SAVITRIBAI PHULE PUNE UNIVERSITY

SYLLABUS

OF

THIRD YEAR B. PHARMACY

(w.e.f. Academic Year 2015-16)

3.5.1 T Industrial Pharmacy-I (Theory)

(3 hrs / week)

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

Knowledge:

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

Skills:

1. State the correct use of various equipments in Pharmaceutics laboratory relevant to tablets, capsules & coating.
2. Explain formulation, evaluation and labelling of tablets & capsules.
3. Perform pharmaceutical calculations to determine evaluation parameters like Hausner ratio, Heckel plot & Kawakita plot of preparations.
4. Describe use of ingredients in formulation and category of formulation.
5. Use equipments and apparatus needed for the preparation as per SOP.
6. Select the suitable packaging material (container-closure) for the preparation.
7. Prepare labels to suit regulatory requirements.

Sr. No.	Topic	Hrs
1	Concept of formulation design, Principles of dosage form design, **Biopharmaceutical, therapeutic and drug related considerations.**	4
2	**Tablets formulation and technology** Introduction, Advantages & Disadvantages, Types of tablets. Introduction to tablet additives,	20

	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, Pelletization, Spherical crystallization, Fluidized bed granulation** Force volume relationship, lubricating efficiency. Heckel plot, Kawakita equation Tablet compression machines. Types of tooling. **Defects in tableting & remedies thereof**. Chewable tablets, Effervescent tablets, Dispersible tablets, Mouth dissolving tablets, Layered & Compression coated tablets. IPQC & QC of tablets as per IP, BP, USP.	
3	**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. Plant layout for tablet manufacture and coating. IPQC & QC as per IP, BP, USP.	6
4	**Capsules** Manufacturing and quality control of gelatine for capsule. Introduction and concept of size selection of capsules. Manufacture of hard gelatine capsule shell, standards and defects. Hard gelatin capsules: Formulation development of hard gelatine capsule, standards & defects thereof. Volumetric and dosator principle in capsule filling, Hand operated semiautomatic and automatic equipments. In process quality control & quality control as per IP, BP, USP. Problems in capsule filling & remedies thereof. Soft gelatine capsules: formulation and development, introduction to base adsorption. Manufacturing equipment. In process quality control & quality control as per IP,BP,USP Plant layout for capsule manufacture.	15

3.5.1 P Industrial Pharmacy-I

(3 hrs / week)

List Of Practicals: Formulation, Preparation and Evaluation of the following dosage forms.

Tablets

Sr. No.	Title
1	Study of tablet press and its parts
2	Preparation and evaluation of tablets by direct compression technique.
3	Preparation & evaluation OF Tablets using non aqeuous wet granulation
4	Preparation & evaluation using aqueous Wet granulation
5	Preparation & evaluation using Dry granulation
6	Preparation and evaluation of mouth dissolving tablets.
7	Preparation and evaluation of chewable tablets.
8	To study effect of binders concentration on hardness & Disintegration of tablet
9	Preparation & evaluation of effervescent tablets
10	Evaluation of marketed coated tablet as per IP(EXCLUDING DISSOLUTION)
11	Evaluation of marketed enteric coated marketed tablet
12	Effect of various additives on flow property of granules
12	Effect of lubricant concentration on flow properties of granule
13	Filling and evaluation of hard gelatine capsule.
14	Preparation and evaluation of hard gelatine capsule.
15	Evaluation of marketed soft gelatine capsule.

Dissolution test for at least one tablet & capsule should be done

List of books

1) Indian Pharmacopoeia 2014.
2) United States Pharmacopoeia 2014.
3) Theory and Practice of Industrial Pharmacy. Edition Lachmann, Libermann, Kanig, Edition
4) Modern Pharmaceutics, Banker and Rhodes, Marcel Dekker.
5) Pharmaceutics The design and manufacture of medicines: Aulton M E , Edition 3

3.5.2 T Pharmaceutical Analysis-III

(3 hrs / week)

Learning objectives:

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

A. Knowledge:

1. Know the different types of instrumental analytical techniques available for quality control of APIs & Pharmaceutical dosage forms.
2. Know various sampling techniques employed in analysis of solid, semisolid and liquids dosage forms
3. Understand principles, instrumentation and applications of UV-VIS, Flourimetry, Atomic absorption, atomic emission, Spectroscopies, Flame photometry, Phosphorimetry and Nepheloturbidimetry.

B. Skills:

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

Sr. No.	Topic	No. of 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	
1.	**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.	5
2.	**Analytical Sample preparation Techniques**: Preparing samples for analysis, sampling plans, separating analytes from interferents,	4

	separation techniques based on size, density, complexation, liquid-liquid extraction.	
3.	**UV Visible Spectroscopy**: Theory, Beer lamberts law, its deviations and limitations, Woodward rule, concept of photometry and spectrophotometry, 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
4.	**Flame Photometry**- Principle, Instrumentation and application	3
5.	**Atomic Absorption Spectroscopy**-Theory, Instrumentation, line broadening, Doppler effect, Flame types, different Interference and their Corrections, Pharmaceutical applications	5
6.	**Atomic Emission Spectroscopy** - Instrumentation, Principle and Application	4
7.	**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.	8
8.	**Spectroscopy based on scattering**-Nepheloturbidimetry-Introduction Principle, Instrumentation and Applications.	4

3.5.2 P Pharmaceutical Analysis-III

(3 hrs / week)

1. Calibration of UV-VIS Spectrophotometer.
2. Determination of Beer's Law, Limit and calculation of different absorptivity constants.
3. Calculation of λ_{max} by Woodward rule (Min. two)
4. Assay of APIs and formulations by UV Spectrophotometry including calibration curve method, Single point standardization, Double point standardization and $A^{1\%}_{1cm}$ method (Any four)

5. Estimation of Na, K, Ca, Li from Pharmaceutical formulations by flame photometry (Any two)
6. Assay of APIs & formulations by Fluorimetry (Any two)
7. 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, 2015, British Pharmacopeia Secretariat, London, UK
3. United States Pharmacopeia, 2015, 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. Analytical Chemistry by Christian G D, 6/Ed., John Wiley & Sons.
9. A Textbook of Pharmaceutical Analysis by Connors KA, 4/ed., John Wiley & Sons.
10. Practical Pharmaceutical Chemistry Part-I & II by Beckett A H & Stanlake J B, 4/Ed., CBS Publisher & Distributors.
11. Handbook of Instrumental Techniques for Analytical Chemistry by Frank Settle, First Indian Reprint 2004, Pearson Education
12. Instrumental Methods of Analysis by Willard Merit, Dean Settle, 7th edition, CBS Publisher & Distributor
13. Instrumental Methods of Chemical Analysis by BK Sharma, Goel Publishing House.
14. Instrumental Methods of Chemical Analysis by GW Ewing, McGraw-Hill Book Company
15. A Practical Approach to Pharmaceutical Analysis(Instrumental & Manual), Rajesh kumar Nema, Mahesh Verma, CBS Publishers & Distributors

3.5.3 T Medicinal Chemistry-I

(3 hrs / week)

Learning objectives:

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

A] Knowledge:

1. Understand significance and establish relevance of Medicinal Chemistry in Pharmaceutical Sciences.
2. Establish correlation of physicochemical properties affecting drug action and pharmacokinetics.
3. Explain different types of receptors, forces involved in drug receptor interaction and signal transduction mechanism.
4. Explain 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 in diuretics and drugs acting on autonomic nervous system & cardiovascular system.

B] Skill:

1. Make correct use of various equipments & take safety measures while working in medicinal chemistry laboratory.
2. Understand and develop skills in various purification techniques of solvents/liquids used in synthesis.
3. Prepare acid and basic salts of drugs and evaluate their physicochemical properties.
4. Determine the partition co-efficient and dissociation constant of compounds.
5. Develop the skills involved in thin layer chromatography techniques and purification of synthesized compounds by column chromatography.
6. Synthesize, recrystallize and understand reaction mechanisms involved in synthesis of medicinally important organic compounds.

Sr. No	Topic	No. of hrs
01	**General considerations:** Structure of biological membrane, physicochemical properties affecting drug action; solubility, partition coefficient, Ferguson principle, stereo chemical aspects of drug action, Bioisosterism, Introduction to Drug absorption; distribution, metabolism and elimination, Protein binding,	05

	Blood brain barrier.	
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.	04
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)	08
3.2	**Cholinergic agents:** Biosynthesis, release and metabolism of Neurotransmitters, Acetylcholine. Cholinergic receptor subtypes and their structural features, Cholinergic agonists, Cholinergic antagonists, acetylcholinesterase inhibitors, Ganglionic blockers and neuromuscular blockers. (Carbachol, Dicyclomine hydrochloride)	09
3.3	**Cardiovascular drugs** a. Cardiotonic drugs b. Anti-anginal agents c. Anti-arrhythemic agents d. Anti-hypertensive agents, e. Anti-hyperlipidemic drugs f. Anti-coagulants and anti-thrombolytics (Losartan, Clofibrate Hydralazine, Captopril)	15
3.4	**Diuretic agents (Furosemide, Chlorthiazide)**	04

3.5.3 P Medicinal Chemistry-I

(3 hrs / week)

1. Purification techniques of solvents by Fractional distillation and vacuum distillation
2. Preparation of acid/basic salts of drugs and evaluation of their physicochemical properties. (Any two)

3. Determination of partition co-efficient and dissociation constant of compounds (Any two)
4. Thin layer chromatography technique and purification of synthesized compounds by column chromatography (Any two)
5. Synthesis & purification of following compounds using precipitation or recrystallization. (Any six)

   Benzimidazole, 1, 2, 3, 4-tetrahydro carbazole, 2,3-diphenyl Quinoxaline,Bis-β napthol, Anthanilic acid, sulphonamide, Benzoic acid from benzyl alcohol, Propranolol, 1,4-dihydropyridine

Recommended Books

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincot 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

(3 hrs / week)

Topic No	Name of the topic and contents	Hrs
	Pharmacology of drug shall includes : classification, mechanism of action, pharmacological actions, pharmacokinectics, therapeutic uses, adverse effects, drug interactions, contraindications, dosages, treatment of poisoning (if any) *Pharmacotherapy shall include: Pharmacology of drug/s used for clinical management of diseases/ disorders*	
	SECTION I	
1	**Autonomic Nervous system:** **General Considerations:** Sympathetic and Parasympathetic Nervous system with neurotransmitters and their receptors with Signal Transduction mechanisms	**03**
2	***Cholinergic system and drugs*:** Biosynthesis, Storage, Release and Metabolism of Acetylcholine(ACh) Cholinergic receptors, Parasympathomimetics: Pharmacology of *ACh* and *Anticholineesterase* Organophosphorus Poisoning *and its treatment* Pharmacotherapy of Galucoma and Mysthenia gravis	**06**

3	***Anti-cholinergic drugs:*** Pharmacology of Atropine *and other antimuscarinic drugs* Antimuscarinic Poisoning and its Treatment	**02**
4	**Ganglion Stimulating and Blocking drugs:** Pharmacology of *Ganglion Stimulating and Blocking drugs*	**02**
5	**Adrenergic system and drugs:** Biosynthesis, Storage, Release, Metabolism of *catecholamines* Pharmacology of Catecholamines and indirectly acting Sympathomimetics.	**05**
6	**Anti-adrenergic drugs:** *Pharmacology of* Adrenoceptor blocking drugs reversible, irreversible, non-selective and selective antagonists	**03**
7	**Neuromuscular blocking drugs:** *Pharmacology of* Peripherally and centrally acting muscle relaxants	**02**
	SECTION II	
8	**Endocrine Pharmacology** Functions, Receptor and mechanisms of Hormone actions, Hypothalamus-Pituitary relationship, Anterior and Posterior Pituitary hormones **Drugs acting on Uterus:** *Pharmacology of uterine stimulants and relaxants*	**04**
9	**Adrenocorticosteroids and corticosteroid antagonists** Biosynthesis, Mechanism of Action and Pharmacology	**04**
10	**Thyroid and antithyroid drugs** Biosynthesis, Mechanism of Action and Pharmacology **Parathyroid hormones:** Drugs regulating calcium homeostasis, Vitamin D	**04**
11	**Insulin, Oral hypoglycemic agents, Glucagon** **Insulin:** Biosynthesis**,** secretion, mechanism of action and pharmacology Pharmacotherapy of diabetes mellitus *(including diabetic complications)* **Glucagon:** *Biosynthesis**,** secretion, mechanism of action and pharmacology*	**04**

12	**Androgens, Antiandrogens, and Anabolic Steroids**	**03**
13	**Estrogens, Progestins, *contraceptive*s and Specific Estrogen Receptor Modulators (SERMs), Aromatase Inhibitors, *antiprogestin***	**03**

Recommended Books:

1.Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, Little Brown and Co, Boston

2.Crossland, James and; Lewis,s Pharmacology Basis of Therapeutics, (Pergamon Press, New York)

3.Goodman and Gilman; Pharmacological Basis of Therapeutics, McGraw-Hill

4.Katzung, B.G; Basic and Clinical Pharmacology, Lange Medical Publisher, USA

5.Rang, H.P. and Dale, M.M.; Pharmacology, Churchill Livingston, UK

6. Satoskar , R.S. and Bhandarkar S.D. Pharmacology and Pharmacotherapeutics (Popular Prakashan, Bombay)

7.Sharma H.L. Sharma K. K. General Pharmacology Basic Concepts. Paras Publication.

8.Tripathi K. D. Essentials of Medical Pharmacology, Jaypee Publication.

9.Harrison's Principle and Practice of Medicine,18th Edition, Churchill, Livingston, .London

10Roger 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. Vyawahare N. S., and Vora S., General Pharmacology, Nirali Publication, Pune

14. Mycek M. J,Harvey, RA and Champe PC Lippincott's Illustrated Reviews:Pharmacology Lippincott Williams & Wilkins.Phillodelphia.

3.5.4 P Pharmacology-II

(3 hrs / week)

Sr. No	Title of the Experiment
1	Introduction to commonly used instruments in experimental pharmacology.
2	Care and handling of common laboratory animals, animal welfare and introduction of CPCSEA and its guidelines, OECD guidelines.
3	Introduction to animal physiology with their biochemical reference values in various

	Animal species.
4	Study of various routes of drug administration
5	Study of various anesthetics employed to anesthetize laboratory animals.
6	Introduction to the techniques of Euthenesia
7	Study of physiological salt solutions, drug solution and use of molar solution in various animal experiments.
8	Study of various methods for collection of blood, body fluids and urine from experimental animals.
9	Computer simulations of following experiments through computerized simulated software programme using software such as X-Pharma, X-cology etc. a) To study various types of bioassay and its principles b) Study of synergism and drug antagonism using isolated tissues. c) Study of the miotic and mydriatic effect of drugs using rabbit eyes
10	Recording Concentration Response Curves (CRC) of Acetylcholine using suitable isolated tissue preparations
11	Recording Concentration Response Curves (CRC) of Histamine using suitable isolated tissue preparations
12	To record the effect of Physostigmine on Concentration Response Curves (CRC) of Acetylcholine using suitable isolated tissue preparations (Synergism)
13	To record the effect of Atropine on Concentration Response Curves (CRC) of Acetylcholine using suitable isolated tissue preparations (Antagonism)

Isolated tissue experiments must be carried out using at least two different preparations for each method

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, (Kothari Book Depot, Mumbai)

6.Chatterjee, C.C., Human Physiology. Medical Allied Agency, Kolkata.

7.Ganong, W.F., Review of Medical Physiology. Prentice-Hall International, London.

8.Guyton, A.C., Textbook of Medical Physiology. W. B. Saunders Co., Philadelphia, USA.

9.Perry W.L.M. Pharmacological Experiments on Isolated Preparation, E&S Livingstone, London

10. Goyal R. K., Practicals in Pharmacology, B. S. Shah Prakashan, Ahemadabad

3.5.5 T Analytical Pharmacognosy & Extraction Technology

(3 hrs / week)

Learning objectives:

A] Knowledge: on completion of theory, learner should be able to:

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

B] Skill: on completion of laboratory experiments, learner should be able to:

1. Explain & demonstrate correct handling of inflammable solvents & corrosive chemicals.
2. Generate micrometric data & identify the crude drugs.
3. Conduct successive extraction & qualitative tests to ascertain chemical nature of crude drugs.
4. 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.

5. Apply theoretical knowledge of various quality control parameters studied in theory, explain significance of use of various chemicals/solvents/conditions; undertake various estimations/determinations; infer from results obtained & report evaluation results.
6. Able to handle various equipments as per SOPs & learn various demonstrations (of experiments).
7. Understand meaning & significance of 'Good Laboratory Practices' learn in theory & demonstrate through laboratory behavior.
8. Listen carefully, raise logical query, draw information, understand rationale during field visits & prepare brief report for evaluation.

Sr.no	Topic	Hrs.
1	**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 fluid extraction, Solid phase extraction, Microwave-assisted extraction, Ultrasound extraction (Sonication). B] Non-chromatographic separation techniques: Fractional distillation, fractional liberation, sublimation, chemical derivatization, fractional crystallization, centrifugation, Froth-floatation technique. C] Chromatographic separation techniques: Principle and applications of following for the plant derived products: Paper Chromatography, TLC, HPLC, HPTLC & Column chromatography.	**20**
2	**Application of extraction techniques:** Source, properties, isolation & tests of following phytochemicals : a. Direct solvent extraction of strychinine, atropine, reserpine, piperine, taxol,sennosides, digoxin, diosgenin, andrographolides, artemisinin, boswellic acid,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 f. Microwave-assisted water extraction: Polyphenols of green tea	**10**

3	3. **Herbal drug analysis:** A] Analysis: Types & need; meaning of identity, purity, potency & safety; socialrelevance of natural product analysis; difficulties in analysis of natural products;proximate phytochemical analysis: meaning, significance & method; adulteration:definition & types of adulteration. B] Sampling techniques: Principle & procedure of sampling C] 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, bitterness value, haemolyticactivity, tannin content, swelling index, foaming index (as per WHO). D] Quality control (safety) parameters of herbal drugs: Principle, procedure &significance involved in determination of pesticide residues, arsenic and toxicmetals, microorganisms, aflatoxins, radioactive contamination. E] Overview of 'Good practices for pharmaceutical quality control laboratories' (as perWHO).	**15**

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 S. S., SumanPreet Singh Khanuja, Gennaro Longo, Dev Dutt Rakesh,**Extraction technologies for medicinal & aromatic plants**, International centrefor science and high technology, 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,Medicinal plants.** Lavoisier, 1999. ISBN 1898298637.
5. Kokate C. K., Gokhale S.B. and Purohit A.P., **Textbook of Pharmacognosy**,NiraliPrakashan, Pune, 2008, ISBN: 8185790094.
6. Mukherjee Pulok K., **Quality Control of Herbal Drugs: An Approach toEvaluation of Botanicals**. Business Horizons, 2002. ISBN 8190078844.
7. Otto Sticher, **Natural product isolation**. Natural Product Reporter, 25, 517–554, 2008. (http://disruptechno2.free.fr/FMS/Natural%20product%20isolation%20(Otto20Sticher).pdf)

8. **Quality control methods for medicinal plant materials**, World HealthOrganization, 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.

3.5.5 P Analytical Pharmacognosy & Extraction Technology

(3 hrs / week)

1. Generation of micrometric data: Leaf constants, Length & width of fibers, diameter of starch grains (Min 3 Exp.)
2. Proximate chemical analysis: Successive extraction followed by qualitative chemical analysis of extracts (Min 1 Exp.)
3. Solvent extractions: strychinine from Nux vomica; piperine from Black pepper;diosgenin from Dioscorea tubers; confirmation of extracted material byqualitative tests or TLC. (Min 2 Exp.)
4. Determination of Ash values, moisture content, extractive values, swelling index,foaming index, crude fiber content (Min 5 Exp.)
5. Determination of total phenolic content/ total flavanoids content/ total tannincontent (Min 2 Exp.)
6. Detection of adulterants in crude drugs (Min 2 Exp.)
7. Microwave extraction (Demonstration)
8. Isolation of phytoconstituents by column chromatography (Demonstration)
9. Field visit: Visit to industry/ cultivation farm/ processing unit & submission ofreport thereof.

Recommended Books:

1. Jeffrey B. Harborne. **Phytochemical Methods: A Guide to Modern Techniquesof Plant Analysis.** Springer, 1998.ISBN 0412572702, 9780412572708.
2. Kadbadi S.S., Deore S.L. &Baviskar B.A., **Experimental Phytopharmacognosy**,Nirali Publication, Pune, 2011. ISBN 9381237131.

3. Khandelwal K. R., **Practical Pharmacognosy**, Pragati Books Pvt. Ltd. ISBN8185790302.
4. Kokate C. K., **Practical Pharmacognosy**, VallabhPrakashan, 1993.
5. **Quality control methods for medicinal plant materials**, World HealthOrganization, Geneva, 1998. ISBN 9241545100.
6. Wallis T. E., **Practical Pharmacognosy**. J.A. Churchill Ltd., London, 1953.

3.5.6 T Pharmaceutical Business Management & Disaster Management

(3 hrs / week)

Learning Objective:

On completion of following theory topics learner should be able to: Know the fundamental of management theories.

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

Sr.no	Topic	Hrs.
1	**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	3
2	**Planning:** Nature and purpose of planning, important steps in planning, types of planning, planning process, advantages and limitations.	3
3	**Objectives:** Types of objectives, importance of objective, management by objectives, advantages and limitations.	2
4	**Organizing:** Organizational structure, basic principles of organization, departmentalization, delegation, decentralization, staffing, line & staff organization.	2
5	**Decision making:** Types of decision, Definition and Importance of decision making, Decision making process	2
6	**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 including numerical	5

	problem	
7	**Material management:** Classification of materials, objectives and principals of purchasing, inventory control.	**2**
8	**Pharmaceutical Marketing:** Difference between marketing and selling, channels of distribution, wholesale, retail, departmental.	**3**
9	**Sales promotions:** objective, principles & techniques. Ethics of sales, Advertising- needs & methods, Merchandising, Detailing. Medical representative: Role & Qualities.	**4**
10	**Marketing research:** Nature & importance. Sales forecasting methods, analysis, advantages and limitations.	**2**
11	**Product management:** Product life cycle, launching a new product.	**2**
12	**Price:** definition, factors affecting , procedure for determination of price, types of price.	**2**
13	**Human Resource and Development** **Motivation:** definition, & concept. Theory's- Maslow's theory, Hertzberg' s theory, Vroom's theory, expectancy theory, reinforcement theory, equity or Social comparison theory X & Y. **Leadership:** definition, importance, qualities of leadership, leadership styles, trait theory, managerial grid. **Communication:** importance, functions, communication process, forms of communication, types of communication. **Interview techniques: -** presentation skills- group discussion. **Performance appraisal:** need and techniques, recruitment and training	**7**
14	**Introduction to Disaster Management:** Meaning, nature, characteristics Types of disasters: Causes and effects of following type of disaster. **Geological and mountain area disasters:** earthquakes, volcanic eruption, landslides, and snow avalanches. **Wind and water related natural disaster:** floods and flash floods, droughts, cyclones, and tsunamis. **Manmade disasters:** fires and forest fires, nuclear, biological and chemical disaster and road accidents. Disaster a global view, disaster profile of India.	**3**
15	**Disaster Management: Preparedness and Mitigation** Disaster Preparedness: Concept & nature, disaster preparedness plan.	**3**

	Disaster preparedness for people and infrastructure, Community based disaster preparedness plan. Disaster Mitigation: meaning and concept, disaster mitigation strategies. The Disaster Management cycle.	

Recommended Books:

1) Peter Drucker; The Practice of management, Harper and Row, New York, 1954.

2) Harold Koontz, Cyril O'Donnel & Heinz Weihrich; Management, 7th edition, 1980.

3) P.C. Tripathi & P.N. Reddy; Principals of Management, Tata McGraw Hill publishing Co/ Ltd, 2nd edition, New Delhi.

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) G. Vidyasagar; 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 Intoduction, 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, New Delhi.

13) Principles and Methods of Pharmacy Management by Harry Smith.

14) Marketing Management by Philip Kotlar.

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, New Delhi.

20). www.GIS. Development.net

21). www.iirs.nrsa.org

22). http://quake.usgs.gov

3.5.7 T Active Pharmaceutical Ingredients Technology

(3 hrs / week)

Learning objectives:

On completion of following theory topics, a learner should

1. Know overview of API and fine chemical industry.
2. Understand basics of chemical process kinetics, some classes of reactions with examples of API for each unit process.
3. Understand chemical process, reaction system, equipments used in API manufacturing and layout design for API manufacturing.
4. Explain techniques and process of synthetic routes and optimization of reactions, raw material & reagent selection, scale up techniques for APIs, Quality control aspects, material safety data sheet (MSDS), Scale up techniques in API manufacturing, environmental aspects in manufacturing of APIs, green chemistry approaches, health hazards with chemical handling.
5. Explain principle, industrial process, scale up techniques, Industrial manufacturing process, flow charts of some important APIs.
6. Explain Chirality in API industry with some examples.
7. Understand Polymorphism in APIs
8. Know Quality assurance (QA) and quality control (QC) of APIs and GMP Guidelines in API manufacturing like ICH Q7, Q7A and Q11

Sr. No	Topic	No. of Hrs
1	Overview of API, API intermediates and fine chemicals industry.	02
2	Unit processes in synthesis: Nitration, Amination by reduction, Esterification, Hydrolysis, Oxidation, Alkylation along with examples related to APIs for each unit process	10

3	Factors affecting chemical processes, reaction system, general list of equipments used in API manufacturing, layout of process equipments	02
4	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
5	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
6	Chirality in API Industry, Resolution of racemate, Asymmetric synthesis, few case studies like (S)-Propranolol, (S)-Metoprolol	03
7	Polymorphism in APIs	02
8	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. 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 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; 5 edition ,2002.
13. ICH Guidelines, www.ich.org

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

3.6.1 T Industrial Pharmacy-II

(3 hrs / week)

Learning Objective: On completion of following theory topics & laboratory experiments, **learner should be able to:**

1. Explain disperse systems, its classification, theories of disperse systems, thermodynamic v/s kinetic stability considerations.
2. Explain suspensions, types, formulation development, manufacturing, excipients used, evaluation of suspensions etc.
3. 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 & stress testing.
4. Explain semi-solids, anatomy & physiology of skin, selection of bases; penetration enhancers, formulation development, Percutaneous absorption, flux measurement & evaluation.
5. Describe layout for manufacturing of suspensions, emulsions & semi-solids as per schedule M.

Skills:

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

Sr. No.	Topic	Hrs
1	**Disperse systems:** Free energy consideration, thermodynamic v/s kinetic stability. DLVO theory, Classification of disperse system	4
2	**Suspensions:** Flocculated & Deflocculated system. Stokes law. Formulation development, manufacturing Excipients used in suspensions: suspending agents, wetting agents, dispersants, deflocculating & flocculating agents Structured vehicle, preservatives, color, flavor. Formulation of suspensions: Low solid content, high solid content, antacid suspension, suspensions for reconstitution. 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 labeling of suspensions.	12
3	**Emulsions:** Physicochemical principles, theory of emulsification energy barriers to coalescence. Film barriers, steric stabilization. Stability of emulsions: Creaming, coalescence, cracking, HLB value & phase inversion temperature, Kraft point cloud point. Excipients used in emulsions: Emulsifier & choice of emulsifier, vehicles, preservatives, antioxidants, color, flavour. Formulation of emulsions, Multiple emulsions, microemulsions. Evaluation of emulsion Emulsion stability, stress testing. Evaluation: Phase separation, pH, globule size, viscosity, redisperibility.	12
4	**Semisolid dosage forms** Anatomy and physiology of skin (Introduction) Types: ointment, cream, paste and gels. Formulation development and manufacturing: Semisolid bases and additives special reference to penetration enhancers, Selection criteria of bases. Percutaneous absorption: Flux and its measurement, factors affecting drugs Properties, vehicle related and patient related Evaluation parameters: globule particle size, pH, spreadability, permeation,	12

	drug release, viscosity, drug content, extrudability, skin irritation test,	
5	**Manufacturing equipments:** suspension, emulsion and semisolids Layout and designing of manufacturing facility for suspension, emulsion and semisolids as per schedule M.	5

3.6.1 P Industrial Pharmacy-II

(3 hrs / week)

Formulation, Preparation, Evaluation & labelling of the following dosage forms. (Preparation of BMR)

1. Suspensions • Calamine lotion • Milk of Magnesia • Paracetamol Suspension • Antacid Suspension Evaluation Parameters: Sedimentation volume, Organoleptic Properties, pH, Viscosity, Stability ,Acid neutralizing capacity, Rosset Rice test, pH stat test and assay of any one preparation

2. Emulsions • Liquid paraffin oral Emulsion • Turpentine Liniment • Formulation of Emulsion (HLB Consideration) Evaluation Parameters: Organoleptic Properties, pH, Globule size, wt/ml, and assay of any one preparation type of emulsion

3. 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.

List of books

1) Indian Pharmacopoeia 2014.
2) United States Pharmacopoeia 2014.
3) Theory and Practice of Industrial Pharmacy. Edition Lachmann, Libermann, Kanig, Edition
4) Modern Pharmaceutics, Banker and Rhodes, Marcel Dekker.
5) Pharmaceutics The design and manufacture of medicines: Aulton M E , Edition 3

3.6.2 T Pharmaceutical Analysis-IV

(3 hrs / week)

Learning objectives:

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

A. Knowledge:

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

B. Skills:

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

Topic No.	Name of the topic and contents	No. of 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	
1.	**Introduction to chromatography techniques**: Introduction, Basic theory, Types, Column Chromatography, theory(rate & plate) Principle, Column packing techniques, Van Deemter Equation in detail, Efficiency of column, Capacity factor and other system suitability parameters, application.	7
2.	**Introduction to Planar Chromatography**- classification, TLC, HPTLC &	9

	Paper Chromatography-Introduction, Brief history, **Paper Chromatography**: Techniques, Development, application, Different types of chromatographic paper. **Thin Layer Chromatography:** Principle, Adsorbents, Activity of Adsorbents, methods TLC plate preparation, Development of TLC and its evaluation, applications. **High Performance Thin Layer Chromatography (HPTLC):** Theory, Instrumentation, types of HPTLC plates, types of development chambers and development techniques, HPTLC scanning and evaluation, Applications Automated Multiple Development, Horizontal TLC, any other development modes, applications.	
3.	**Electrophoresis**-Principle, Instrumentation, Various types of Developments	4
4.	**Thermal Methods of Analysis-** DSC, DTA, TGA, ITC- 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. d. Isothermal titration calorimetry.	10
5.	**X- Ray Diffraction**-Introduction, Instrumentation, Pharmaceutical applications and simple calculations, calculation of Radii, different crystal faces, Polymorphism.	5
6.	**Radiochemical Methods**-Nuclear reactions and radiations, Neutron sources, Measurement of radioactivity, tagging of compounds, Pharmaceutical Applications.	5
7.	**Validation** -Introductions to equipment qualification, Analytical Methods Validation as per ICH/ USP guidelines.	5

3.6.2 P Pharmaceutical Analysis-IV

(3 hrs / week)

1. Separation & determination of Rf values of mixture of amino acids by Ascending, Radial and two dimensional Paper chromatography (Min. three)

2. Separation & determination of Rf values of mixture of carbohydrates/amino acids by TLC (Min. three)
3. Validation of spectrophotometric assay methods as per ICH guidelines (Min. two)
4. Column chromatographic separation techniques (Min two)
5. Interpretation of XRD spectrum. (Min. two)
6. Demonstration experiments: HPTLC/DSC/Electrophoresis (Any one)

Recommended books

1. Indian Pharmacopoeia, 2014, Indian Pharmacopoeia Commission, Govt. of India
2. British Pharmacopoeia, 2015, British Pharmacopeia Secretariat, London, UK
3. United States Pharmacopeia, 2015, 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. Analytical Chemistry by Christian G D, 6/Ed., John Wiley & Sons.
9. A Textbook of Pharmaceutical Analysis by Connors KA, 4/ed., John Wiley & Sons.
10. Practical Pharmaceutical Chemistry Part-I & II by Beckett A H & Stanlake J B, 4/Ed., CBS Publisher & Distributors.
11. Handbook of Instrumental Techniques for Analytical Chemistry by Frank Settle, First Indian Reprint 2004, Pearson Education
12. Instrumental Methods of Analysis by Willard Merit, Dean Settle, 7th edition, CBS Publisher & Distributor
13. Instrumental Methods of Chemical Analysis by BK Sharma, Goel Publishing House.
14. Instrumental Methods of Chemical Analysis by GW Ewing, McGraw-Hill Book Company
15. A Practical Approach to Pharmaceutical Analysis(Instrumental & Manual), Rajesh kumar Nema, Mahesh Verma, CBS Publishers & Distributors

3.6.3 T Medicinal Chemistry-II

(3 hrs / week)

Learning objectives:

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

A] Knowledge:

1. Explain drug metabolism & its significance in drug discovery.
2. Explain 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 in Local anesthetics, Oral Anti-hyperglycemics, Diagnostics and drugs acting on Central nervous system.

B] Skill:

1. Determine molar refractivity of compounds.
2. Separate solvents by Steam distillation technique.
3. Understand the mechanism and carry out Dean stark azeotropic water separation.
4. Synthesize, recrystallize and understand reaction mechanisms involved in synthesis of medicinally important organic compounds
5. Synthesize medicinally important organic compounds using microwave assisted organic synthesis.

Sr. No	Topic	No. of hrs
01	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.	
1.1	Local anesthetics (Procaine, Mepivacaine)	04
1.2	Oral Anti-hyperglycemic drugs (Metformin, Tolbutamide,)	05
1.3	CNS Stimulants a. Analeptics and respiratory stimulants b. Hallucinogens (Caffeine, Phentermine)	04

1.4	CNS Depressants a. General anesthetics b. Sedative & Hypnotics c. Anticonvulsants (Thiopental sodium, Phenytoin, Diazepam, Sodium valproate)	08
1.5	Psychotherapeutic agents a. Antipsychotics b. Antidepressants c. Anxiolytics (Amitryptiline, Chlorpromazine, Haloperidol, Fluoxetine)	08
1.6	Drugs used in Neurodegenerative diseases a. Parkinson' s disease b. Alzheimer' s disease (Amantadine)	04
1.7	Anti-migraine agents	02
1.8	Diagnostic agents: Radio opaque diagnostic agents and agents for organ function tests.	03
2	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	07

3.6.3 P Medicinal Chemistry-II

(3 hrs / week)

1. Determination of molar refractivity of compounds.
2. Separation of ortho and para- nitro phenol by Steam distillation.
3. Dean stark azeotropic water separation.
4. Synthesis & purification of following compounds using precipitation or recrystallization. (Any six)

   Phenytoin from benzoin, Benzocaine from PABA, Isonicotinic acid from picoline, Barbituric acid from diethyl malonate, Phenothiazine, Ethyl Nicotinate, Hippuric acid, m-Nitro-phenol and fluorescein.

5. Microwave assisted synthesis of compounds in point 1 of theory (Any Two)
6. Recording & interpretation of IR spectrum of synthesized compounds (Any two)

Recommended Books

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincot 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

(3 hrs / week)

Topic No	Name of the topic and contents	Hrs
	Pharmacology of drug shall includes : classification, mechanism of action, pharmacological actions, pharmacokinectics, therapeutic uses, adverse effects, drug interactions, contraindications, dosages, treatment of poisoning (if any) *Pharmacotherapy shall include: Pharmacology of drug/s used for clinical management of diseases/ disorders*	
	SECTION I	
1	**General Anesthesia:** Stages and Principles of Anesthesia, Pharmacology of Intravenous and Inhalational Anesthetics.	**02**
2	**Local Anesthetics:** *Pharmacology of injectable and surface anesthetics*, Clinical Uses *and techniques of administration of local anesthetics*	**02**
3	**Alcohols and alcoholism:** Pharmacology of Alcohol, and management of chronic alcoholism. *Treatment for alcoholic liver diseases*	**03**
4	**Psychopharmacological drugs:** Antipsychotic, anti-anxiety, Sedative, Hypnotics, Antidepressant, Antimanic drugs	**08**
5	**Antiepileptic Drugs:** Classification of epileptic Seizure, *Pharmacology of one prototype drug from each class of antiepileptic drugs used in Grand Mal, Petit Mal epilepsies.*	**04**
6	**Pharmacotherapy of Parkinson's disease and Alzheimer's disease**	**04**

	SECTION II	
7	**Opioid Analgesics and antagonist:** Classification and Pharmacology of opioid Analgesics (Morphine), opioid Antagonists.	***04***
8	***Pharmacology of*** **Non-steroidal anti-inflammatory drugs**	***03***
9	***Pharmacotherapy of Rheumatoid Arthritis, Osteoartritis and Gout***	***03***
10	**Drugs Used in Respiratory tract *disorders:*** Pharmacology of drugs used in Bronchial asthma, COPD and Cough.	***04***
10	**Drugs Used in Gastrointestinal tract *disorders:*** **i)** *Pharmacotherapy of Peptic Ulcers- Pharmacology of* Proton Pump Inhibitors, H2-Receptor Antagonists, Mucosal Defense Enhancers, Antacids and cytoprotectants **ii) *Pharmacology of*** Emetics and Anti-Emetics **iii)** *Pharmacotherapy of* Constipation. **iv)** *Pharmacotherapy of diarrhea.*	**08**

Recommended Books:

1.Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, Little Brown and Co, Boston

2.Crossland, James and; Lewis,s Pharmacology Basis of Therapeutics, (Pergamon Press, New York)

3.Goodman and Gilman; Pharmacological Basis of Therapeutics, McGraw-Hill

4.Katzung, B.G; Basic and Clinical Pharmacology, Lange Medical Publisher, USA

5.Rang, H.P. and Dale, M.M.; Pharmacology, Churchill Livingston, UK

6.Satoskar , R.S. and Bhandarkar S.D. Pharmacology and Pharmacotherapeutics (Popular Prakashan, Bombay).

7.Sharma H.L. Sharma K. K. General Pharmacology Basic Concepts. Paras Publication.

8.Tripathi K. D. 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. Vyawahare N. S., and Vora S., General Pharmacology, Nirali Publication, Pune

14. Mycek M. J,Harvey, RA and Champe PC Lippincott's Illustrated Reviews:Pharmacology Lippincott Williams & Wilkins.Phillodelphia

3.6.4 P Pharmacology-III

(3 hrs / week)

Sr. No	Title of the Experiment
1	Determination of unknown concentration of Acetylcholine using suitable isolated tissue preparations by Matching bioassay method
2	Determination of unknown concentration of Histamine using suitable isolated tissue preparations by Matching bioassay method
3	Determination of unknown concentration of Acetylcholine using suitable isolated tissue preparations by Bracketing bioassay method
4	Determination of unknown concentration of Histamine using suitable isolated tissue preparations by Bracketing bioassay method
5	Determination of unknown concentration of Acetylcholine using suitable isolated tissue preparations by Interpolation bioassay method
6	Determination of unknown concentration of Histamine using suitable isolated tissue preparations by Interpolation bioassay method
7	To Study of analgesic activity of drugs using Eddy's hot plate analgesiometer in mice
8	To Study of locomotor activity of drug using actophotometer in mice
9	To Study of muscle relaxant property of drug using rotarod in mice

Isolated tissue experiments must be carried out using at least two different preparations for each method

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, (Kothari Book Depot, Mumbai)

6.Chatterjee, C.C., Human Physiology. Medical Allied Agency, Kolkata.

7.Ganong, W.F., Review of Medical Physiology. Prentice-Hall International, London.
8.Guyton, A.C., Textbook of Medical Physiology. W. B. Saunders Co., Philadelphia, USA.
9.Perry W.L.M. Pharmacological Experiments on Isolated Preparation, E&S Livingstone, London
10. Goyal R. K., Practicals in Pharmacology, B. S. Shah Prakashan, Ahemadabad

3.6.5 T Natural Product Chemistry

(3 hrs / week)

A] Knowledge: on completion of theory, learner should be able to:

1. Understand & explain various physical, chemical, spectroscopic means & methodsused in structural elucidation of natural products. He/she should be able tointerpret data generated from above techniques.
2. Understand & explain tools & techniques used in study of biosynthetic pathwaysin plants.
3. Explain source, chemistry & applications of drugs from marine origin. He/sheshould be able to compare & contrast marine & terrestrial sources of medicinalmaterials.
4. Explain difficulties in elucidation of biosynthetic pathways in plant & explainapproaches used with their merits & demerits.
5. Understand & explain underlying reasons as why natural products are appropriatematerial in discovering new drugs & also explain their contribution in moderndrug discovery.
6. Explain source, extraction, processing, chemistry & applications of naturalproducts used in pharmaceutical & allied industry such as coloring & sweeteningagents.

B] Skill: on completion of laboratory experiments, learner should be able to:

1. Extract & subsequently conduct experiments to derive various physical constantsrequired in characterization of natural products.
2. Charge, elute & gather pure material using column chromatography.
3. Record UV/IR spectrum of given sample & interpret them.
4. Interpret NMR/Mass spectrum
5. Able to handle various equipments as per SOPs & learn various demonstrations(of experiments).
6. Listen carefully, raise logical query, draw information, understand rationaleduring field visits & prepare brief report for evaluation.

Sr. No	Topic	No. of hrs
1	**Overview of means & methods used in structural elucidation of natural products** ***A] Characterization & determination of carbon skeleton of natural products:*** i] *Methods used to establish purity & elemental composition.* *Physical methods of characterization:* M.P./B.P., optical rotation,Refractive index *Analytical methods of characterization:* Elemental compositiondetermination by combustion analysis/high-resolution spectrometry,relative molecular mass. *Chromatographic methods of characterization:* constants derived fromTLC/HPTLC, HPLC, and GC. *Spectroscopic methods of characterization:* UV, IR, Proton NMR spectrum& Mass Spectrometry. ii] Simple chemical derivatives iii] Determination of carbon skeleton: Chemical & spectroscopicmethods. ***B] Location of functional groups & molecular stereochemistry:*** i] Spectroscopic interrelationships: IR & NMR methods ii] Chemical methods: oxidative strategies, ozonolysis, ring formationreactions, reaction with acids, rates of reaction. iii] Determination of absolute stereochemistry: molecular rotationdifferences, asymmetric induction, optical rotator dispersion & circulardichroism, NMR methods, crystallographic methods.	15
2	**Characterization & structure elucidation of certain classes of secondarymetabolites:** A] Terpenoids:i) General chromatographic characteristics ii) General means of structure elucidation by chemical & physicalmethods B] Alkaloids: i) General means of structure elucidation by chemical methods. C] Flavonoids: i) General means of structure elucidation by spectral methods.	11
3	**Methods in biosynthetic studies:** Tracer techniques; isolated organs, tissues &cells;grafts; mutant strains.	3
4	**Marine drugs:** cardiovascular-active & anti-cancer agents from marine source.	4
5	**Natural product based drug discovery:** A] Strategies of drug discovery; suitability of natural products in drug discovery as	4

	far astheir diversity, chirality, complexity, receptor binding property & biological relevanceare concerned. B] Overview of contribution of natural product in new drug discovery.	
6	**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, Gymnemasylvestre.	8

Recommended Books :

1. Agarwal O. P., **Chemistry of Organic Natural Products** vol.1, Krishna Prakashan,Merrut, 2004. ISBN: 81-85842-98-1.
2. Agarwal O. P., **Chemistry of Organic Natural Products** vol.2, Krishna Prakashan,Merrut, 2005. ISBN: 81-85842-98-1.
3. Atherden, L.M., Bently and Driver's **Textbook of Pharmaceutical Chemistry**, 8thEd., Oxford University Press, 2004. ISBN: 9780195609639.
4. Bruneton Jean, Caroline K. Hatton, **Pharmacognosy, Phytochemistry, Medicinalplants.** Lavoisier, 1999. ISBN 1898298637.
5. Chatwal G.R., **Organic Chemistry of Natural Products** by vol. I and II. HimalayaPublishing House, 2010.ISBN-14: 09789350246441.
6. Evans W. C., Trease G. E., **Trease and Evan's Pharmacognosy.** W.B. Saunders,2002. 16th Ed. ISBN-10: 0702029335.
7. Finar I.L., **Organic Chemistry: Stereochemistry & the Chemistry of NaturalProducts**, Vol.II., Pearson Education India, 5th Ed. ISBN**:** 81-7758-541-X.
8. Gokhale S.B., Gaud R.S., Surana S.J., **Natural Excipients**, Nirali Publications, 2008.ISBN 978-81-85790-60-2.
9. Hanson J.R., **Natural Products: The Secondary Metabolites**, Royal Society ofChemistry, UK, 2003. ISBN 0-85404-490-6.
10. Kokate C. K., Gokhale S.B. and Purohit A.P., **Textbook of Pharmacognosy**, NiraliPrakashan, Pune, 2008, ISBN: 8185790094.

11. Mukherjee Pulok K., **Quality Control of Herbal Drugs: An Approach to Evaluationof Botanicals**. Business Horizons, 2002. ISBN 8190078844.
12. Rajpal V. &Kohli D. P. S., **Herbal Drug Industry**, Riddhi International, 2nd Ed.,2009. ISBN: 9788190646727.
13. Rangari V.D., **Pharmacognosy & Phytochemistry** (Vol I), Career Pub., Nashik,2009, ISBN: 978-81-88739-45-5.
14. Rangari V.D., **Pharmacognosy & Phytochemistry** (Vol II), Career Pub., Nashik,2009, ISBN: 978-81-88739-65-3.
15. Tadeusz F. Molinski, Doralyn S. Dalisay, Sarah L. Lievens and Jonel P. Saludes,**Drug development from marine natural products**, Nature Reviews: DrugDiscovery,8,69-84, 2009.
16. Wallis T. E., **Textbook of Pharmacognosy.** CBS Publisher & Distributors,1985.ISBN:81-239-0886-5.

3.6.5 P Natural Product Chemistry

(3 hrs / week)

1. Determination of melting point, solubility, optical rotation, refractive index ofpure natural compounds. (Min. 3 Expt.)
2. Extraction & TLC characterization of eugenol, caffeine, bixin&curcumin (Min. 2Expt.)
3. Isolation of phytoconstituents by column chromatography (Min. 1 Expt.)
4. Recording & interpretation of UV/IR spectrum of pure natural products. (Min. 2Expt.)
5. Analysis of sugars in natural gums by TLC
6. Detection of adulterants in lipid samples (Chemical & TLC methods)
7. Interpretation of IR & NMR spectra of natural products. (Min. 6 Expt.)
8. Characterization of phytoconstituents by using HPLC (Demo)
9. Field visit: Visit to industry/ cultivation farm/ processing unit & submission ofreport 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. Kadbadi S.S., Deore S.L. &Baviskar B.A., **Experimental Phytopharmacognosy**,Nirali Publication, Pune, 2011. ISBN 9381237131.

4. Khandelwal K. R., **Practical Pharmacognosy**, Pragati Books Pvt. Ltd. ISBN8185790302.
5. Kokate C. K., **Practical Pharmacognosy**, VallabhPrakashan, 1993.
6. Krishnaswamy N. R., **Chemistry of Natural Products: A Laboratory Handbook**,CRC Press; 2nd Ed., 2012. ISBN-10: 1466505249.
7. Siddiqui A.A., Siddiqui S. **Natural Products Chemistry Practical Manual,** CBSPublishers & Distributors, 2008. ISBN-10: 8123916213.

3.6.6 T Bioorganic Chemistry & Drug Design

(3 hrs / week)

Learning objectives:

On completion of following theory topics, a learner should

1. Understand the significance of Bioorganic Chemistry and establish its relevance in drug design & discovery.
2. Explain approaches in rational drug design.
3. Understand various drug targets, their biochemical features, physiological & patho-physiological roles and significance in drug design.
4. Explain biotransformation of pro-drug design aspect in drug design.

Sr. No	Topic	No. of hrs
01	**Bioorganic Chemistry** Introduction to Bioorganic Chemistry, Basic consideration, Molecular Adaptation, Molecular Recognition and 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. **A. Enzymes:** Oxidoreductases: Monoamine Oxidase and Cyclooxygenase-1and 2, HMG-CoA reductase, DHFR (Human), DHFR (Bacterial), Transferase: Tyrosine Kinase (Leishmanial, Bacterial and Human). Hydrolases: Human Factor Xa, Bacterial Serine Protease Hydrolases (Mettaloproteases): ACE, Human Carboxypeptidase, Esterases: AChE, Phosphodietrase-1, Phosphodiesterase-5	10

	Lysases: DOPA Carboxylase, Carbonic Anhydrase, Histidine Carboxylase Isomerases: Thymidylate Synthase (Fungal and Human), Phosphofructokinase (Leishmanial)	
	B. Nucleic Acids: DNA and RNA as drug targets, mechanisms of intercalation, complexation, alkylation, oxidative degradation, strand breaking by the drugs, targets in protein synthesis eg. Topoisomerase-II, reverse transciptase (human and viral). mRNA, rRNA and antisense therapy.	04
	C. Receptors $GABA_A$, Cholinergic, Adrenergic, Adenosine, Angiotensin, Dopamine, Glucagon, GLP-1, Prostanoid, Serotonin, Progesterone, Glucocorticoid, Estrogen, PPAR-γ, Thyroid Hormone, Insulin receptors	08
03	**Drug Design** Introduction to drug design and discovery, phases involved, case studies e.g. development of ciprofloxacin, anti-diabetics etc. Introduction to QSAR: Hansch & Free Wilson Analysis, lead discovery & optimization. Principles of drug design with examples from following categories: antihypertensives, psychotherapeutics. Molecular docking strategies & different methods of docking. Mechanism based drug design including quantum mechanics, molecular mechanics and molecular modeling.	13
04	**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
05	Introduction to pro-drugs, different strategies for design of pro-drugs with suitable 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, Bioinorganic 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)

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

A. Knowledge:

1. Define Biotechnology & its state its scope in pharmacy
2. Know the basics of biotechnology techniques and the various systems used.
3. Know the method of genetic engineering for production of rDNA products including monoclonal antibodies.
4. Know the information about the application of genetic engineering in animals.
5. Have a knowhow of enzymes and their uses by immobilization.
6. Illustrate use of Fermenter for production of fermentation products and information about their purification by downstream process.
7. State the application of Fermenter process in production of vitamins and antibiotics.

Sr. No	Topic	No. of hrs
1	Introduction to Biotechnology, Scope, Potential & Achievements	1
2	**Gene transfer:** Transformation, Transduction and Conjugation	3
3	**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
4	**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
5	Examples of Biotechnology derived Products: Human insulin, Somatotropin, Interferons, (Production of their rDNA constructs and uses) Introduction to Human Gene Therapy	4
6	Introduction to transgenic animals and their applications. Germplasm storage & cryopreservation	3
7	Steps involved in Monoclonal antibody production and its applications.	2
8	Enzyme Technology; Immobilization of enzyme & its applications	3
9	Fermentation Technology; Fermenter its accessory components and working, Down streaming Process in brief.	5
10	General application of fermentation in Manufacturing of Antibiotics and Vitamins with one example each.	4

Recommended Books:

1. Olive Kaiser ,Rainer Muller, Pharmaceutical Biotechnology: Drug Discovery and Clinical Application, Wiley VCH publisher, 2004
2. Peter J. Russel, Genetics 5 th Edition ,The Benjamin Cummins

Publishing California;1998

3. Watson WH Freeman and company N.Y. Recombinant DNA 2 nd edition Holtzbrinck Publishers 1992
4. Glick, Molecular biotechnology 3 rd edition ASM press Washington, USA 2003 61
5. Vyas and Dixit Pharmaceutical Biotechnology, 1 st CBS Publisher New Delhi, 1991
6. Dr. S. Iganacimuthu, Basic Biotechnology – Tata McGraw Hill Publishers
7. P. K. Gupta, Elements Of Biotechnology, Rastogi Publication, 10 th edition, 2004
8. S.S. Purohit, Biotechnology Fundamentals and Applications Student edition Agrobios Publisher;2002
9. H. S. Chawala, Introduction of Plant Biotechnology, 2 nd edition, IBH Publishing Co. Pvt.Ltd. New Delhi, 2002
10. M.H. Razdan, Introduction to Plant Biotechnology , 2 nd edition 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 Allied Ltd