North MaharashtraUniversity, Jalgaon.

Syllabus of
Third Year B. Pharmacy [Sem V &Sem VI]
(CGPA Pattern)

W.E.F. Academic Year 2014-15

T 3.5.1. Pharmaceutical Chemistry – VI (Medicinal Chemistry - I)
(Theory) (4Hrs /week)

Section I

Sr.no.	Topic	Hours
1	I**ntroduction:** Medicinal Chemistry: Definition And Objectives— using the internet for medicinal chemistry; Sources of Drugs- Serendipity, Random Screening, Extraction from Natural Sources, Molecular Modifications. Lead compound-definition, discovery and optimization.	06
2	**Theoretical Aspects of Drug Action:** The Ferguson Principle; Drug targets: Molecular mechanisms of drug action. Physicochemical parameters affecting drug action: Solubility, **Partition Coefficient, Surface Activity, *pKa,* Ionisation.** **Stereoche**mistry and drug action: Optical isomerism, Geometrical isomerism, Bio-isosterism.	08
3	**Metabolism** Routes of Elimination: Factors Affecting Metabolism – Genetic Factors, Physiological Factors, Pharmaceutical Factors, Drug Interactions. Metabolic Process- Phase I (Oxidation, Reduction &Hydrolysis) and Phase II (Glucuronide Conjugation, Acetylation, Methylation, Sulphate Conjugation, Conjugation with amino acids and Mercapturic acid formation)	08
4	**Introduction to Receptor Concept** History, Affinity, Receptor & biological response, Drug Receptor interaction, Forces involved in drug receptor interaction. Receptor Theories, Conformational flexibility and multiple modes of Action	08

SECTION II

The following topics should be covered with the points listed below

1**.** Introduction

2. Classification

3. Mechanism of action

4. Structure-activity relationship

5. Pharmacokinetics (Metabolism) and

6. Therapeutic uses

7. *Synthesis of drugs

Sr.no.	Topic	Hours
5	**Cholinergic Drugs:** (i) cholinergic agonists (methocholine, carbochol*, bethanechol, pilocarpine) (ii) Ach esterase inhibitors (physostigmine, neostigmine*, tacrine*, ambenonium chloride, isofluorphate, pralidoxime) (iii) Cholinergic antagonists (atropine scopolamine, homatropinehydrobromide, ipratropium bromide); synthetic cholinergic antagonists (cyclopentolate*, dicyclomine*, ben/otropinemesylate, procyclidine hydrochloride, isopropamide iodide, tropicamide) (iv) Ganglion blocking agents (trimethaphan, camsylate, mecamylamine) (v) Neuromuscular blocking agents (tubocurarine, gallamine, triethiodide, succinyl choline chloride)	07
6	**Adrenergic Drugs:** (i) α-adrenergic agonists (phenylephrine, naphazoline, xylometazoline, oxymetazoline, methyldopa, clonidine*, guanabenz, guanfacine) (ii) β-adrenergic agonists (isoproternol, terbutaline*, albuterol, salmeterol, isoxsuprine, ritodrine) (iii) α-adrenergic antagonists (tolazine, phentolamine, phenoxybenzamine, prazosin, doxazosin) (iv) β-adrenergic antagonists (propranolol*, atenolol, metoprolol, acebutalol, alprenolol, timolol, labetalol*) other adrenergic agents (amphetamine, pseudophedrine, ephedrine, guanethidine*, propylhexedrine, reserpine).	05
7	**CVS Drugs:** (i) antianginal agents (amyl nitrite, isosorbide dinitrate, pentaerythritoltetra nitrate, verapamil, bepridil, diltiazem, nifendipine*, amlodipine, nimodipine, dipyridamole) (ii) antiarrhythmic agents (quinidine, procainamide*, disopyramide, lidocaine, tocainide, mexilitine, encainide, amiodarone, proafenone, verapamil, diltiazen, propranolol, sotalol*). (iii) Antihypertensive agents (a) review of adrenergic agents (b) review of Ca channel blockers (c) ACE inhibitors (captopril*, enalapril, benzepril, ramipril) (d) angiotensin II receptor antagonists (losartan, valsartan*, candersartan) (iv) Vasodilators and K-channel agonists (diazoxide, minoxidil)	18

	(v) Antihyperlipidemic agents (clofibrate*, gemfibrozil, niacin, lovastatin, atorvastatin)	

Reference Books:

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry,11 th Ed., Eds., John H Block and John M Beale, Lippincott Williams & Wilkins, 2004.

2. Foye's Principles of Medicinal Chemistry, Eds., T. L. Lemke and D. A. Williams,Williams& Wilkins, Baltimore, 2002.

3. Medicinal Chemistry, AshutoshKar, 4 th Edition, New Age International Publishers,2007.

4. The Art of Drug Synthesis, Eds., Douglas S Johnson and Jie Jack Li, WileyInterscience, 2007.

5. Pharmaceutical Chemistry, Vol. 1: Drug Synthesis, Eds., H. J. Roth, A. Kleeman, andT. Beissewenger, Ellis Horwood Ltd., 1988.

6. The Organic Chemistry of Drug Synthesis, Daniel Lednicer, Vols. 1 to 7, Wiley.

7. Profiles in Drug Synthesis : V.N. Gogte

8. Textbook of Pharmaceutical Chemistry by Harkishansing&Kapoor

9. Principle of Medicinal Chemistry (Volume I & II) by Kadam, Mahadik and Bothara

10. Text Book of Practical Organic Chemistry - A.I. Vogels

11. Practical Organic Chemistry - Mann and Sanders

12. Systematic Identification of Organic Composition, Shriner and Fuson

P 3.5.1. Pharmaceutical Chemistry – VI (Medicinal Chemistry - I) (Practical) (Duration : 3 hrs/week)

Minimum Twelve numbers of Experiments should be performed.

***Minor ****Major Experiments**

1) **Purification techniques of solvents/liquids and synthesized products by Fractional distillation and distillation under vacuum and recrystalization**
2) Demonstration of reaction monitoring by TLC.
3) *o*-Iodo benzoic acid acid (Sandmeyer Reaction)**
4) Benzoic acid*
5) Benzophenone**
6) Benzylidineacetophenone **
7) Synthesis of phenyl benzoate from phenol*

Microwave oven synthesis of the following compounds [Ref. 4, 5, 6]

1) Demonstration of Microwave oven synthesis
2) Benzil*
3) Benzpinacol*
4) Benzillic acid*
5) 3-methyl -1- phenyl -5-pyrazolone**
6) 4-nitrobenzyl benzoate*
7) Cinnamic acid (perkin/ Knoevenagel condensation)
8) 2,3 Diphenylquinoxaline**
9) 1,2,3,4-tetrahydrocarbazole (Fischer Indole Synthesis)

Book Recommended

1. Text Book of Practical Organic Chemistry - A.I. Vogel

2. Practical Organic Chemistry - Mann and Sanders

3. Systematic Identification of Organic Composition, Shriner and Fuson

4. Indian Journal of Pharmaceutical Education and Research, 39 (4) Oct-Dec. 2005, 188-190

5. Organic Synthesis Special techniques V. K. Ahluwalia, RenuAggrawal, Nerosapublishinghouse , p. no. 90 - 114

T 3.5.2. Pharmaceutics – VI(Pharmaceutical Technology I)

(Theory) **(Duration : 4 Hrs/Week)**

Section I

Sr. No.	TOPICS	Hrs.
1.	**Preformulation:** Objective, study of physico chemical properties of drug like physical form, particle size, shape, density, wetting, dielectric constant, solubility, PKa, partition coefficient, dissolution on an organoleptic property and their effect on formulation , stability and bioavailability.	**04**
2.	**Tablets:** Formulation development: Types of tablets, properties of drugs such as compressibility, flow ability, dose, stability, site of drug release & absorption, additives & factors affecting their selection. Formulation and manufacturing, IPQC and QC of tablets. Introduction to advance granulation techniques: Extrusion-spheronization & pelletization & spherical crystallization, fluid bed granulation. Problems in tabletting & remedies there of.	**09**
3.	**Coating of Tablets: -** Types (sugar, film & press coating). Material used & processed employed for each, coating equipments including different types of coating pans and advanced coating pans. fluid bed and enteric coating. Evaluation of coated tablets & packaging of coated tablets	**03**
4.	**Hard Gelatin & Soft Gelatin Capsules :-** Introduction, shell excipients, Mfg. of shells, properties of raw materials, environmental controls, evaluation, filling principles and equipments for hard Soft gelatin capsules. Processing, I.P.Q.C., evaluation of finished capsules & official standards.	**04**
5.	**Semisolid Dosage Forms: -** Classification, dermatological & transdermal preparations- Gels & Ointment Preparations. Transdermal permeation enhancer (physical, chemical and biological)-Probable Mechanism & Examples of drug penetration. Ointments: bases, formulation factors. Mfg. processes & equipments, IPQC, QC and packaging.	**06**
6.	**Suppositories**: Ideal requirements of suppository base, manufacturing equipment and procedure, IPQC and QC tests and packaging.	**04**

Section II

Sr. No.	TOPICS	Hrs.
7.	**Disperse Systems: -** Introduction, theories of emulsifications and suspensions-DLVO Theory, types of additives used in formulations, vehicles, stabilizers, preservatives wetting agents, emulsifying agents, colors and flavors. HLB values and its determination. Manufacturing, packaging and evaluation of emulsions and suspensions. Introduction to micro emulsions, multiple emulsions, nanoemulsion and nanosuspensions.	**08**
8.	**Pharmaceutical Aerosols:** Definition, propellants**,** general formulation, manufacturing and packaging methods, pharmaceutical application and Evaluation, Mathematical problems on pharmaceutical aerosol systems.	**06**
9.	**Pilot Plant Scale Up:** Groups responsibilities-Facilities, Significance of pilot plant scale up studies, Pilot scale manufacturing techniques (formula, equipment, process, stability and quality control) for tablets, capsules, liquid orals includes suspension and emulsions and semisolid includes ointments and gels**.** Technology transfer.	**11**
10.	**(Good Manufacturing Practices-** GMP and CGMP and its requirements for tablets, capsules, ointments, gels, emulsions and suspensions	**05**

Books Recommended:

1. **Leon Lachman et al**. Theory & practice of Industrial pharmacy, Lea &Febiger Varghese Publishing house, Mumbai.
2. **H.A. Lieberman & Leon Lachman**. Pharmaceutical Dosage Forms: Tablet Vol. 1, 2, 3. Marcel Dekker Series.
3. **G.S. Banker & C.T. Rhodes**. Modern Pharmaceutics. Marcel Dekker Series.
4. **H. C. Ansel**-- P'ceutical dosage forms & drug delivery systems. B.I. Waverly Pvt.ltd, New Delhi.
5. **Alfanso R. Gennaro**-- Remington's Pharmaceutical Sciences. Mack Publishing Company, Easton Pennsylvania.
6. **E.A.Rawling**-- Bentleys T.B. of pharmaceutics. BaillereTindall {London} & All India Traveller Book Seller Delhi.
7. **H. Lockhart**-- Packaging of Pharmaceuticals and healthcare products. Blackie academic & professional. London.

8. **D A Dean, E R Evans & I.H. Hall**--Pharmaceutical packaging Technology. Taylor & Francis Newyork.
9. **Swarbrick&Boyan**-- Encyclopedia of Pharm. Tech. Vol. 1, 2, 3. Marcel Dekker Series.
10. **Nielloud**-- Pharmaceutical emulsion and suspensions- Vol. 105-Marcel Dekker.
11. **Niazi-** -Handbook of Pharmaceutical manufacturing formulations- (Vol. 1-6).
12. **J.R. Robinson & Lee** – Controlled drug delivery systems: Fundamentals & Applications. Marcel Dekker Series.
13. **Dilip M**. **Parikh-** Handbook of Pharmaceutical Granulation Technology: Marcel Dekker, Vol. 81,New York.
14. **Podezeck& Jones**-- Pharmaceutical Capsules.
15. **IssacGhebre-Sellassie**.-Pharmaceutical pelletization technology. New York Marcel Dekker

P 3.5.2. Pharmaceutics – VI(Pharmaceutical Technology I) (Practical) (Duration :3 hours/ week)

1. Physico-chemical evaluation of any four excipients*.

2. Preparation and evaluation of compressed tablet (wet, dry granulation & direct compression) **

3. Evaluation of marketed tablet formulations*

4. Formulation of film coated tablets and evaluation**.

5. Filling of hard gelatin capsule & its evaluation**

6. Formulation and evaluation of ointments*

7. Formulation and evaluation of Emulsions (liq. paraffin emulsion)*

8. Formulation and evaluation of Suspensions (calamine lotion & antacid suspension) **

9. Formulation and evaluation of dry syrup*

10. Formulation and evaluation of Suppository (Two)**

11. Formulation and evaluation of gels**.

12. Formulation and evaluation of aerosol systems*.

Major Expt.: * *

Minor Expt.: * {All preparations may act as minor expt}

Books Recommended:

1. **Leon Lachman et al**. Theory & practice of Industrial pharmacy, Lea &Febiger Varghese Publishing house, Mumbai.

2. **H.A. Lieberman & Leon Lachman**. Pharmaceutical Dosage Forms: Tablet Vol. 1, 2, 3 Marcel Dekker Series.

3. **G.S. Banker & C.T. Rhodes**.ModernPharmaceutics.Marcel Dekker Series.

4. **H. C. Ansel**-- P'ceutical dosage forms & drug delivery systems. B.I. Waverly Pvt.ltd, New Delhi.

5. **Alfanso R. Gennaro**-- Remington's Pharmaceutical Sciences. Mack Publishing Company, Easton Pennsylvania.

6. **E.A.Rawling**-- Bentleys T.B. of pharmaceutics. BailliereTindall {London} & All India Traveller Book Seller Delhi.

7. **H. Lockhart**-- Packaging of Pharmaceuticals and healthcare products. Blackie academic & professional.Londan.

8. **D A Dean, E R Evans & I.H. Hall**--Pharmaceutical packaging Technology. Taylor & Francis Newyork.

9. **Swarbrick&Boyan**-- Encyclopedia of Pharm. Tech. Vol. 1, 2, 3. Marcel Dekker Series

10. **Nielloud**-- Pharmaceutical emulsion and suspensions- Vol. 105-Marcel Dekker.

11. **Niazi-** -Handbook of Pharmaceutical manufacturing formulations- (Vol. 1-6)

12.**Dilip M**. **Parikh-** Handbook of Pharmaceutical Granulation Technology: Marcel Dekker, Vol. 81,Newyark

13. **Podezeck& Jones**-- Pharmaceutical Capsules

14. **Official Compenelias I**.P. B.P. U.S.P.

T 3.5.3. Pharmacology – I

(Theory) **(Duration :4 Hrs/Week)**

Objectives

1. To introduce students to basic concepts in general pharmacology
2. Role of Pharmacologists in drug development and drug use.
3. To impart knowledge regarding mechanisms of drug action, ADR, drug interactions
4. To inform them regarding the steps involved in drug discovery. Along with stages of preclinical testing (efficacy testing, safety testing, toxicity testing) and clinical drug development (four phases of Clinical trials).
5. To highlight the importance of knowledge of Pharmacotherapeutics to preclinical, clinical and hospital pharmacologist
6. To introduce them to Pharmacotherapy of drugs acting on ANS and GIT

Sr. No.	TOPICS Section I	Hrs.
1.	**General Pharmacology: -** a) Introduction, definition, history of pharmacology in India b) Routes of administration of drug including novel drug delivery systems (inunction, iontophoresis, antibody assisted drug delivery, administration of biologicals) c) Absorption of drugs and-factors affecting them d) Drug distribution, biotransformation and excretion e) Mechanism of drug action – Types of Receptors, signal transduction mechanisms, theories of drug receptor interactions, Dose response relationship, Concept of Bioavailability f) Factors modify drug action – synergism, antagonism, drug tolerance, and tachyphylaxis.	**02** **03** **02** **06** **05** **03**
2.	**Toxicology : -** a) Defination, sub-branches and Concept of toxicology and toxicity b) Toxicity studies in animals (Acute toxicity study (LD50) by OECD guideline number 420 c) Acute, sub acute, chronic toxicity testing as per OECD guidelines d) Poisons, types and classification and general treatment of poisoning. Treatment of heavy metals (lead, arsenic, mercury) poisoning.	**09**

	Section-II	
3.	New Drug Development Process: outline of steps involved in the process of drug discovery	**02**
4.	1. Process of Neurohumoral transmission 2.Autonomic nervous system and its branches – sympathetic and parasympathetic nervous system 3.Classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration of drugs acting for following classes of drugs A. Parasympathomimetics and parasympatholytics B. Sympathomimetics (including bronchodilator and nasal decongestants) and sympatholytics C. Ganglion blockers and stimulants D. Neuromuscular junction blockers	**04** **03** **04** **04** **01** **01**
5.	**Autacoids: –** Introduction, classification of drugs and classification of receptors, respective agonists and antagonists, and therapeutic drugs related to autacoids like 1. Histamine 2. 5-HT 3. Prostaglandins 4. Leukotrienes 5. Platelet activating factor	**02** **02** **02** **01** **01**
6.	Non-steroidal anti-inflammatory drugs (NSAID): Classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration of	**03**

Book Reading:

1. Satoskar R. S. , Bhandarkar S. D., Rege N. N., Pharmacology and Pharmacotherapeutics, Popular Prakashan Mumbai,

2. Tripathi K. D., Essentials of Medical Pharmacology, Jaypee Prakashan , New Delhi

3. Barar F.S. K. Essentials of Pharmacotherapeutics, S. Chand & Company, New Delhi

4. Patil P. N and Gulati O. D. Topic in the History of Pharmacology, B.S.Shah Prakashan Ahmedabad.

5. Rang and Dale, Pharmacology, Elsevier

Extra Reading:

1. Goodman Gillmans The Pharmacological Basis of Therapeutics, McGrwe Hill, New Delhi

2. Diprio J. L. Pharamcotherapy Handbook McGrew Hill, New Delhi

3. Official Book, Indian Pharmacopoeia, British Pharmacopoeia, U.S. Pharmacopoeia

P 3.5.3. Pharmacology – I

(Practical) (Duration :3hrs/Week)

Objectives

1. Introduction to experimental animals and ethical issues related to their use (CPCSEA guidelines)
2. Collection of biological samples from experimental animals (blood, urine, CSF, bile, feces, different tissues (only through charts and video demonstrations) and protocols to handle them – separation of serum/plasma, different types of blood cells, preservation and processing of tissues for microscopy, electron microscopy, biological estimation etc)
3. Introduction to experimental design- concept of positive/negative control, biological variations, blinding techniques, concept of placebo
4. Simulated practicals: isolated frog heart, Dose response curves (shapes, dose Vs response, Log Dose Vs Response, DRCs by agonists, partial agonist, effects of antagonist of DRC of agonist etc.)
5. Concepts of bioassays. Simulated bioassays using suitable software for interpolation assay
6. Behavioral testing using video demonstrations- along with animations related to drug actions- related therapeutics (related to treatment/ poisoning etc)
7. Wet lab experiments:
    a. DRC of acetylcholine of chicken ileum, goat trachea sourced from slaughter houses (If the institute has acquired due permission from IAEC then –tissues from rat may be used)
    b. Effect of Atropine on DRC of Acetylcholine using above mentioned tissues
    c. Effect of Physostigmine on DRC of Acetylcholine using above mentioned tissues
    d. Determination of PD2 value of acetylcholine on above mentioned tissues
    e. Determination of estrous cycle in rats
    f. Isolation of white blood cells from blood samples and determination of their viability using trypan blue method
    g. Electrophoresis of DNA samples and visualization in UV chamber
    h. Non-invasive behavioral experiments where drug administration and related effects on whole animals can be demonstrated. e.g. Elevated plus maze, actophotometer, immersion method,

1. Study of laboratory animals and their specific characteristics, use of experimental animals and tissues derived from them in pharmacological screening and evaluations of drugs, Care and Handling of Experimental animals, Ethical Issue related thereof (concept of CPCSEA and IAEC covered)
2. Demonstration of routes of administration (oral, intraperitoneal, intravenous, subcutaneous, sub-plantar, intramuscular) {students are expected to perform administration of sterile water/ saline by oral, intraperitoneal and intravenous route)*
3. Equipments used in isolated tissue experiments (including information on digital data acquisition system)
4. Study of various physiological salt solutions used in experimental pharmacology.
5. Simulated experiment of recording of dose response curve of acetyl choline/ histamine on rat/ guinea pig ileum using suitable software (www.animalsimulator.com or any such Soft-ware)
6. To record the Dose Response Curve for acetylcholine on rat ileum OR goat trachea OR chicken ileum (any one tissue as per availability)**
7. Determination of PD2 of Acetylcholine on rat ileum OR goat trachea OR chicken ileum (any one tissue as per availability)**
8. Simulated experiment of study of effect of Physostigmine on DRC of Ach using suitable software (www.animalsimulator.com or any such Soft-ware)*
9. Demonstration of collection of blood sample from rat tail vein and determination of blood glucose level in it by suitable method.
10. Simulated experiment of study of various effects of drugs on isolated frog heart using suitable software (www.animalsimulator.com or X-cology, Ex-pharm)*
11. To study Myosis and Mydriasis activities using simulation software (www.animalsimulator.com or X-cology, Ex-pharm)*
12. Demonstration of Anti-inflammatory activity (using any one phlogistic agent like λ-carrageen, Histamine, or any suitable agent) {Only demonstration, Not to be performed by students}
13. Determination of effects of NSAIDs on membrane stability of red blood corpuscles from human volunteers / experimental animals**
14. Isolation of white blood cells from human / experimental animal blood (using density gradient/ dextran sedimentation and determination of their viability microscopically using trypan blue method)**

15. Demonstration of effect of Carbachol on the autonomic nervous system of experimental animals (rat) either wet lab OR video demonstration {not expected to be performed by students}

Minor * **Major****

Minimum 12 experiments from above list must be conducted

Books Recommended

1) Ghosh M.N. Fundamentals of Experimental pharmacology. Hilton & Company Kolkata 2005 3rd edition.

2) Vogel G.H. Drug discovery and evaluation. Springer Germany 2002 2nd edition.

3) Goyal R.K. Practicals in pharmacology. B.S. Shah Prakashan Ahmedabad 2005 5th edition.

4) Kulkarni S.K. Handbook of Experimental Pharmacology. Vallabh Prakashan. New Delhi, 5th edition.

5) Perry W. L. M. Pharmacological Experiments on Isolated preparations. E.&S. Livingstone, London1970, 2nd edition.

6) Kasture S.B.Text book of Experimental Pharmacology, Career Publication Nashik.1 st edition, 2006.

7) Official books - Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia.

8) www.animalsimulator.com

T 3.5.4. Pharmacognosy –IV

(Theory) (Duration :3 Hours/Week)

Section-I

Sr. No.	TOPICS	Hrs.
1.	**Alkaloids** • Introduction, Classification, Physical & Chemical properties, distribution, General extraction methodology of alkaloids. • Biological source, diagnostic features, chemical constituents, chemical tests, uses, adulterants and substituent's of following a. **Pyridine- Piperidine**: Tobacco, Areca and Lobelia b. **Tropane:** Belladonna, Hyoscyamus, Datura, Coca c. **Quinoline and Isoquinoline**: Cinchona, Ipecac, Opium*. d. **Indole**: Ergot*, Rauwolfia*, Catharanthus, Nux-vomica and Physostigma e. **Imidazole:**Pilocarpus **f. Steroidal**: Kurchi, Ashwagandha* g. **Alkaloidal amine**: Ephedra and Colchicum. h. **Glycoalkaloid**: Solanum. i. **Purines**: Coffee, Tea* and Cola. j. **Quinazoline:** Vasaka *** Detail Pharmacognostic study of plants**	**17**
2.	1. **Enzyme** Biological Sources, Preparation, Identification Tests and Uses of Diastase, Papain, Pepsin, Trypsin, Pancreatin, streptokinase, serratiopeptidase.	**03**

Section-II

Sr. No.	TOPICS	Hrs.
3.	**Introduction to biosynthesis** • General Techniques of Biosynthetic Studies and Basic Metabolic Pathways. • A Brief Account of Primary and Secondary Metabolite's Production from Carbon Metabolism In plants. • Study of shikimicacid andMevalonic acid Pathway**.**	**07**

4.	**Plant tissue culture** • Introduction, to plant tissue culture, Laboratory requirements for plant tissue culture, Preparation of culture media, callus culture, cell suspension culture, and protoplast culture with reference to medicinal plants. • Production of secondary plant metabolites by tissue culture technique. Industrial Applications of plant tissue culture In Pharmacognosy.	**09**
5	**Plant bitters and sweeteners.**	**03**
6	**Study of Neutraceuticals as health foods.**	**03**
7	**A brief introduction to natural colors & dyes-Saffron, annatto**	**03**

P 3.5.4. Pharmacognosy –

(Practical) (Duration :3Hours/Week)

1. Morphology*,Microscopic** and powder characteristics* study of eight - selected drugs given in theory.
2. Isolation of total alkaloid (any two) **
3. Estimation of total alkaloids**
4. TLC study of alkaloids*.
5. Isolation and identification of papain or any one enzymes*
6. Some experiments on plant tissue culture for production of secondary metabolites (Demonstration)
    a. Preparation of media
    b. Formation of callus

* Minor experiments

** Major experiments

Books Recommended

1. Chemistry of Alkaloids by S. W. Pelletier
2. Alkaloids by Manske.
3. Horborn J. B. Phytochemical methods, Chapman and Hall, International Edition, London.
4. Kokate C. K. Purohit A. P. and Gokhale S. B. , Pharmacognosy (degree) NiraliPrakashan
5. Kokate C. K. Practical Pharmacognosy, VallabhPrakashan, Delhi.
6. Brain K. R. and Turner T. D., The practical Evaluation of phytopharmaceuticals, Wright-Scientechnica, Bristil.
7. PulokMukharji, Quality control of Herbal drugs.
8. Medicinal Plants of India, Indian Council of Medical Research, New Delhi.
9. Nadkarni A. K. Indian Materia Medica, 1-2, Popular Prakashan Pvt. Ltd.Bombay.
10. Pharmacopoeia of India, 1985,1996, Govt. of India, Ministry of Health and Family Welfare.
11. Iyengar M.A., Study of Crude Drugs, Manipal Power Press, Manipal.
12. Iyengar M.A. , Pharmacognosy Lab Manual. Manipal Power Press, Manipal.

13. The Wealth of India, Raw Marerials (All Volumes), Council of Scientific and Industrial Research, New Delhi.
14. Trease, G.E. and Evans, W.C. Pharmacognosy, 12th Edition, BailliereTindall, Eastbourne, U.K.
15. Wallis, T.E. Analytical Microscopy, J.A. Churchill Limited, London.
16. Wallis, T.E. Textbook of Pharmacognosy, J.A. Churchill Limited, London.
17. Tyler, V.E., Brady, R., Pharmacognosy
18. Wagner, S.B., Zgainsky, Plant drug Analysis.
19. V.D.Rangari, Pharmacognosy and Phytochemistry Volume I & II.
20. British Herbal Pharmacopoeia
21. Herbal Pharmacopoeia, IDMA, Mumbai
22. A.N. Kalia, A textbook of Industrial Pharmacognosy, CBS Publishers and Distributors
23. Natural Products, A Laboratory Guide – Raphael Ikan – Academic Press
24. Pharmacognosy, Phytochemistry, Medicinal Plants 2nd Edn. – Jean Bruneton
25. Manitto P. The biosynthesis of natural products, Ellis Harwood, Chichester

    Manske RHF, The alkaloids Academic press, New York
26. Clarke ECG, Isolation and Identification of Drugs, The Pharmaceutical Press, London
27. De Mayo, The chemistry of Natural Products, 2-3, Interscience New York
28. Gamborg O. L. Wetter L. R. , Plant tissue culture methods, National Research Council of Cannada, Sakatchewan.
29. Henry T. A. , The plant alkaloids, McGraw Hill, New York.
30. Kokate C. K. Practical Pharmacognosy, Vallabh Prakashan, Delhi.
31. Martindale, the extra pharmacopoeia, pharmaceutical society of great Britain, London.
32. The Chemistry of Natural Products by De Mayo P, Interscience, New York.
33. Marine Natural Products Chemistry by Faulkner D. J. and Fenical W. H., Plenum Press, New York.
34. The Biochemistry of Alkaloids by Robinson T., Springer- Verlag.
35. Peach K, and Tracey M. V., Modern methods of plant analysis, 1-4, Narosa Publishing house, New Delhi

T 3.5.5. Pharmaceutical Analysis-II

(Theory) **(Duration :3 Hours/Week)**

Sr. no.	Topic	Hrs
	SECTION-I	
1.	**Analytical separations:** Concepts in distributions of solutes in immiscible solvents, distribution coefficients (ratios), solvent-solvent extractions, solid-phase extractions	**03**
2.	**Refractometry:** Principle, Theory, Instrumentation and Applications.	**04**
3.	**Nephelo-turbidimetry**: Principles, Theory, Instrumentation and Applications	**04**
4.	**Polarimetry:** Principle, theory, instrumentation and applications including ORD and CD	**03**
5.	**Thermal Analysis**: Introduction, principle, methods, instrumentation and factors affecting results, Applications of TG, DSC, and DTA.	**07**
6.	**Introduction to Gasometric analysis**	**02**
	SECTION-II	
6.	**Basic introduction to Electrochemistry and Electrochemical Methods of Analysis.**	**01**
7.	**Electrochemical Analysis:** a. **Conductometry:** Principle, Theory, Effect of dilution, Instrumentations, Types of conduct metric titrations and Applications. b**. Potentiometry:** Nernst equation, Types of electrodes, Indicator and reference electrodes, examples, measurement of potential. Measurement of pH Types of potentiometric metric titrations . c. **Polarography:** Principle, Theory, Instrumentation Dropping Mercury electrode, Half wave potential, ILKOVIC equation and Applications. d**. Amperometry:** Principles, Theory, Instrumentation and Applications. e. **Coulometry:** Principles, Theory, Instrumentation and Applications.	**18**
8.	**Karl Fisher titration**: Introduction , instrumentation and applications	**03**

P 3.5.5. Pharmaceutical Analysis-II

(Practical) **(Duration: 3hrs/week)**

Sr.no.	Experiments
1.	Calibration of Refractometer and measurement of RI .* (At least 03 samples)
2.	Calibration of Conductometer and to measure conductance of distilled water. Determination of cellconstant.*
3.	Conductometric titration of strong acid- strong base**
4.	Conductometric titration of weak acid- strong base**
5.	Estimation of boric acid by Conductometric titration.**
6.	Calibration of pH meter and measurement of pH*
7.	Potentiometric titration of strong Acid Vs strong base **
8.	pKa determination of phosphoric acid / boric acid**
9.	Determination of specific rotation using Polarimeter. *
10.	Assay of Dextrose injection by Polarimeter as per I.P 1996.*
11.	Calibration of Nephaloturbidimeter*
12.	Determination of Sulfate using Nephaloturbidimeter**
13.	Water determination by Karl-fischer method*

* Minimum 12 experiments should be covered

* Indicate Minor experiments ** Indicate Major experiments

Books Recommended:

1. Bassett J, Denny R C, Jeffery G H, Mendharn J, Vogel's Textbook of Quantitative Inorganic Analysis, ELBS/Longman, London.

2. Grant- Statistical Quality control (McGraw Hill).

3. Beckett A H and Stenlake J B, Practical Pharmaceutical Chemistry Vol. I and II., The Anthlone Press of University of London.

4. Connors K A, A Textbook of Pharmaceutical Analysis, Wiley Interscience, New York.

5. Gary Christian- Analytical Chemistry (John Wiley)

6. Instrumental methods of Analysis- Ewing.

7. Higuchi &Brochmann- Hanssen- Pharmaceutical Analysis- (Interscience)

8. Garrat- The quantitative analysis of Drug (Toppan & Co.)

9. Vogel Text Book of Practical Organic Chemistry – 5th editions.

10. Pharmaceutical Analysis Vol. I & II, A.V.Kasture, S.G.Wadhodkar, K.R.Mahadik,H.N.More –Nirali Publication.

11. Analytical Chemistry an introduction, Skoog/West/Holler, 6th Edition

12. Florey- Analytical profiles of drug substances (Academic press)

13. Instrumental methods of Analysis- Willard, Dean, Merrit and settle-(Wadsworth Pub.Co.)

14. Merck Index.

15. Pharmaceutical Drug analysis by Ashutosh Kar.

16. Principles of Instrumental analysis, Skoog/Holler/Nieman, 5th Edition.

17. Latest editions of IP, BP, USP, EP and International Pharmacopoeia.

18. Meites-Handbook of Analytical Chemistry (McGraw Hill).

19. Hamilton, Simpson and Ellis- Calculation of Analytical Chemistry (McGraw Hill).

20. Analytical chemistry- garryChrisian

21. Instrumental methods of analysis- Chatwal andAnand

T 3.6.1. Pharmaceutical Chemistry – VII (Medicinal Chemistry -II)
(Theory) (Duration : 4 hrs/week)

The following topics should be covered with the points listed below

1. Introduction
2. Classification
3. Mechanism of action
4. Structure-activity relationship
5. Pharmacokinetics (Metabolism) and
6. Therapeutic uses
7. *Synthesis of drugs

Sr.no.	Topic	Hours
	Section I	
1	**Antiseptic & Disinfectants –**Chlorocresol, Phenol	2
2	**Quinoline Antibacterials -** Fluroquinolones like norfloxacin*, ciprofloxacin*, sparfloxacin*, Gatifloxacin*	4
3	**Anthelmintics -** Piperazine citrate, Albendazole, Mebendazole, Levamisole, Niclosamide	7
4	**Antifungal agents -** Clotrimazole, Griseofulvin, Ketoconazole, Miconazole nitrate	7
5	**Sulfonamides –** Short, intermediate and long acting sulfonamides, sulfonamides for ophthalmic infections, for burn therapy and for intestinal infections, ulcerative colitis and for reduction of bowel flora, DHFR inhibitors	7
6	**Antiamoebic Drugss** –Metronidazole*, diloxanidefuroate, Tinidazole*, Ornidazole*, flurazolidone	03
	Section II	
7	**Antineoplastics agents:** a. alkylating agents like mechlorethamine, chlorambucil*, cyclophosphamide*, mitomycin C, busulfan, carmustine, lomustine, dacarbazine and procarbazine. b. Antimetabolites like azaserine, methotrexate*, 5fluorouracil, araC, 6MP and 6TG	10

	c. Antibiotics like dactinomycin, doxorubicin, bleomycin, and other natural products like vincristine, vinblastine, paclitaxel (only highlights of structure to be discussed) d. Miscellaneous compounds like cisplatin and some newer derivatives e. Combination therapy	
8	**Antitubercular agents** – PAS*, ethonamide, isonamide, pyrazinamide, ethambutol*, antitubercular antibiotics (streptomycin, rifampin, viomycin and cycloserine – the first three only highlights of structure to be discussed). Combination therapy. Antileprotic drugs – dapsone* and clofazimine	04
9	**Antimalarials** – Natural products like cinchona alkaloids (with stereochemistry and drug action) and artemisinin and its derivatives like artether and artemether and artesunate. Synthetic antimalarials such as 8aminoquiacridines eg. Primaquine, Quinoline methanolsegmefloquine: misc, like halofantrine and lumefantrine: DHFR inhibitors like pyrimethamine* and cycloguanil and sulfonamides like sulfodoxine, sulfadiazine*, and sulfalene. Combination therapy.	06
9	**Antibiotics** - penicillins (natural and semisynthetic penicillinslike Penicillin G, PenicillinV, ampicillin*, amoxicilline*, oxacillin ,nafcillin, methacillin and ampicillin prodrugs like bacampicillin and pivampicillin), cephalosporins (cephalexin, cephalothin, cefaxitin, cefuroxime, cefotaxime, cefepine and cefpirome) tetracycline, chlortetracycline, oxytetracycline, doxycycline and miocycline and its prodrug – rolitetracycline); macrolides (erythromycin, rocithromycin, azithromycin – only highlights of structure to be discussed); aminopglycosides (gentamicins and neomycins – only highlights of structure to be discussed) Chloramphenicol.	10

Reference Books:

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, 11 th Ed., Eds., John H Block and John M Beale, Lippincott Williams & Wilkins, 2004.
2. Foye's Principles of Medicinal Chemistry, Eds., T. L. Lemke and D. A. Williams, Williams & Wilkins, Baltimore, 2002.
3. Medicinal Chemistry, AshutoshKar, 4 th Edition, New Age International Publishers, 2007.
4. The Art of Drug Synthesis, Eds., Douglas S Johnson and Jie Jack Li, Wiley Interscience, 2007.
5. Pharmaceutical Chemistry, Vol. 1: Drug Synthesis, Eds., H. J. Roth, A. Kleeman, and T. Beissewenger, Ellis Horwood Ltd., 1988.
6. The Organic Chemistry of Drug Synthesis, Daniel Lednicer, Vols. 1 to 7, Wiley.
7. Profiles in Drug Synthesis : V.N. Gogte
8. Textbook of Pharmaceutical Chemistry by Harkishansing&Kapoor
9. Principle of Medicinal Chemistry (Volume I & II) by Kadam, Mahadik and Bothara
10. Text Book of Practical Organic Chemistry - A.I. Vogels
11. Practical Organic Chemistry - Mann and Sanders
12. Systematic Identification of Organic Composition, Shriner and Fuson

P 3.6.1. Pharmaceutical Chemistry – VII (Medicinal Chemistry - II) (Practical) (Duration : 3 hrs/week)

Minimum Twelve numbers of Experiments should be performed.

***Minor ****Major Experiments**

1) **Purification techniques of solvents/liquids and synthesized products by Fractional distillation and distillation under vacuum and recrystalization**

1. Benzylideneacetophenone(Claissen Schmitt Reaction)**
2. Benzhydrol from Benzophenone (MVP Reduction)*
3. Benzocaine*
4. Synthesis of 3,5-dinitrobenzoic acid from benzoic acid**
5. Synthesis of benzyl alcohol from benzoic acid (Cannizzarao reaction)*
6. 9-acetylanthracine from anthracine*
7. p-acetamidobenzenesulphonyl chloride from acetanilide**
8. p-acetamidobenzenesulphonamide from p-acetamidobenzenesulphonyl chloride*
9. Methyl red**
10. *o*-chlorobenzoic acid (Sandmeyer Reaction)**
11. Resacetophenone from resorcinol*
12. iodobenzene from aniline*
13. p-acetaniside from p-anisidine*
14. Benzalactoacetophenone from acetophenone and benzaldehyde*
15. Pentaerythritol from acetaldehyde. **

Book Recommended

1. Text Book of Practical Organic Chemistry - A.I. Vogel

2. Practical Organic Chemistry - Mann and Sanders

3. Systematic Identification of Organic Composition, Shriner and Fuson

4. Indian Journal of Pharmaceutical Education and Research, 39 (4) Oct-Dec. 2005, 188-190

5. Organic Synthesis Special techniques V. K. Ahluwalia, RenuAggrawal, Nerosapublishinghouse , p. no. 90 - 114

T 3.6.2. Pharmaceutics –VII (Biopharmaceutics& Pharmacokinetics)
(Theory) (Duration : 3 hrs/week)

Section- I

Sr. No.	TOPICS	Hrs.
1.	**Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting.**	**02**
2.	**Absorption of drugs: -**Introduction, Definition, Gastrointestinal absorption of drugs, Structure and Physiology of cell membrane, Mechanism of drug absorption, Factors affecting drug absorption (Pharmaceutical and Patient related), Theories of drug dissolution, Factors affecting drug dissolution and dissolution rate, pH-Partition hypothesis, Absorption of drug from extravascular routes.	**08**
3.	**Distributionof drugs: -** Introduction, Definition, Physicochemical properties of drug, organ/tissue size, blood flow to the organ, physiological barriers to the diffusion of drugs {Factors affecting distribution}, Apparent volume of distribution.	**04**
4.	**Protein binding of drugs: -** Introduction, Definition, Binding of drugs to blood components & extravascular tissue proteins. Factors affecting protein drug binding. Significance of protein/tissue drug binding.	**03**
5.	**Biotransformation of drugs:-**Introduction, Definition, Drug metabolizing organs, Drug metabolizing enzymes, Phase I and Phase II reactions. actors affecting biotransformation of drugs {Physicochemical properties of drugs, Chemical & Biological factors}.	**04**
6.	**Non- linear pharmacokinetic: -**Introduction, tests to detect nonlinearity in pharmacokinetics. Causes of nonlinearity{examples of drug showing nonlinearity in absorption, distribution, metabolism, & excretion}.Michaelis Menten equation and specific derivation for three situations by considering values of K_m and C. Estimation of K_m and V_{max}.	**02**

Section- II

Sr. No.	TOPICS	Hrs
7.	**Excretion of drugs:-**Introduction, Definition. Renal excretion of drugs {Glomerular filtration, active tubular secretion and active or passive tubular reabsorption}, Urine pH, drug pK_a and urine flow rate. Concept of clearance, Renal clearance, excretion ratio. Factors affecting renal excretion. Renal function and dose adjustment in renal failure. Non renal routes of drug excretion - Biliary excretion- factors affecting biliary excretion and enterohepatic cycling of drugs. Minor pathways of drug	**04**

	excretion{Pulmonary, Mammary, Skin, GI, and Genital excretion}.	
8.	**Pharmacokinetics: Basic considerations: -** Pharmacokinetic basic consideration, Rate, Rate constants and Orders of reactions. Concept of mixed order kinetics {Non linear kinetics}. Pharmacokinetic models – Importance, types {Compartment, non compartmental analysis, and Physiologic models}	**02**
9.	**Compartment modeling: -** Pharmacokinetic of one compartment model drug, mathematical treatment to pharmacokinetic upon I.V. bolus dosing, constant rate I.V. infusion, and extravascular administration. Urinary excretion data studies (Rate excretion and sigma minus methods), Multicompartment model behavior (excluding derivation or mathematical treatment), Central, & peripheral compartments, distribution phase & pseudo distribution equilibrium phase. Plasma concentration & therapeutic response. An introduction to pharmacodynamics.	**08**
10.	**Bioavailability and Bioequivalence:** Introduction, Definition, Objectives of bioavailability studies. Considerations in bioavailability study design – absolute versus relative bioavailability, single versus multiple dose study and healthy subjects versus patients. Measurement of bioavailability {Pharmacokinetic and Pharmacodynamic methods}.Drug dissolution rate and bioavailability - In vitro drug dissolution testing models – factors related to dissolution apparatus, dissolution fluids, and process parameters. Closed, Open compartment apparatus. Type I and II apparatus. In vitro- In vivo correlation. Bioequivalence studies. Methods of enhancement of bioavailability.	**04**
11.	**Design of Dosage Regimens: -** Introduction, Definition and applications of dosage regimen. Factors affecting dosage regimens – dose size, dosing frequency, drug accumulation during multiple dosing {accumulation index}, utility curves, & therapeutic window, multiple dose pharmacokinetics. Fluctuation, steady state concept, time to reach steady state, loading and, maintenance doses. Individualization {Pharmacokinetic and pharmacodynamic variability}, dosing of drugs in individuals. Monitoring drug therapy {Therapeutic, Pharmacodynamic, and Pharmacokinetic}.	**04**

P. 3.6.2. Pharmaceutics –VII (Biopharmaceutics& Pharmacokinetics) (Practical) (Duration : 3 hrs/week)

1) Determination of disintegration time of Tablet*
2) Dissolution Studies: Ointment* Marketed enteric coated Tablet*
3) To study the effect of enzymes / surfactant on dissolution of Tablet**
4) To study the effect of pH on dissolution of Tablet. **
5) In vitro diffusion study of drugs through one biological and two synthetic Membrane**.
6) To study the absorption of drugs using everted sac technique**
7) Equilibrium dialysis method- demonstration of protein binding
8) Equilibrium dialysis method- demonstration of drug-drug interaction at protein bind sites**.**
9**)** To study the urinary excretion of Riboflavin in healthy volunteers**
10) To determine pharmacokinetic parameters from plasma concentration time profile***.**
11) To determine Area under Curve (AUC) by trapezoidal rule from plasma concentration time profile***.**

Major Expt. **

Minor Expt. *

Books Recommended for Theory and Practical:

1. Leon Shargel, Applied Biopharmaceutics and Pharmacokinetics - McGraw Hill
2. V.Venkateshwarlu, Biopharmaceutics and pharmacokinetics- Pharma Book Syndicate
3. GibaldiM,Biopharmaceutics and clinical pharmacokinetics-. Pharma Book Syndicate
4. Rowland M. &Tozer, Clinical pharmacokinetics: Concept and application- B.I. Waverly Pvt. Ltd.
5. Notari R.E., Biopharmaceutics, and clinical pharmacokinetics- Marcel Dekker, Inc.
6. S.B. Jaiswal and D.M.Brahmankar, Biopharmaceutics and Pharmacokinetics A Treatise – VallabhPublicationDelhi.
7. Hitendra S. Mahajan. Theoretical and Experimental aspects of Biopharmaceutics and Pharmacokinetics- Career Publications.

T. 3.6.3. Pharmacology –II

(Theory) **(Duration : 4 Hours/Week)**

Section I

Sr. No.	TOPICS	Hrs.
1.	**Central Nervous System: -** a) Neurotransmitters involved in central nervous system (CNS) with their role in physiology and pathology of CNS disorders b) Pharmacology of alcohol and treatment of alcohol abuse c) General anesthetics – emphasize on the general anesthetics in actual clinical use at present d) Pharmacology of following classes of drugs acting on CNS: • Local Anesthetics • Antiparkinsonian drug • Sedatives, hypnotics and anxiolytics • CNS stimulants and respiratory stimulants • Anticonvulsants • Antipsychotics • Antidepressants. • Opiates and opoid analgesics	03 03 03 02 02 02 03 03 03 03 03 03

SectionII

Sr. No.	TOPICS	Hrs.
1.	**Concept of bioassays : -** a) Types of Bioassay – Matching, bracketing, interpolation and multiple point assays b) Alternatives to conventional bioassays including Radio-immuno assays, Enzyme linked immunosorbent assays, ligand-binding assays, receptor binding assays, functional assays (using fluorescene techniques, chemiluminiscence techniques)	**10**

2.	**1)** Pharmacology of drugs acting on r**espiratory system: -** a) Mucolytics b) Antitussives c) Expectorants d) Anti-Asthmatic drugs	**10**
3.	2) Pharmacology of drugs acting on **Endocrine system: -** a) Thyroid and antithyroid drugs. b) Insulin and insulin analogues, oral hypoglycaemic drugs. c) Male and female sex hormones and oral contraceptives. d) Oxytocin and other uterine stimulants and relaxants.	**10**

Book Reading:

1. Satoskar R. S. , Bhandarkar S. D., Rege N. N., Pharmacology and Pharmacotherapeutics, Popular Prakashan Mumbai,

2. Tripathi K. D., Essentials of Medical Pharmacology, Jaypee Prakashan , New Delhi

3. Barar F.S. K. Essentials of Pharmacotherapeutics, S. Chand & Company, New Delhi

4. Patil P. N and Gulati O. D. Topic in the History of Pharmacology, B.S.Shah Prakashan Ahmedabad.

5. Rang and Dell, Pharmacology, Elsevier

Extra Reading:

1. Goodman Gillmans The Pharmacological Basis of Therapeutics, McGrwe Hill, New Delhi

2. Diprio J. L. Pharamcotherapy Handbook McGrew Hill, New Delhi

3. Official Book, Indian Pharmacopoeia, British Pharmacopoeia, U.S. Pharmacopoeia

P 3.6.3. Pharmacology –II
(Practical) (Duration : 3 Hours/Week)

1) Determination of effect of Physostigmine on DRC of acetylcholine using pig ileum OR rat ileum OR goat trachea OR chicken ileum (any one tissue as per availability)**

2) Determination of effect of Atropine on the DRC of acetylcholine using pig ileum OR rat ileum OR goat trachea OR chicken ileum (any one tissue as per availability)**

3) Bio-assay of acetylcholine/histamine on guinea pig ileum OR rat ileum OR goat trachea OR chicken ileum by interpolation method (any one tissue as per availability)**

4) Bio-assay of acetylcholine/histamine on guinea pig ileum OR rat ileum OR goat trachea OR chicken ileum by three point assay method (any one tissue as per availability)**

5) Bioassay of Atropine on guinea pig ileum OR rat ileum OR goat trachea OR chicken ileum by interpolation method (any one tissue as per availability) – by determining % inhibition of effect of acetylcholine**

6) Bio-assay of acetylcholine/histamine on guinea pig ileum OR rat ileum OR goat trachea OR chicken ileum by three point assay method (any one tissue as per availability)**

7) Phases of estrous cycle in rats by microscopic examination of vaginal smears {Phases of Proestrus , Oestrous, Diestrus and Metaestrus shoud be identified)**

8) Determination of antidepressant effect of drugs using forced swim test / tail suspension test in mice (Oral and IP administration of drug)*

9) To study the effects of drugs on locomotor activity using Actophotometer (Oral and IP administration of drug)*

10) Demonstration of study of Anticonvulsant activity using MES/ PTZ using simulated software (www.animalsimulator.com or any other suitable software)

11) To study the analgesic activity of drug using Hot Plate/ OR Tail Flick/ Or Caudal Immersion, method in rats/ OR mouse **(**Oral and IP administration of drug)*

12) Demonstration of Haloperidol induced catalepsy in rats

13) Demonstration of difference in Pharmacokinetics of any one drug administered by oral route and intravenous route {The analytical method should be UV-visible spectroscopy based, and the drug should has short half life so that student can finish this experiment within 3 hours}

14) Marble burying paradigm in mice to determine obsessive compulsive behavior**

15) Simulated experiment of determination of PA2 value using suitable software **.

NOTES: - **1. Minor** * **Major****

Minimum 12 experiments from above list must be conducted

Books Recommended

1) Ghosh M.N. Fundamentals of Experimental pharmacology. Hilton & Company Kolkata 2005 3rd edition.

2) Vogel G.H. Drug discovery and evaluation.Springer Germany 2002 2nd edition.

3) Goyal R.K. Practicals in pharmacology. B.S. Shah Prakashan Ahmedabad 2005 5th edition.

4) Kulkarni S.K. Handbook of Experimental Pharmacology. Vallabh Prakashan. New Delhi, 5th edition.

5) Perry W. L. M. Pharmacological Experiments on Isolated preparations.E.&S. LivingstoneLondon 1970 , 2nd
edition.

6) Kasture S.B.Text book of Experimental Pharmacology, Career Publication Nashik.1 st edition, 2006

7) Official books - Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia

8) www.animalsimulator.com

T 3.6.4. Pharmacognosy – V (Chemistry of Natural Products)

(Theory) (Duration : 3 hrs / week)

Section-I

Sr. No.	TOPICS	Hrs.
1.	Chemistry and Spectral Characterization of Simple Natural Origin Molecules Using modern analytical tools (UV, IR, NMR, and Mass).	**04**
2.	Concept of Stereoisomerism of Natural Products	**03**
3.	Introduction**,** Chemistry, biogenesis and pharmacological activity of medicinally Important Monoterpenes, Sesquiterpenes, Diterpenes, Triterpenoid	**12**
4.	**Glycosides**: Introduction, Chemistry and Biosynthesis of Cardio Active Glycoside (Digitoxin, Digoxin), Sennoside, Diosgenin, Hecogeninand Sarasapogenin.	**05**

Section-II

Sr. No.	TOPICS	Hrs.
1.	**Alkaloids:** Introduction, Chemistry, Biogenesis and Pharmacological Activity of Atropine Quinine, Reserpine, Morphine, Papaverine, Ephedrine, Ergot and Vinca alkaloids.	**08**
2.	**Carotenoids:** Introduction, α-carotenoids, β-carotenes, vitamin A	**05**
3.	Introduction, Chemistry and Biogenesis of Medicinally Important Lignans and Flavonoids.	**04**
4.	Chemistry and Therapeutic Activity of Penicillin, Streptomycin and Tetracycline.	**04**

P 3.6.4. Pharmacognosy – V(Chemistry of Natural Products) (Practical) (Duration : 3hrs / week)

1. Laboratory experiments on isolation**, separation, purification** and Spectroscopic analysis* of various groups of chemical constituents of pharmaceutical significance.
2. Estimation of Total flavonoids *

* Minor experiments

** Major experiments

Book recommended

1. Chemistry of Alkaloids by S. W. PelletierAlkaloids by Manske.
2. Steroids by Fieser and Fieser.
3. Medicnal Natural Products –A biosynthetic Approach- Paul M Dewick
4. Organic Chemistry by I. L. Finar Vol. II.
5. Chemistry of Natural Products by K. W. Bentley.
6. Chemistry of Natural Products by O. P. Agrawal.
7. Biosynthesis of Aromatic Compounds by Ulrich Weiss & J. Michael Edwards.
8. Horborn J. B. Phytochemical methods, Chapman and Hall, International Edition, London.
9. Kokate C. K. Purohit A. P. and Gokhale S. B. , Pharmacognosy (degree) NiraliPrakashan
10. Kokate C. K. Practical Pharmacognosy, VallabhPrakashan, Delhi.
11. Brain K. R. and Turner T. D., The practical Evaluation of phytopharmaceuticals, Wright-Scientechnica, Bristil.
12. PulokMukharji, Quality control of Herbal drugs.
13. Trease, G.E. and Evans, W.C. Pharmacognosy, 12th Edition, BailliereTindall, Eastbourne, U.K.
14. Wallis, T.E. Analytical Microscopy, J.A. Churchill Limited, London.
15. Tyler, V.E., Brady, R., Pharmacognosy
16. V.D.Rangari, Pharmacognosy and Phytochemistry Volume I & II.
17. Herbal Pharmacopoeia, IDMA, Mumbai
18. Natural Products, A Laboratory Guide – Raphael Ikan – Academic Press
19. Pharmacognosy, Phytochemistry, Medicinal Plants 2nd Edn. – Jean Bruneton
20. Raphael Ikon, Natural products a laboratory Guide, Academic Press
21. Manitto P. The biosynthesis of natural products, EllisHarwood, Chichester
22. Manske RHF, The alkaloids Academic press, New York

23. Clarke ECG, Isolation and Identification of Drugs, The Pharmaceutical Press,London
24. De Mayo, The chemistry of Natural Products, 2-3, Interscience New York
25. Martindale, the extra pharmacopoeia, pharmaceutical society of great Britain,London.
26. The Chemistry of Natural Products by De Mayo P, Interscience, New York.
27. Marine Natural Products Chemistry by Faulkner D. J. and Fenical W. H., Plenum Press, New York.
28. Biochemistry of Phenolic Compounds by Harborne J. B., Academic Press, New York.
29. Official Methods of Analysis, Association of Official Analytical Chemists publication,Washington.
30. Pharmacopoeia Of India, 1985, 1996, Govt. Of India, Ministry Of Health and Family Welfare.
31. Terpenoids in Plants by Pridham J. B., Academic Press, New York
32. The Biochemistry of Alkaloids by Robinson T., Springer- Verlag.
33. Experimental Phytopharmacognosy –A Comprehensive Guide By SS Khadabdi, DeoreSl, and BA Baviskar, NiraliPrakashan, Pune.
34. Standardization Of Botanicals- Testing & Extraction Methods Of Medicinal Herbs By V. Rajpal, Eastern Publisher, New Delhi

T 3.6.5. Pharmaceutical Jurisprudence & Ethics

(THEORY) (Duration : 4 Hrs/Week)

Scope:

The subject deals with several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments is the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, will be discussed.

Objectives:

At the end of the course, the student shall able to

- Know and understand the Pharmaceutical legislations and their implications in the development and marketing.
- Understand and follow the code of ethics during the pharmaceutical practice
- Know and understand various Indian pharmaceutical acts and laws
- Know about the process of drug discovery and developments
- Know the regulatory authorities and agencies governing the manufacture and sale of Pharmaceuticals
- Know the regulatory approval process and their registration in Indian and international markets

Sr No	Topic	Hrs
	Section I	
1	**Definition and scope of Forensic Pharmacy**	**1**
2	**Pharmaceutical Legislation-A brief review** Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee	**2**
3	**Code of Pharmaceutical ethics** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.	**2**
4	**Pharmacy act-1948 & new Amendments** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties	**2**
5	**Drugs and cosmetics act 1940 and rules 1945 & New**	**09**

	Amendments Objectives, Definitions, Legal definitions of schedules to the act and rules Import of drugs - Classes of drugs and cosmetics prohibited from import, Import under license or permit. Manufacture of drugs - Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. Detailed study of schedule M, N and Y. Sale of Drugs - Wholesale, Retail sale and Restricted license. Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Administration of the act and rules - Drugs Technical Advisory Board, Central Drug Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors	
6	**Medicinal and Toilet preparations (Excise Duties) Act 1955** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Offences and Penalties.	**2**
7	**Narcotic drugs and psychotropic substance act 1985 and rules** Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, opium poppy cultivation and Production of poppy straw manufacture, sale and export of opium, Offences and Penalties.	**2**
8	**Drugs and Magic remedies (Objectionable Advertisement) act 1955** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	**2**
9	**Pharmaceutical Policy 2002 and its amendments** Objectives, Approaches in the review, Salient features	**2**
10	**Sales promotion employees (Conditions of service) Act** **Regulatory affairs**	**2**
11.	**Consumer Protection Act**	**4**
	Section II	
12	**Prevention of cruelty to Animals act-1960** Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.	**2**
13	**Drugs (price control) order-1995 & New Amendments** Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Implementation of prices Fixed/ revised.	**2**
14	**New Drug Discovery and development**	**8**

	Stages of drug discovery, Drug development process, pre-clinical studies, nonclinical activities, clinical studies, Concept of generics, Generic drug product development	
15	**Regulatory authorities and agencies** Overview of regulatory authorities of United States, Australia, United Kingdom. International Conference on Harmonization, World Health Organization.	**04**
16	**Regulatory Approval Process** Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.	**06**
17	**Registration of drug product in overseas market** Procedure for export of pharmaceutical products, Technical documentation, Common Technical Document (CTD), electronic Common Technical Document (eCTD)	**06**
18	**Right to information act, 2005 –** Introduction & applications	**02**

Recommended books

1. Forensic Pharmacy by B. Suresh

2. Pharmaceutical Jurispudance by B.S.Kuchekar

3.Text book of Forensic Pharmacy by B.M. Mithal

4. Hand book of drug law-by M.L. Mehra

5. A text book of Forensic Pharmacy by N.K. Jain

6. Drugs and Cosmetics Act/Rules by Govt. of India publications.

7. Medicinal and Toilet preparations act 1955 by Govt. of India publications.

8. Narcotic drugs and psychotropic substances act by Govt. of India publications

9. Drugs and Magic Remedies act by Govt. of India publications.

10. Drug Regulatory Affairs by SachinItkar, Dr. N.S. Vyawahare, NiraliPrakashan.

11. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.

12. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5thedition, Drugs and the Pharmaceutical Sciences,Vol.190.

13. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.

14. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and

biologics/edited by Douglas J. Pisano, David Mantus.

P.3.6.6 Project Report

Project report during T.Y. B. Pharm. For Project report one project should be given in group of 3 Students. Under one teacher, 5-7 group can study and complete their project. Oral examination will be conducted by appointing External Examiner from Industry or Academic for the project and grades will be allotted individually.