SYLLABI OF BACHELOR OF PHARMACEUTICAL SCIENCES

FINAL YEAR B. PHARMACY

4.1 (T) PHARMACEUTICS-III

(Theory) 90 Hrs. (3 hrs per week)

Topic No	SECTION-I	Hrs.
1.	**Sterile formulations** **i) Preformulation Methodology for Parenteral Products :** Physicochemical properties of drug substances, accelerated stability study, preformulation studies for proteins, peptides	5
	ii) General Requirements : Routes of administration, significance of tonicity adjustment and sterility, freedom from pyrogens and particulate matter, stability aspects and quality control tests, sterility tests for ointment, antibiotic preparations, powders.	10
	iii) Small Volume Parenterals (SVPs) : Classification, formulation of solutions and suspensions, types of vehicles, selection of vehicles and added substance, processing and manufacturing of SVPs, Pilot plant scale up for SVPs. Special types of SVPs*:* Formulation of peptides and proteins, freeze dried products, parenteral suspensions, emulsions and Reconstituted products.	7
	iv) Large Volume Parenterals (LVPs): Types of LVPs, concept of formulation, influence of physiological, formulation and packaging parameters, stabilization of LVPs, processing of LVPs, Total Parenteral Nutrition (TPN) and Peritoneal dialysis fluid. Pilot plant scale up for LVPs.	5
	v) Ophthalmic Products : General requirements, formulation, types of dosage forms. Contact lens and lens care products.	4
	vi) Packaging of Parenterals : Various materials used, official quality control tests, packaging components and types, specifications and methods of evaluation, stability, factors influencing choice of containers, prefilled syringes, blow-fill-seal technique.	4
	vii) GMP-Design of Parenteral Production Facility: Product characteristics, water treatment plant, operational assessment and area planning, batch Vs continuous operation, environmental control zones, filling area design, utility distribution systems, heating ventilation air conditioning (HVAC), HEPA filter testing and rating, laminar flow area working, development of facility layout, automation in parenteral industry.	5
2.	**Validation of Sterilization Techniques:** Introduction: Basic concepts, types and stages of validation, Validation Master Plan (VMP), equipment and process validation for steam sterilization and membrane filtration techniques.	3

SECTION- II		
3.	**Modified Drug Release Systems** **i) Fundamental Concept of Modified Drug Release :** Definitions of controlled release, sustained release time release drug delivery systems. Pre requisites of drug candidates, various approaches and classification, dose calculation for controlled release. Brief introduction to polymers parameters affecting selection of polymers for modified release systems.	12
	ii) Novel Drug Delivery Systems : Introduction, merits, demerits, and application of following : (Formulation aspect is excluded) Mucosal drug delivery system, Transdemal drug delivery system (TDDS), Parenteral implants, Ophthalmic insets, Intrauterine drug delivery system (IUDs), Liposomes, Targeted drug delivery systems ; micro encapsulation of living cells and tissues, hemoglobin, multienzyme systems artificial cells as drug carriers, Probiotics and Prebiotics. Externally modulated devices and delivery; iontophoresis and sonophoresis.	9
4.	**Microencapsulation :** Introduction, concept of microencapsulation, merits, demerits and application. Types of Microencapsulation: chemical encapsulation processes, complex, coacervation, polymer-polymer incompatibility, interfacial polymerization, and in-situ polymerization. Mechanical encapsulation process: spray drying, spray congealing, fluidized bed coaters, extrusion, and spheronisation techniques, rotational suspension separation, solvent evaporation. Evaluation of microcapsules.	10
5.	**Formulation And Processing of Therapeutic Aerosols :** Aerosol component and factors affecting its selection. Recent advances, objectives of therapeutic aerosols, fundamentals and principle of design, drug substances, important physicochemical properties of aerosol system solutions, suspensions and emulsions, formulation design and stability, typical formulations from, metered dose, intranasal and topical applications, factors influencing drug deposition, manufacturing techniques, product evaluation including safety considerations.	10
6.	**Optimization Techniques in Pharmaceuticals** : Basic concept of optimization, factors variable and design of experiment, introduction to two level factorial design with suitable pharmaceutical samples.	4

4.1 Pharmaceutics-III (practical 3Hrs/week)

1) Validation of aseptic area.
2) Pharmacopoeial evaluation of glass and plastic containers and rubber closures used for injectables.
3) Formulation, isotonicity, packaging and quality control of the following SVPs as per Indian pharmacopoeia. Also explain industrial scale manufacturing processes.

a) Sterile water for injection
b) Ascorbic acid injection
c) Calcium gluconate injection
d) Atropine sulphate injection
e) Chloramphenicol injection
f) Sodium chloride injection

4) Formulation, isotonicity, packaging and quality control of the following LVPs as per Indian pharmacopoeia. Also explain industrial scale manufacturing processes.
   a) Intraperitonial dialysis fluid
   b) Contact lens solution
   c) Sodium chloride and Dextrose infusion
5) Formulation, isotonicity, packaging and quality control of following parameters :
   a) Sulphacetamide eye drops BPC
   b) Tetracycline eye ointment IP
   c) Xylomethazoline nasal drops IP
6) Optimization of formulations using 2 level factorial design: (of any one following dosage form)
   a) Suspension b) Microsphere c) Emulsion
7) Formulation and evaluation of marketed lyophilized products as reconstitutable solution for injection.
8) Evaluation of marketed parenteral suspensions and emulsions. Evaluation parameters: particle size determination, test for sterility and rheological behavior using Brookfield viscometer.
9) Micro encapsulation (using one solid and one liquid drug) by coacervation and polymer incompatibility, evaluation of microcapsules.
10) Formulation of sustained release formulations (any one of following dosage forms)
   a) Tablet b) Capsule
11) Accelerated stability testing of a SVP and LVP

Recommended books :

1. K. E. Avis, H. A. Lieberman ; Pharmaceutical dosage forms, Parenteral medications, 2nd ed,Vol I,II & III, Marcel Decker 1993.
2. S. J. Turco; Sterile Dosage Forms; their preparation and clinical applications, 4th ed., Lee and Febiger, 1993.
3. A. J. Hickey; Pharmaceutical Inhalation Aerosol Technology; 1st ed, Marcel Decker, 2004.
4. B. Rothery; ISO 14000 and ISO 9000, Gower Publishers.
5. P. Tyle; Drug Delivery System, 1st ed, Marcel Decker, 1988.
6. I. R. Berry; R.A. Nash; Pharmaceutical Process Validation; 2nd ed, Marcel Dekker, 1993.
7. J. Swarbrick, J. Boylan; Encyclopedia of Pharmaceutical technology, 2nd ed, Marcel Dekker, 2002.
8. D. H. Shah; SOP Guidelines, Business Horizons Publishers.
9. W. P. Olson, M. J. Groove; Aseptic Pharmaceutical Manufacturing Technology, Interpharmpress.
10. Indian Pharmacopoeia, vol.I , II & III, 2007.

11. L. A. Trissel; Handbook on Injecteble drugs, American society for hospital Pharmacist Publication.
12. Encyclopedia of Pharmaceutical technology, 2nd ed.,vol.III, 1999.
13. Haward.C. Ansel; Pharmaceutical calculations, 13th Ed, Lippincott Williams & Wilkins Publication, 2010
14. Cooper and Gunn ;Dispensing for Pharmaceutical Students, 12th Ed, CBS Publication
15. Leon Lachman and Lieberman; The theory and practice of pharmacy, 3rd Ed, CBS Publication, 1986.
16. N. K. Jain; Advances in controlled and novel drug delivery, 1st Ed., CBS Publication, 2001.
17. Y. W. Chien ; Controlled drug delivery, Fundamentals and Applications,, 2nd Ed. Marcel Dekker.
18. Lockheart; Packaging of Pharmaceuticals of Healthcare products, Marcel Decker, 1998.
19. Herburn Kenneth; Quality control of Packaging Materials, in Pharmaceutical Industry, Marcel Dekker, 1990.
20. Carleton and Agalloco; Validation of Pharmaceutical sterile Products, 2nd Ed, Mercel Dekker,1999.
21. Michael Levin; Pharmaceutical Process Scale-Up, 2nd Ed, vol-157, CRS Press,2006.
22. Benita; Microencapsulation- methods & Industrial Applications, 2nd Ed, vol-158, Taylor & Francis Publication, 2006.
23. Mitra; Ophthalmic Drug Delivery System, 1st Ed, Vol-58, Marcel Dekker, 1993.
24. Hadgraf & Guy; Transdermal Drug Delivery, 1st Ed, Vol-35, Marcel Dekker, 1989.
25. Ray & May; Freeze Drying / Lyophilization of pharmaceutical & Biological Products, , Marcel Dekker,
26. R.C.Rowe & P.J.Sheskey; handbook of Pharmaceutical excipients, 5th Wd, Pharmaceutical Press,2006.
27. Peter.J.Tarcha; Polymers for Controlled drug delivery, 1st Ed,CRC Press,1991.

4.2 (T) BIOPHARMACEUTICS AND PHARMACOKINETICS
(Theory) 60 Hrs. (2 hrs per week)

Topic No	SECTION-I	Hrs.
1.	**Concept, definition and introduction** to Biopharmaceutics, Pharamacokinetics, Pharmacodynamics and clinical Pharmacokinetics with respect to design of dosage regimens. Plasma drug conc. Profile.	3
2.	**Absorption of Drug** Cell membrane, Mechanisms of drug absorption, Factors affecting drug absorption- i) Physicochemical ii) Physiological iii) Pharmaceutical. pH partition hypothesis..	6
3.	**Drug distribution** Introduction, types of drug distribution, factors affecting drug distribution. Concept of apparent volume of distribution. Protein binding (intravascular and extravascular). Significance of drug-protein binding and drug displacement interactions. Kinetics of protein binding.	5

4.	**Drug metabolism.** Study of factors affecting metabolism. Bioactivation and first pass effect.	2
5.	**Excretion** Introduction, types of drug excretion, Renal excretion, Mechanism, concept of clearance, factors affecting renal clearance, Non renal routes of elimination. Extraction ratio, hepatic clearance, biliary excretion, extra hepatic circulation.	4
6.	Prodrug: Biopharmaceutical aspect of prodrug.	2
7.	**Bioavailability and Bioequivalence:** Definition and concept of absolute & relative bioavailability. Methods of assessing bioavailability. Measures of bioavailability (C_{max}, t_{max}. AUC etc.) Bioequivalence study and introduction to various study designs. Single dose bioequivalence study and relevant statistics, Review of regulatory requirements for conducting bioequivalence study. Clinical significance of bioavailability and bioequivalence. Introduction to orange book.	8
	SECTION- II	
8.	**Dissolution studies.** Introduction to Biopharmaceutical classification system, Mechanism of dissolution, *In-vitro* studies, and all latest models: Zero order, Matrix, First order, Higuchi. *In-vitro in-vivo* correlation: Definition, objectives & methods.	5
9.	Introduction to pharmacokinetics, Introduction to pharmacokinetic models. Physiologic versus compartment approach	2
10.	**Compartment models** – Concepts and their importance in the study of pharmacokinetics. One compartment open model. Assessment of pharmacokinetic parameters from plasma and urine data after i. v. bolus, i.v. infusion, i. v. injection with loading dose and oral administration. Percent absorbed time plot and determination of absorption rates based on one compartment model. Introduction to 'Two compartment model.'	6
11.	**Non-Linear Pharmacokinetics** Detection of non-linearity (saturation mechanism).Michaeles Menten equation. Definition of V_{max} and K_m. Determination of V_{max} and K_m. Significance of Non-Linear Pharmacokinetics: Case studies.	5
12.	**Applications of Pharmacokinetics** i) Therapeutic drug monitoring. Case study of Digoxin and theophyline. ii) Individualization: Need and method of indivisualisation. Dosage adjustment in renal and hepatic failure.	6
13.	**Numerical:** Based on AUC, Elimination half life ($t_{1/2}$), Volume of distribution (Vd), Clearance (Cl), elimination rate constant (ke) and amount of drug (X).	6

References-

1. Brahmankar and Jaiswal; Biopharmaceutics and Pharmacokinetics: A treatise; 2nd Edition; CBS Publication;2009
2. Leon Shargel and Andrew B. C.Yu: Applied Biopharmaceutics and Pharmacokinetics 5th Edition; McGraw Hill; 2005

3. Rowland and Tozer Text book of Clinical Pharmacokinetics 2nd edition, Lippincott Williams & Wilkins; 1995
4. Robert E. Notari, Biopharmaceutics and Clinical Pharmacokinetics: An Introduction Fourth Edition, Revised and Expanded. Marcel Dekker, New York.2005
5. Remington: The Science and Practice of Pharmacy, 21st Edition. Philadelphia, PA: Lippincott Williams & Wilkins, 2005
6. J Swarbrick, Current Concepts in the Pharmaceutical Sciences: Biopharmaceutics, Lea & Febiger, Philadelphia (1970)
7. Javed Ali, Roop.K.Khar and Alka Ahuja: Textbook of Biopharmaceutics and Pharmacokinetics: 1st edition; Birla Publication, 2001-2002
8. Robinson, J.R.Lee, V.H.L. Controlled Drug Delivery: Fundamentals and Applications 2nd edition, Macel Dekker, New York, 1987
9. H.F.Lodish and J.E.Rothman "The assembly of cell membranes Sci. Am. 240: 48-63, 1979
10. R.I.Oberle, G.L.Amidon; J. Pharmacokinetics and Biopharmaceutics, 15:529-544, 1987
11. A.Rubinstein, V.H.K.Li and J.R. Robinson In oral sustained release formulation, Design and Evaluation, New York, Pergamon, 1988 cap. 6
12 A. Tsuji, Tamai Pharm. Res. Carrier mediated intestinal transport of drugs; 13(7), 963-977, 1996

4.3 (T) MEDICINAL CHEMISTRY – II

(Theory) 90 Hrs. (3 Hrs/week)

Topic No	SECTION-I	Hrs.
1	Introduction to drug design and discovery, phases involved, different methods in brief, some case studies e.g. development of ciprofloxacin, antidiabetics, and recent cephalosporins. Introduction to QSAR, Lead discovery & optimization Introduction to different target sites of bacteria, fungi, viruses, parasites with respect chemical composition, comparison with mammalian targets, enzymes, receptors etc. Principles of Drug Design including some case studies from following categories- antihistaminic, antihypertensive, psychotherapeutics. QSAR, Hansch & Free Wilson Analysis, Mechanism based Drug Design including Quantum Mechanics, Molecular Mechanics and Molecular Modeling.	12
2	Drug Metabolism: Study of drug metabolising enzymes, phase I & phase II reactions with selected examples of following drugs, Diazepam, Tolbutamide, Cyclobarbital, Paracetamol, Imipramine, Amphetamine, Mesoridazine and Sulindac. Applications of drug metabolism studies in new drug discovery.	06
	History and general aspects of the design & development of drugs including, classification, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses and recent developments of following categories	
	Chemotherapeutic Agents	

3	a. Synthetic antibacterial agents eg. Sulfonamides, Quinolones, Nitrofurans etc. b. Antitubercular & Antileprotic agents c. Antifungal agents d. Antimalarials e. Antiamebic agents f. Trypanosomicidal drugs, drugs acting against leishmaniasis. g. Anthelmintics h. Antiviral agents including antiretroviral i. Antineoplastic agents including recent drugs and monoclonal antibodies	5 4 3 6 2 2 2 5 6
	SECTION II	
4	**Antibiotics:** β-lactam antibiotics: (Penicillins and Cephalosporins, oxopenams carbepenams, monobactams) The aminoglycosides The tetracycline The macrolides The Lincomycins The Polypeptides Unclassified antibiotics	20
5	Hormones: Thyroid and antithyroidal agents	02
6	Steroids a. Steroidal anti-inflammatory agents b. Sex hormones and their synthetic analogs c. Antifertility agents	09
7	Opioid analgesic agents: Receptor subtypes and opioid antagonists	06
8	NSAIDs & Antipyretics	04
9	Prostaglandin analogs	02
10	Antihistaminic agents: Structural features of Histamine receptor and its Subtypes and their structural features, H1 blockers and H2 blockers, Proton Pump Inhibitors	05
11	Scheme of synthesis of following drugs from various therapeutic categories: Carbachol, dantrolene sodium, methyldopa, propranolol, atenelol, salbutamol, fenfluramine, thiopental sodium, lignocaine, benzocaine, propoxyphene, loperamide, methadone, chlorpheniramine, prolidine, prazocin, guanethidine, terbutaline, captopril, 17 β-estradiol, prednisolone, amitryptiline, hydralazine, imipramine, doxepin, diazepam, chlorpromazine, haloperidol, trifluperazine, ibuprofen, diclofenac, phenytoin, sodium valproic acid, lamotrigene, losartan, alprazolam, respiridone, metazepine, fluoxetine, clofibrate, zolpidem, sumatriptan, ondansetron, omeprazole	09

4.3 (P) MEDICINAL CHEMISTRY - II
(Practical) 90 Hrs. (3 hrs. per week)

1. Synthesis of following medicinally important compounds or drug intermediates.
    a. Hydroquinone to 2,5-dihydroxyacetophenone
    b. Anthranilic acid
    c. Anthranilic acid to o-iodobenzoic acid
    d. 2-phenyl indole
    e. Benzene to propyl benzene
    f. 4-fluroacetophenone
    g. 2-methyl benzimidazole
    h. 2-mercapto benzimidazole
    i. Hanztch Synthesis
    j. Ethylnicotinate
    k. Caprolactam
    l. Canizarro reaction (benzyl alcohol)
    m. O-nitro aniline to p-nitro aniline

2. Column chromatographic separation
3. Preparative TLC
4. Separation of o/p-nitro phenols by steam distillation
5. Establishing Pharmacopoeial standards & spectral studies of drugs synthesized
6. Demonstration experiments

6.1. High vacuum distillation
6.2. Recrystalisation
6.3. Steam distillation
6.4. Dean stark azeotropic water separation
6.5. P^H based amino acid separation
6.6. Catalytic hydrogenation

Recommended Books for Theory and Practicals

1 An Introduction to the Chemistry of Heterocyclic Compounds, by Acheson RN, Interscience Publishers New York.
2 Bentely and Driver's Textbook of Pharmaceutical Chemistry by Atherden LM, 8th edition Oxford University Press London.
3 Inorganic Medicinal and Pharmaceutical Chemistry by Block & Roche, 1st edition, Varghese Publishing House.
4 A Textbook of Pharmaceutical Chemistry by Chatten LG, Vol I & II, Marcel Dekker New York.
5 Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry by Wilson and Gisvold, J. Lippincot Co. Philadelphia.
6 Stereochemistry of Carbon Compounds by Eliel EL, 32nd reprint 2005, TATA McGraw Hill.
7 The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 by Lednicer Daniel, 1st edition, John Wiley & Sons INC..
8 Profiles in Drug Synthesis Vol 1 & 2 by Gogate.

9 Exploring QSAR Vol; I Fundamentals and Applications in Chemistry and Biology by C Hansh and A Leo Vol. II: hydrophobic, Electronic and Steric Constants by C Hansh, A Leo and D Hockman ACS Book Catalog.
10 Organic Chemistry by Finar IL, Vol. I & II, Pearson Education.
11 Foye's Principles of Medicinal Chemistry by Foye, 6th edition, Lippincott William Wilkins.
12 Comprehensive Medicinal Chemistry by Hansh C, Vol IV, Elsevier Pergamon.
13 Quantitative Drug Design- A Critical Introduction by Martin YC, Marcel Dekker Inc. New York.
14 Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
15 Computer Aided Drug Design, by Pops and Perruns, Academic Press, NY
16 Burger's Medicinal Chemistry by Wolff ME, John Wiley & Sons, New York.
17 Antibacterial Chemotherapeutic Agents by SL Dax, Blackie Academic and Professional Publications, Chapman and Hall, 1997.
18 Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II, 10th Edition, Nirali Prakashan.
19 Introduction to Medicinal Chemistry' – How Drugs Act and Why by Alex Gringauz, Willey-VCH Publication 1997.
20 Drug Design by Bothara KG & Kulkarni VM, 3rd edition, Nirali Prakashan.
21 An Introduction to Drug Design by SN Pandeya & IR Dimmock, 1st edition, New Age International Publishers.
22 Structure based Drug Design by Veerapandian, 1st edition, Taylor & Francis New York, London.
23 Pharmaceutical Substances by Kleeman & Engel, 4th edition, Thieme Publications.
24 Practical Pharmaceutical Chemistry by Beckett AH & Stenlake JB, Vol. I and II, 4th edition, CBS Publisher & Distributor.
25 Steric Constants by C Hansch, A Leo and D Hockman, ACS Book Catalog.
26 Textbook of Practical Organic Chemistry, The ELBS Longman, London.
27 Computer Software Application in Chemistry by Jurs PC, John Wiley & Sons, New York.
28 Jenkins's Quantitative Pharmaceutical Chemistry by Knevel AM and Digangi FE, McGraw Hill Book Co. New York.
29 Practical Organic Chemistry by Mann FC & Saunders BC, The English Language Book Society and Longman Group Limited, London.
30 Quantitative Drug Design - A Critical Introduction by Martin YC, Marcel Deckker Inc. New York.
31 Vogel's A Text book of Practical Organic Chemistry by Vogel, 3rd edition, The English language book society and Longman group limited, London.
32 Advanced practical Medicinal Chemistry by Ashutosh Kar, 1st edition, New Age International Publications.
33 Vogel's Elementary Practical Organic Chemistry Small Scale Preparation by Arthur I.,2nd Edition, Part-I, CBS Publication.

4.4 (T) PHARMACEUTICAL ANALYSIS-III
(Theory) 90 Hrs. (3 Hrs/week)

Topic No	SECTION-I	Hrs.

The following analytical techniques to be discussed with special reference to quality control and assurance of the pharmaceuticals, its scope and importance in the pharmaceutical industry along with suitable examples.		
1	Infrared Spectroscopy: Origin of IR spectra, Molecular vibrations, fundamental bands, Vibrational frequency, Fermi resonance, Instrumentation, Applications, Important spectral regions, FTIR and Raman spectroscopy – Theory, Instrumentation, sample handling, structural analysis.	07
2	X-ray diffraction techniques: Introduction, Instrumentation, Pharmaceutical applications and simple calculations based on 2θ, calculation of Redia, different crystal faces. Polymorphism	07
3	Atomic Emission Spectroscopy Instrumentation , Principle and Application	05
5	Nuclear Magnetic Resonance (NMR) Spectroscopy: Theory, Chemical shift, shielding-deshielding, Spin-Spin Coupling (Splitting), Coupling Constant, Chemical and Magnetic Equivalence, Double resonance, NOE, Shift reagents, Solvents, Factors affecting chemical shift, Anisotropy, Instrumentation, application and simple structure determination, HID calculation. C^{13} NMR-Introduction.	14
6	Mass spectrometry: Introduction, Theory, Instrumentation, Resolution and application. Brief discussion on GC-MS, LC-MS and MS-MS	07
7	ESR: Introduction, principle & instrumentation	03
8	Validation, Quality Audit: Quality of equipment, validation of equipment and Validation of Analytical Methods as per ICH or USP guidelines.	08
SECTION-II		
9	Gas chromatography: Theory, Instrumentation and applications. Van Deemter equation, Band broadening, HETP, and various parameters, Sample handling, Columns, Detectors, Derivatisation quantitation (area normalization, percent area, Internal standard, External standard method), Application.	10
10	High performance Liquid Chromatography (HPLC): Theory, Instrumentation and applications, Adsorption, partition, Isocratic, Gradient, Pumps, Columns phases, Detectors, Tubing, Degassing techniques, Quantitation technique, Trouble shooting in brief. Ion Exchange and ion pair and ion chromatography. Capillary Zone electropohoresis, System Suitability Testing, UPLC- theory columns, advantages over HPLC	10
11	Flash Chromatography	02
12	Super Critical Fluid Extraction, Simulated moving bed technology Instrumentation, Principle and Application.	06
14	Radio Chemical Methods – Nuclear reactions and radiations, Neutron sources, Measurement of radioactivity, tagging of compounds, Pharmaceutical Applications.	06
15	Scanning Electron Microscopy, Scanning Probe Microscopy, TEM ESCA, brief introduction, principle and application of all these techniques	05

4.4 (P) PHARMACEUTICAL ANALYSIS-III
(Practical) 90Hrs. (3 hrs. per week)

Calibration of Spectrophotometer as per official procedure.

1. Spectrophotometric estimation of two-component formulations by simultaneous analysis. (Minimum two experiments)
2. Validation of Analytical methods (Spectrophotometry & HPLC) as per official USP/ICH Guidelines (minimum four experiments)
3. Spectrophotometric Analysis of two components by Q-Method. (Minimum four experiments)
4. Separation of amino acid on Ion Exchange Resins. (Minimum three experiments)
5. Separation on anion exchange of Cations/Anions/ Pharmaceuticals (minimum three experiments)
6. Recording of IR spectra of compounds with different functional groups (-COOH, -COOR, -CONHR, $-NH_2$, -NHR, -OH, -CHO, -CO etc.) (Minimum two experiments)
7. Demonstration Practicals/Calculations/Interpretations

9.1 Study of Quantitation Techniques in HPLC or GC (% Area / Area Normalization, Internal Standard addition)

9.2 Study of system suitability parameters as per BP/USP protocol for HPLC or GC methods.

9.3 Workshop to interpret the structure of simple organic compounds using UV, IR, NMR, MS

9.4 Interpretation of X-ray powder diffraction pattern and to identify crystal types.

Recommended Books for Theory and Practical

1. Instrumental Methods of Chemical Analysis by GW Ewing, McGraw-Hill Book Company.
2. Applications of Absorption Spectroscopy of Organic Compounds by I.R. Dyer, Prentice Hall Inc.
3. Organic Spectroscopy by William Kemp, English Language Book Society, Macmillan.
4. Pharmaceutical Analysis by Higuchi.
5. Pharmaceutical Analysis: Modern Methods, James W. Munson (Marcel Decker, New York)
6. Instrumental Methods of Analysis, Willard Merit, and Dean Settle, CBS Publications, Seventy Edition.
7. A Textbook of Pharmaceutical Analysis by K.A. Conners, 3rd edition, John Wiley and Sons.
8. Principles of Instrumental Analysis by Skoog, 5th edition, Thomson Brookslcole.
9. Principles of Chromatography by KR Mahadik, K G Bothara, 1st edition, Nirali Prakashan.
10. Introduction to Chromatography (Theory and Practice) by VK Srivastav and KK Shrivastav.
11. Radio bioassays (Vol. I and II), by Faud S. Ashkar.
12. Handbook of Instrumental Techniques for Analytical Chemistry by Frank Settle, Practice Hall Publications.
13. Instrumental Methods of Chemical Analysis by BK Sharma, Goel Publishing House.
14. Analytical Chemistry: Principles, 2nd edition, John. H. Kennedy.
15. Remington The Science and Practice of Pharmacy, 20th edition, Lippincott Williams & Wilkins.
16. Practical Pharmaceutical Chemistry (Vol. II & I), A.H. Beckett and J.B. Stenlake, Anthlone Press of the University of London.
17. Indian Pharmacopoeia.
18. British Pharmacopoeia.
19. United States Pharmacopoeia.
20. A Textbook of Analytical Chemistry, Y. Anjaneyulu, K.Chandreshekhar, Valli Manickam, Pharma Med Press.
21. Analytical Chemistry, S. M. Khopkar, New Age International Publishers , 3 rd edition

22. Organic Analytical Chemistry- Theory and Practice- Jag Mohan, Narosa Publishing House
23. Chromatography concepts and contrasts, James. M. Miller, 2nd edition, John Wiley and Sons. Inc
24. Introduction to Spectroscopy- Donald L. Pavia, Gary M. Lampman, George S. Kriz, Thomson/ Brooks Cole
25. Pharmaceutical Analysis- David G. Watson

4.5 (T) PHARMACOLOGY
(Theory) 90 Hrs. (3 Hrs/week)

Topic No	SECTION-I	Hrs.
Basic pharmacology (classification, mechanism of action, pharmacokinetics, pharmacological actions, adverse effects, contraindications, therapeutic uses, drug interaction, dosage, symptoms and treatment of poisoning) and Clinical Management of diseases and drugs acting on following categories:		
	Chemotherapy a) Introduction to Chemotherapy including Drug resistance b) Sulfonamides and trimethoprim c) Penicillins and Cephalosporins d) Tetracyclines and Chloramphenicol e) Macrolide, Aminoglycoside , Polyene and Polypeptide antiboitics f) Quinolones and Fluoroquinolones g) Antifungal agents h) Antiviral agents including anti-HIV agents i) Chemotherapy of Tuberculosis, Leprosy, and Malaria j) Chemotherapy of Protozoal infections (amoebiasis, Giardiasis) k) Pharmacology of antihelmintic drugs l) Chemotherapy of neoplastic diseases (Anticancer drugs)	20
2	**Cardio-vascular system diseases** a) Drugs used for Congestive Cardiac Failure (CCF) b) Anti-arrhythmic drugs c) Antianginal and other anti-ischemic drugs d) Anti-hypertensive drugs	10
3	**Drugs acting on kidney** a) Diuretics b) anti-diuretics	03
4	**Immunopharmacology** a) Pharmacology of immunosuppressants and stimulants b) Vaccines and Sera.	04
5	**Principles of Toxicology** a) General principle of treatment of poisoning b) Signs, Symptoms and treatment of acute and chronic poisoning due to: Heavy metals (Lead, Mercury, Arsenic), snake venom	08
Sections II: Hospital Pharmacy and Clinical Pharmacology		

6	**Hospital Pharmacy: To discuss in detail of various aspects of hospital pharmacy.**	03
8	**Hospital drug Policy**. Hospital and therapeutic committee, hospital formulary, role of hospital pharmacist in hospital committees and practice of rational drug therapy	08
8	**Hospital Documentation** Introduction to prescription recording, drug profile, patient medication profile,	05
9	**Drug distribution in Hospitals** Outpatient and in patient services, unit dose, drug distribution system, floor ward stock system, satellite pharmacy services, bed side pharmacy, distribution of control drugs	05
10	**Patient compliance and counseling** Methods of assessment of compliance, Reason for patient non-compliance, strategies to improve compliance, precaution and directions for medication, administration instructions	05
11	**Adverse Drug reactions (ADR):** Epidemiology, Classification, Risk factors, Monitoring, Detecting and reporting of ADR	04
12	**Drug interactions:** Types**,** General Considerations and Mechanisms	02
13	**Introduction to Clinical Trials** History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments 1. **Ethical issues in clinical trials-** Principle of regulatory requirements, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), The Nuremberg Code, The Declaration of Helsinki, The Belmont Report 2. **Good Clinical Practice-**Concept, importance, and GCP guidelines including ICH guidelines	12
14	**Bioavailability, bioequivalence and Therapeutic Drug Monitoring-** Concept, organization, advantages, special issues, applications.	04

Recommend Books

1. Balaraman R., Gulati O.D., Patil P.N. and Goyal R.K. (Edi): Topics in History of Pharmacology. *BS Shah Publications, Ahmedabad.*
2. Barar F.S.K.: Essentials of Pharmacotherapeutics, *S. Chand & Co., New Delhi.*
3. Bauer L.A.: Applied Clinical Pharmacokinetics, *McGraw-Hill Professional, Singapore.*
4. Bevan J.A. and Thompson J.H.: Essentials of Pharmacology, *Harper and Row Publishers, Philadelphia.*
5. Bowman W.C. and Rand M.J.: Textbook of Pharmacology, *Blackwell Scientific Publications, Oxford.*
6. Butterworth S.: Modi's Textbook of Medical Jurisprudence and Toxicology.
7. Craig C.R. and Stitzel R.E.: Modern Pharmacology, *Little Brown and Co., Boston.*

8. Das M.M. and Dutta S.K.: Ghosh's Modern Concepts on Pharmacology & Therapeutics, *Hilton & Co., Calcutta.*
9. DiPiro J.T.: Encyclopedia of Clinical Pharmacology, *Marcel Dekkar, New York.*
10. DiPiro J.T.: Pharmacotherapy: A Pathophysiological Approach. *Elsevier Publications, London.*
11. Drill V.A.: Pharmacology in Medicine, *McGraw Hill Co., New York.*
12. Goodman and Gillman: Pharmacological Basis of Therapeutics, *McGraw-Hill, Medical Publishing Division, NewYork.*
13. Hansten P.D.: Drug Interactions, *Lea & Febiger, Philadelphia.*
14. Harisons: Principles of Internal Medicine, *McGraw Hill Publications, Singapore.*
15. Herfindal E.: Clinical Pharmacy and therapeutics, *Williams and Wilkins Publications, New York.*
16. Indian Pharmacopoeia, Govt. of India, *Controller of publication, New Delhi.*
17. Katzung B.G.: Basic and Clinical Pharmacology, *Lange Medical Publications, California.*
18. Krantz and Carr: Pharmacology Principle of Medical Practice, *Williams & Wilkins Co, Baltimore.*
19. Laurence D.R. and Bennett P.N.: Clinical Pharmacology, *Churchill Livingstone, Edinburgh.*
20. Parikh C.K.: Parikh's Text Book of Medical Jurisprudence and Toxicology. *CBS Publishers and Distributors, Mumbai.*
21. Parthasarathy G.: A textbook of Clinical Pharmacy Practice- Essential Concepts and Skills, *Orient Longman, Hongkong.*
22. Pradhan S.N., Maickel R.P. and Dutta S.N.: Pharmacology in Medicine-Principles and Practice, *S.P. Press International Inc., Maryland.*
23. Rang H.P. and Dale M.M.: Pharmacology, *Churchill Livingstone, Edinbergh.*
24. Rodrignes A.D.: Drug-drug Interactions, Vol. 116, *Marcel Dekkar, New York.*
25. Satoskar R.S. and Bhandarkar S.D.: Pharmacology & Pharmacotherapeutics, *Popular Prakashan, Bombay.*
26. Speight T.M. and Holford N.H.G.: Avery's Drug Treatment, *Blackwell Publishing, New York.*
27. Stockley I.H.: Drug Interactions, *Pharmaceutical Press, London.*
28. Tripathi K.D.: Essentials of Medical Pharmacology, *Jaypee Brothers, Medical Publishers, New Delhi.*
29. Walker R. and Edwards C.: Clinical Pharmacy and Therapeutics. *Churchill Livingstone, London*
30. Vyawahre NS, Vora S. A textbook of Pharmacology, Nirali Prakashan, Pune.

4.5 Pharmacology- III

(Practical) (90 hrs: 3 hrs/week)

Hospital Pharmacy

Critical appraisal of fixed dose drug combinations of marketed preparations with respect to comments on prescriptions of some proprietary preparations and multiple drug therapy (rational /irrational) mentioning possible indications, dose, route of drug administration, justification of inclusion of each ingredient, and adverse reactions, contraindications, precautions and special instructions for patients. (Minimum 10 combinations to be discussed).

Clinical Pharmacology

Prescription auditing and standard treatment protocols: Comment on given prescriptions with reference to case reports mentioning possible indications and contraindications with dose, route of administration and justification of each ingredient. Comment on special instructions, drug interactions and ADRs (if any), discharge medication (on the basis of available evidences from literature) (Minimum 10 prescriptions to be discussed).

Biostatistics

To carry out the statistical analysis of given experimental data using appropriate method(s) based on parametric or non-parametric methods (Minimum 5 exercises).

Recommend Books

1. Bolton, Sanford and Bon: Charles Pharmaceutical Statistics, (Drugs and the Pharmaceutical Sciences: a Series of Textbooks and Monographs), *Dekker, New York, USA.*
2. Burn J.H.: Practical Pharmacology, *Blackwell Scientific Co., Oxford.*
3. Daniel Wayne W. Biostatistics: A Foundation for Analysis in the Health Sciences , Wiley Series in Probability and Statistics, *Wiley Interscience, USA.*
4. Ghosh M.N.: Fundamentals of Experimental Pharmacology, *Scientific Book Agency. Bombay.*
5. Goyal R.K.: Practical Experimental Pharmacology. *BS Shah Prakashan, Ahmedabad.*
6. Jaju B.P.: Pharmacological Practical Exercise Book, *Jaypee Brothers, New Delhi.*
7. Kulkarni S.K.: Hand Book of Experimental Pharmacology, *Vallabh Prakashan, New Delhi.*
8. Laurence D.R. and Bacharach A.L.: Evaluation of Drug Activity: Pharmacometritics, *Academic Press, London.*
9. Patil C.R.: X-Cology (Software), *Pragati Book Co. Pvt. Ltd., Pune*.
10. Perry W.L.M.: Pharmacological Experiments on Isolated Preparations. *E&SP Livingstone, London.*
11. Ravindran R.: X-Pharm (Software), Indian Journal of Pharmacology, *JIPMER, Pondicherry.*
12. Sheth U.K., Dadkar N.K. and Kamat U.G.: Selected Topics in Experimental Pharmacology, *Kothari Book Depot, Bombay.*
13. Tozer R.: Clinical Pharmacokinetics, *Williams and Wilkins Publications, New York.*
14. Turner R.A.: Screening Methods in Pharmaocolog

4.6 PHARMACOGNOSY III

(Theory 90 Hrs, 3 Hrs/week)

Sr. No	SECTION- I	Hrs.
Note: - Drugs mentioned in Bold must be studied in detail for their cultivation, collection and extraction.		
1.	**Alkaloids:** Introduction,definition, occurrence, properties, classification, chemistry.General Biosynthetic pathways for Indole,Tropane Quinoline and Isoquinoline alkaloids Systematic pharmcognostic study of following crude drugs containing Alkaloids. • Indole-**Ergot, Rauwolfia, Nux-vomica,** Vinca. • Tropane - **Datura**, Coca, Belladona. • Purines -Tea, Theobroma. • Quinoline - **Cinchona.** • Isoquinoline - **Opium, Ipecac.** • Pyridine/ Ppiperidine - **Lobelia**. • Imidazole - Pilocarpus. • Quinazoline - **Vasaka** • Amino alkaloids - Colchicum, **Ephedra**. • Steroidal - **Ahwagandha, kurchi**, solanum, khasianum.	20
2.	**Marine Drugs** – Sources and Pharmacological activities of newer medicinal agents of Marine source with special reference to Anti-inflammatory, cardiovasucular, anticancer agents and marine toxins.	4
3.	**Flavonoids-** Introduction, properties, classification, chemistry, extraction and general biosynthetic pathway. 1. Flavones: Roman chamomile,*Passiflora incarnate,*Grape fruit. 2. Isoflavones: Derris Roots,Soyabean, 3. Flavonol: Buch Wheat,Green Tea 4. Flavonones: Liquorice,Citrus Peels 5. Chalcones: Safflower 6. Bioflavones- Gingko 7. Anthocynidine- Blueberry,Blackcurrent,Vine 8. Flavonolignans: *Sylibum marianum*	8
4.	**Plant Allergens** –Classification (inhalants, injectants, contactants, infectants and infestants), plants causing Hay fever, allergy. Preparation of allergenic extracts.	3
5.	**Drugs of Traditional systems of medicine –** Vernacular names, Biological source, chemical constituents and uses of Gulwel, Bhuiamla, Bramhi, Shankhpushpi, Madhunashini, Nagarmotha,Bhilwa, Rasna, Gokhru, Punarnava, Neem, Safed musli and Pipali**.**	8
	SECTION II Herbal Drug Technology	
6.	A] Phytochemical investigation – Preliminary Phytochemical Screening, applications of chromatographic technique in evaluation of herbal drugs. B] A study of analytical profiles for Structural elucidation of following	8

	Phytoconstituents Reserpine, Atropine, Quinine, Morphine, Digoxin	
7.	Phytochemical screening of crude drugs: Extraction, isolation, purification chromatographic profiles of following phytoconstituents. Caffeine, Eugenol, Curcumin, Alloin and Hesperidin	7
8.	A Brief account of plant based industries involved in work on medicinal and aromatic Plants in India	3
9.	Regulatory requirements of herbal medicines. • Infrastructure • Quality control and evaluation parameters. Regulatory control for Import and Export of herbal products.	6
10.	Principles of Ayurveda, Ayurvedic Dosage forms and their Evaluation.	9
11.	Toxicity in Herbals and their interaction. (Liquorice, Cinchona, Cannabis, Garlic, Digitalis, St John's wort)	6
12.	12] Herbal cosmetic. • Introduction and brief history. Skin and hair care products, production and quality control thereof	6

Reference Books:

1. Trease and Evans, Pharmacognosy, Saunders company, London.
2. Tyler, Brady, and Robbers, Pharmacognosy, Lea Febiger, USA.
3. Wallis T. E., Text Book of Pharmacognosy, CBS publishers & distribution, Delhi.
4. Kokate, Purohit, Gokhale, Pharmacognosy, Nirali Prakashan, pune.
5. Rangari V.D., Pharmacognosy & Phytochemistry, Vol I, II, Career Publication,
6 E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company.
6. Pridham J B, Swain T, Biosynthetic pathway in higher plants, Academic Press, New York.
7. Scheuer P G, Marine natural products, Academic Press, London.
8. Shah and Quadri Text Book of Pharmacognosy.
9. Atal C K, Cultivation and utilization of medicinal and aromatic plant.
10. Chopra, Indigenous drug of India.
11. Wealth of India.
12. Nadkarni, Material Medica.
13. Shehnaz Husain's Beauty Book, Orient Press.
14. Jain Urjita, Beauty through herbs, Institute of Herbs.
15. Chaudhari R D, Herbal Drug Industry, Eastern publication
16. Dr. Pulok K. Mukharjee, "Quality control Herbal Drugs" Business Horizons,
17. Ayurvedic Pharmacopoeia.
18. British Pharmacopoeia.
19. Martindale Extra Pharmacopoeia.
20. Wagner, Plant drug analysis.
21. Stal Egon, Thin layer chromatography.
22. M. A. Iyengar, S. G. K Nayak "Pharmacognosy Lab Manual", Manipal Press.
23. Mohd. Ali, "Pharmacognosy" CBS Publication. New Delhi.
24. Aushotosh Kar "Pharmacognosy & Pharmacobiotechnology" New Age International Publisher.

25. S.S. Agarwal, M. Paridhavi “Herbal drug Technology” Universities Press,
26. Dr. Pulok K. Mukharjee, “Quality control Herbal Drugs” Business Horizons,
27. Pulok Mukharjee, Robery Verpoorte “GMP for Botanicals” Business Horizons,
28. M.A. Iyengar, S.G.K Nayak “Anatomy of crude drugs” Manipal press, Manipal.
29. Paul M. Delvick “Medicinal Natural Production Wiley & Sons Publication.
30. T.M. Vasudevan & K.S. Laddha “Herbal Drug Microscopy” Yucca Publication.
31. Dr. V. Rajpal “Standardization of Botinicals Eastern Publication, New Delhi
32. Hiremath, Shobha Rani, “Textbook of Industrial Pharmacy”,Universsity Press,.
33. Satyanarayana “Biotechnology”,Books and Allieds Pvt Ltd.
34. Razdan M.K. An Introduction to Plant Tissue Culture, Oxford publisher

4.6 PHARMACOGNOSY III

(Practical) (90 hrs: 3 Hrs./week)

1] Study of morphological, microscopical characters, chemical / microchemical Tests for following crude drugs in entire and in powdered form (including Surface preparation wherever required).

Leaf – Datura, Vinca, Vasaka
Bark – Cinchona, Kurchi,
Seed – Nux-Vomica
Root- Rauwolfia, Ashwagandha
Stem- Ephedra.

2] Identification of crude drugs mentioned in theory syllabus by their Morphological and physical characteristic.

3] Determination of volatile oil content and its evaluation(atleast two herbs).

4] Determination of lipid content by solvent extraction method.

5] Extraction, Isolation, evaluation by UV and chromatography of following phytopharmaceuticals.

- Caffeine from tea
- Eugenol from clove oil
- Curcuminoids from curcuma longa
- Hesperidine from orange peel
- Quinine from cinchona bark
- Aloin from Aloe vera

6] Extraction of oleo- resin from Capsicum /Ginger.

7] Preparation and evaluation of herbal cosmetics, (Minimum 4 each)

- Hairs cosmetics
- Skin cosmetics

8] Evaluation of Marketed Herbal Formulations (Minimum 3)

9) Column Chromatography for separation of Phytoconstituents (Demonstration)

Reference Books:

1. Kokate C.K, Practical Pharmacognosy, Vallabh Prakashan.
2. Khandelwal K.R, Practical Pharmacognosy, Nirali prakashan, Pune.
3. Iyangar M.A, Pharmacognosy of powdered crude drug.
4. Iyangar M.A, Anatomy of crude drug.
5. Brain & Turner, The practical evaluation of phytopharmaceutics.
6. Harborne J.B, Phytochemical method.
7. Wagner, Plant drug analysis.
8. Stahl Egon, Thin layer chromatography.
9. Wallis T.E, Text book of Pharmacognosy.
10. Ayurvedic Pharmacopoeia of India.
11. Indian Pharmacopoeia.
12. British Pharmacopoeia.
13. Martindale, Extra Pharmacopoeia.
14. Handa Paresh, Herbal Beauty care, Orient Press.
15. Shehnaz Husain's Beauty Book, Orient Press.
16. Jain Urjita, Beauty through Herbs, Institute of Herbs.

4.7 Pharmaceutical Jurisprudence

(Theory) (60 Hrs:2 hrs/week)

Sr. No	SECTION- I	Hrs.
	Study of following in detail	
1.	Legislation to regulate import, manufacture, distribution & sales of drugs & cosmetics. The Drugs and Cosmetics Act 1940 & rules 1945 & amendments.	9
2.	Legislation to regulate then profession of Pharmacy. The Pharmacy act 1948	5
	Brief study of following legislations	
3.	The Drugs and Magic Remedies Act & Rules 1976.	3
4.	The Drugs Price Control Order 1998 with latest amendments.	3
5.	Narcotic Drugs & Psychotropic substances act 1985.	3
	Aim, Objectives and Salient features only of following legislations	
6.	Prevention of Food Adulteration Act 1954.	2
7.	Consumer Protection Act.	2
8.	Industrial Development & Regulation Act 1951.	1
9.	Industrial Safety & Health.	1
10.	Cyber Law.	1
	SECTION II	
11.	1. Intellectual Property Rights(IPR) a) Introduction of IPR (Patents, Design, Trademarks, Copyrights, Geographical Indications etc)	3

	b) Patent System ➢ Definition of Patent ➢ Criteria for obtaining patent (Novel, Non-obvious Applications)	3
	c) Filing and Processing of Patents ➢ General procedure for securing patents in India.: Case studies ➢ Opposition to Grant of Patent ➢ Patent infringement: Case studies d) Silent features of Indian Patents Act 1970 with latest amendments with	3
	e) special reference to- ➢ Product & Process Patents. ➢ Provision of compulsory license ➢ Exclusive Marketing Right ➢ The Term of Patent ➢ Patent offices in India	6
12.	Pharmaceutical patents in U. S. and the Hatch Waxman Act with reference to generic Drugs ➢ The Orange book ➢ The difference between New Drug Application (NDA) and Abbreviated New Drug Application (ANDA) ➢ The contents of ANDA and bioequivalence ➢ Patent Certification(Para-I, Para-II, Para-III and Para-IV)	5
13.	Drug Regulatory Affairs a) Brief Information of agencies of Drug Regulatory affairs in different countries ➢ U.S. - Food & Drug Administration (FDA) ➢ Australia- Therapeutic Goods Administration (TGA) ➢ Europe- European Agency for the Evaluation of Medicinal Products (EMEA) ➢ Japan-Ministry of Health and Welfare (MHW) ➢ U.K. (MHRA)	4
	b) Preparation of the Investigation New Drug Application (IND) and New Drug Application (NDA) or Biologics & Licensing Application (BLA), Electronic Submission, Drug Master File (DMF)	4
	c) World Wide Harmonization of Regulatory Affairs (ICH) & World Health Organization (WHO) guidelines	2

Recommended Books

1. Kuchekar B. S., Khadtare A. M., Itkar S. C., Forensic Pharmacy, 6 th Edition, Aug. Nirali Prakashan. 2006.
2. Mittal B. M.- A Textbook of Forensic Pharmacy, 9 th Edition, Vallabh Prakashan;1999

3. James Swarbrick, James C Boylon, Encyclopedia of Pharmaceutical Technology, 2 th Edition, Marcel Decker Inc.;1998
4. Deshpande S. W. -Drugs & Cosmetics Act; 4th Edition;2006
5. Bubharam N. R. - Whatever one should know about patents, 2nd Edition, Pharmabook Syndicate.
6. Guarino Rechard A. – New Drug Approval Process, 3rd Edition, Marcel Decker.;2004
7. Deshpande S. W. – Drug & Magic Remedies Act, 1954.;2008
8. P. Narayan – Intellectual Property Law, Edition 3rd; Eastern Law House; 2001.