreviated and Supplemental New Drug Applications

PRACTICALS:

1. Product development report of different products: Antihypertensive drugs, Proton pump inhibitor drugs, Antipsychotic drugs, etc.
2. Design the prototype formulae on the basis of literature search
3. Design the pack inserts with the help of product profile
4. Labelling requirements
5. Selection of packaging material

BOOKS RECOMMENDED:

1. US FDA guidelines for product development through website
2. Cooper and Guns dispensing for pharmacy students, by guns and carter
3. Theory and practice of Industrial Pharmacy Leon Lachman, Herbert A Lieberman and Joseph L. Kaning, Varghese Publishing House, Bombay
4. Bantles pharmaceuticals
5. Pharmaceutical packaging development by Marcel Dekke.
6. IP, BP, USP AND EP.

Branch:- Pharmaceutical Chemistry (Branch Code:- 02)

**ADVANCED MEDICINAL CHEMISTRY-II
(Chemistry of Synthetic Drugs)**

THEORY

Subject code – 0212

Hours – (04/week)

Following classes of drugs with special references to brief chemistry, mechanism of action, synthesis of marketed drugs, SAR, clinical importance and recent advances:

1. Antibacterial, anti-neoplastics, antiviral, antimalarial.
2. Drugs for aids, amoebiasis, tuberculosis and leprosy.
3. CVS- antihypertensive, antiarrhythmics, antianginals, cardiotonics;
CNS- anesthetics, sedative-hypnotics, analgesics, anticonvulsants, antipsychotics and CNS stimulants.
4. Immunosuppressant, Immunostimulants.

PRACTICALS:

Synthesis; determination of R_f value and purity by thin layer chromatography; spectral analysis and M.P. determination of following drugs/ drug intermediates and other drugs related to theory syllabus:

Phenytoin, Mefenamic acid, Para amino phenol, caprolactam from cyclohexanone, isatin from phthalimide, antipyrin, dibenzal acetone from benzaldehyde, coumarins from resorcinol, pinacol from acetone, sulphanilamide from acetanilide, phenobarbitone, diketopiperazine, nifedipine and propranolol.

BOOKS RECOMMENDED:

1. Progress in Medicinal Chemistry, Series by Ellis & Wert.
2. Wilson & Gisvolds – Text book of organic medicinal and pharmaceutical chemistry, 10th Edition, 1998.
3. Medicinal Chemistry by Burger.
4. Principles of Medicinal Chemistry by Foye.
5. Organic Drug Synthesis, Vol. 1, 2, 3 & 4 by Lednicer.
6. Annual Reports in Medicinal Chemistry by Hans, Jurgen Hess.
7. Medicinal Chemistry Series by Ariens.
8. Progress in Medicinal Chemistry Series by Ellis and West.
9. Comprehensive Medicinal Chemistry – Series – I-VI (Academic Press)
10. Selected Organic Synthesis by Fleming

CHEMISTRY OF NATURAL PRODUCTS

THEORY

Subject code-0222

Hours– (04/week)

1. Carbohydrates- Introduction, Classification, Disaccharides; determination of structure, sucrose, maltose, lactose, Polysaccharides; cellulose, starch, introduction to lignin & pectin.
2. Fats, oils, waxes, lipoproteins- Introduction, General classification and chemistry.
3. Amino acids, Peptides & Proteins- Introduction, Classification, Synthesis of amino acids, polypeptides. Synthesis of naturally occurring proteins, structure of polypeptides, amino and carboxyl terminal determination, Proteins; Introduction, classification, composition, structure and chemistry of oxytocin, insulin, angiotensin and peptides of medicinal importance. Purines and nucleic acid.
4. Steroids- General introduction, Stereochemistry, nomenclature and structural elucidation of sterols (cholesterol), sapogenin (diosgenin), progesterone, estrone, cortisone.
5. Cardiac glycosides- Cardiac, saponins, anthraquinones etc.
6. Alkaloids- General introduction and Classification, General methods of isolation & structure determination, structural elucidation of morphine, ergotamine, atropine, reserpine, colchicines, quinine, nicotine and vinca.
7. Vitamins- General introduction & classification, Stereo chemical aspects of Vitamin A, ascorbic acid, general chemistry of vitamin B₁, vitamin B₂, vitamin B₁₂.

PRACTICALS:

Practical Related with Isolation and Characterization of Medicinally active Natural products.

BOOKS RECOMMENDED:

1. Natural Product Chemistry, Vol. 1 & 2 by Nakanishi.
2. Organic Chemistry, Vol. 2 by Finar.
3. The Alkaloid, Chemistry and Physiology by Manske.
4. Medicinal Plant Alkaloids by Sim.
5. New Natural Products and Plant Drugs with Pharmacological, Biological or Therapeutic Activity by Wagner, Wolff.
6. Modern Methods of Plant Analysis by Paech, Tracey.

7. Modern Methods of Plant Analysis by Geissman.
8. Alkaloids by Fieser and Fieser.
9. History of Natural Products by K. W. Bentley.
10. Steroids by Fieser and Fieser
11. Selected Organic Synthesis by Fleming.
12. The Alkaloid, Chemistry and Physiology by Manske.
13. IUPAC, Chemistry of Natural Products, International symposium.

Branch: - Pharmacology (Branch Code: - 03)

**RECENT ADVANCES AND EMERGING TRENDS IN
PHARMACOLOGY SCIENCE**

THEORY

Subject code-0312

Hours– (04/week)

1. Digestive system
 - a. Pharmacotherapy of peptic ulcer, diarrhea, constipation
 - b. Agents affecting gastrointestinal water flux and motility: emesis and antiemetic, bile acids and pancreatic enzymes
2. Therapy of Infections diseases
 - a. General principal, antibacterial drugs sulphonamides, quinolones, penicillins, cephalosporins, tetracyclines, chloramphenicol
 - b. Drugs used in the chemotherapy of protozoal infection: Malaria
 - c. Drugs used in the chemotherapy of protozoal infections: Trypanosomiasis, leishmaniasis, amebiasis, giardiasis, trichomoniasis, and other protozoal infection
 - d. Drugs used in the chemotherapy of helminthiasis
 - e. Drugs used in the chemotherapy of leprosy, tuberculosis, fungal infections, viral infection
 - f. Drugs used in the chemotherapy of neoplastic diseases
 - g. Immunomodulators: Immunosuppressive agent and immunostimulants
 - h. Newer Chemotherapeutic agents
3. Hormones and Hormone Antagonists:
 - a. Adenohypophyseal hormones and their hypothalamic releasing factors.
 - b. Hormones of posterior pituitary
 - c. Thyroid and antithyroid drugs
 - d. Estrogens and progestins, antifertility agents
 - e. Androgens
 - f. Adrenocorticotrophic hormones; adrenocortical steroids and their synthetic analogs: inhibitors of the synthesis and actions of adrenocortical hormones.
 - g. Insulin, oral hypoglycemic agent and the pharmacology of pancreatic hormones.
 - h. Agent affecting calcification and bone turnover.
 - i. Calcium phosphate, parathyroid hormones, vitamin D, calcitonin and other compounds.

- j. Vasopressin and other agents affecting the renal conservation of water.
- 4. Emerging Trends & Recent advances in:
 - a. Receptor and G- protein
 - b. Cyclic neucleotides
 - c. TNF, apoptosis
 - d. Ion channel modulators
 - e. Neurosteroids and cannabioids
 - f. Nitric Oxide
 - g. ANF,anti oxidants: Melatonin
 - h. Chiral pharmacology
 - i. Gene therapy
 - j. Neuropeptide, Substance P, angeiotention II modulators.

PRACTICALS

1. Study of agonist and antagonist
2. pD₂ Value
3. pA₂ Value
4. 5HT bioassay (Graphical, four point)
5. Oxytocin bioassay (Graphical)
6. Antagonist bioassay
7. Ach bioassay (Rat funds)
8. Histamine assay guinea pig ileum (Graphical and four point assay)
9. Blind screening of drugs
10. Estimation of drugs in body fluids using modern analytical techniques.

BOOKS RECOMMENDED

1. R. Craig and R. E. Stitzel, Modern Pharmacology.
2. Goodman and Gilman's: The Pharmacological Basis of Therapeutics; Edited by: Alfred Goodman; Theodrove. W. Rall, Alan S. Nies and Palmar Taylor.
3. R. Laurence and P. N. Benett; Clinical Pharmacology.
4. F.S.K. Brar; Essentials of Pharmacotherapeutics.
5. H. P. Rang and M. M. Dale; Pharmacology.
6. James Crossland; Lewis's Pharmacology (Revised).
7. G. GrahameSmith and J. K. Aronson; Oxford Textbook of Clinical Pharmacology and Drug Therapy.
8. S. Singh; Essentials of Pharmacology; Academia Publishers.

JOURNALS RECOMMENDED

1. Annual Review Pharmacology and Toxicology
2. Drugs
3. Pharmacological Reviews
4. Trends in Pharmacological Sciences
5. Indian Journal of Physiology & Pharmacology
6. Indian Journal of Experimental Biology
7. Indian Journal of Pharmacology

PHARMACOLOGICAL METHODS AND TOXICOLOGY

THEORY

Subject code-0322

Hours– (04/week)

1. Principles of pharmacological and clinical evaluation of drugs.
2. Pharmacological techniques to evaluate drugs belonging to following categories:
 - a) Antipsychotics, antianxiety agents; nootropics; antidepressants, antiparkinsonian agents, antiepileptics, analgesic, anti-inflammatory agents, local anaesthetics.
 - b) Antihypertensives, antiarrhythmics, antithrombotics, drugs for myocardial infarction.
 - c) Antiulcer drugs, antidiabetics, antitussives
 - d) Evaluation of antioxidants
 - e) Transgenic animals, genetically prone animal models
 - f) Anticancer drugs
 - g) In-vitro techniques
 - h) Antifertility agents
3. Drugs toxicity, safety evaluation of new drugs
4. Regulation for laboratory animal care and ethical requirements.

PRACTICALS

1. Screening methods in pharmacology
2. Screening of antipsychotics, antianxiety, nootropics, antidepressants, antiparkinsonian, antiepileptics, analgesic, anti-inflammatory, antihypertensive, anti MI, anti ulcer, antidiabetic and antioxidants.

BOOKS RECOMMENDED

1. M. N. Ghosh, Fundamentals of Experimental Pharmacology.
2. Robert A. Turner and Peter Hebborn; Screening methods in Pharmacology, Vol.- I & II.
3. Ian Kitchen, Textbook of In-vitro Practical Pharmacology.
4. D. R. Laurence and A. L. Bacharach; Evaluation of Drug Activities: Pharmacometrics, Vol. - I & II.
5. U. K. Sheth, N. K. Sadkar and Usha G Kamat; Selected Topics in Experimental Pharmacology.
6. Pharmacological Experiments of isolated preparations by Edinburgh University Pharmacology staff, 1968.
7. Randall C. Baselt; Analytical procedures for Therapeutics Drug Monitoring and Emergency Toxicology.
8. Drug-Bioscreening Drug Evaluation Techniques in Pharmacology in Emmanuel B. Thompson.
9. H. G. Vogel and W. H. Vogel; Drug Discovery and Evaluation; Springer-Verlag, Berlin Heidelberg.

Branch: - Pharmacogony (Branch Code: - 04)

BIOGENESIS AND CHEMISTRY OF NATURAL PRODUCTS

THEORY

Subject code - 0412

Hours– (04/week)

1. Biomolecules of natural origin used as medicine. Natural substances as raw material in drug synthesis.
2. Study of basic metabolic pathway. Techniques employed in the elucidation of basic metabolic pathway.
3. Study of various factors influencing production or biogenesis of biomedicinals.
4. Study of heterocyclic present in active principle of Biomolecules. Biogenesis and structure elucidation of compounds belonging to following categories – (at least one from each category)
 - a. Alkaloids : tropane, quinine, imidazole, isoquinoline, indole, etc.
 - b. Glycosides: anthraquinone, saponin, sterol etc.
 - c. Isoprenoid compounds.
 - d. Lignan and flavonoids, coumarin.
 - e. Plant growth regulators
 - f. Antibiotics: Penicillin, semi synthetic penicillin, tetracycline, macrolids, aminoglycosides, betalectin.
 - g. Protein (insulin vasopressin, and oxytocin etc.) and vitamin (A, B-12, C etc.).
 - h. Carbohydrates.
 - i. Tannins and resins.
 - j. Steroids: Cholesterol and plant sterols.
 - k. Fats, oils.
 - l. Terpenoids.

PRACTICALS

Estimation of elements and functional groups present in natural drugs, extracts, formulations.

1. Qualitative and quantitative analysis of natural products as prescribed in syllabus.
2. Comparative study and analysis of extracts obtained through conventional and modern methods.

BOOKS RECOMMENDED:

1. Pharmacognosy by G.E. Trease, W.C. Evans, ELBS.
2. Pharmacognosy by Varro E.Tyler, Lynn. R.Brady, James E.Robbers.
3. Text Book of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
4. Herbal cosmetics Hand book – H.Panda.
5. Homoeopathic pharmacy – Steven B.Kayne.
6. Dictionary of Indian Folk medicine and Ethnobotony – Dr.S.K.Jain.
7. Thin Layer Chromatography – E/ Stahl, 2nd Edition 1969
8. Ayurvedic Pharmacopoeia of India: Govt. of India.
9. Spectroscopic Identification of Organic compounds, Silverstein R. M. Bassler
- 10.C. and Morrill T. C. 5th Ed. John Wiley and Sons Inc. 1991.
- 11.Chromatography of Alkaloids by Vapoorte, Swendson.
- 12.Elements of chromatography by P.K.Lala.
- 13.Introduction to chromatography theory & Practicals by V.K. Srivastava, K.Kishore.
- 14.Principles of Biotechnology by Leininger.
- 15.Jenkins Quantitative Pharmaceutical Chemistry by A.N.Knevell.
- 16.Handbook of vitamins by L.J.Machlein.
- 17.Clerk's Isolation & Identification of drugs by A.C.Mottal.
- 18.Phytochemical methods of chemical analysis by Harbone.
- 19.Organic chemistry vol.II by I.L.Finar.
- 20.The Essential oil by Gunther.E.
- 21.The use of Pharmacological techniques for the evaluation of natural products
- 22.B.N.DhavanR.C.Srimal. CDRI, Lucknow.
- 23.Practical Pharmacognosy, Khandelwal, K. R. 7th Ed., Nirali Prakashan, Pune 2000
- 24.Pharmacopoeia of India, Ministry of health, Govt of India 1996
- 25.Practical Pharmacognosy, Kokate C. K. Vallabh Prakashan, New Delhi

INDUSTRIAL PHARMACOGNOSY

THEORY

Subject code-0422

Hours– (04/week)

1. Presents status and future aspects of Pharmacognosy in the herbal industries.
2. Guideline related to quality control of herbal drugs- GAP, WHO, ICH, CGMP, D & C for herbal and ayurvedic drugs.
3. Problems encounters in discovering and processing of new drugs from plants. Pilot plant scale up technique for herbals.
4. Standardisation of herbs, herbal formulation and extract by Pharmacognostical, Phytochemical, Pharmacological/ Biological (including toxicological parameter) & analytical approach.
5. Techniques for processing of medicinal for dosage form and technique transformation of ayurvedic formulation to newer dosage forms.
6. Information and application of herbs & herbal formulation available in Indian & international market
7. Isolation, analytical interpretation, characterisation and uses of phytoconstituents: Caffeine, Atropine, Curcumin, Taxol, Ergometrine, Podophyllum, Diosgenin, Digoxin, Solasodine, Berberine, Quinine, Emetine, Withanolids, Rutine, Artemisine.
8. Targeted drug delivery system of phytoconstituent.

PRACTICALS:

1. Macroscopical and microscopical evaluation including Quantitative microscopy.
2. Physical, Chemical and Biological evaluation in quality control of crude drugs.
3. Preliminary phytochemical screening of medicinal plants, extracts and formulations.
4. Isolation of different phyto constituents and estimation using spectroscopic and chromatographic techniques.
5. Estimation of secondary metabolites like alkaloids, terpenoids and flavonoids by different methods.
6. Estimation of plant phytoconstituents using modern methods like UV, HPLC and
7. HPTLC etc.
8. Extraction, isolation and characterisation of plant phytoconstituents
9. Formulation and evaluation of herbal cosmetics and other formulations.

BOOKS RECOMMENDED:

1. Pharmacognosy by G.E. Trease, W.C. Evans, ELBS.
2. Pharmacognosy by Varro E.Tyler, Lynn. R.Brady, James E.Robbers.
3. Text Book of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
4. Plant Physiology of Frank B.Salisbury, Cleon. W.Ross, CBS Pub. Delhi
5. Indian Medicinal Plants by Kirthikar, Basu.
6. Indian Meteria Medica by K.M. Nalkarni
7. The Essential Oils by Guenther. E.
8. Modern Toxicology vol.II by P.K.Gupta, D.k. Salunkhe
9. Proceeding of the seminar on scope of Aromatic plants & Processing Industries.
10. Pharmacographia Indica by W.Dymock.
11. A Hand Book of Common remedies in Siddha system of medicine- CCRIMH.
12. Clinical applications of the Ayurvedic remedies.
13. Baidyanth Book of Ayurvedic Knowledge.
14. Perfumery technology by Wallis, Billot.M.
15. Jenkin's quantitative pharmaceutical Chemistry by A.M.Knevell.
16. Phytochemical methods of chemical analysis by Harbone.
17. Pharmacoepl standards for Ayurvedic formulations –CCRAS, Delhi.
18. Practical Pharmacognosy by Dr.C.K.Kokate.
19. Practical Pharmacognosy by Dr.P.K.Lala.
20. Bibiliography on pharmacognosy of medicinal plants-Roma Mitra.
21. British Herbal Pharmacopoeia.
22. Essential oils and waxes: H.F.Linskens & J.F.Jackson.
23. The Ayurveda Encyclopedia – Swami Sada Shiva Tirtha.
24. Encyclopedia of Natural medicine – Michael Murray & Joseph. Pizzorno
25. Toxic plants and other Natural toxicants – Tom Garland & Catharine Barr.
26. Alternate medicine – Dr. K.B.Nangia
27. Ayurvedic Medicines – H.Panda.
28. Pharmacognosy and Pharmacobiotechnology – Ashutoshkar.
29. Foundations of Ayurveda – K.H.Krishnamurthy.
30. The complete Germancommision, E.Monographs-Blumenthal Buse, Gold bery, Gruenwald Hall.
31. Gruenwald Hall.
32. The Ayurvedic system of medicine – K.N.Sengupta.
33. Herbal cosmetics Hand book – H.Panda.
34. Homoeopathic pharmacy – Steven B.Kayne.
35. Dictionary of Indian Folk medicine and Ethnobotony – Dr.S.K.Jain.
36. Practical Pharmacognosy, Khandelwal, K. R. 7th Ed., Nirali Prakashan, Pune
37. Pharmacopoeia of India, Ministry of health, Govt of India 1996
38. Practical Pharmacognosy, Kokate C. K. Vallabh Prakashan, New Delhi
39. Indian Herbal Pharmacopoeia, Vol. III IDMA, Mumbai
40. Thin Layer Chromatography – E/ Stahl, 2nd Edition 1969
41. Ayurvedic Pharmacopoeia of India: Govt. of India.
42. Spectroscopic Identification of Organic compounds, Silverstein R. M. Bassler G.

Branch: - Quality Assurance (Branch Code: - 05)

QUALITY ASSURANCE –II

THEORY

Subject code-0512

Hours– (04/week)

1. Validation and calibration of equipments and instruments.
2. Elements of validation, benefits, types of process validation, validation protocol, process characterization and optimization.
3. Validation of processes: Mixing, granulation, drying, compression, filtration, filling.
4. Validation of sterilization methods and equipments: Dry heat sterilization, autoclaving, membrane filtration, gaseous sterilization and sterilization by radiation.
5. Validation of analytical procedures as per ICH.
6. Validation of air handling equipments and facilities in sterile and non-sterile areas, cleaning validation.
7. Validation of water purifying systems (de-mineralized water, distilled water and water for injection).
8. Validation and security measures for pharmaceutical data processing.
9. Validation of computer aided instruments.

PRACTICALS

Practicals based on theory.

BOOKS RECOMMENDED:

1. IP, BP & USP
2. Enzymes – Biochemistry, Biotechnology, Clinical Chemistry
3. Michael E. Swartz, Analytical method development & validation.

Total Quality Management-II

THEORY:

Subject code- 0522

Hours – (04/week)

1. Certification and licensing procedures, Quality, safety and legislation for cosmetic products, Quality, safety and legislation for herbal products.
2. Schedule U requirements.
3. Product development stage documentation.
4. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.
5. Waste disposal, scrap disposal procedures and records.
6. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.
7. Retention samples and records.
8. Quality control documentation.
9. Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities.
10. Finished products release, quality review, quality audits, batch release document.
11. Loan license (contract manufacture) auditing.
12. Recent amendments to Drugs and Cosmetic Act and other relevant rules.
13. Relevant provisions of Consumer Protection Act, Environmental Protection Act, Factories Act.

BOOKS RECOMMENDED:

1. Guideline for Developing National Drug Polices- WHO Publication, 1998.
2. Quality Assurance of Pharmaceuticals- A Compendia of Guidelines and Related Materials, Vol.-1, WHO publication.
3. A Guide of Total Quality Management- kaushik maitra and sedhan k. Ghosh.
4. GMP- Mehra.
5. ISO 9000 and Total Quality Management- Sedhan k. Ghosh.
6. How To Practice Gmp- P.P. Sharma.
7. Good Manufacturing Practice for Pharmaceutical- A Plan For Total Quality Control-Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol.78,Marcel Dekker Inc.
8. OPPI- Quality Assurance.
9. USP.

Branch: - Clinical Pharmacy (Branch Code: - 06)

APPLIED PHARMACOTHERAPEUTICS – II

THEORY

Subject code -0612

Hours– (04/week)

A brief pathophysiology and pharmacotherapy of diseases associated with the following systems with special emphasis on the drugs of choice.

1. Gynecology and Obstetric disorders: Menopause and Hormone replacement therapy, oral contraceptives.
2. Infectious disease: Tuberculosis, meningitis, respiratory tract infections, gastroenteritis, endocarditis, septicemia, urinary tract infections, Malaria, HIV & opportunistic infections, fungal infections, STDs.
3. Oncology: Basic principles of cancer therapy with special emphasis on the general chemotherapeutic regimen in the management of cancer
4. Gastrointestinal system: Peptic ulcer disease, inflammatory bowel disease, alcoholic liver disease, viral hepatitis and drug induced liver disorders, dosage adjustment in liver failure.
5. Ophthalmology: Glaucoma, conjunctivitis.
6. General prescribing guidelines for rational drug therapy in pediatrics, geriatrics, pregnancy and lactation
7. Pathophysiology of inflammation and repair.
8. Dermatology: Acne, psoriasis, drug induced skin reactions
9. Nutrition, Malnutrition and deficiency states- enteral & parenteral nutrition
10. Immunology: Function and evaluation of immune system, systemic lupus erythematosus, systemic sclerosis, systemic vasculitis

PRACTICALS

1. Ward round participation: Students will be posted in various medicine departments and have to attend morning ward rounds everyday other than their OPDs (Out patient department). Students have to follow up patients from the day of admission till the day of discharge. They also have to actively take part in various clinical pharmacy services/activities like providing drug and poison information, patient counseling, ADR monitoring and reporting and other related activities.
2. Case presentation: Case presentation has to be done based on respective theory topics, which are followed during ward rounds. The cases have

to be presented according to SOAP format or pharmaceutical case plan. Case presentations should also include respective patient counseling aspects along with counseling AIDS (if any).

BOOKS RECOMMENDED

1. Clinical Pharmacy and Therapeutics: Roger Walker and Clive Edwards. 3rd Edn. Churchill Livingstone, Edinburgh, 2003.
2. Textbook of therapeutics, Drug and disease management: Eric T Herfindal. 7th Edn. Williams & Wilkins Publications 2003.
3. Pharmacotherapy, A Pathophysiologic Approach: Joseph T Dipiro. 5th Edn. McGraw-Hill Medical publishing division 2002.
4. Applied therapeutics: Mary Anne Koda-Kimble, Lloyd Yee Young et al, 8th Edn. Lippincott Williams and Wilkins publications 2005.
5. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill-Publications, 2001.
6. Principles of Internal Medicine: Harrisons: Braunwald et al, 16th Edn. Mc Graw Hill Publications, 2005.
7. Davidsons Principles and Practice of Medicine: Christopher Haslett, et al, 19th Edn. Churchill Living stone Publications, 2002.
8. American Hospital Formulary Services: GK Mc Evoy, Published by American Society of Hospital Pharmacists, 2004.

CLINICAL AND HOSPITAL PHARMACY II

THEORY

Subject code -0622

Hours – (04/week)

Section A: Clinical Pharmacy.

1. Pharmacoepidemiology: Definitions and scope, measurement of outcomes, concept of risk, pharmacoepidemiological methods, advantage and disadvantage of various methods.
2. Pharmacoeconomics : Definition, scope, types of economic evaluation, cost models and cost effectiveness analysis
3. Drug utilization evaluation (DUE): Definition, Types of DUE, Establishment of DUE program, DUE cycle
4. Quality assurance of clinical pharmacy services
5. Antibiotic sensitivity testing
6. Toxicology
 - a. General principles involved in the management of poisoning
 - b. Clinical symptoms and management of poisoning with the following agents

Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.

- i. Antidepressants
- ii. Barbiturates and benzodiazepines.
- iii. Alcohol: ethanol, methanol.
- iv. Paracetamol and salicylates.
- v. Caustics: inorganic acids and alkali.
- vi. Heavy metals: Arsenic, lead, mercury, iron, copper
- vii. Venomous snake bites

Section B: Hospital Pharmacy.

1. Purchase and inventory control
2. Drug distribution: Outpatient and inpatient services, dispensing during off-hours
3. Safe use of medication in hospital
 - a. Medication errors
 - b. Poly pharmacy and its implication
4. Rational drug therapy: WHO list of essential drugs, the economic and social need for rational utilization of drugs in the Indian situation

Section C: Community Pharmacy

1. Community pharmacy management: Finance, personnel, infrastructure and materials.
2. Prescribed medication orders (prescription): Interpretation and legal requirements.

OTC drugs and prescription drugs

PRACTICALS:

1. Drug information: Students are supposed to answer to drug information queries on their OPD days which have to be documented on respective forms.
2. Patient Counseling: Counseling of OP and IP.

BOOKS RECOMMENDED:

1. A textbook of clinical pharmacy practice- Essential concepts and skills. G Parthasarathi et al, 1st Edn. Orient longman publications, 2004.
2. Basic skills in interpreting lab data: Scott L Traub, 2nd Edn. Published by American Society of Health System Pharmacist 1996.
3. Hospital pharmacy: William & Hassan JR, 5 th Edn, 1986.
4. Practice standards and definition - The Society of Hospital Pharmacist of Australia 1996.
5. Pharmacotherapy - A pathophysiologic Approach: Joseph T Dipiro, 5th Edn.
6. Mc Graw-Hill medical publication, 2002.
7. Comprehensive Pharmacy Review: Leon Shargel, 5th Edn. Published by Lippincott Williams & Wilkins 2004.
8. Remington's - The Science and Practice of Pharmacy, Vol I & II, AR Gennaro et al, Mack Publishing company, 20 th Edition, 2004.

DRUG DISCOVERY DEVELOPMENT AND CLINICAL RESEARCH

THEORY

Subject code -0632

Hours– (04/week)

1. Drug development process
 - a. Introduction
 - b. Various Approaches to drug discovery
 - c. Preclinical testing
 - i. Pharmacological
 - ii. Toxicological
 - iii. IND Application
 - iv. Drug characterization
 - v. Dosage form
2. Clinical development of drug
 - a. Introduction.
 - b. Various phases of clinical trial.
 - c. ANDA submission.
 - d. Good Clinical Practice – ICH, ICMR, CDSCO guidelines
 - e. Challenges in the implementation of guidelines.
 - f. Ethics in clinical research
 - i. Composition of ethics committee.
 - ii. Responsibilities
 - iii. Procedures
 - a. Overview of regulatory environment in USA, Europe and India.
 - b. Role and responsibilities of clinical trial personnel as per ICH GCP
 - i. Sponsor
 - ii. Investigators
 - iii. Clinical research associate
 - iv. Auditors
 - v. Contract research coordinators
 - vi. Regulatory authority
 - c. Protocol designing for clinical studies
 - d. Informed consent Process
 - e. Data management and its components
 - f. Adverse Event Reporting
3. Critical evaluation of Biomedical Literature
4. Therapeutic drug Monitoring: Introduction, individualization of therapy, indications for TDM, TDM of digoxin, gentamycin, phenytoin, carbamazepine, valproic acid, lithium, amiodarone and theophylline.

BOOKS RECOMMENDED

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes .
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
7. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

Branch: - Industrial Pharmacy (Branch Code:- 07)

NOVEL DRUG DELIVERY SYSTEMS

THEORY

Subject code-0712

Hours– (04/week)

1. Basic considerations of novel drug delivery systems: Biopharmaceutical aspects and technology transfer of controlled release dosage forms.
2. Oral drug delivery systems: Based on different control mechanism such as Osmotic pressure, membrane controlled pH, ion-exchange, gastrointestinal transit etc.
3. Mucosal drug delivery: Physiological, biopharmaceutical consideration, formation and models used.
 - a. Buccal: Physiology and permeability of oral mucosa, penetration enhancement, drug delivery systems and in-vitro and in-vivo techniques.
 - b. Nasal: Anatomy and physiology of nasal mucosa, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation.
 - c. Pulmonary: Structure and function of pulmonary system, factors affecting deposition in lungs. Dosage forms: Nebulizers, pressurized inhalation aerosols, aerosol powder devices.
 - d. Rectal: Physiology, advantages, dosage forms and evaluation models.
Intrauterine and intravaginal drug delivery devices.
4. Ocular delivery: Ocular delivery mechanism and development of ocular controlled release.
5. Transdermal drug delivery: Permeation through skin, permeation enhancers, technologies nanoparticles.
6. Micro-encapsulation: various techniques, parameters affecting microcapsules, microcapsule stability, mechanisms, manufacturing equipments.
7. Advances in drug delivery: Pulsatile, colon specific, intra-arterial, noncorneal drug delivery and systemic delivery of ophthalmic diseases.
8. Miscellaneous:
 - (a) Liposoms, Niosoms, Aquasoms, Nanoparticles, Microsphere.
 - (b) Microchip as drug delivery, Nanotubes, Dendimers, Resealed erythrocytes.

PRACTICALS:

Preparation and evaluation of oral, nasal, pulmonary, ocular, transdermal drug delivery system, Mucoadhesive drug delivery system, targeted drug delivery system, micro encapsulation etc.

Recommended Books:

1. P. Tyle; Drug Delivery Devices, fundamental and applications; Marcel Dekker.
2. Morton Rosoff; Controlled release of drugs; VCH Publishers.
3. Osborne, and Amann; Topical drug delivery formulations; Marcel Dekker.
4. P. Tyle; Drug delivery devices: Marcel Dekker.
5. Barry; Dermatological formulation; Marcel Dekker
6. Robinson; Novel Drug Delivery systems; Marcel Dekker
7. N.K. Jain; controlled and novel drug delivery; CBS Publication, New Delhi
8. P. Johnson and J. G. Lloyd – Jones; Drug delivery systems; VCH Publisher
9. P. Tyle and B. P. Ram; Targeted therapeutics systems; Marcel Dekker.
10. C.G. Wilson & N. Washington; Physiological Pharmaceutics; Ellis Horwood Limited.
11. H.S. Bean, A.H. Beckett, and J.E. Carless; Advances in Pharmaceutical Sciences; Vol. 5, Academic Press.
12. R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivery; Marcel Dekker
13. T.J. Roseman and S.Z. Mansdorf; Controlled release delivery systems; Marcel Dekker
14. A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology; Marcel Dekker.
15. J. Kreuter; Controlled drug delivery system; Marcel Dekker
16. P.B. Deasy; Microencapsulation and related drug processes; Marcel Dekker.

INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT

THEORY

Subject code-0722

Hours– (04/week)

1. Pilot plant scale: up, pilot plant design: tablets, capsules liquid orals, parenteral and semisolid preparations. Basis requirement for design of product, facility equipments selection, personnel, Pharmaceutical process validation for various products.
2. Quality Assurance: GMP consideration, quality assurance and process control. Total quality management and productivity. ISO 9000 series salient features.
3. Optimization techniques: Optimization parameter, classical optimization, statistical design and applied optimization methods.
4. Production planning: Plant site selection, layout and organization of pharmaceutical industries. Vendor development capacity (plant, machine human resources) assessment of production rate changes, inventory management costing of product and cost controls, planning product mix.
5. Drug and Cosmetics Act: Requirement related to manufacture and sale of drugs.
6. Machinery Engineering: Introduction to mechanical, electrical and electronic parts of pharmaceutical machinery, equipments. Material handling for various pharmaceutical products.
7. Safety: Industrial hazards due to fire, accident, mechanical and electrical equipment chemical and pharmaceutical, monitoring and preventive system.
8. Effluent testing and Treatment: For pharmaceutical industry.
9. Automation: Flexible manufacturing system, computer control system: data acquisition, distributed control and centralized control system. Typical models for solid and liquid manufacturing.
10. Production Management: Organization structure, objectives and polices, good manufacturing practices, layout of buildings, service, equipments and maintenance – detail discussion. Material management handling and transportation, production planning and control, industrial relations. Safety laws related to production and licensing factories act.

PRACTICALS:

1. Development of formulation at laboratory scale, converting same to pilot plant and scaling up to industrial scale.
2. Planning of production, safety arrangements and treatment of effluent at pilot scale.
3. Preparing an ISO documents for a Pharmaceutical unit having Tablet/ Capsule/ Liquid/ Ointment/ Injectables production.

BOOKS RECOMMENDED:

1. P. R. Watt; Tablet machine instrument in pharmaceuticals: John Wiely and Sons.
2. Rothery; ISO 14000 and ISO 9000; Grower.
3. G. C. Cole: Pharmaceutical production facilities, Design and applications; Taylor and Francis
4. J.R. Berry and R. A. Nash; Pharmaceutical process validation; Marcel Dekker
5. S. Bolton; Pharmaceutical statistics; Marcel Dekker.
6. S.H. Will and J.R. Stoker; good manufacturing practices for pharmaceuticals; Marcel Dekker.
7. R. F. Brewe; Design of Experiments for process improvement and quality assurance; Narosa.
8. Jaiswal; Management of quality control and standardization: Kanishka Publisher, New Delhi
9. D.H. Stamatis: Understanding ISO 9000 and implementing the basics to quality; Marcel ekker.
10. P. Gilson, G. Green halgh and K. Kerr; Manufacturing management; Chapman and Hall.
11. S.S. Rao; Optimization theory and applications; Wiley Eastern Limited.
12. J. F. Despautz: Automation and validation of information in pharmaceutical processing; Marcel Dekker.
13. J.M. Juran and A.B. Godfrey; Juran's Quality Handbook; McGraw Hill.
14. S. N. Katju's Law and drugs; Law Publishers (I) Pvt. Ltd.

Branch:- Pharmaceutical Biotechnology (Branch Code:- 08)

BIOPROCESS TECHNOLOGY

THEORY

Subject code-0812

Hours– (4 /Week)

1. Basic Principles in Fermentation
2. Isolation, Screening and Application of Industrially Important Microbes: Primary and secondary screening, maintenance of stock cultures, strain improvement for increased yield.
3. Design of Fermentation Process:
 - a. Detailed study of the design and operation of bioreactor, ancillary parts and functions; impeller design & agitation power requirements; on-line measurement and control of dissolved oxygen, carbon-dioxide, temperature, pH and foam.
 - b. Types of reactors – CSTR, tower, air-lift, bubble-column, packed bed, hollow fibre – configuration and applications.
4. Mass Transfer – theory, diffusional resistance to oxygen transfer, Oxygen requirements of micro organism, measurement of mass transfer coefficient and factors affecting them; effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air, air sampling and testing standards for air purity
5. Rheology: Rheological properties of fermentation systems and their importance in bioprocessing
6. Fermentation Kinetics: Reaction kinetics : Michaelis Menten constant and Monod equation derivations for biomass estimation; Lineweaver–Burke plot.
7. Cultivation Systems: closed, semi-open and open systems; graphical plots representing the above systems; use of immobilized culture systems to prepare fine chemicals.
8. Scale up of Fermentation Process: Principles, theoretical considerations and techniques used
9. Downstream Processing: Theory, equipment design and operation, methods, filtration, solvent extraction, chromatographic separation, crystallization, turbidity analysis and cell yield determination metabolic response assay, enzymatic assay, bioautography, techniques for disruption of cells for product recovery.
11. Bioprocess of the following Industrially Important Microbial Metabolites: Alcohol, Citric acid and Lactic acid, Penicillin, Streptomycin, Griseofulvin, Cephalosporins, Amphotericin B, Rifampicin, Vitamin B12 and Riboflavin, Glutamic acid and Lysine, Nucleotides : Cyclic AMP & GMP.

12. Computer control of fermentation processes & Regulatory aspects: System configuration and applications, Regulations governing the manufacture of biological products.

PRACTICALS

1. Isolation and secondary screening of industrially important microorganisms.
2. Strain improvement (for increased yield) by stress inducers.
3. Preparation, calibration, and standardization of a bioreactor.
4. Power calculations, KLa determinations and MTR calculations of a typical bioprocess.
5. Construction of growth curve and determination of specific growth rate and doubling time.
6. Biomass estimation by monitoring protein synthesis and sugar depletion.
7. Enzyme kinetic study
 - a. Effect of metal ion concentration.
 - b. Effect of pH.
 - c. Effect of temperature.
 - d. Effect of varying substrate concentration.
 - e. Kinetic parameter calculations.
8. Protein separation by aqueous two-phase partitioning.
9. Fermentation process of alcohol and wine production.
10. Fermentation of vitamins and antibiotics.
11. Whole cell immobilization engineering
 - a. Using various polymers.
 - b. Study of physical characteristics.
 - c. Comparison of efficacy of immobilized and free cells.
12. Down stream processing
 - a. methods of cell disruption.
 - b. typical isolation process for antibiotics.
 - c. purification by chromatographic techniques.
13. Microbiological assay of antibiotics.
14. Thermal death kinetics of bacteria and its applications.

REFERENCES

1. Industrial Microbiology : L.E. Casida.
2. Industrial Microbiology : B.M. Miller and W.Litsky.
3. Microbial Technology Vols I & II : H. Pepler.
4. Industrial Biotechnology : Vedpal S Malik and Padma Sridhar.

5. Biochemistry of Industrial Microorganisms, C Rainbow and AH Rose.
6. Current protocols in molecular biology, Vols I & II : F.M Asubel, John Wiley Publishers.
7. Biotechnology of antibiotics and other bioactive microbial metabolites : Gianeario Lancini and Rolando Lorenzetti.
8. Biological reaction engineering : I J Dunn, E. Heinzle, J Ingham, J.E. Prenosil.
9. Bioreactor design and product yield : Butterworth and Heinemann.
10. Enzyme assays – a practical approach: Robert Eisenthal and Michael J Danson.
11. Fermentation and biochemical engineering handbook: Henry C Vogel
12. Biochemical Engineering by F.C. Webb (McGraw Hill, New York)
13. Biochemical Engineering by R. Steel (Chemical Publishing Co. Inc., New York).
14. Biochemical Engineering by Fundamentals by Bailey and Ollis (McGraw Hill, New York.)
15. Biochemical Engineering by Aiba S., Humphrey. A.E and Milli N.F (Academic Press, NY)
16. Bioprocess Engineering Principles by Paulin M. Doran (Academic Press, London)

ADVANCES IN PHARMACEUTICAL BIOTECHNOLOGY- II

THEORY

Subject code-0822

Hours–(4 / Week)

1. Genomics & Proteomics: Concepts and techniques
2. Animal Cell Culture: General cell culture media design, nutrient composition, Natural media, Synthetic media, Further Considerations in media formulation, Nutritional components of media, The role of serum in cell culture, Choosing a medium for different cell types, Characterization of cell lines, Species Verification, Characterization of cell type and stage of differentiation, Microbial contamination, Preservation of animal cell lines, Variation and instability in cell lines, Preservation of cell lines, Freezing of cells, Quantification of cell viability, Cell banks. Growth of animal cells in culture; General procedures for cell culture, established and transformed cell cultures, primary culture, tissue and organ culture, Applications of cell culture

- in Pharmaceutical Industry and research. In-vitro fertilization and embryo transfer in humans / mammals, Growth of viruses in culture; Propagation and enumeration; application of above techniques for antiviral screening.
3. Plant Cell Culture: Commercial production of tissue cultured plants- (i) Technology transfer, equipment and procedures (ii) Aseptic techniques and control of contamination in a commercial laboratory, quarantine, pathological indexing, packaging. Micropropagation and Somaclonal variation, Somatic embryogenesis system and artificial seed production. Commercial production of secondary metabolites using cell cultures - Use of bioreactors, immobilized cells. Biotransformation. applications and limitations. Cryopreservation and ex situ conservation of germplasm. Genetic improvement of plants through tissue culture, (a) Transgenic Plants, (b) In vitro pollination and fertilization, embryo rescue, endosperm culture and production of seedless plants (c) Protoplast culture and its use in genetic improvement, (d) Genetic engineering in plant biotechnology. Genetic Engineering of metabolic pathway in medicinal plants
 4. Modern Techniques in Biotechnology: Gel Electrophoresis: Agarose gel, SDS- PAGE & their applications. Southern, Northern, Western, South western, and Far Western Blotting. Enzyme Linked Immunosorbent Assay (ELISA).
 5. PCR and its Applications: The use of PCR in gene assembly: multiplex, nested, RT PCR, overlap extension and SOEing, PCR in gene recombination: Deletion, recombination, addition, and Site specific mutagenesis, PCR in molecular diagnostics, Detection of hepatitis, herpes, HIV, and EBV, The role of PCR in detecting minimum residual diseases (MRD), Gene Disorder, Detection of mutation in Neoplastic diseases.
 6. Biotechnology of Antibiotics: Molecular & Genetic Approaches to Yield Improvement in Actinomycetes, Molecular Biology, Biochemistry, and Fermentation of Aminoglycoside Antibiotics, Comparative Genetics and Molecular Biology of b-Lactam Biosynthesis, Biochemistry and Genetics of Actinomycin Production, Molecular Biology, Biochemistry, and Fermentation of Tetracycline Formation, Antibiotics from Genetically Engineered Microorganisms, Recombinant Bioconversions of Bioactive Molecules: New Processes for Production of 7-ACA from Cephalosporin, Chemoenzymatic Production of the Antiviral Agent Efavirenz.

PRACTICALS

1. Setting up of Animal Cell Culture laboratory
2. Maintenance and preservation of various cell lines.
3. Antiviral screening of herbal drugs on cell lines (in vitro studies)
4. Plant cell culture: micromanipulation of callus culture, seed culture
5. Agarose gel electrophoresis for DNA / Plasmid visualization
6. SDS-PAGE electrophoresis for protein separation
7. Use of PCR instrument for gene amplification with help of primers.

REFERENCES

1. Biotechnology – The biological principles: MD Trevan, S Boffey, KH Goulding and P. Stanbury.
2. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S. Lawrence Zipursky, Paul Matsudaira, James Darnell.
3. Modern Biotechnology : S.B Primrose.
4. Industrial Biotechnology : Vedpal S Malik and Padma Sridhar.
5. Gene transfer and expression protocols – methods in Molecular Biology, Vol. VII, Edit E.T. Murray.
6. Current protocols in Molecular Biology, Vol.I & II : F.M. Asubel, John Wiley Publishers.
7. Cell Biology, Vol.I, II & III Edited by Julio E Celis.
8. Culture of animal cells: Ian Freshney
9. Pharmacopoeia of India 1996, 2007
10. Biotechnology of Antibiotics, Second Edition, Edited by W. R. Strohl, Published by Informa Health Care, 1997, ISBN 0824798678, 9780824798673 (Drugs and Pharmaceutical Sciences, Vol 82)
11. Basic Biotechnology: Bullock J. D. and Kristiansen B.