SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF PHARMACEUTICAL SCIENCES

Syllabus of Third Year B. Pharmacy

Pattern 2015

(EFFECTIVE FROM ACADEMIC YEAR 2017-18)

Credit and Grading Based Semester System

THIRD YEAR B.PHARMACY **SEMESTER –V**

3.5.1 T INDUSTRIALPARMACY-I
(3hrs/week), CREDIT: 03

Learning Objective:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

Knowledge:

- Understand the concepts of solid dosage form design & formulation strategies.
- Explain tablets as a dosage form, physico-chemical principles guiding tablet formulation, various tablet additives, manufacture & evaluation, equipments, defects in tabletting & remedies.
- Learn the concept, types, pharmacopoeial specifications, techniques & equipments used in tablet coating.
- Describe capsules, types, additives, size selection, manufacturing & evaluation, equipments, &defects.
- To understand the concept of technology transfer

Skills:

- State the correct use of various equipments in Pharmaceutics laboratory relevantto tablets, capsules &coating.
- Explain formulation, evaluation and labeling of tablets &capsules.
- Perform pharmaceutical calculations to determine evaluation parameters like Hausner ratio, Heckel plot & Kawakita plot of preparations.
- To understand rational behind use of formulation ingredients.
- To learn the equipments and apparatus needed for the preparation as per SOP.
- Select the suitable packaging material (container-closure) for the preparation.
- Prepare labels to suit regulatory requirements.
- To learn the conduct survey and report its finding.

Sr.No	Topics	Hrs
	SECTION- I	
01	Concept of formulation design, Principles of solid dosage form design. **Biopharmaceutical, therapeutic and drug related considerations.**	03
02	**Tablets formulation and technology** Introduction, Advantages & Disadvantages, Types of tablets. Introduction to tablet additives,	03
	Granulation: Need, Mechanisms, processes and equipments for wet granulation and Dry granulation processes. *Advanced granulation techniques* -, Characterization and Evaluation of granules. coprocessed excipient and manufacturing: Extrusion, spheronization,	06

	Pelletization, Spherical crystallization, Fluidized bed granulation	
	Physics of tablet compression, Force volume relationship, lubricating efficiency. Heckel plot, Kawakita equation Tablet compression machines. Types of tooling. Defects in tableting & remedies thereof.	04
	Chewable tablets, Effervescent tablets, Dispersible tablets, Mouth dissolving tablets with one example. Schedule M requirement. IPQC & QC of tablets as per IP, BP, USP	04
03	Concept of Scale up and technology transfer of Tablet dosage form. Plant layout for tablet manufacturing. Schedule M requirements	03
SECTION-II		
04	**Coating technology** Introduction and concept of tablet coating. Types of tablet coating including Sugar, Film & Enteric coating. Material, processes employed &equipments for tablet coating. **Coating defects & remedies**. Compression coated tablets and coating..	07
05	**Capsules** a. Various materials used in capsule shell manufacturing. b. Manufacturing and quality control of gelatin for capsule. Introduction and concept of size selection of capsules. Manufacture of hard gelatin capsule shell, standards anddefects. c. Hard gelatin capsules: Formulation development of hard gelatin capsule, standards & defects thereof. Volumetric and dosator principle in capsule filling, Hand operated semiautomatic and automatic equipments. Problems in capsule filling & remedies thereof. d. Soft gelatin capsules: formulation and development, introduction to base adsorption. Manufacturing equipment. In process quality control & quality control as per IP,BP,USP **e.** Plant layout for capsule manufacture. Schedule M requirements	03 06 06

3.5.1 P INDUSTRIALPARMACY-I
(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	Study of tablet press and its parts
02	Preparation and evaluation of tablets by direct compression technique.
03	Preparation & evaluation using aqueous/non aqueous Wet granulation
04	Preparation & evaluation of tablets using Dry granulation
05	Preparation and evaluation of Mouth dissolving tablets/Chewable Tablets.

06	To study effect of binders concentration on hardness & Disintegration of tablet
07	Evaluation of marketed coated tablet as per IP(EXCLUDING DISSOLUTION)
08	Evaluation of marketed enteric coated tablet.
09	Effect of flow promoter on flow property of granules.
10	Filling and evaluation of hard gelatin capsule.
11	Evaluation of marketed soft gelatin capsule.
12	To perform In-vitro Dissolution test for at least one type of Tablet or Capsule formulation.
13	To study different packaging and its labeling materials of solid dosage forms and to perform leak test for Blister/strip pack
14	To conduct a survey of any one drug, its different solid dosage forms (Tablets and capsules) available in market and submit its report highlighting the rational /logic behind designing of different dosage forms of same drug.
15	To conduct one day industrial visit and submit a report of visit comprising layout of plant and product details.

Recommended books

1. Indian Pharmacopoeia2014.
2. United States Pharmacopoeia2014.
3. British Pharmacopoeia 2015.
4. Theory and Practice of Industrial Pharmacy. Edition Lachmann, Libermann, Kanig, Edition.
5. Modern Pharmaceutics, Banker and Rhodes, MarcelDekker.
6. M E Aulton, K Taylor, Pharmaceutics: The Science of Dosage Form Design, 2nd edition,2001
7. Ansel's Introduction to Pharmaceutical dosage forms & Drug Delivery Systems 9th edition, 2nd Indian reprint, 2011.
8. Remington: The Science and Practice of Pharmacy, Volumes 1-2, 22nd edition, 2012

3.5.2 T PHARMACEUTICAL ANALYSIS -III
(3hrs/week), CREDIT: 03

Learning objectives:
On successful completion of following theory topics & laboratory experiments, a learner should be able to

Knowledge:

- Explain the different types of instrumental analytical techniques available for quality control of APIs & formulations.
- Adopt various sampling techniques employed in analysis of solid, semisolid and liquid dosage forms while working in industry
- Explain the principles, instrumentation and applications of UV-VIS, Flourimetry, Atomic absorption, atomic emission spectroscopes, Flame photometry, Phosphorimetry and Nepheloturbidimetry.

Skills:

- Independently operate, calibrate various analytical instruments for the assay of various APIs and formulations as per Pharmacopoeial standards.
- Independently process, interpret the data obtained through experimentation and report the results as per regulatory requirements.
- Take appropriate safety measures while handling instruments, chemicals and apparatus.

Sr.No	Name of Topic	Hrs
	SECTION-I	
The following topics 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		
01	**Introduction to Instrumental Methods of Analysis**: Classification of instrumental methods of analysis, electromagnetic Spectrum & its interaction with matter (reflection, refraction, diffraction, absorption, transmission, scattering of radiation etc), concept of band and line spectra, atomic and molecular spectroscopy.	05
02	**Analytical Sample preparation Techniques**: Preparing samples for analysis, sampling plans, separating analytes from interferents, separation techniques based on size, density, complexation, liquid-liquid extraction.	04
03	**UV Visible Spectroscopy**: Basic concepts of spectroscopy, Theory, Beer lamberts law, its deviations and limitations, Woodward rule, concept of photometry and spectrophotometry, Factors affecting absorption maximum, Instrumentation-single beam and types of double beam UV-Visible spectrophotometer, Optimum conditions for Spectrophotometric measurements, Single and Multicomponent analysis Methods, Derivative Spectrophotometry, Spectrophotometric titration, Applications of UV-Visible spectrophotometry.	12
	SECTION-II	
04	**Atomic Absorption Spectroscopy,** -Theory, Classification of AES methods, Instrumentation, line broadening, Doppler effect, Flame types, different Interference and their Corrections, Pharmaceutical applications	05

05	**Atomic Emission Spectroscopy:** Flame Photometry, Instrumentation, Principle and Applications.	07
06	**Fluorimetry & Phosphorimetry**- Excitation and emission spectra, Molecular luminescence, measurement of fluorescence, factors affecting fluorescence, quantitative aspects of fluorescence, Instrumentation, Spectrofluorometry, advantages and disadvantages, applications, synchronous fluorescence. Phosphorimetry, Instrumentation, advantages and disadvantages, Applications.	08
07	**Spectroscopy based on scattering**-Nepheloturbidimetry-Introduction, Principle, Instrumentation and Applications.	04

3.5.2 PPHARMACEUTICAL ANALYSIS - III
(3 hrs / week), CREDIT 02

Sr. No.	Title of Experiment
01	Measurement of effect of various solvents on absorption maxima.
02	Determination of Beer's Law, Limit and calculation of different absorptivity constants.
03	Calculation of λmax by Woodward rule (Any two)
04	Assay of APIs and formulations by UV Spectrophotometry including calibration curve method, Single point standardization, Double point standardization and A1% 1cm method (Any four)
05	Estimation of Na, K, Ca, Li from Pharmaceutical formulations by flame photometry (Any two)
06	Assay of APIs & formulations by Fluorimetry (Any two)
07	Assay of APIs & formulations by Nepheloturbidimetry (Any two)

Note: Assay methods should follow the monographs given in Pharmacopoeia

Recommended books

1. Indian Pharmacopoeia, 2014, Indian Pharmacopoeia Commission, Govt. of India
2. British Pharmacopoeia, 2016, British Pharmacopeia Secretariat, London, UK
3. United States Pharmacopeia, 2016, US Pharmacopoeial Convention. USA
4. Vogel's Text Book of Quantitative Chemical Analysis, 6/Ed., Pearson Education.
5. Fundamentals of Analytical Chemistry by Skoog, West, Holler, Harvest, 8/Ed., Thomson Brookslcole.
6. Pharmaceutical Analysis by Higuchi, Reprint 2004, CBS Publisher & Distributors.
7. The quantitative analysis of drugs by Garrat DC, 3/Ed., CBS Publisher & Distributors.
8. Practical Pharmaceutical Chemistry Part-I & II by Beckett A H & Stanlake J B, 4/Ed., CBS Publisher & Distributors.
9. Handbook of Instrumental Techniques for Analytical Chemistry by Frank Settle, First Indian Reprint 2004, Pearson Education
10. Instrumental Methods of Analysis by Willard Merit, Dean Settle, 7th edition, CBS Publisher & Distributor

11. Instrumental Methods of Chemical Analysis by BK Sharma, Goel Publishing House.
12. Instrumental Methods of Chemical Analysis by GW Ewing, McGraw-Hill Book Company
13. A Practical Approach to Pharmaceutical Analysis(Instrumental & Manual), Rajesh Kumar Nema, Mahesh Verma, CBS Publishers & Distributors

3.5.3 T MEDICINAL CHEMISTRY-I
(3hrs/week), CREDIT: 03

Learning Objectives:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

Knowledge:

- Know general aspects of the design of the drugs, history, classification, nomenclature, structure activity relationship (SAR), mechanism of action, therapeutic uses, adverse effects and recent developments in categories such as adrenergic & cholinergic agents and drugs affecting cardiovascular system.

Skills:

- Make correct use of various equipments and take safety measures while working in Medicinal Chemistry Laboratory.
- Synthesize medicinally important compounds and purify them using, TLC & Column Chromatography.
- Characterize the synthesized compounds using IR and NMR spectra's.
- Purify the solvents using fractional and vacuum distillation.
- Explain reaction mechanisms involved in synthesis of medicinally important compounds.

Sr. No.	Topic	Hrs.
	SECTION-I	
01	**General considerations:** Structure of biological membrane, physicochemical properties affecting drug action; solubility, partition coefficient, ionization, Ferguson principle, stereo chemical aspects of drug action, Bioisosterism, Introduction to Drug absorption; distribution, metabolism, elimination and toxicity, Protein binding, Blood brain barrier.	07
02	**Receptors:** Types of receptors, types of forces involved in drug receptor interaction; intracellular cyclic nucleotides and other mediators of biological response, Drug-Receptor mechanism including signal transduction.	05
03	History and general aspects of the design & development of drugs including classification, nomenclature, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses and recent developments of following categories and scheme of synthesis of drugs mentioned in bracket.	
3.1	**Adrenergic agents:** Agonists and antagonists, Biosynthesis, release and metabolism of noradrenaline, Receptor subtypes and their structural features. (Methyldopa, Atenolol, Prazocin, Guanethidine, Terbutaline, Salbutamol)	08
	SECTION-II	
3.2	**Cholinergic agents:** Biosynthesis, release and metabolism ofNeurotransmitters, Acetylcholine. Cholinergic receptor subtypes and their structural features, Cholinergic agonists, Cholinergic antagonists, acetylcholinesterase inhibitors, Ganglionic blockers and neuromuscular blockers.(Carbachol, Dicyclomine hydrochloride, Neostigmine)	09
3.3	**Drugs affecting Cardiovascular System** a. Cardiotonic drugs b. Anti-anginal agents c. Anti-arrhythemic agents d. Anti-hypertensive agents e. Anti-hyperlipidemic drugs	12

	(Losartan, Clofibrate, Hydralazine, Captopril)	
3.4	**Diuretic agents** (Furosemide, Chlorthiazide)	04

3.5.3 P MEDICINAL CHEMISTRY-I
(3 hrs / week), CREDIT 02

Sr. No.	Title of Experiment
01	Purification techniques of solvents by Fractional distillation and vacuum distillation.
02	Preparation of acid/basic salts of drugs and evaluation of their physicochemicalproperties.(Any two)
03	Thin layer chromatography technique and purification of synthesized compounds bycolumnchromatography (Any two)
04	Synthesis & purification of following compounds using precipitation orrecrystallization.(Anysix) a. Benzimidazole b. 1, 2, 3, 4-tetrahydro carbazole c. 2,3-diphenyl Quinoxaline d. Bis-β-napthol e. Anthanilic acid f. Sulphanilamide g. Benzoic acid from benzyl alcohol h. Propranolol i. 1,4-dihydropyridine

Recommended Books

1. Wilson and Griswold's Textbook of Organic Medicinal and Pharmaceutical Chemistry,Lippincott Co. Philadelphia.
2. Foye's Principles of Medicinal Chemistry by Lemke, 6th edition, Lippincott William Wilkins.
3. Burger's Medicinal Chemistry by Wolff ME, John Wiley & Sons, New York.
4. Introduction to Medicinal Chemistry', How Drugs Act and Why by Alex Gringauz, Willey-VCH Publication 1997.
5. Comprehensive Medicinal Chemistry by Hansh C, Vol IV, Elsevier Pergamon.
6. An Introduction to Drug Design by SN Pandeya & IR Dimmock, 1st edition, New Age International Publishers.
7. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
8. Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II, 10th Edition, Nirali Prakashan.
9. Drug Design by Bothara KG & Kulkarni VM, 3rd edition, Nirali Prakashan.
10. Pharmaceutical Substances by Kleeman & Engel, 4th edition, Thieme Publications.
11. The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 by Lednicer Daniel, 1st edition, John Wiley & Sons INC.
12. Textbook of Practical Organic Chemistry, the ELBS Longman, London.
13. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language Book Society and Longman Group Limited, London.

14. Vogel' s A Text book of Practical Organic Chemistry by Vogel, 3rd edition, The English language book society and Longman group limited, London.
15. Advanced practical Medicinal Chemistry by Ashutosh Kar, 1st edition, New Age International Publications.
16. Vogel's Elementary Practical Organic Chemistry Small Scale Preparation by Arthur I., 2nd Edition, Part-I, CBS Publication.
17. Spectrometric identification of organic compounds by R. M. Silverstein, John Wiley and sons USA.
18. A Textbook of Pharmaceutical Chemistry by Chatten LG, Vol I & II, Marcel Dekker New York.
19. Analytical profiles of drug substances by Klaus Florey (All Volumes)

3.5.4 T PHARMACOLOGY- II
(3hrs/week), CREDIT: 03

Learning Objectives:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

Knowledge:

- The Neurotransmitters involved in the autonomic nervous system, there Synthesis and metabolism.
- Various adrenoreceptors and cholinoceptor, their subtypes and the clinical spectrum of their general and selective agonist and antagonist.
- The agents that stimulate or relax skeletal muscle, including the cholinergic neuromuscular agonists and antagonists as well as the neuromuscular agents acting at noncholinergic sites.
- The essential pharmacotherapy and pharmacological features of common and important drugs used in cardiovascular diseases and respiratory disorders.

Skills

- The guidelines for animal experimentations.
- Various routes of drug administration, methods for blood collection from experimental animals.
- Composition of physiological salt solutions and basic instruments used in experimental pharmacology.
- Performance of isolated experiments using various isolated preparation and the effects of different drugs on the concentration response curves.
- Study the action of various drugs using preclinical models/ computer simulations.
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Sr. No.	Name of the topic and contents	Hrs
	SECTION I	
Pharmacology of drug shall includes : classification, mechanism of action, pharmacological actions, pharmacokinetics, therapeutic uses, adverse effects, drug interactions, contraindications, dosages and treatment of poisoning (if any) etc. Discuss important drugs used in current clinical practices. Pharmacotherapy shall include: Rationale approaches and clinical management of diseases/ disorders		
01	**Autonomic Nervous system:** General Considerations: Sympathetic and Parasympathetic Nervous system with neurotransmitters and their receptors with Signal Transduction mechanisms	03
02	**Cholinergic system and drugs:** Biosynthesis, Storage, Release and Metabolism of Acetylcholine (ACh), Parasympathomimetics: Pharmacology of ACh and Anticholineesterases, Organophosphorus Poisoning and its treatment, Pharmacotherapy of Glaucoma and Myasthenia gravis.	06
03	**Anti-cholinergic drugs:** Pharmacology of Atropine and other antimuscarinic drugs, Antimuscarinic	03

	poisoning and its treatment.	
04	**Introduction to Ganglion Stimulating and Blocking agents**	01
05	**Pharmacology of Peripherally and centrally acting muscle relaxants**	02
06	**Adrenergic system and drugs:** Biosynthesis, Storage, Release, Metabolism of catecholamines, Pharmacology of Catecholamines and indirectly acting Sympathomimetics.	05
07	**Anti-adrenergic drugs:** Pharmacology of Adrenoceptor blocking agents, reversible, irreversible, non-selective and selective antagonists.	03
SECTION II		
08	**Diuretics and anti-diuretics**	03
09	**Pharmacotherapy of Cardiovascular disorders** Congestive heart failure, Hypertension, Angina including Myocardial infarction and ischemia, Atherosclerosis and Arrhythmia. Drugs used in treatment of Cardiovascular Shock.	16
10	**Drugs Used in Respiratory tract disorders:** Pharmacology of drugs used in Bronchial asthma, COPD and Cough.	03

Recommended Books:

1. Craig, CR and Stitzel BE. Modern Pharmacology, Little Brown and Co, Boston.
2. James Crossland. Lewis's Pharmacology Basis of Therapeutics, Pergamon Press, New York.
3. Goodman and Gilman. Pharmacological Basis of Therapeutics, McGraw-Hill.
4. Katzung, BG. Basic and Clinical Pharmacology, Lange Medical Publisher, USA.
5. Rang HP and Dale MM. Pharmacology, Churchill Livingston, UK.
6. Satoskar RS and Bhandarkar SD. Pharmacology and Pharmacotherapeutics. Popular Prakashan, Bombay.
7. Sharma HL and Sharma KK. General Pharmacology Basic Concepts. Paras Publication.
8. Tripathi KD. Essentials of Medical Pharmacology, Jaypee Publication.
9. Harrison's Principle and Practice of Medicine,18th Edition, Churchill, Livingston, London.
10. Roger and Walker. Clinical Pharmacy and Therapeutics, Churchill, Livingston, London.
11. Dipiro Joseph L. A pathphysiological Approach, Elsevier.
12. Davidson's Principle of Internal Medicine, Mc Graw-Hill companies.
13. Guyton AC. Textbook of Medical Physiology. W. B. Saunders Co., Philadelphia, USA.

3.5.4 P PHARMACOLOGY- II
(3 hrs / week), CREDIT 02

Sr.No	Title of Experiment
01	Care and handling of common laboratory animals, introduction of CPCSEA guidelines.
02	Introduction to animal physiology with their biochemical reference values in various animal species.
03	Study of various routes of drug administration in animals.
04	Study of various anesthetics employed to anesthetized laboratory animals.
05	Introduction to the various techniques of Euthanasia.
06	Study of various methods for collection of blood, body fluids and urine from experimental animals.
07	Introduction to commonly used instruments in experimental pharmacology.
08	Study of physiological salt solutions, drug solution and use of molar solution in various animal experiments.
09	To record Concentration Response Curves (CRC) of ACh/Histamine using suitable isolated tissue preparation.
10	To record Concentration Response Curves (CRC) of ACh/Histamine using suitable isolated tissue preparation.
11	To record the effect of Physostigmine on Concentration Response Curves (CRC) of Acetylcholine using suitable isolated tissue preparations (Synergism).
12	To record the effect of Atropine on Concentration Response Curves (CRC) of Acetylcholine using suitable isolated tissue preparations (Antagonism).
13	To study the effect of various drugs on heart rate. (Using suitable computerized simulated software programme (demonstration).
14	To study the effect of various drugs on blood pressure in heart. (Using suitable computerized simulated software programme/ demonstration).
15	To study the effect of various drugs on rabbit eye. (Using suitable computerized simulated software programme/ demonstration).

Recommended Books:

1. Ghosh MN. Fundamental of Experimental Pharmacology, Hilton & Company, Calcutta.
2. Kulkarni SK. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
3. Burn JH. Practical Pharmacology Blackwell Scientific, Oxford London.
4. Jaju BP. Pharmacology: A Practice Exercise Book, Jaypee Brothers, New Delhi.
5. Sheth UK, Dadkar NK and Kamat UG. Selected topics in experimental pharmacology.
6. Chatterjee CC. Human Physiology. Medical Allied Agency, Kolkata.
7. Ganong WF. Review of Medical Physiology. Prentice-Hall International, London.
8. Perry WLM. Pharmacological Experiments on Isolated Preparation, E&S Livingstone, London.
9. Goyal RK. Practicals in Pharmacology, B. S. Shah Prakashan, Ahemadabad.

3.5.5 T ANALYTICAL PHARMACOGNOSY & EXTRACTION TECHNOLOGY (3hrs/week), CREDIT: 03

Learning objectives:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

Knowledge:

- Comprehend & explain underlying principle of mass transfer process in extraction, effectof various factors, specific care in herbal material, & various approaches in extractionprocesses with their theoretical consideration, methodological steps, & applications.
- Understand & explain principle & applications of chromatographic& nonchromatographic separation methods.
- Explain source material & extraction methods of phytochemicals specified; drawschematic representation of such processes;
- Explain need of analysis of natural products & explain their significance; Understand &explain various parameters with their principles, significance & applications.

Skill:

- Explain & demonstrate correct handling of inflammable solvents & corrosive chemicals.
- Generate micrometric data & identify the crude drugs.
- Conduct successive extraction & qualitative tests to ascertain chemical nature of crude drugs.
- Apply theoretical knowledge obtained for extraction of phytochemicals, set extraction assembly,process material before extraction; explain significance of use of various chemicals/solvents/ conditions; undertake extraction, verify extracted material by qualitative tests & report yield.
- Apply theoretical knowledge of various quality control parameters studied in theory, explain significance of use of various chemicals/solvents/conditions; undertake variousestimations /determinations; infer from results obtained & report evaluation results.
- Able to handle various equipments as per SOPs & learn various demonstrations (of experiments).
- Understand meaning & significance of 'Good Laboratory Practices' learn in theory &demonstrate through laboratory behavior.
- Listen carefully, raise logical query, draw information, understand rationale during fieldvisits & prepare brief report for evaluation.

Sr.No.	Topic	Hours
	SECTION-II	
01	**Extraction & separation techniques**: a. Extraction techniques: Fundamentals of mass transfer process; principle,working, merits, demerits & applications of maceration, decoction, infusion,percolation, Soxhlet extraction, Counter current extraction, Supercritical fluidextraction, Solid phase extraction, Microwave-assisted extraction, Ultrasoundextraction (Sonication).	15

	b. Non-chromatographic separation techniques: Fractional distillation,fractional liberation, sublimation, chemical derivatization, fractionalcrystallization, centrifugation, Froth-floatation technique. c. Chromatographic separation techniques: Principle and applications offollowing for the plant derived products: Paper Chromatography, TLC,HPLC, HPTLC & Column chromatography.	
02	**Application of extraction techniques:** Source, properties, isolation & testsof following phytochemicals : a. Direct solvent extraction of strychnine, atropine, reserpine, piperine,taxol,sennosides, digoxin, diosgenin, andrographolides, artemisinin, boswellicacid,podophyllotoxin, curcumin, citral, eugenol& menthol. b. Extraction by steam distillation: Peppermint oil c. Extraction by enfleurage method: Rose oil d. Extraction by supercritical fluids: Caffeine, resveratrol, pyrethrins, Lycopenes. e. Ultrasound-assisted extraction: Isoflavones of soy 1. f. Microwave-assisted water extraction: Polyphenols of green tea	10
SECTION-II		
03	**Herbal drug analysis:** a. Analysis: Types & need; meaning of identity, purity, potency & safety; b. Socialrelevance of natural product analysis; difficulties in analysis of naturalproducts;proximate phytochemical analysis: meaning, significance & method;adulteration:definition & types of adulteration. c. Sampling techniques: Principle & procedure of sampling d. Quality control (efficacy) parameters of herbal drugs: Principle, procedure&significance involved in determination of foreign matters, ash values,extractablematters, moisture content, volatile matters, volatile oil, bitternessvalue, haemolyticactivity, tannin content, swelling index, foaming index (as per WHO). e. Quality control (safety) parameters of herbal drugs: Principle, procedure&significance involved in determination of pesticide residues, arsenic andtoxicmetals, microorganisms, aflatoxins, radioactive contamination. f. Overview of 'Good practices for pharmaceutical quality control g. laboratories' (as perWHO). h. Current approaches in standardization – Biology approaches and DNA fingerprinting.	20

Recommended Books:

1. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders,2002.16th Ed. ISBN-10: 0702029335.
2. Handa SS., SumanPreet Singh Khanuja, Gennaro Longo, Dev Dutt Rakesh,Extractiontechnologies for medicinal & aromatic plants, International centrefor science and hightechnology, Trieste, Italy, 2008.

3. Hans-Jörg Bart & Stephan Pilz, Industrial Scale Natural Products Extraction,Wiley-VCH Verlag& Co., Germany, 2011. ISBN: 978-3-527-32504-7.
4. Jean Bruneton, Caroline K. Hatton, Pharmacognosy, phytochemistry, Medicinalplants. Lavoisier, 1999.ISBN 1898298637.
5. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, Nirali Prakashan, Pune, 2008, ISBN: 8185790094.
6. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons, 2002. ISBN 8190078844.
7. Otto Sticher, Natural product isolation. Natural Product Reporter, 25, 517–554, 2008.
8. Quality control methods for medicinal plant materials, World Health Organization,Geneva, 1998. ISBN 9241545100.
9. Rangari V.D., Pharmacognosy & Phytochemistry (Vol I), Career Pub., Nashik,2009,ISBN: 978-81-88739-45-5.
10. Rangari V.D., Pharmacognosy & Phytochemistry (Vol II), Career Pub., Nashik,2009,ISBN: 978-81-88739-65-3.
11. Satyajit D. Sarker, Zahid Latif, Alexander I. Gray, Natural Products Isolation,2nd Ed.,Humana Press Inc. Totowa, New Jersey; 2006. ISBN 1-59259-955-9.
12. Wallis T. E., Textbook of Pharmacognosy. CBS Publisher &Distributors, 1985.ISBN:81-239-0886-5.

3.5.5P ANALYTICAL PHARMACOGNOSY & EXTRACTION TECHNOLOGY (3 hrs / week), CREDIT 02

Sr.No	Title of Experiment
01	Generation of micrometric data: Leaf constants, Length & width of fibers, diameter of starch grains (Min 3 Exp.)
02	Proximate chemical analysis: Successive extraction followed by qualitative chemical analysis of extracts (Min 1 Exp.)
03	Solvent extractions: strychnine from Nux vomica; piperine from Black pepper;diosgeninfromDioscorea tubers; confirmation of extracted material byqualitative tests or TLC.(Min 2 Exp.)
04	Determination of Ash values, moisture content, extractive values, swelling index,foaming index, crude fiber content (Min 5 Exp.)
05	Determination of total phenolic content/ total flavanoids content/ total tannincontent (Min2 Exp.)
06	Detection of adulterants in crude drugs /Adultration in fixed oils (Min 2 Exp.)
07	Microwave extraction (Demonstration)
08	Isolation of phytoconstituents by column chromatography (Demonstration)
09	Field visit: Visit to industry/ cultivation farm/ processing unit & submission ofreport thereof.

Recommended Books:

1. Jeffrey B. Harborne. Phytochemical Methods: A Guide to Modern TechniquesofPlant Analysis. Springer, 1998.ISBN 0412572702, 9780412572708.
2. Kokate C. K., Practical Pharmacognosy, VallabhPrakashan, 1993.
3. Quality control methods for medicinal plant materials, World HealthOrganization,Geneva, 1998. ISBN 9241545100.
4. Wallis T. E., Practical Pharmacognosy. J.A. Churchill Ltd., London, 1953.

3.5.6 T PHARMACEUTICAL BUSINESS MANAGEMENT & DISASTER MANAGEMENT (3hrs/week), CREDIT: 03

Learning Objective:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

Knowledge:

- To learn the Pharmaceutical business and management strategy.
- To gain knowledge of marketing research, product management.
- To learn about human resource and development needs.
- To learn about the disaster management and preparedness ,mitigation

Sr. No	Topic	Hrs.
	SECTION-I	
01	**Fundamentals of management:** Management basic concepts: definition, need for management, function of management. Management thoughts, contribution of Taylor, Fayol, Peter Drucker in modern management. Functions and responsibilities of a manager	02
02	**Planning:** Nature and purpose of planning, important steps in planning, types of planning, planning process, advantages and limitations.	03
03	**Objectives:** Types of objectives, importance of objective, management by objectives, advantages and limitations.	02
04	**Organizing:** Organizational structure, basic principles of organization, departmentalization, delegation, decentralization, staffing, line& staff organization with respect to production and QC/QA department.	02
05	**Decision making:** Types of decision, Definition and Importance of decision making, Decision making process(explain giving example from pharma industry.	02
06	**Controlling:** Concepts and purpose of control techniques, budgetary and non-budgetary control, management audit, management information system, break even analysis, network techniques (PERT & CPM), profit includingnumerical problem	04
07	**Material management:** Classification of materials, objectives and principles of purchasing, inventory control.	03
08	**Drug store and Hospital management:** Introduction to drug store, Introduction to Hospital, role of drug store and hospitals related to patient care management.	02
09	**Pharmaceutical Marketing:** Difference between marketing and selling, channels of distribution, wholesale, retail, departmental.	03
	SECTION-II	

10	**Sales promotions:** objective, principles & techniques. Ethics of sales, Advertising- needs & methods, Merchandising, Detailing. Medical representative: Role & Qualities.	04
11	**Marketing research:** Nature & importance. Sales forecasting methods, analysis, advantages and limitations.	02
12	**Product management:** Product life cycle(explain with case study), launching a new product, EICS.	03
13	**Price:** definition, factors affecting, procedure for determination of price, types of price.	03
14	**Human Resource Management.** **a. Motivation:** definition, & concept. Theories- Maslow's theory, Hertzberg's theory, Vroom's theory, expectancy theory, reinforcement **theory, equity or Social comparison theory X & Y.** **b. Leadership:** definition, importance, qualities of leadership, leadership styles, trait theory, managerial grid**.** c. **Communication:** importance, functions, communication process, forms of communication, types of communication. **d. Interview techniques: -** presentation skills- group discussion. **e. Performance appraisal:** need and techniques, recruitment and training	07
15	**Introduction to Disaster Management:** Meaning, nature, characteristics Types of disasters: Causes and effects of following type of disaster. Preparedness and Mitigation: Concept & nature, disaster preparedness plan**.** **Disaster preparedness for people and infrastructure, Community based disaster preparedness plan.** **Disaster Mitigation: meaning and concept, disaster mitigation strategies. The Disaster Management cycle.**	03

Recommended Books:

1. Peter Drucker; The Practice of management, Harper and Row, New York,1954.
2. Harold Koontz, Cyril O'Donnell& Heinz Weihrich; Management, 7th edition,1980.
3. Tripathi PC. & P.N. Reddy; Principals of Management, Tata McGraw Hill publishing Co/ Ltd, 2nd edition, NewDelhi.
4. Koontz H. &Weihrich H.; Essentials of Management, Tata McGraw Hill publishing Co/ Ltd, 5th edition, New Delhi,1998.
5. Satya Saran Chatterjee; An Introduction to Management, The world Press Pvt. Ltd, 12th Edition, Calcutta, 1998.
6. Vidyasagar G.; Pharmaceutical Industrial Management, Pharma book Syndicate, Hyderabad,2005.
7. Philip Kotler& Gary Armstrong; Principles of Marketing, Pearson Education Pvt. Ltd., 10th Edition, Singapore,2005.
8. Mickey Smith; Principles of Pharmaceutical Marketing, CBS Publisher &Distributors, 3rd Edition, New Delhi,2001.
9. J.C. Gandhi; Marketing A Managerial Introduction, Tata McGraw Hill publishing Co/ Ltd, 8th Edition New Delhi,1995.
10. Mickey Smith; Pharmaceutical Marketing in the 21th Century, Viva Books Pvt. Ltd., New Delhi,2001.

11. Horngren, Sundem& Stratton; Introduction to Management Accounting, Prentice Hall of India Pvt. Ltd., 11th Edition, New Delhi,2000.
12. Cost Accounting & Management Accounting: Everest Publication, NewDelhi.
13. Principles and Methods of Pharmacy Management by HarrySmith.
14. Marketing Management by PhilipKotlar.
15. Marketing in New Millennium by Dr. M. J. Xavier,1998.
16. Principles and Management: Koonz O'Donnel.
17. Bryant Edwards (2005): Natural Hazards, Cambridge University Press,U.K.
18. Roy, P.S. (2000): Space Technology for Disaster management: A Remote Sensing & GIS Perspective, Indian Institute of Remote Sensing (NRSA)Dehradun.
19. Sharma, R.K. & Sharma, G. (2005) (ed) Natural Disaster, APH Publishing Corporation, NewDelhi.
20. S.M.ZHA Hospital management, Himalaya Publication House, 2011
21. Mehta RM., Drug Store and Business Management,Vallabh, prakashan,2005

3.5.7T ACTIVE PHARMACEUTICAL INGREDIENTS TECHNOLOGY (3hrs/week), CREDIT: 03

Learning objectives:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

Knowledge:

- Explain basics chemical process kinetics with respect to various classes of reactions.
- Explain chemical process, reaction system, equipment used in API manufacturing and layout design.
- Explain design of synthetic routes, optimization of reactions, raw material and reagents selection; scale up techniques, quality control aspects, Material Safety Data Sheet (MSDS), environmental aspects, green chemistry approaches, health hazards of chemical handling and manufacturing process flow charts of some important APIs.
- Explain manufacturing techniques of some chiral APIs and polymorphism in APIs
- Practice Quality Assurance (QA), Quality Control (QC) and follow GMP in API manufacturing including ICH Q7, Q7A and Q11 while working in API industry.

Sr. No	Topic	Hrs
	SECTION-I	
01	Overview of API, API intermediates and fine chemicals industry.	02
02	**Unit Processes in Synthesis:** Nitration Amination by reduction, Esterification, Hydrolysis, Oxidation, Alkylation, Sulfonation along with examples related to APIs for each unit process	10
03	Factors affecting chemical processes, reaction system, general list of equipment used in API manufacturing, layout of process equipment.	02
04	**Industrial processes & scale up techniques:** Industrial manufacturing methods and flow charts of APIs like: Ranitidine, Atenolol, Amlodipine, Metformin, Amoxicillin trihydrate and Diosgenin. Overview of biochemical process in API technology	08
	SECTION-II	
05	**Optimization of Organic Reactions and Processes:** Introduction, the purpose of chemical development, approaches for selection of most appropriate synthetic and scale up routes, choice of raw materials, reagents etc., effect of process variables on yield and quality of products, quality control, in process analysis as an aid to optimization, work up & product isolation, planning for scale up, design of environment friendly processes, effluent minimization and control, types of health hazards in API manufacturing unit and their prevention using green chemistry approaches. Basic knowledge about Material Safety Data Sheet (MSDS) for safety and handling of chemicals without health hazards.	14
06	**Chirality in API Industry:** Resolution of racemate, Asymmetric synthesis, few case studies like (S)-Propranolol, (S)-Metoprolol	03

07	Polymorphism in APIs	02
08	**APIs:** Brief overview of QA/QC GMP Guidelines in API manufacturing (ICH Q7, Q7A and Q11)	04

Recommended Books:

1. Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up , Peter J. Harrington ,John Wiley and Sons Inc. Publication 2011
2. Strategies for Organic Drug Synthesis and Design by Daniel Lednicer, 2nd Edition, John Wiley and Sons Inc. Publication, 2008
3. Process Chemistry in Pharmaceutical Industry , Kumar Gadamasetti, Vol I & II, CRC Press; First edition, 2007.
4. Practical Process Research and Development , Neal G. Anderson, Academic Press., 2000
5. Principles of Process Research and Chemical Development in the Pharmaceutical Industry by O. Repic, John Wiley &Sons.Inc Publication New York, NY, 1998.
6. in Organic Synthesis, Groggins P. H, (Third Edition). *P. H. Groggins*. McGraw-Hill, New York, 1947.
7. Fire Safety Management by SatishTandon, Arise Publishers & Distributors; 1st edition, 2008.
8. Pollution Prevention of Chemical Processes, Allen David, Wiley-Blackwell, 1996.
9. The Treatment and Handling of Wastes, Bradshaw, A.D. Chapman and Hall for the Royal Society; First Edition, 1992.
10. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by Sharp John, CRC Press; 1st edition , 2004
11. Management Information Systems by Laudon Kenneth C. Prentice Hall; 12th Edition, 2011.
12. Plant Design and Economics for Chemical Engineers by Peters, Max S., McGraw-Hill Science/Engineering/Math; 5th Edition, 2002.
13. ICH Guidelines.

THIRD YEAR B.PHARMACY **SEMESTER –VI**

3.6.1T INDUSTRIAL PARMACY -II
(3hrs/week), CREDIT: 03

Learning Objective:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

Knowledge:

- Explain disperse systems, its classification, theories of dispersesystems, thermodynamic v/s kinetic stability considerations.
- Explain suspensions, types, formulation development, manufacturing, excipients used, evaluation of suspensionsetc.
- Describe emulsions, their physico-chemical properties, theory of emulsification, HLB value & phase inversion temperature, Kraft point, cloud point, excipients, formulation & evaluation of emulsions; cracking, coalescence, stability & stresstesting.
- Explain semi-solids, anatomy & physiology of skin, selection of bases; penetration enhancers, formulation development, Percutaneous absorption, flux measurement & evaluation.
- Describe layout for manufacturing of suspensions, emulsions & semi-solis asper schedule M.

Skills:

- State the correct use of various equipments in Pharmaceutics laboratoryrelevant to suspensions, emulsions & semi-solids, prepareBMR.
- Explain & carry out formulation of Suspensions like Calamine lotion, Milk of Magnesia, Paracetamol Suspension, Antacid Suspension & carry outEvaluation.
- Formulate emulsions: Liquid paraffin oral Emulsion, Turpentine Liniment, Formulation of Emulsion with HLB Consideration &evaluation.
- Describe use of ingredients in formulation and category of formulation.
- Prepare semisolids: Pain balm, Antifungal ointment/cream, Medicated Gel, Antiacne preparation, Non staining Iodine ointment with Methyl Salicylate & evaluation.
- Prepare the labels so as to suit the regulatory requirements.

Sr.No.	Topic	Hrs
	SECTION-I	
01	**Disperse systems:** Classification of disperse system, Free energy consideration, thermodynamic v/s kinetic stability. DLVO theory.	03

02	**Suspensions:** a. Flocculated & Deflocculated system. Stokes law. b. Excipients used in suspensions:suspending agents, wetting agents, dispersants, deflocculating &flocculating agents Structured vehicle, Preservatives, color, flavor. a. Formulation of suspensions: Low solid content, high solid content, antacid suspension, suspensions for reconstitution. a. Evaluation of suspensions: Rheology, Particle size, volume of sedimentation and degree of sedimentation, particle charges & caking in suspensions. , importance of changes in solubility because of changes in particle size polymorphic form temperature Storage, packaging & Labeling of suspensions.	04 03 03
03	**Emulsions:** a. Physicochemical principles, theory of emulsification energy barriers to coalescence. Film barriers, steric stabilization. Stability of emulsions: Creaming, coalescence, cracking, HLB value & phase inversion temperature. b. Excipients used in emulsions: Emulsifier & choice of emulsifier, vehicles, preservatives, antioxidants, color, flavour. c. Formulation of emulsions, Introduction to Multiple emulsions, microemulsions. Emulsion stability, stress testing. Evaluation: Phase separation, pH, globule size, viscosity, redisperibility.	04 03 03
	SECTION-II	
04	**Semisolid dosage forms** a. Anatomy and physiology of skin (Introduction), Types of semisolid dosage forms: ointment, cream, paste and gel. b. Semisolid bases and additives, Selection criteria of bases, special reference to penetration enhancers. Percutaneous absorption: Selection criteria of drug for semisolid dosage form, Flux and its measurement, factors affecting: drugs Properties, vehicle related and patient related. c. Evaluation parameters: globule size, pH, spreadability, permeation, drug release, viscosity, drug content, extrudability, skin irritation test (Draize Test and HET Cam test).	03 06 04
05	**Manufacturing equipments:** suspension, emulsion and semisolids. Layout and designing of manufacturing facility for suspension, emulsion and semisolids as per schedule M.	06
06	Concept of Scale up & technology transfer for dispersed system.	03

3.6.1 P INDUSTRIAL PHARMACY-II
(3hrs/week) CREDIT-02

Sr.No	Title of Experiment
Formulation, Preparation, Evaluation &labeling of the following dosage forms. (Preparation of BMR)	
01	**Suspensions:**Calamine lotion • Milk of Magnesia • Paracetamol Suspension • Antacid Suspension Evaluation Parameters: Sedimentation volume, Organoleptic Properties, pH, Viscosity, Acid neutralizing capacity, Rosset Rice test, pH stat test and assay of any one preparation
02	**Emulsions:**Liquid paraffin oral Emulsion • Turpentine Liniment • Formulation of Emulsion (HLB Consideration) Evaluation Parameters: Organoleptic Properties, pH, Globule size, density, and assay of any one preparation type ofemulsion
03	**Semisolids:**Pain balm • Antifungal ointment/cream • Medicated Gel • Antiacne preparation • Non staining Iodine ointment with Methyl Salicylate Evaluation Parameters: pH, Spreadability, Organoleptic properties and assay of any one preparation.
04	To conduct a survey of any one drug, its different dispersed/semisolid dosage forms available in market and submit its report highlighting the rational /logic behind designing of different dosage forms of same drug.
05	To study different packaging and its labeling materials of semisolid dosage forms.

Recommended Books

1. Indian Pharmacopoeia2014.
2. United States Pharmacopoeia2014.
3. Theory and Practice of Industrial Pharmacy. Edition Lachmann, Libermann, Kanig, Edition
4. Modern Pharmaceutics, Banker and Rhodes, MarcelDekker.
5. M E Aulton, K Taylor, Pharmaceutics: The Science of Dosage Form Design, 2nd edition,2001
6. Ansel's Introduction to Pharmaceutical dosage forms & Drug Delivery Systems
7. 9th edition, 2nd Indian reprint, 2011.
8. Remington: The Science and Practice of Pharmacy, Volumes 1-2, 22nd edition, 2012
9. De Silva O, Rougier A, Dossou KG. 1992. The HET-CAM test: a study of the irritation potential of chemicals and formulations. Altern Lab Anim 20:432-437.

3.6.2 TPHARMACEUTICAL ANALYSIS -IV
(3hrs/week), CREDIT: 03

Learning objectives:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

A. Knowledge:

- Explain principles, instrumentation and applications of various chromatographic, thermal, X ray,Diffraction and radio chemical techniques employed for the analysis of APIs and formulations.
- Validate various analytical instruments & methods as per ICH/USP guidelines.

B. Skills:

- Independently operate and calibrate various analytical instruments for the assay of various APIs andformulations as per Pharmacopoeial standards.
- Independently process, interpret the data obtained through experimentation and report the results as per regulatory requirements.
- Independently validate UV-VIS Spectrophotometric assay method as per ICH guidelines.
- Take appropriate safety measures while handling instruments, chemicals and apparatus.

Sr. No.	Topics	Hrs
The following topics 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		
	SECTION-I	
01	**Introduction to chromatography techniques**: Introduction, Basic theory,Types, Column Chromatography, theory(rate & plate) Principle, Columnpacking techniques, Van Deemter Equation in detail, Efficiency of column,Capacity factor and other system suitability parameters, application.	07
02	**a. Introduction to Planar Chromatography**: Introduction, Brief history, Classification, preparative TLC, Solvents selection for planer chromatography,HPTLC & Paper Chromatography **b. Paper Chromatography**: Techniques, Development, Different types of chromatographic papers, applications. **c. Thin Layer Chromatography:** Principle, Adsorbents, Activity ofAdsorbents, methods of TLC plate preparation, Development of TLC and its evaluation, applications. **d. High Performance Thin Layer Chromatography (HPTLC):** Theory,Instrumentation, types of HPTLC plates, types of development chambers and development techniques, HPTLC scanning and evaluation, Automated Multiple Development, Horizontal TLC and applications.	09
03	**Electrophoresis**: Principles,Classification, Instrumentation, Various types of Developments, Applications.	04
	SECTION-II	
04	**Thermal Methods of Analysis**	10

	a. Differential Scanning Calorimetry (DSC) Definition, Types,Instrumentation, Principle, applications. b. Thermogravimetric Analysis (TGA): Introduction, Definition, Types,Instrumentation, Principle, applications. c. Differential Thermal Analysis (DTA): Introduction, Definition,Principle, Instrumentation, applications.	
05	**X- Ray Diffraction**-Introduction, Instrumentation, Pharmaceuticalapplications, different crystalfaces, Polymorphism.	05
06	**Radiochemical Methods**-Nuclear reactions and radiations, Neutron sources, Measurement of radioactivity, tagging of compounds, Pharmaceutical Applications.	05
07	**Validation** - Analytical Methods Validation as per ICH & USP guidelines.	05

3.6.2 P PHARMACEUTICAL ANALYSIS -IV
(3 hrs / week) CREDIT 02

Sr.No	Title of Experiment
01	Separation & determination of Rf values of mixture of amino acids by Ascending, Radial and two dimensional Paper chromatography (Min. 3)
02	Separation & determination of Rf values of mixture of carbohydrates/amino acids by TLC (Min. 3)
03	To perform calibration of UV-VIS Spectrophotometer.
04	Validation of UV-Spectrophotometric assay methods as per ICH guidelines (Any two validation parameters) (Min. 2)
05	Column chromatographic separation techniques (Min. 2)
06	Interpretation of XRD spectrum. (Min. 2)
07	Demonstration experiments: HPTLC/DSC/Electrophoresis (Any 1)

Recommended books

1. Indian Pharmacopoeia, 2014, Indian Pharmacopoeia Commission, Govt. of India
2. British Pharmacopoeia, 2016, British Pharmacopeia Secretariat, London, UK
3. United States Pharmacopeia, 2016, US Pharmacopoeial Convention. USA
4. Vogel's Text Book of Quantitative Chemical Analysis, 6/Ed., Pearson Education.
5. Fundamentals of Analytical Chemistry by Skoog, West, Holler, Harvest, 8/Ed., Thomson Brookslcole.
6. Pharmaceutical Analysis by Higuchi, Reprint 2004, CBS Publisher & Distributors.
7. The quantitative analysis of drugs by Garrat DC, 3/Ed., CBS Publisher & Distributors.
8. Practical Pharmaceutical Chemistry Part-I & II by Beckett A H & Stanlake J B, 4/Ed., CBS Publisher & Distributors.
9. Handbook of Instrumental Techniques for Analytical Chemistry by Frank Settle, First Indian Reprint 2004, Pearson Education
10. Instrumental Methods of Analysis by Willard Merit, Dean Settle, 7th edition, CBS Publisher & Distributor
11. Instrumental Methods of Chemical Analysis by BK Sharma, Goel Publishing House.
12. Instrumental Methods of Chemical Analysis by GW Ewing, McGraw-Hill Book Company
13. A Practical Approach to Pharmaceutical Analysis(Instrumental & Manual), Rajesh kumar Nema, Mahesh Verma, CBS Publishers & Distributors

3.6.3 T MEDICINAL CHEMISTRY-II
(3hrs/week), CREDIT: 03

Learning Objectives:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

A. Knowledge:

- Know general aspects of drug metabolism, the drug design aspects on the basis of drug metabolism and metabolism of therapeutically important drugs. Know the general aspects of design of the drugs, history, classification, nomenclature, structure activity relationship (SAR), mechanism of action, therapeutic uses, adverse effects and recent developments in the CNS active drugs and drugs acting on blood.

B. Skills:

- Make correct use of various equipments and take safety measures while working in Medicinal Chemistry Laboratory.
- Synthesize medicinally important compounds and purify them using recrystallization techniques.
- Synthesize medicinally important compounds by microwave assisted synthesis.
- Characterize the synthesized compounds using IR and NMR spectra's.
- Purify the solvents using fractional and vacuum distillation.
- Explain reaction mechanisms involved in synthesis of medicinally important compounds.

Sr. No.	Topic	Hrs.
	SECTION-I	
01	**Drug Metabolism**: Study of drug metabolizing enzymes, phase I & phase II reactions with examples of following drugs, Diazepam, Tolbutamide, Metformin, Procaine, thiopentone, Caffeine, carbamazepine, Chlorpromazine, Sodium valproate. Applications of drug metabolism studies in new drug discovery	08
02	History and general aspects of the design & development of drugs including classification, nomenclature, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses and recent developments of following categories and scheme of synthesis of drugs mentioned in bracket.	
2.1	**CNS Active Drugs** 2.1.1. Local anesthetics 2.1.2 General anesthetics 2.1.3 Sedative & Hypnotics 2.1.4 Anticonvulsants (Procaine, Mepivacaine Thiopental sodium, Diazepam, Phenytoin, Sodium valproate)	 04 03 04 04
	SECTION-II	
2.2	**CNS Active Drugs** 2.2.1 Anxiolytics 2.2.2 Antidepressants 2.2.3 Antipsychotics 2.2.4 Parkinson' s disease 2.2.5 Alzheimer' s disease	04 04 04 02 02 02

	2.2.6 CNS Stimulants (Amitryptiline, Chlorpromazine, Haloperidol, Fluoxetine, Amantadine, Caffeine, Phentermine)	
2.3	**Drugs acting on blood:** Coagulants and anti-coagulants(Warfarin)	04

3.6.3 P MEDICINAL CHEMISTRY-II
(3 hrs / week) CREDIT 02

Sr.No	Title of Experiment
01	Demonstration on Steam distillation.
02	Dean stark azeotropic water separation.
03	Synthesis & purification of following compounds using precipitation or recrystallization. (Any 6) a. Phenytoin from benzoin b. Benzocaine from PABA c. Isonicotinic acid from picoline d. Barbituric acid from diethyl malonate e. Phenothiazine f. Ethyl Nicotinate g. Hippuric acid h. *m*-Nitro-phenol i. Fluorescein.
04	Microwave assisted synthesis (Any 2)
05	Recording & interpretation of IR spectrum of synthesized compounds (Any 2)

Recommended Books

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Co. Philadelphia.
2. Foye's Principles of Medicinal Chemistry by Lemke, 6th edition, Lippincott William Wilkins.
3. Burger' s Medicinal Chemistry by Wolff ME, John Wiley & Sons, New York.
4. Introduction to Medicinal Chemistry', How Drugs Act and Why by Alex Gringauz, Willey-VCH Publication 1997.
5. Comprehensive Medicinal Chemistry by Hansh C, Vol IV, Elsevier Pergamon.
6. An Introduction to Drug Design by SN Pandeya & IR Dimmock, 1st edition, New Age International Publishers.
7. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
8. Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II, 10th Edition, Nirali Prakashan.
9. Drug Design by Bothara KG & Kulkarni VM, 3rd edition, Nirali Prakashan.
10. Pharmaceutical Substances by Kleeman & Engel, 4th edition, Thieme Publications.
11. The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 by Lednicer Daniel, 1st edition, John Wiley & Sons INC..
12. Textbook of Practical Organic Chemistry, The ELBS Longman, London.
13. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language Book Society and Longman Group Limited, London.

14. Vogel' s A Text book of Practical Organic Chemistry by Vogel, 3rd edition, The English language book society and Longman group limited, London.
15. Advanced practical Medicinal Chemistry by Ashutosh Kar, 1st edition, New Age International Publications.
16. Vogel's Elementary Practical Organic Chemistry Small Scale Preparation by Arthur I., 2nd Edition, Part-I, CBS Publication.
17. Spectrometric identification of organic compounds by R. M. Silverstein, John Wiley and sons USA.
18. A Textbook of Pharmaceutical Chemistry by Chatten LG, Vol I & II, Marcel Dekker New York.
19. Analytical profiles of drug substances by Klaus Florey (All Volumes)

3.6.4 T PHARMACOLOGY- III
(3hrs/week), CREDIT: 03

Learning Objectives:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

A. Knowledge:

- The pharmacology and pharmacotherapy of various general and local anesthetics.
- The appropriate drug therapy and management of patients with specific CNS disorders.
- The indications, mechanism of action, adverse effects and contraindications for the major classes of drugs used in the treatment of Parkinson's Disease, Migraine and Alzheimer's disease.
- Pharmacological features of different classes of NSAIDs.
- The essential pharmacotherapyof Rheumatoid Arthritis, Osteoarthritis and Gout.

Skills:

- The basic principles of bioassay, types of bioassay along with advantages and disadvantages.
- Performance of isolated experiments using various isolated preparation and the effect of different drugs on the concentration response curves.
- Study the preclinical screening of various drugs.

Sr. No.	Topic	Hrs.
	Pharmacology of drug shall includes : classification, mechanism of action, pharmacological actions, pharmacokinetics, therapeutic uses, adverse effects, drug interactions, contraindications, dosages and treatment of poisoning (if any) etc. Discuss important drugs used in current clinical practices. Pharmacotherapy shall include: Rationale approaches and clinical management of diseases/ disorders	
	SECTION I	
01	**General Anesthesia:** Stages and Principles of Anesthesia, Pharmacology of Intravenous and Inhalation Anesthetics.	03
02	**Local Anesthetics:** Pharmacology of injectable and surface anesthetics, Clinical Uses and techniques of administration of local anesthetics.	02
03	**Alcohols and alcoholism:** Pharmacology of Alcohol and management of alcoholism. Treatment for alcoholic liver diseases.	03
04	**Psychopharmacological drugs:** Sedative, Hypnotics, anti-anxiety, Antidepressant, Antipsychotic drugs.	10

05	**Antiepileptic Drugs:** Classification of epileptic Seizure, Pharmacology of drugs used in the treatment of epilepsy.	04
SECTION II		
06	**Pharmacotherapy of Parkinson's disease, Alzheimer's disease and Migraine**	04
07	**Opioid Analgesics and antagonist:** Classification and Pharmacology of Opioid analgesics (Morphine), Opioid Antagonists.	04
08	**Pharmacology of Non-steroidal anti-inflammatory drugs**	03
09	**Pharmacotherapy of Rheumatoid Arthritis, Osteoarthritis and Gout**	03
10	**Drugs Used in Gastrointestinal tract disorders:** **i)** Pharmacology of drugs used in the treatment of peptic ulcer and its pharmacotherapy. **ii)** Pharmacology of Emetics and Anti-Emetics **iii)** Pharmacotherapy of Constipation and Diarrhea.	09

Recommended Books:

1. Craig, CR and Stitzel BE. Modern Pharmacology, Little Brown and Co, Boston.
2. James Crossland. Lewis's Pharmacology Basis of Therapeutics, Pergamon Press, New York.
3. Goodman and Gilman. Pharmacological Basis of Therapeutics, McGraw-Hill.
4. Katzung, BG. Basic and Clinical Pharmacology, Lange Medical Publisher, USA.
5. Rang HP and Dale MM. Pharmacology, Churchill Livingston, UK.
6. Satoskar RS and Bhandarkar SD. Pharmacology and Pharmacotherapeutics. Popular Prakashan, Bombay.
7. Sharma HL and Sharma KK. General Pharmacology Basic Concepts. Paras Publication.
8. Tripathi KD. Essentials of Medical Pharmacology, Jaypee Publication.
9. Harrison's Principle and Practice of Medicine,18th Edition, Churchill, Livingston, .London.
10. Roger and Walker. Clinical Pharmacy and Therapeutics, Churchill, Livingston, London.
11. Dipiro Joseph L. A pathphysiological Approach, Elsevier.
12. Davidson's Principle of Internal Medicine, Mc Graw-Hill companies.
13. Guyton AC. Textbook of Medical Physiology. W. B. Saunders Co., Philadelphia, USA.

3.6.4 P PHARMACOLOGY- III
(3hrs/week) CREDIT 02

Sr.No	Title of Experiment
01	Introduction to OECD guidelines (425) for Acute oral toxicity.
02	Introduction to principles of bioassay, its types including advantages and disadvantages.
03	Determination of unknown concentration of Acetylcholine/ Histamine using suitable isolated tissue preparations by Matching bioassay method (*Minimum 3 experiment*)
04	Determination of unknown concentration of Acetylcholine/ Histamine using suitable isolated tissue preparations by Bracketing bioassay method (*Minimum 3 experiment*)
05	Determination of unknown concentration of Acetylcholine/ Histamine using suitable isolated tissue preparations by Interpolation bioassay method (*Minimum 3 experiment*)
06	To study analgesic activity of drugs using Eddy's hot plate analgesiometer in mice (Using suitable computerized simulated software programme/demonstration)
07	To study locomotor activity of drug using actophotometer in mice (Using suitable computerized simulated software programme/ demonstration
08	To study muscle relaxant property of drug using rotarod in mice (Using suitable computerized simulated software programme/ demonstration)
09	To study the anticonvulsant activity of drugs using electroconvulsometer in mice (Using suitable computerized simulated software programme/ demonstration)

Recommended Books:

1. Ghosh MN. Fundamental of Experimental Pharmacology, Hilton & Company, Calcutta.
2. Kulkarni SK. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
3. Burn JH. Practical Pharmacology Blackwell Scientific, Oxford London.
4. Jaju BP. Pharmacology: A Practice Exercise Book, Jaypee Brothers, New Delhi.
5. Sheth UK, Dadkar NK and Kamat UG. Selected topics in experimental pharmacology.
6. Chatterjee CC. Human Physiology. Medical Allied Agency, Kolkata.
7. Ganong WF. Review of Medical Physiology. Prentice-Hall International, London.
8. Perry WLM. Pharmacological Experiments on Isolated Preparation, E&S Livingstone, London.
9. Goyal RK. Practicals in Pharmacology, B. S. Shah Prakashan, Ahemadabad.
10. Vogel HG: Drugs Discovery and Evaluation Pharmacological Assay, 2nd Ed Springer, Germany, 2002.
11. OECD 425 Guidelines (www.oecd.org)

3.6.5 T NATURAL PRODUCT CHEMISTRY
(3hrs/week), CREDIT: 03

Learning Objectives:

On successful completion of following theory topics & laboratory experiments, a learner should be able to

A. Knowledge:

- Understand & explain tools & techniques used in study of biosynthetic pathways in plants.
- Explain source, chemistry & applications of drugs from marine origin. He/she should be able to compare & contrast marine & terrestrial sources of medicinal materials.
- Explain difficulties in elucidation of biosynthetic pathways in plant & explain approaches used with their merits & demerits.
- Understand & explain underlying reasons as why natural products are appropriate material in discovering new drugs & also explain their contribution in modern drug discovery.
- Explain source, extraction, processing, chemistry & applications of natural products used in pharmaceutical & allied industry such as coloring, sweetening agents & polymers.
- Compare & contrast nutraceuticals & functional foods & understand & explaintheir significance.
- Explain & classify natural products used as dietary supplements.
- Understand & explain significance of natural pesticides & explain source, chemistry & applications.
- Explain source, extraction, processing, chemistry & applications of natural products used in pharmaceutical & allied industry such as bioavailability & skin permeation agents; wound healing agents, biofuels.

Skill:

- Extract & subsequently conduct experiments to derive various physical constants required in characterization of natural products.
- Charge, elute & gather pure material using column chromatography.
- Record UV/IR spectrum of given sample & interpret them.
- Able to perform the evaluation of isolated phytoconstituents by chemical, chromatographic and spectral means.
- Listen carefully, raise logical query, draw information, understand rationale during field visits & prepare brief report for evaluation.

Sr.No.	Topic	Hrs
	SECTION I	
01	**Natural product based drug discovery:** a. Overview of contribution of natural product in new drug discovery. b. Strategies of drug discovery; suitability of natural products in drug discovery as far astheir diversity, Chirality, complexity, receptor binding property & biological Relevance is concerned.	06

02	**Marine drugs:** cardiovascular-active & anti-cancer agents from marine source.	04
03	**Methods in biosynthetic studies:** Tracer techniques; isolated organs, tissues &cells;grafts; mutant strains.	04
04	**Natural products used as Pharmaceutical excipients & of allied industrial utility** **a.** Natural colors & dyes: meaning of dye, mordent etc, chemical classification,properties; Study of Cochineal, Henna, Annatto, Indigo, Beet &Turmeric b. Natural sweeteners: meaning of nutritive & non-nutritive sweeteners, Tastemodifiers, chemical classification, properties; study of Serendipity berry,Katemfe,Liquorice, Stevia, Gymnema sylvestre. c. Natural Polymers:Meaning, study and applications of Gums, latex, Mucilage, Gelatin, Chitosan, Carageenan, collagen.	08
SECTION II		
05	**Herbal dietary supplements:** Definitions, classification, inorganic mineralsupplements, digestive enzymes, probiotics, prebiotics, omega-3-polyunsaturated fatty acids, dietary fibers, Carotenoids, soya products,Spirulina, Ginkgo biloba, garlic, turmeric, grape seed proanthocyanidins,Resveratrol.	07
06	**Natural pesticides:** Methods of pest control, classification, pesticides & environment; pharmacognostic account of Pyrethrum, Neem, Rotenone & Citronella	03
07	**Natural products as** **a.** Oral bioavailability enhancers: Introduction, Definition & History, Concepts of bioavailability enhancers, Approaches for enhancement of absorption, Problems/ Disadvantages/Herdalswith Bioenhanceres, Future prospects. Overview of piperine, Glycerhizine, Quercetine, Naringine, as a bioenhancers. b. Skin permeation enhancers: Types, FunctionsOverview of Eucalyptus oil, Lemonine, Menthol, Phospholipids, Aloe Vera&Capsaicin as Skin permeation enhancers. c. Radiation protection agentsIntroduction: Radioactivity, Radiation Classification, Radioprotectants, Plant products showing radioprotection effects – Curcuma longa, Gingko biloba, Panax ginseng, Tinospora cordifolia, Mentha piperita. d. Natural products used in wound management [Hyaluronic acid; Corn protein(Zein); Hide glue derived from gelatin] e. Biofuels: Overview of biofuels (bioethanol, biodiesel), general method of preparation, significance of biofuels in national economy.	13

Recommended Books:

1. Bruneton Jean, Caroline K. Hatton, Pharmacognosy, Phytochemistry,Medicinalplants. Lavoisier, 1999. ISBN 1898298637.
2. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders,2002.16th Ed. ISBN-10: 0702029335.

3. Gokhale S.B., Gaud R.S., Surana S.J., Natural Excipients, Nirali Publications,2008.ISBN
4. 978-81-85790-60-2.
5. Hanson J.R., Natural Products: The Secondary Metabolites, Royal Society ofChemistry, UK, 2003. ISBN 0-85404-490-6.
6. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy,NiraliPrakashan, Pune, 2008, ISBN: 8185790094.
7. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluationof Botanicals. Business Horizons, 2002. ISBN 8190078844.
8. Rajpal V. & Kohli D. P. S., Herbal Drug Industry, Riddhi International, 2nd Ed.,2009. ISBN: 9788190646727.
9. Rangari V.D., Pharmacognosy & Phytochemistry (Vol I), Career Pub., Nashik,2009, ISBN: 978-81-88739-45-5.
10. Rangari V.D., Pharmacognosy & Phytochemistry (Vol II), Career Pub., Nashik,2009, ISBN: 978-81-88739-65-3.
11. Tadeusz F. Molinski, Doralyn S. Dalisay, Sarah L. Lievens and Jonel P. Saludes,Drugdevelopment from marine natural products, Nature Reviews: DrugDiscovery,8,69-84,2009.
12. Wallis T. E., Textbook of Pharmacognosy. CBS Publisher &Distributors,1985.ISBN:81-239-0886-5.
13. 13.Ajazuddin a, Amit Alexander "Role of herbal bioactives as a potential bioavailability enhancerfor Active Pharmaceutical Ingredients" Fitoterapia 97 (2014) 1–14
14. Robert E.C. Wildman, Handbook of Nutraceuticals and Functional Foods, 2nd Ed., CRC
15. Press, 2006. ISBN-10: 0849364094.

3.6.5 P NATURAL PRODUCT CHEMISTRY
(3 hrs / week) CREDIT 02

Sr.No	Title of Experiment
01	Extraction and isolation of phytoconstituents a. Volatile oils- (Min. 2 Expts) i) Camphor ii) Eugenol iii) Menthol iv) Citral b. Alkaloids - (Min. 2 Expts) i) Nicotine ii) Vasicine iii) Reserpine iv) Berberine c. Glycosides- (Min. 2 Expts) i) Glycerrhizine ii) Withenolides iii) Sennosides iv) Rutin/Quercetin v) Andrographolides d. Natural Colorants- (Min. 2Expts) i) Lycopine ii) Bixin iii) Curcumin iv) Henna

02	Estimation of phytoconstituents i) Estimation of Eugenol by I.P method ii) Estimation of Menthol by I. P. method iii) Estimation of Caffeine by HPLC
03	Evaluation of isolated phytoconstituents by chemical tests, chromatography and spectral analysis (UV and/IR) from above isolated compounds (Min. 4 Expts.)
04	Isolation of Phytoconstituents by column chromatography (Min. 1 Expt.)
05	Determination of M. P., solubility, Optical rotation, Refractive Index, Spectral analysis of pure natural compound (Min. 3 Expt.)
06	Field Visit- Visit to industry/cultivation farm/processing Unit and submission of reports thereof.

Recommended Books:

1. Hans-Jörg Bart & Stephan Pilz, Industrial Scale Natural Products Extraction, Wiley-VCH Verlag& Co., Germany, 2011. ISBN: 978-3-527-32504-7.
2. Jeffrey B. Harborne. Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis. Springer, 1998.ISBN 0412572702, 9780412572708.
3. Kokate C. K., Practical Pharmacognosy, VallabhPrakashan, 1993.
4. Krishnaswamy N. R., Chemistry of Natural Products: A Laboratory Handbook,CRC Press; 2nd Ed., 2012. ISBN-10: 1466505249.
5. Siddiqui A.A., Siddiqui S. Natural Products Chemistry Practical Manual,CBSPublishers &Distributors, 2008. ISBN-10: 8123916213.

3.6.6 T BIO-ORGANIC CHEMISTRY AND DRUG DESIGN
(3 hrs / week) CREDIT 03

Learning objectives:

On successful completion of following theory topics, a learner should be able to

A. Knowledge:

- Explain the significance of Bioorganic Chemistry and establish its relevance in drug design and discovery.
- Describe various approaches in rational drug design.
- Explain various drug targets and their biochemical features, physiological &pathophysiological rolesand their significance in drug design.
- Explain pro-drug concept in drug design.

Sr. No.	Topic	Hrs.
	SECTION – I	
01	**Bioorganic Chemistry:** Introduction to Bioorganic Chemistry, Basic considerations, Molecular Adaptation, Molecular Recognition and their relevance in Drug Design	02
02	General biochemical features, physiological role, their substrates/antagonists of following drug targets with reference to mechanism of action of drugs.	
2.1	**Enzymes:** a. **Oxidoreductases:** Monoamine Oxidase and Cyclooxygenase-1 and 2,HMGCoA reductase, DHFR (Human), DHFR (Bacterial), b. **Transferase:** Tyrosine Kinase (Leishmanial, Bacterial and Human). c. **Hydrolases**: Human Factor Xa, Bacterial Serine ProteaseHydrolases (Mettaloproteases): ACE, Human Carboxypeptidase. d. **Esterases**: AChE, Phosphodietrase-1, Phosphodiesterase-5 e. **Lysases:** DOPA Carboxylase, Carbonic Anhydrase, Histidine Carboxylase f. **Isomerases:** Thymidylate Synthase (Fungal and Human),Phosphofructokinase (Leishmanial)	10
2.2	**Nucleic Acids:** DNA and RNA as drug targets, mechanisms of intercalation, complexation,alkylation, oxidative degradation, strand breaking by the drugs, targets inprotein synthesis eg. Topoisomerase-II, reverse transciptase (human andviral). mRNA, rRNA and antisense therapy.	04
2.3	**Receptors:** GABAA, Cholinergic, Adrenergic, Adenosine, Angiotensin, Dopamine,Glucagon, GLP-1,Serotonin, Glucocorticoid, Estrogen, PPAR-γ, Thyroid Hormone, Insulin receptors	08
	SECTION – II	
03	**Drug Design** Introduction to drug design and discovery (phases involved), lead discovery & optimization, case studies e.g. development of ciprofloxacin, anti-diabetics etc. Introduction to QSAR: Hansch & Free Wilson Analysis, 3D QSAR (CoMFA and CoMSIA) Drug discovery with examples from following categories: anti-hypertensives, psychotherapeutics.	07

04	Molecular docking strategies & different methods of docking. Mechanism based drug design Quantum mechanics, Molecular mechanics and Molecular modeling.	06
05	**Approaches in rational drug design of enzyme inhibitors.** A. Ligand Based Drug Design concepts with suitable examples. B. Structure Based Drug Design concepts with suitable examples.	04
06	Introduction to pro-drugs, different strategies for design of pro-drugs withsuitable examples based on biotransformation.	04

Recommended Books:

1. Bioorganic Chemistry: A Chemical Approach to Enzyme action by Hermann Dugas, Springer New York, 1999.
2. Bioorganic and Supramolecular Chemistry by P.S. Kalsi, New Age International Publication 2007.
3. Kerns, E.H.; Di, L. Drug-Like Properties: Concepts, Structure Design and Methods: from ADME to Toxicity Optimization, Academic Press, Oxford, 2008
4. Burger's Medicinal Chemistry and Drug Discovery, 7th Edition, Vol. 1-6. Principles and Practice, edited by M. E. Wolff, John Wiley & Sons: New York, 2010.
5. Foye's Principles of Medicinal Chemistry, 7th Edition, edited by T.L. Lemke, D. A. Williams, V. F. Roche, and S.W. Zito, Williams and Wilkins: Philadelphia, 2013.
6. Computer-assisted drug design / Edward C. Olson, Christoffersen Editor, Ralph E. 2009, American Chemical Society.
7. Quantitative Drug Design - A Critical Introduction by Martin YC, Marcel Deckker Inc. New York.
8. Veerapandian, Structure Based Drug Design. Taylor and Francis, 1997.
9. Drug Design, V.M. Kulkarni, K.G. Bothara, Nirali Prakashan
10. An Introduction to Medicinal Chemistry, Graham L. Patrick ,Oxford University Press 1995
11. The Organic Chemistry of Drug Design & Drug Action, Richard B. Silverman, Elsevier Academic Press, 2014.
12. Chemical Biology: Approaches to Drug Discovery and Development to Targeting Disease, Edited by Natanya Civjan, Wiley (2012)

3.6.7 T PHARMACEUTICAL BIOTECHNOLOGY

(3 hrs / week) CREDIT 03

Learning objectives:
On successful completion of following theory topics, a learner should be able to

Knowledge:

- Define Biotechnology & its state its scope inpharmacy
- Know the basics of biotechnology techniques and the various systemsused.
- Know the method of genetic engineering for production of rDNA products including monoclonalantibodies.
- Know the information about the application of genetic engineering inanimals.
- Have a knowhow of enzymes and their uses byimmobilization.
- Illustrate use of Fermenter for production of fermentation products and information about their purification by downstream process.
- State the application of Fermenter process in production of vitamins andantibiotics.

Sr. No	Topic	Hrs
	SECTION I	
01	Introduction to Biotechnology, Scope, Potential & Achievements	01
02	**Gene transfer:** Transformation, Transduction and Conjugation	03
03	**Genetic Engineering techniques:** Isolation of DNA, Genomic &cDNA libraries, Gel electrophoresis,, Blotting techniques, DNA Hybridization, Site directed mutagenesis, Restriction Fragment Length Polymorphism (RFLP),DNA fingerprinting. Gene synthesis & gene machine, Gene sequencing methods.	10
04	**Recombinant DNA technology:** Introduction and principle of rDNA technology, Gene cloning- Introduction, enzymes acting on DNA (restriction endonucleases, S1 nuclease, alkaline phosphatase, polymerase, ligase,), types of cloning vectors(PUC 19, PBR 322,YAC,COSMID,Ti and Shuttle vector), expression vectors(pGEX-3X, pPIC, CHO)	10
	SECTION II	
05	Examples of Biotechnology derived Products: Human insulin, Somatotropin, Interferons, (Production of their rDNA constructs and uses) Introduction to Human Gene Therapy	04
06	Introduction to transgenic animals and their applications. Germplasm storage & cryopreservation	03

07	Steps involved in Monoclonal antibody production and its applications.	02
08	Enzyme Technology; Immobilization of enzyme & its applications	03
09	Fermentation Technology; Fermenter its accessory components and working, Down streaming Process in brief.	05
10	General application of fermentation in Manufacturing of Antibiotics and Vitamins with one example each.	04

Recommended Books:

1. Olive Kaiser ,Rainer Muller, Pharmaceutical Biotechnology: Drug Discovery and Clinical Application, Wiley VCH publisher, 2004
2. Peter J. Russel, Genetics 5th Edition ,The Benjamin Cummins Publishing California;1998
3. Watson WH Freeman and company N.Y. Recombinant DNA 2nd edition Holtzbrinck Publishers1992
4. Glick, Molecular biotechnology 3rd edition ASM press Washington, USA 200361
5. Vyas and Dixit Pharmaceutical Biotechnology, 1st CBS Publisher New Delhi,1991
6. Dr. S. Iganacimuthu, Basic Biotechnology – Tata McGraw Hill Publishers
7. P. K. Gupta, Elements Of Biotechnology, Rastogi Publication, 10th edition, 2004
8. S.S. Purohit, Biotechnology Fundamentals and Applications Student edition Agrobios Publisher;2002
9. H. S. Chawala, Introduction of Plant Biotechnology, 2nd edition, IBH Publishing Co. Pvt.Ltd. New Delhi,2002
10. M.H. Razdan, Introduction to Plant Biotechnology, 2ndedition Oxford and IBH Publishing Co. Pvt. Ltd, New Delhi.2003
11. K. Sambamurthy, Ashutosh Kar, Pharmaceutical Biotechnology, 2nd edition New AGE International (LP) Limited,2007.
12. U. Satyanarayana, Biotechnology,Books and AlliedLtd