SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF PHARMACEUTICAL SCIENCES

Syllabus of Final Year B. Pharmacy

(EFFECTIVE FROM ACADEMIC YEAR 2018-19)

PATTERN 2015

Credit and Grading Based Semester System

FINAL YEAR B.PHARMACY **SEMESTER –VII**

4.7.1 T STERILE PRODUCTS
(3hrs/week), CREDIT: 03

Learning Objective:

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

Knowledge:

- Describe the General requirements, routes of administration, significance of tonicity adjustment and sterility and Pre-formulation of sterile products
- Describe various packaging materials used, types, choice of containers, official quality control tests and methods of evaluation.
- Describe the GMP and design and layout of Parenteral Production Facility, environmental control zones, heating ventilation air conditioning (HVAC), HEPA filter and laminar area flow systems.
- Explain Classification and formulation of SVP, types and selection of vehicles and added substance, processing, manufacturing and Quality control of SVPs along with Special types of SVPs and Pilot plant scale up.
- Explain Large Volume Parenterals (LVPs),Types, concept of formulation, influence of physiological factors, processing, manufacturing and Quality control of LVPs, along with Parenteral Nutrition, intravenous admixture and Peritoneal dialysis fluid and Pilot plant scale up.
- Explain General requirements, formulation, types and evaluation of ophthalmic products.
- Describe Blood Products and SurgicalDressings

Skills:

- Formulation development and Pharmacopoeial evaluation and labeling of SVPs, LVPs, and ophthalmicpreparations
- Expertise in sealing ofampoules
- Describe use of ingredients in formulation and category of formulation
- Pharmacopoeial evaluation of packagingmaterials
- Importance and validation of asepticarea
- Evaluation of marketedpreparations
- Significance and Accelerated stability testing of marketed samples.

Sr.No.	Topic	Hrs
	SECTION-I	
01	Sterile formulations: Pre-formulation: Physicochemical properties of drug substances,General requirements, routes of administration, significance of tonicity adjustment andsterility.	05
02	Packaging of Parenterals : Various materials used, factors influencing choice of containers, packaging components and types, official quality control tests and methods of evaluation, prefilled syringes, blow-fill-seal technique	05

03	GMP-Design of Parenteral Production Facility: Product characteristics, personnel, batch Vs continuous operation, development of facility layout, environmental control zones, filling area design, heating ventilation air	05
	conditioning (HVAC), HEPA filter testing and rating, laminar area flow systems.	
04	Small Volume Parenterals (SVPs): Classification, types of vehicles, selection of vehicles and added substance, processing and manufacturing of SVPs, Pilot plant scale up forSVPs.	08
SECTION-II		
05	Large Volume Parenterals (LVPs): Types of LVPs, concept of formulation, influence of physiological factors, stabilization of LVPs, processing and manufacturing of LVPs, Parenteral Nutrition, intravenous admixture and	05
06	Lyophilization basics: Introduction, Principle, steps involved and Application of Freeze drying process. Component, Parameters, Construction and Working of Lyophilizer/ Freeze dryer	03
07	Ophthalmic Products: General requirements, formulation, types of dosage forms, evaluation of ophthalmic product. Contact lens and lens care products,	04
08	Blood Products: Collection and storage of whole human blood, fractionation of plasma. Quality control of blood products. Plasma Volume Expanders.	05
09	Surgical Products: Definition Sutures and Ligatures of different types, Primary wound dressing, absorbents, surgical cotton, surgical gauzes bandages, advances (Super porous hydrogels) absorbent foam (polyurethane) dressings, Quality controltesting.	03
10	Introduction to injectable / parenteral devices	02

4.7.1 P STERILE PRODUCTS
(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	Validation of aseptic area and demonstration of gowning procedure.
02	Pharmacopoeial evaluation of glass and plastic containers and rubber closures used for injectable.(only physicochemical tests)
03	Formulation and quality control of SVPs as per Indian pharmacopoeia. Any 3 (at least two ampoulesealing)
04	Formulation and quality control of LVPs as per Indian pharmacopoeia. Any 2
05	Accelerated stability testing of a SVP or LVP marketed samples.
06	Formulation, packaging and quality control of ophthalmic: Eye drop and Eye
07	Evaluation of marketed lyophilized products as reconstitutable solution or suspension for injection, Parenteral suspensions or emulsions. Evaluation parameters: particle size determination, test for sterility and rheological behavior using Brookfield viscometer.
08	To study and scrutinize labels of marketed surgical/blood products /injectable/implant devices.

Note: Every student should make a 10 minute PowerPoint presentation explaining result and discussion component of any one practical performed.

Recommended books

1. K. E. Avis, H. A. Lieberman ; Pharmaceutical dosage forms, Parenteral medications, 2nd ed,Vol I,II & III, Marcel Decker1993.
2. S. J. Turco; Sterile Dosage Forms; their preparation and clinical applications, 4th ed., Lee and Febiger, 1993.
3. W. P. Olson, M. J. Groove; Aseptic Pharmaceutical Manufacturing Technology, Interpharmpress.
4. Indian Pharmacopoeia, vol.I, II & III, 2014.
5. L. A. Trissel; Handbook on Injectable drugs, American society for hospital Pharmacist Publication.
6. Haward.C. Ansel; Pharmaceutical calculations, 13th Ed, Lippincott Williams & Wilkins Publication,2010
7. Cooper and Gunn ;Dispensing for Pharmaceutical Students, 12th Ed, CBS Publication
8. Leon Lachmann and Lieberman; The theory and practice of pharmacy, 3rd Ed, CBS Publication,1986
9. Lockheart; Packaging of Pharmaceuticals of Healthcare products, Marcel Decker, 1998.
10. Herburn Kenneth; Quality control of Packaging Materials, in Pharmaceutical Industry Marcel Dekker,1990.
11. Michael Levin; Pharmaceutical Process Scale-Up, 2nd Ed, vol-157, CRS Press, 2006.
12. Mitra; Ophthalmic Drug Delivery System, 1st Ed, Vol-58, Marcel Dekker, 1993.
13. Ray & May; Freeze Drying / Lyophilization of pharmaceutical & Biological Products, MarcelDekker.
14. Cooper and Gunn's Tutorial pharmacy,S.J.Carter,sixth edition, 2005, CBS Publication.
15. Remington: The Science and Practice of Pharmacy, Volumes 1-2, 22nd edition, 2012
16. William Whyte; Cleanroom Technology: Fundamentals of Design, Testing and Operation 2nd ed, March 1, 2010,Wiley Publication

4.7.2 T PHARMACEUTICAL ANALYSIS -V
(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 spectroscopies, 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.	Topic	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	**High performance Liquid Chromatography (HPLC):** Theory, instrumentation and applications, Isocratic & Gradient types, Pumps, Columns, Detectors,Tubings, Degassing techniques, Quantitation techniques including Area normalization, percent area, Internal and external standard methods, Trouble shooting in brief and System suitability testing, **UPLC:** Introduction and advantages over HPLC.	11
02	**Infrared Spectroscopy:** Origin of IR spectra, Molecular vibrations, fundamental bands, Vibrational frequency, Fermi resonance, Important spectral regions. **FTIR:** Theory, Instrumentation, sample handling, different attachments used in recording FTIR. Analysis and Interpretation of organic compounds based on FTIR Spectra Introduction to Near Infrared (NIR) & Raman spectroscopy with respect totheory, instrumentation and applications.	07
03	Introduction, principle, and applications ofScanning Electron Microscopy (SEM) and Transmission Electron Microscopy (TEM)	04
SECTION-II		
04	**Gas Chromatography:** Theory, instrumentation, sample handling, columns,detectors, derivatisation and quantitation (area normalization, percent area, Internal standard and	10

	External standard method) and applications.	
05	**Flash Chromatography**: Theory, instrumentation and applications.	03
06	**Super Critical Fluid Chromatography**: Theory, instrumentation and applications.	05
07	**Introduction to Automated methods of Analysis:** Flow injection analysis.	05

4.7.2 PPHARMACEUTICAL ANALYSIS - V
(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	UV Spectrophotometric estimation of two-component formulations by simultaneous equation method (Minimum three)
02	UV Spectrophotometric analysis of two component formulations by Q-Method. (Minimum two)
03	Recording of IR spectra of compounds with different functional groups (-COOH, -COOR, - CONHR, -NH2,-NHR, -OH, -CHO, -CO etc.) (Minimum two)
04	IR-Spectral interpretation of aliphatic and aromatic compounds (Minimum two)
05	Demonstration experiments: Gas Chromatography /Atomic Absorption Spectrophotometry/ SEM

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

4.7.3 T MEDICINAL CHEMISTRY-III
(3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- 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 antibiotics, anti-infective agents and anti-neoplastic agents.

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 column chromatography.
- Characterize the synthesized compounds using IR and NMR spectras.
- Purify the solvents using fractional and vacuum distillation.
- Explain reaction mechanisms involved in synthesis of medicinally important compounds.

Sr.No.	Topic	Hrs.
1. 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.		
SECTION-I		
1.1	**Antibiotics:** a. β-lactam antibiotics: Penicillins and Cephalosporins, oxopenams, carbapenams, monobactams and beta lactamase inhibitors b. The aminoglycosides c. The tetracycline d. The macrolides e. The Lincomycins f. The Polypeptides g. Unclassified antibiotics (AmoxycillinTrihydrate, Cephadroxil)	15
1.2	**Antineoplastic agents including recent drugs and monoclonal antibodies** (Melphalan, Chlorambucil, Methotrexate)	08
SECTION-II		
1.3	**Anti-infective agents:** a. Synthetic antibacterial agents eg. Sulfonamides, Quinolones, Nitrofuransetc. b. Antitubercular&Antileprotic agents c. Antifungal agents d. Antimalarials e. Antiamebic agent	22

	f. Trypanosomicidal drugs, drugs acting against leishmaniasis. g. Anthelmintics h. Antiviral agents including antiretroviral (Metronidazole, Ciprofloxacin, Proguanil, Amodiaquine, PAS, Isoniazid,Clotrimazole, 5-Flocytosine, Nevirapine, Saquinavir, Albendazole)	

4.7.3 P MEDICINAL CHEMISTRY-III
(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	Synthesis of following medicinally important compounds/drug intermediates withrecrystallization of each compound and motoring reactions over TLC. a. Ibuprofen b. 4-Fluoro acetophenone c. Methyl benzoate d. 2-Methyl benzimidazole e. Any organic compound involving Biginelli Reaction f. Caprolactam g. Benzyl alcohol
02	Purification of above synthesized compounds by Column chromatography (Any two)
03	Interpretation of IR spectra of synthesized compounds (Any three)
04	Interpretation of ^{1}H-NMRs Standard spectra of organic compounds (Any two)
05	Demonstration experiments: Gas Chromatography /Atomic Absorption Spectrophotometry/ SEM

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, 6thedition, 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, 1stedition, New Age
7. International Publishers.
8. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
9. Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II,10th Edition, Nirali Prakashan.
10. Drug Design by Bothara KG & Kulkarni VM, 3rdedition, Nirali Prakashan.
11. Pharmaceutical Substances by Kleeman& Engel, 4th edition, Thieme Publications.
12. The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 by Lednicer Daniel, 1stedition, John Wiley & Sons INC.

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

4.7.4 T PHARMACOLOGY- IV
(3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- Classification, mechanism of action, antibacterial spectrum, resistance, therapeutic uses, adverse effects and contraindications of various antibiotics.
- Various endocrine hormones, its types, receptors involved and mechanisms involved.
- Biosynthesis, Mechanism of action, Pharmacology and regulation of Thyroid, antithyroid drugs and Parathyroid hormones.
- Biosynthesis, Secretion, Mechanism of action, Pharmacology of insulin and glucagon and Pharmacotherapy of Diabetes Mellitus.
- Pharmacology of Androgens, Estrogens, Progestin and oral contraceptives.

Skills

- Use of isolated tissue preparations for bioassay methods.
- Basic aspects to carryoutCritical appraisal of marketed fixed dose combinations (FDC).
- Understanding Prescription auditing and standard treatment protocols.

Sr. No	Name of the Topic and Contents	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: Rational approaches and clinical management of diseases/ disorders		
	SECTION I	
01	General principles of chemotherapy of infections and mechanism of drug resistance.	01
02	Classification, mechanism of action, antibacterial spectrum, resistance, therapeutic uses, adverse effects and contraindications of: a. Penicillins, cephalosporines and β-lactamase Inhibitors b. Sulfonamides and urinary antiseptics c. Amino glycosides and macrolides d. Quinolones and fluroquinolones. e. Tetracycline and chloramphenicol f. Tuberculosis and leprosy including National TB programmes (DOTS) g. Antimalarials, anthelmintics and antiamoebics h. Antiviral (Including anti -HIV drugs) and antifungals i. Antineoplastic drugs	23
	Section II	
03	**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	05
04	**Adrenocorticosteroids and corticosteroid antagonists** Biosynthesis, Mechanism of Action and Pharmacology	04

05	**Thyroid and antithyroid drugs** Biosynthesis, Mechanism of Action and Pharmacology **Parathyroid hormones:** Drugs regulating calcium homeostasis, Vitamin D	04
06	**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	05
07	**Androgens, Estrogens, Progestin and oral contraceptives**	03

Recommended Books:

1. Goodman and Gillman: Pharmacological Basis of Therapeutics, McGraw-Hill, Medical Publishing Division, New York.
2. Barar FSK: Essentials of Pharmacotherapeutics, S. Chand & Co., New Delhi.
3. Bevan JA and Thompson JH: Essentials of Pharmacology, Harper and Row Publishers, Philadelphia.
4. Bowman WC and Rand MJ: Textbook of Pharmacology, Blackwell Scientific Publications, Oxford.
5. Butterworth S: Modi' s Textbook of Medical Jurisprudence and Toxicology.
6. Craig C.R. and Stitzel RE: Modern Pharmacology, Little Brown and Co., Boston.87
7. DiPiro JT: Encyclopedia of Clinical Pharmacology, Marcel Dekkar, New York.
8. DiPiro JT: Pharmacotherapy: A Pathophysiological Approach. Elsevier Publications, London.
9. Hansten PD: Drug Interactions, Lea &Febiger, Philadelphia.
10. Harisons: Principles of Internal Medicine, McGraw Hill Publications, Singapore.
11. Herfindal E: Clinical Pharmacy and therapeutics, Williams and Wilkins Publications, New York.
12. Katzung BG: Basic and Clinical Pharmacology, Lange Medical Publications, California.
13. Krantz and Carr: Pharmacology Principle of Medical Practice, Williams & Wilkins Co, Baltimore.
14. Laurence D.R. and Bennett P.N.: Clinical Pharmacology, Churchill Livingstone, Edinburgh.
15. Parikh CK: Parikh' s Text Book of Medical Jurisprudence and Toxicology. CBS Publishers and Distributors, Mumbai.
16. Rang HP and Dale MM: Pharmacology, Churchill Livingstone, Edinbergh.
17. Satoskar RS and Bhandarkar SD: Pharmacology &Pharmacotherapeutics, Popular Prakashan, Bombay.
18. Tripathi KD: Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, New Delhi.

4.7.4 P PHARMACOLOGY- IV
(3hrs/week), CREDIT: 02

Sr. No	Title of the Experiment
01	To find out the concentration of given drugs using three point bioassay method on suitable isolated tissue preparations (Min.02 Expt.)
02	To find out the concentration of given drugs using four point bioassay method on suitable isolated tissue preparations (Min.02 Expt.)
03	**Critical appraisal of marketed fixed dose combinations** with respect to comments on prescriptions of some proprietary preparations and multiple drug therapy (rational/irrational) mentioning possible indications, dose, route of drug administration, justification of inclusion of each ingredient, adverse reactions, contraindications, precautions and special instruction to patients. (Minimum 04 rational and 02 irrational combinations to be discussed)
04	**Prescription auditing and standard treatment protocols:** Comment on given prescriptions with reference to case reports mentioning possible indications and contraindications with dose, route of administration and justification of each ingredient. Comments on special instruction, drug interaction and justification of discharge medication (on the basis of available evidences from literature) (Minimum 05 prescriptions to be discussed)

Recommended Books:

1. Burn JH: Practical Pharmacology, Blackwell Scientific Co., Oxford.
2. Daniel Wayne W. Biostatistics: A Foundation for Analysis in the Health Sciences , Wiley
3. Series in Probability and Statistics, Wiley Interscience, USA.
4. Ghosh MN: Fundamentals of Experimental Pharmacology, Scientific Book Agency. Bombay.
5. Goyal RK: Practical Experimental Pharmacology. BS Shah Prakashan, Ahmedabad.
6. Jaju BP: Pharmacological Practical Exercise Book, Jaypee Brothers, New Delhi.
7. Kulkarni SK: Hand Book of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
8. Laurence DR and Bacharach AL: Evaluation of Drug Activity: Pharmacometritics, Academic Press, London.
9. Patil CR: X-Cology (Software), Pragati Book Co. Pvt. Ltd., Pune.
10. Perry WLM: Pharmacological Experiments on Isolated Preparations. E&SP Livingstone, London.
11. Ravindran R: X-Pharm (Software), Indian Journal of Pharmacology, JIPMER, Pondicherry.
12. Sheth UK, Dadkar NK and Kamat UG: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Bombay.
13. Turner RA: Screening Methods in Pharmaocology

4.7.5 T NATURAL DRUG 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 various factors affect on level of secondary metabolites, how these can be minimized to ensure quality in raw material, effect of post harvesting manipulations,and changes during storage etc& methods to control these modification.
- Explain variousguidelines issued by WHO in relation with cultivation, collection, storage etc.
- Understand & explain concept of health & pathogenesis, philosophical basis, diagnosis &treatment aspects of Ayurveda, Unani, Siddha &Homoepatic system of medicine; Understand& explain method of preparation of Ayurvedic dosage forms; significance of novel drugdelivery of natural products; herbs used in cosmetic preparation & methods of their formulations.
- Understand and explain the applications of plant tissue culture for Secondary metabolite production.
- Explain in vitro screening methods and its applications for biological evaluation of natural products
- Explain the approaches and potentials of herbal new drug delivery systems like liposomes, phytosomes, nanoparticles and vesicles
- Understand & explain various physical, chemical, spectroscopic means & methods used instructural elucidation of natural products. He/she should be able to interpret data generated from above techniques.

Skill*:*

- Prepare, label & evaluate herbal/TSM formulations
- Evaluate marketed cosmetic & nutraceutical formulations
- Conduct preformulation parameters & understand underlying rationale
- Conduct in vitro assays for correlation with biological efficacy
- Able to handle various equipments as per SOPs & learn various demonstrations (of experiments).
- Listen carefully, raise logical query, draw information, understand rationale during fieldvisits & prepare brief report for evaluation.

Sr.No.	Topic	Hrs
	SECTION I	
01	**Cultivation, Harvesting and Storage of Crude Drugs** Factors influencing level of plant metabolites, method of cultivation, harvesting and storage, primary and secondary factors affecting on deterioration of crude drugs, WHO guidelines for good agricultural and collection practices (GACP).	04
02	**Plant Biotechnology** Applications of Plant Tissue Culture in production of secondary metabolites a. Production-Selection of cell lines for high yield of secondary metabolites	05

	b. Elicitors induced production of secondary metabolites c. Biotransformation using Plant Cell Culture d. Types of cultures, Transgenic plants, Gene Transfer	
03	**In-vitro Screening Methods & its Applications for Natural Products** a. Anti-inflammatory activity- COX-I & COX-II assay b. Anti-cancer activity- Sulphorhodamine-B assay (SRB), MTT assay, Brine Shrimp lethality assay c. Anti-oxidant activity-Free Radical Scavenging Activity (DPPH), Hydrogen Peroxide (H_2O_2) scavenging assay, Nitric oxide Scavenging Activity, Reducing Power method.	05
04	**Traditional systems of medicine (AYUSH):** a. Basic principles of therapy in traditional system of medicine like Ayurveda, Unani, Siddha and Homeopathy (AYUSH). b. Ayurvedic dosage forms-Method of preparation and evaluation of Asava, Arishtha, Taila, Ras-Rasayana, Avaleha, Bhasma, Churna and Vatika.	06
	SECTION II	
05	**Overview of novel drug delivery systems for herbal drugs.** a. Introduction, Novel drug delivery approaches, Potentials of Novel Drug Delivery for Herbal drugs. b. Liposomes & Phytosomes c. Nanoparticals d. Novel Vesicular Herbal Formulations	04
06	**Cosmecuticals:** Overview of herbs used in cosmetics for skin & hair care,general method of preparation & evaluation of a. Skin care products: Cold cream, vanishing cream, moisturizer, lip balm, lipstick, sunscreen lotion/cream, anti-acne, anti-wrinkle cream. b. Hair care products: Shampoo, Conditioner, Dyes, Colorants, Styling gel.	04
07	**Overview of means & methods used in structural elucidation of natural products** a. Physical methods of characterization: M.P./B.P., optical rotation,Refractive index b. Analytical methods of characterization:Elementalcomposition,determination by combustion analysis. c. Chromatographic methods of characterization: constants derived fromTLC/HPTLC d. Spectroscopic methods of characterization: UV, IR, Proton NMR spectrum & Mass Spectrometry.	08
08	**Structural elucidation of following Phytoconstituents by chemical and spectroscopical methods (UV, IR, NMR & Mass)** a. Alkaloids-Morphine, Atropine, Caffeine, Ephedrine b. Glycosides- Digoxin, Sennosides, c. Terpenoids- Taxol, Citral d. Flavonoids-Quercetin	09

Recommended Books:

1. Agarwal SS. &Paridhavi M., Herbal drug technology, Universities Press, 2007. ISBN-10:8173715793.
2. Alessandro Burianiet al., Omic techniques in systems biology approaches to traditionalChinese medicine research: Present and future. J. Ethnopharmacol., 140 (2012) 535– 544.
3. Aluko, Rotimi E., Functional Foods and Nutraceuticals, Food Science Text Series, Springer Pub., 2012.ISBN 978-1-4614-3480-1.
4. Ashutosh Pareek, Divya Goswami, Mahendra Singh Ashawat, Herbs in New Era of Cosmaceuticals: Opportunity & Challenges: Herbal Cosmetics. Lap Lambert Academic Publishing, 2012. ISBN-10: 3659149322.
5. Bhushan Patwardhan, Ashok D. B. Vaidya, Mukund Chorghade and Swati P. Joshi, Reverse Pharmacology and Systems Approaches for Drug Discovery and Development. Current Bioactive Compounds 2008, 4, 201-212.
6. Bruneton Jean, Caroline K. Hatton, Pharmacognosy, Phytochemistry, Medicinal plants.Lavoisier, 1999.ISBN 1898298637.
7. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders, 2002. 16thEd.ISBN-10: 0702029335.
8. Fox, L.T.; Gerber, M.; Plessis, J.D.; Hamman, J.H. Transdermal drug delivery enhancement by compounds of natural origin. Molecules, 16, 10507-10540, 2011.
9. Goel S.C., Herbs in Radiation protection, DRDO, New Delhi, 2011, ISBN: 978-81-86514-33-7.
10. Joshi Kalpana., Warude P.C. and BhushanPatwardhan. Molecular markers in herbal drugtechnology. Cur. Sci., 87(2): 159-165, 2004.
11. Kang M. J. et al., Bioavailability enhancing activities of natural compounds from medicinal plants. J. Med. Plants Res., 3(13), 1204-1211, 2009.
12. Kesarwani K., & Gupta R., Bioavailability enhancers of herbal origin: An overview. Asian Pac J Trop Biomed, 3(4): 253-266, 2013.
13. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, Nirali Prakashan, Pune, 2008, ISBN: 8185790094.
14. Leo M.L. Nollet, Fidel Toldra, Handbook of Analysis of Active Compounds in FunctionalFoods, CRC Press, 2012.ISBN: 978-1-43-981588-5.
15. Mei Wang et. al., Metabolomics in the Context of Systems Biology: Bridging TraditionalChinese Medicine and Molecular Pharmacology.Phytother. Res. 19, 173–182 (2005).
16. Mukherjee P.K., Venkatesh P., Ponnusankar S., Ethnopharmacology and integrative medicine - Let the history tell the future. J. Ayurveda Integr. Med. 2010; 1(2):100-9. doi:10.4103/0975-9476.65077.
17. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals.Business Horizons, 2002.ISBN 8190078844.
18. NIIR Board of Consultants and Engineers, Cultivation and Processing of Selected Medicinal Plants.Asia Pacific Business Press Inc. 2006. ISBN: 8178330032.
19. Nikolaus J. Sucher, Maria C. Carles, Genome-Based Approaches to the Authentication ofMedicinal Plants. Planta Med., 74: 603–623; 2008.
20. Panda H., Herbal Cosmetics Hand Book, Vedic Books Sales Rank, 2004. ISBN: 8178330806.
21. Purohit, S.S. &Vyas, S.P. Medicinal Plant Cultivation: A Scientific Approach, EasternBook Corporation, 2007. ISBN: 8177542141.
22. Rajpal V. & Kohli D. P. S., Herbal Drug Industry, Riddhi International, 2nd Ed.,

2009.ISBN: 9788190646727.
23. Rangari V.D., Pharmacognosy & Phytochemistry (Vol I), Career Pub., Nashik, 2009, ISBN: 978-81-88739-45-5.
24. Rangari V.D., Pharmacognosy & Phytochemistry (Vol II), Career Pub., Nashik, 2009, ISBN: 978-81-88739-65-3.
25. U. Sathyanarayana, Biotechnology, Books and Allied (P) LTD.
26. Sharma Ravindra, Agro Techniques of Medicinal Plants. Riddhi International 2004. ISBN: 9788170353461.
27. Sivamani R.K., et al., Phytochemicals and naturally derived substances for wound healing. Advances in Wound Care. 1(5): 213-217, 2012. doi:10.1089/wound.2011.0330.
28. V. Kusum Devi, Nimisha Jain, Kusum S Valli, Importance of novel drug delivery systemsin herbal medicines, Pharmacog. Rev., 4(7), 27-31, 2010.
29. Wallis T. E., Textbook of Pharmacognosy. CBS Publisher & Distributors, 1985.ISBN:81-239-0886-5.
30. WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants, World Health Organization, Geneva, 2003.
31. WHO monographs on selected medicinal plants. World Health Organization, Geneva, 1999.
32. WHO Technical Report Series, No. 908, Guide to good storage practices for Pharmaceuticals. World Health Organization, Geneva, 2003. For cytoxicity screening. Nature Protocol (3):1112-6 · February 2006, doi:10.1038/nprot.2006.179
33. Wieland Voigt, Sulforhodamine B Assay and Chemosensitivity. Methods in Molecular Medicine, vol. 110: Chemosensitivity: Vol. 1: In Vitro Assays Edited by: R. D. Blumenthal © HumanaPress Inc., Totowa, NJ
34. Philip Skehan,* RitsaStoreng, Dominic Scudiero, Anne Monks, James McMahon, David Vistica, Jonathan T. Warren, Heidi Bokesch, Susan Kenney, Michael R. Boyd. New Colorimetric Cytotoxicity Assay for Anticancer-Drug Screening. Journal of the National Cancer Institute Vol. 82, No. 13, July 4, 1990
35. Ayoub SS. In vitro cyclooxygenase activity assay in tissue homogenates. Methods Mol Biol. 2010;644:117-20. doi: 10.1007/978-1-59745-364-6_9.
36. Walker MC, Gierse JK. In vitro assays for cyclooxygenase activity and inhibitor characterization Methods Mol Biol. 2010;644:131-44. doi: 10.1007/978-1-59745-364-6_11.
37. k. Anil kumar, T chandramohanreddy et al, High throughput screening assay for Cox-2 and 5lipoxygenase, the target for inflammatory disorders. Indian journal of biochemistry and biophysics. Vol 48 aug 2011 p 256-61
38. Pharmacological Assays of Plant-Based Natural ProductsVolume 71 of the series Progress in Drug Research pp 57-72 Date: 30 December 2015
39. Parimelazhagan Thangaraj, In Vitro Antioxidant Assays, Saudi Pharmaceutical JournalVolume 21, Issue 2, April 2013, Pages 143–152
40. B.N. Meyer, N.R. Ferrigni, J.E. Putnam. Brine Shrimp: A Convenient General Bioassay for Active Plant Constituents. PlantaMedica 45(5):31-4 · May 1982
41. Agarwal O. P., Chemistry of Organic Natural Products vol.1, Krishna Prakashan,Merrut, 2004. ISBN: 81-85842-98-1.
42. Agarwal O. P., Chemistry of Organic Natural Products vol.2, Krishna Prakashan,Merrut,2005. ISBN: 81-85842-98-1.
43. Atherden, L.M., Bently and Driver's Textbook of Pharmaceutical Chemistry, 8th Ed.

Oxford University Press, 2004. ISBN: 9780195609639.
44. Chatwal G.R., Organic Chemistry of Natural Products by vol. I and II. HimalayaPublishingHouse, 2010.ISBN-14: 09789350246441.
45. Finar I.L., Organic Chemistry: Stereochemistry & the Chemistry of NaturalProducts, Vol.II., Pearson Education India, 5th Ed. ISBN: 81-7758-541-X.
46. Florey K., Analytical Profiles of Drug Substances edited by Harry G. Brittain, Elsevier Publication, Vol-1-30.

4.7.5 P NATURAL DRUG TECHNOLOGY
(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	Preparation and Evaluation of Ayurvedic formulations (Min 2 Exp.)
02	Preparation and evaluation of herbal formulations (Min 2 Exp.)
03	Preparation and evaluation of skin care cosmetic products (Min 2 Exp.)
04	Preparation and evaluation of hair care cosmetic products (Min 2 Exp.)
05	Evaluation of prepared/marketed skin and hair care cosmetic products (Min 2 Exp.)
06	Evaluation of marketed nutraceutical product
07	Preformulation and spectral (UVand/ IR) study of isolated compounds
08	Determination of free radical scavenging acidity by spectrophometric method
09	Determination of anti-inflammatory activity of herbal drug by in-vitro method (UV method).
10	Determination of alcohol content in Asava/Aristha
11	Preparation of Biodiesel (Demonstration) [Caution: prepare under due care since it involve corrosive chemicals & inflammable materials]

Recommended Books:

1. Ashutosh Pareek, Divya Goswami, Mahendra Singh Ashawat, Herbs in New Era of Cosmaceuticals: Opportunity & Challenges: Herbal Cosmetics. Lap Lambert Academic Publishing, 2012. ISBN-10: 3659149322.
2. Gaisford, S. and Saunders, M. (2012) Basic Principles of Preformulation Studies, in Essentials of Pharmaceutical Preformulation, John Wiley & Sons, Ltd, Chichester, UK. doi: 10.1002/9781118423226.ch1.
3. Jeffrey B. Harborne. Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis. Springer, 1998.ISBN 0412572702, 9780412572708.
4. Kokate C. K., Practical Pharmacognosy, Vallabh Prakashan, 1993.

5. Krishnaswamy N. R., Chemistry of Natural Products: A Laboratory Handbook.
6. Leo M.L. Nollet, Fidel Toldra, Handbook of Analysis of Active Compounds in FunctionalFoods, CRC Press, 2012.ISBN: 978-1-43-981588-5.
7. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation ofBotanicals. Business Horizons, 2002.ISBN 8190078844.
8. Panda H., Herbal Cosmetics Hand Book, Vedic Books Sales Rank, 2004. ISBN: 8178330806.
9. The Ayurvedic Pharmacopoeia of India, Government of India, Ministry of Health andFamily Welfare,Department of AYUSH.

4.7.6 TBIO-PHARMACEUTICS & PHARMACOKINETICS (3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- Understanding the concept of biopharmaceutics and its applications in formulation development.
- Studying pharmacokinetic processes and their relevance in efficacy of dosage form.
- Learning the concepts of bioavailability and bioequivalencestudies.
- Learning various compartmental models and non compartmental analysis methods.
- Understanding concept and mechanisms of dissolution and in vitro in vivo correlation

Sr.No.	Topic	Hrs
	SECTION-I	
01	Introduction to biopharmaceutics and its importance in dosage form design.	02
02	a. **Absorption**: Factors affecting, mechanisms, first pass effect, pH partition hypothesis. b. **Distribution**: Physiological barriers, factorsaffecting,apparent volume of distribution. c. **Metabolism**: Phase I & phase II, factorsaffecting.Bioactivation&Tissue Toxicity d. **Elimination**: Routes renal & non renal, factors affecting, clearance concept.	08
03	**Compartment models:** Introduction to compartmental and non compartmental analysis. Concepts and their importance in the study of pharmacokinetics. One compartment open model. Assessment of pharmacokinetic parameters from plasma and urine data after i.v. bolus, i.v. infusion, i.v. injection with loading dose and oral administration. Percent absorbed time plot and determination of absorption and elimination rates based on one compartment model. Introduction to two compartmentmodel.	13
	SECTION-II	
04	**Non-Linear Pharmacokinetics**: Detection of non-linearity (saturation mechanism). MichaelesMenten equation. Definition of V_{max} and K_m. Determination of V_{max} and K_m. Significance of non-linear pharmacokinetics.	04
05	Biopharmaceutical classification system, theories of dissolution, dissolution test apparatus(U.S.P/I.P/B.P), in vitro in vivo co-relation, mathematical models.	07
06	**Bioavailability and Bioequivalence:** Definition and concept of absolute & relative bioavailability. Methods of assessing bioavailability. Measures of bioavailability, bioequivalence study and introduction to various study designs. Single dose bioequivalence study, Review of regulatory requirements for conducting bioequivalence study, bio-waivers, bio-similars.	11

Recommended books:

1. Rowland M, Tozer T, Clinical Pharmacokinetics and Pharmacodynamics Concepts andApplications, Ed 4, WolterKluwers – Lippincott,Williams and Wilkins.
2. Niazi S, Textbook of biopharmaceutics and clinical pharmacokinetics, Appleton-century- crofts.
3. Remington: The science and practice of Pharmacy, Ed 22 , Pharmaceutical press.
4. Milo Gibaldi,Biopharmceutics and clinical pharmacokinetics, Ed 4.
5. Venkateshwarulu V. Biopharmaceutics and pharmacokinetics, Ed 2, Pharmamed Press, Hyderabad.
6. Bramhankar D. M, Jaiswal S. B, Biopharmaceutics and pharmacokinetics: A Treatise,Vallabh Prakashan.

4.7.7 T PHARMACEUTICAL JURISPRUDENCE
(3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- To understand .Basic principles, purpose and dimensions of the laws
- Tounderstand the significance and relevance of Pharmaceutical laws in India
- Important rules and regulations and procedures made to execute the laws
- To discuss the purpose of theBoard
- To explain the definitions in theAct;
- To describe the qualifications for membership and the make-up of the Board
- To explain the rule-making authority of theBoard;
- To discuss the responsibilities of theBoard;
- To discuss inspections by the Board or itsrepresentative;
- To learn the various laws governing the manufacturing, sale, research & usage of drugs
- To understand significance of Schedule M and Schedule Y related Manufacturing & clinical trials.
- Identify potential fraud and abuse legal issues of narcotic &psychotropic substance.
- To study quality & prices of essentialmedicine.
- Learner knowledge about Patents, procedure for patent application and IPR.
- To understand the regulatory system for safety and effectiveness of medicine and quality of product

Sr.No.	Topic	Hrs
	SECTION-I	
01	**History of Pharmaceutical Legislation in India** **Code of Pharmaceutical Ethics**	02
02	**The Drugs and Cosmetics Act 1940 & rules 1945 & amendments:** Definitions, Advisory bodies DTAB and DCC Composition and function. Drug Control Laboratories and Government Analysts, Drug inspectors, Licensing Authorities, Controlling Authorities and Customs Collectors. Provisions governing import, manufacture and sale of drugs.Labeling and packaging of drugs. Various offences and corresponding penalties. Provisions applicable to manufacture and sale of Ayurvedic drugs. Broad content of various schedules of the Drugs and Cosmetic Act andRules.	09
03	**Pharmacy Act 1948:** Objectives, definition and composition of PCI, State Councils and Joint State Council. Functions like Education Regulations, preparation of registers and qualifications for entry into registers, Approval of Courses and Institutions. Corresponding offences and penalties	03
04	**The Drugs Price Control Order with latest amendments:** Objectives, definitions, schedules to the order, sales prices of bulk drugs, prices and price list MAPE calculations. Revisions/amendments of pricing.	03

05	**Narcotic Drugs & Psychotropic substances act1985**: Definition. Prohibited and controlled operation. Cultivation of poppy plants, Sale of opium. Import and export of narcotics as amended to date. Offences and corresponding penalties	03
06	**The prevention of cruelty to Animals Act, 1960**	01
07	**Aim, Objectives and Salient features of following legislations** Food Safety and Standards Act 2011. Consumer Protection Act1986, Industrial Development & Regulation Act 1951. Drugs and Magic Remedies Act.	02
SECTION-II		
08	**Intellectual Property Rights(IPR)** Introduction of IPR &Overviewof Patents, Design,Trademarks,Copyrights,Geographical Indicationsetc.	04
09	Criteria for obtaining patent (Novel, Non-obvious Applications). Filing and Processing of Patents. Salient features of Indian Patents Act 1970 with latest amendments. Product & Process Patents, Patent offices in India. Provision of compulsory license, Exclusive Marketing Right, patent infringement and its casestudy,	08
10	Salient features of US patents. The Hatch Waxman Act with reference to generic Drugs, The Orange book, The contents of ANDA and bioequivalence. Patent Certification(Para-I, Para-II, Para-III andPara-IV)	05
11	An Introduction to Standard Institutions and Regulatory Authorities such as ICH, WHO, USFDA, MHRA, TGA, BIS, ASTM, ISO, CDSCO.	05

Recommended books

1. KuchekarB.S.,Forensic pharmacy, 9th edition. NiraliPrakashan.
2. Education Regulations, Pharmacy Council of India, New Delhi
3. The Drugs and Cosmetics Act and the rules by IDMa Publications, Mumbai
4. Pharmaceutical regulatory affairs. SubrahmanyamC.V.S,ThimmasettyJ. VallabhPrakshan.
5. What everyone should know about patents. Subbaram. 2nd edition. Pharmabook Syndicate.
6. Forensic Pharmacy & Ethics. Mahajan J, Narang B.K. JPB Prakashan.
7. A Textbook of forensic pharmacy. Mithal B.M. VallabhPrakashan
8. A Textbook of forensic pharmacy. Jain N.K. VallabhPrakashan.
9. Pharmaceutical Jurisprudence. Girish K, Jani. 4th edition. AtulPrakashan.
10. Pharmaceutical Jurisprudence. Agarwal S.B. Tata Publishers.

FINAL YEAR B.PHARMACY **SEMESTER –VIII**

4.8.1T ADVANCED DRUG DELIVERY SYSTEM
(3hrs/week), CREDIT: 03

Learning Objective:

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

Knowledge:

- Describe the Fundamental Concept of Modified Drug Release and Pre requisites of drug candidates, along with various approaches and classification
- Describe Polymers with respect to introduction to polymers, classification, types, selection, application and examples.
- Describe. Introduction, formulation, merits, demerits, application and evaluation of Novel Drug Delivery Systems
- Explain Therapeutic Aerosols along with typical formulations from, metered dose, intranasal and topical applications,
- Explain concept of microencapsulation, merits, demerits and application, Types of Microencapsulation and Evaluation of microcapsules
- Explain Basic concept of optimization

Skills:

- Formulation development and evaluation of sustained release, transdermal, gastroretentive formulations
- Micro encapsulation techniques
- Evaluation of marketed preparations
- Optimization studies using 2^3 factorial design

Sr.No.	Topic	Hrs
	SECTION-I	
01	**Fundamental Concept of Modified Drug Release :** Definitions of controlled release, sustained release time release drug delivery Systems. Pre requisites of drug candidates, various approaches and Classification, dose calculation for controlled release & sustained release, Robinson Eriksen equation.	04
02	**Polymers**- Introduction to polymers, classification (biodegradable /nonbiodegradable), environment responsive polymers, parameters affecting selection of polymers for modified release systems, application and examples.Evaluation techniques.	04

03	**Novel Drug Delivery Systems:** Introduction, formulation, merits, demerits, application and evaluation of following in brief- Mucosal drug delivery system, Transdermal drug delivery system(TDDS), Parenteral implants, Ophthalmic inserts, Intrauterine drug delivery system (IUDs), Liposomes, Probiotics andPrebiotics. Grastro retentive drug delivery system, Osmotic drug delivery system, Colon targeted drug delivery system, Externally modulated devices and delivery; iontophoresis and sonophoresis.	15
SECTION-II		
04	**Formulation And Processing of Therapeutic Aerosols:** Aerosol component and factors affecting its selection. Recent advances, objectives of therapeutic aerosols, fundamentals and principle of design, drug substances, important physicochemical properties of aerosol system solutions, suspensions and emulsions, formulation design and stability, typical formulations from, metered dose, intranasal and topical applications, factors influencing drug deposition, manufacturing techniques, product evaluation including safety considerations	10
05	**Microencapsulation:** Introduction, concept of microencapsulation, merits, demerits and application. Types of Microencapsulation: chemical encapsulation processes, complex, coacervation, polymer-polymer incompatibility, interfacial	10
06	**Optimization Techniques in Pharmaceuticals** : Basic concept of optimization, factors variable and design of experiment, introduction to two level factorial design with suitable pharmaceutical samples.	02

4.8.1 P ADVANCED DRUG DELIVERY SYSTEM
(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	Evaluation of polymers – Interpretation of DSC& XRD
02	Evaluation of polymers -FTIR, viscosity, swelling index (Minimum 2 Expt.)
03	Micro encapsulation (using one solid and one liquid drug) by coacervation evaluation of microcapsules
04	Formulation & Evaluation of sustained release formulations tablet
05	Evaluation of marketed sustained release tablets/capsules
06	Formulation and evaluation of matrix type transdermal drug deliverysystem.
07	Preparation of beads using ionicgelation.
08	Formulation and evaluation of Effervescent gastro retentivetablet.

09	Demonstration of Design expert software for optimization of any one dosage form.
10	Preparation of any one liposomal product.
11	Every student should make a 10 minutePowerPoint presentation on any one advanced drug delivery system.

Recommended books:

1. Yie. W. Chien ; Controlled drug delivery, Fundamentals and Applications,, 2ndEd. MarcelDekker.
2. P. Tyle; Drug Delivery System, 1st ed, Marcel Decker,1988.
3. Modern Pharmaceutics,Banker,GibertsS.Marcel Dekker,2nd edition,1990.
4. Novel Drug Delivery System,ChienYie.W.MarcelDekker,2005.
5. Targeted and Controlled Drug Delivery Novel carrier Systems,Vyas S.P. KharR.K.CBSpublication,2012.
6. Hadgraf& Guy; Transdermal Drug Delivery, 1st Ed, Vol-35, Marcel Dekker,1989.
7. Benita; Microencapsulation- methods & Industrial Applications, 2nd Ed,vol-158, Taylor &Francis Publication,2006.
8. Peter.J.Tarcha; Polymers for Controlled drug delivery, 1st Ed,CRCPress,1991.
9. J. Hickey; Pharmaceutical Inhalation Aerosol Technology; 1st ed, MarcelDecker, 2004.
10. N. K. Jain; Advances in controlled and novel drug delivery, 1st Ed.,CBS Publication,2001
11. Encyclopedia of Pharmaceutical technology, 2nd ed.,vol.III,1999.

4.8.2 T COSMETIC SCIENCE
(3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- Understand the concepts of cosmetics; anatomy of skin v/s hair, general excipients used incosmetics.
- Explain formulation of cosmetics for skin, manufacturing, equipments&evaluation of creams like cold cream, vanishing cream etc. & powdercosmetics.
- Explain formulation of cosmetics for hair, manufacturing & evaluation of hair shampoos, tonicsetc.
- Describe formulation of cosmetics for eyes, manufacturing & evaluation of eye mascara, shadowetc.
- Understand formulation of manicure products like nail lacquer, removeretc.
- Learn formulation, manufacture & evaluation of baby cosmetics like baby oils, powdersetc.
- Explain the concept of cosmeceuticals, history, difference between cosmetics &cosmeceuticals& cosmeceuticals agents.

Skills:

- State the correct use of various equipments in Pharmaceutics laboratory relevant to cosmetics.
- Perform formulation, evaluation and labeling of cosmetics like moisturizing cream, vanishing creametc.
- Perform formulation, evaluation of eye cosmetics, nail lacquer &shampoo.
- Perform formulation, evaluation &labeling of shaving cream, after shave & baby products.
- Describe use of ingredients in formulation and category offormulation. Prepare labels as per regulatoryrequirements

Sr. No.	Topic	Hrs
	SECTION-I	
1	**Fundamentals and Scope of Cosmetic Science** a. Definition of cosmetics, classification of cosmetics b. Additives in Cosmetics: emollients, waxes, oils, humectants, preservatives, binders, surfactants, colors and perfumes. c. Cosmetics v/s drug formulation. Anatomy and composition of skin and hair. Types of cosmetics. d. Quality of Water in cosmetic Industry e. Packaging, Cleanliness, Hygiene and Microbial control in Cosmetic manufacturing f. Perfumes- Source, classification, blending and fixation	08
2	Formulation, manufacturing & evaluation of following cosmetics	

A)	**Skin care Products** a. **Cosmetics for skin:** Moisturizing cream, cleansing cream, cold cream, vanishing cream, anti ageing and anti wrinkle, antiperspirants,deodorants, b. **Powder cosmetics:** Heavy, medium and light powders,compacts **c. Face mask andpacks** d. **Face make up:** Face powder, compact powders, Cake makeup, Liquid	10
	a. Colored makeup preparations: Lipsticks, Lip balm, Rouge b. Suntan & sunscreen preparations.	
B)	a. Shaving preparations: Formulation of wet shaving dry shaving and after shave preparations. b. Bath preparations: Bath oils, soaps, foams and after bath preparations.	05
	SECTION-II	
C)	Hair products: Shampoos, hair tonics, hair dyes, lightners, depilatories.	04
D)	Eye products: Eye mascara, eye shadow, eye liner, eyebrow pencil	03
E)	Dental care cosmetics: Dentifrices as powders, paste, gels and Mouth washes	02
F)	Manicure products: Nail lacquer, Lacquer remover and evaluation tests	03
G)	Baby cosmetics: Baby powders, oils, lotions, shampoos and soaps.	02
H)	Nail care Products: Nail polish, Nail lacquer, Nail lacquer remover, Nail bleach, nail cream	03
3	**Cosmeceuticals:** Introduction, Definition and difference from cosmetics. History of cosmeceuticals. Cosmeceuticals Agents- retinoids, hydroxyl acids, beta hydroxyl acids, Antioxidants and others.	05

4.8.2 P COSMETIC SCIENCE
(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
Formulation and evaluation of following cosmetics:	
01	Cold cream
02	Vanishing cream
03	Moisturizing cream
04	Sunscreen cream/lotion
05	Lip stick
06	Shampoo
07	Shaving cream
08	After shave lotion
09	Face pack
10	Face powder
11	Eye cosmetics: Eye shadow, Eye liner, Eye Mascara
12	Tooth paste (medicated / nonmedicated)

13	Baby care products - Baby powders, lotions
14	Nail lacquer
15	Market survey of atleast three brands of any cosmetic product and its comparative presentation.

Recommended Books:

1. Barel Andre O., Paye Marc, Maibach Howard I., Handbook of Cosmetic Science and Technology. Marcel Dekker,Inc.
2. Harry'sCosmeticology. By J.B. Wilkinson and R.J. Moore, Longman Scientific and Technical,England.
3. Poucher W.A., Perfumes, Cosmetics and Soaps by, Vol. I, II,III
4. J. B. Wilkinson, R. J. Moore, "Harry's Cosmetology", 7th edition, Longman Scientific and Technical, 1994.
5. Sharma P. P., "Cosmetic Formulation, Manufacturing and Quality Control" 7th edition, Vandana publication, 2001.
6. E.G.Thosmssen" Modern cosmetics Universal Publishing Corporation.
7. Elsner Peter, Howard I. Maibach, Cosmeceuticals. Marcel Dekker,Inc.
8. Dr. Laba "Rheological properties of cosmetics and toiletries" MarcelDekker.
9. AppellL."The formulation and preparation of cosmetics, fragrance and flavours" Micelle press
10. J.Knowlton and S.Rearce " Handbook of cosmetic science and technology" 1st edition; Elsevier science publisher; oxford, UK,1993
11. Mithal BM, Saha RN, A handbook of Cosmetics. Vallabh Prakashan, Delhi.

4.8.3 T PHARMACEUTICAL ANALYSIS -VI
(3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- Explain principles, instrumentation of NMR & ESR spectroscopy, Mass Spectrometry and their applications in Pharmaceutical research, quality control of APIs & formulations.

Skills:

- Independently operate and 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.	Topic	Hrs.
The following topics to be discussed with special reference to quality control andassurance of the pharmaceuticals, its scope and importance in the pharmaceuticalindustry along with suitable examples.		
	SECTION-I	
01	**Nuclear Magnetic Resonance (NMR) Spectroscopy**: Theory, Chemical shift,Shielding-deshielding, Spin-Spin Coupling (Splitting), Coupling Constant,Chemical and Magnetic Equivalence, Double resonance, Shift reagents, Solvents, Factors, affecting chemical shift, Anisotropy, Instrumentation, application and simple structure determination. Introduction to C13 NMR	15
02	**Electron Spin Resonance (ESR):** Introduction, principle and instrumentation.	02
03	Ion Exchange Chromatography: Theory, instrumentation and applications.	04
	SECTION-II	
04	Introduction, principle, and applications ofScanning Electron Microscopy (SEM) and Transmission Electron Microscopy (TEM)	12
05	**Mass spectrometry:** Introduction, theory, instrumentation, resolution, differentMethods/techniques of ionization (EI,CI,FAB,ESI and MALDI) and their Applications. Introduction to GC-MS, LC-MS and MS-MS	12

4.8.3 P PHARMACEUTICAL ANALYSIS-VI
(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	Validation of analytical methods (UV Spectrophotometry & HPLC) as per USP or ICH guidelines (Minimum 2 Expt.)
02	To study system suitability parameters (any two) per IP/BP/USP protocol for HPLC methods.
03	Study of Quantitation Techniques in HPLC (% Area/Area Normalization, Internal Standard addition)
04	Interpretation of UV, IR, NMR, MS spectras of simple organic compounds for structure elucidation (Minimum four compounds)

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, 4th Ed., CBS Publisher & Distributors.
9. 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

4.8.4 T MEDICINAL CHEMISTRY-IV
(3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- 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 antihistaminics, proton pump inhibitors, Serotonergic agents, Autacoids, NSAIDs, analgesics & antipyretics, Narcotic agents, Steroidal Drugs, Hormones, Insulin & Oral Anti-hyperglycemic drugs and Diagnostic agents.

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 column chromatography.
- Characterize the synthesized compounds using IR and NMR spectras.
- 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	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	**Antihistaminic agents andproton pump inhibitors** (Prolidine, Ranitidine, Diphenhydramine, Cetrizine, Chlorpheniramine, Promethazine)	08
1.2	**Autacoids** Prostaglandins, Prostanoids, Leucotriene antagonists	03
1.3	NSAIDs, analgesics & antipyretics (Ibuprofen, Diclofenac, Paracetamol, Piroxicam, Nambutone)	05
1.4	**Narcotic agents:** Opiods, receptor subtypes and 31opioid antagonists (Methadone, Propoxyphen, Dextromethorphan, Fentanyl citrate)	06
	SECTION – II	
1.5	**Steroids and Steroidal Drugs:** Sex hormones and their synthetic analogs, steroidal anti-inflammatory agents, Anti-fertility agents	08
1.6	**Hormones:** Thyroid and antithyroidal agents	01
1.7	Insulin & Oral Anti-hyperglycemic drugs (Metformin, Tolbutamide)	06
1.8	**Diagnostic agents:** Radio opaque diagnostic agents and agents for organ function tests.	04
1.9	**Serotonergic agents**	04

4.8.4 P MEDICINAL CHEMISTRY-IV

(3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	Synthesis of following medicinally important compounds/drug intermediates with Recrystallization of each compound and monitoring reactions over TLC (any six). a. 4-Methyl quinoline b. Isoniazide c. Metronidazole/Albendazole d. Sulphamethoxazole e. Methyl Salicylate f. O-Iodo benzoic acid from Phalimide g. Antipyrine h. Phenytoin from benzoin i. 7-Hydroxy-4-methyl-8-nitrocoumarin j. 10. 6-Methyluracil
02	Purification of above synthesized compounds by Column chromatography (Any two)
03	Preparative TLC (Any Two)
04	Interpretation of IR spectra of synthesized compounds (Any three)
05	Demonstration Experiments (Any one) a. High Vacuum Distillation b. Demonstration on CADD

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 WilliamWilkins.
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 AgeInternational Publishers.
7. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford UniversityPress 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 LanguageBook Society and Longman Group Limited, London.
14. Vogel' s A Text book of Practical Organic Chemistry by Vogel, 3rd edition, TheEnglish language book society and Longman group limited, London.
15. Advanced practical Medicinal Chemistry by AshutoshKar, 1st edition, New AgeInternational 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 Wileyand sons USA.
18. A Textbook of Pharmaceutical Chemistry by Chatten LG, Vol I & II, Marcel DekkerNew York.
19. Analytical profiles of drug substances by Klaus Florey(All Volumes)

4.8.5 T PHARMACOLOGY- V, (Including Biostatistics)
(3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- Important aspect, classification, mechanism of drug-drug interaction and ADRs.
- Basic aspects of drug safety and Pharmacovigilance in relation to monitoring and reporting of ADRs.
- Functioning and role of hospital pharmacy and practice of rational drug therapy and methods of assessment of patient compliance and non-compliance.
- Clinical trials, ethics and practice of Good Clinical Practice involved in clinical trials.
- Process, working and personnel involved in clinical data management and their roles.

Skills

- Use of isolated tissue preparations for antagonistic bioassay methods.
- Basic aspects to carryoutneurobehavioral characterization.
- Understanding various parametric and non-parametric tests used in biostatistics.

Sr. No	Title	Hrs
	SECTION - I	
01	**Drug interactions:** Introduction to Drug-Drug, Drug-food interaction. Classification of Drug-Drug interaction. Basic concepts of mechanisms of drug-drug interactions with suitable examples. **Adverse Drug reactions (ADR):** Epidemiology, Classification and Risk factors	06
02	**Drug Safety and Pharmacovigilance (PV)** Introduction, Terminologies, Global Perspective of PV and ADR monitoring and reporting, Global Adverse events reporting system and reporting forms	05
03	Introduction to Safety Pharmacology (Definitions, objective, scope, importance and pitfalls)	02
04	**Hospital Pharmacy:** Introduction, Hospital and therapeutic committee, hospital formulary, role of hospital pharmacist in hospital committees and practice of rational drug therapy. **Patient Compliance and Noncompliance:** Methods of assessment of compliance, Reason for patient noncompliance, strategies to improve compliance	09
	SECTION - II	
05	**Clinical Trials:** History, important terminologies, Types of clinical research, Phases of clinical research, role of clinical trial in new drug developments	05
06	**Ethical issues in clinical trials-** Principle of regulatory requirements, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), The Nuremberg Code, The Declaration of Helsinki, The Belmont Report	09
07	**Good Clinical Practice-**Concept, importance, and cGCP guidelines including ICH guidelines and schedule Y	04

08	**Clinical Data Managements (CDM)** Basics, process and standards. Role and responsibilities of CDM Personnel	03
09	Introduction to Palliative and End of Life care	02

Recommended Books:

1. Harisons: Principles of Internal Medicine, McGraw Hill Publications, Singapore.
2. Hansten PD: Drug Interactions, Lea &Febiger, Philadelphia.
3. Textbook of Pharmacovigilance: S.K.Gupta, JaypeeBrothers,Medical Publisher
4. Textbook of Clinical trials.David Machin,Simon Day,S.Green,WileyInterscience.
5. Adverse Drug Reaction.A handbook for Prescriber.LakshmanKaralliedde,Simone Clark,UrsulaC.Hodder Education UK.
6. John IG and Frederick P. Ognibene Principles and Practices of Clinical Research, Second Edition.
7. Fay A.R and Rodney K.A: Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance.
8. Gupta SK. Textbook of Pharmacovigilance: Jaypee Brothers, Medical Publishers.
9. Elizabeth B. A, Nicholas Mann's Pharmacovigilance:, Wiley Publishers.
10. John Talbot, Patrick Walle Stephens:Detection of New Adverse Drug Reactions, Wiley Publishers.
11. Patrick Waller: An Introduction to Pharmacovigilance,Wiley Publishers.
12. Barton Cobert,Cobert's Manual of Drug Safety and Pharmacovigilance, Jones & Bartlett Publishers.
13. Parthasarathy G: A textbook of Clinical Pharmacy Practice- Essential Concepts and Skills, Orient Longman, Hongkong.
14. Allwood MC and Fell JT:Textbook of hospital Pharmacy. CBS Publication and distributers Pvt.Ltd.
15. Martin Stephens. Hospital Pharmacy. Pharmaceutical Press, London.

4.8.5 P PHARMACOLOGY- V, (Including Biostatistics) (3hrs/week), CREDIT: 02

Sr. No.	Title of Experiment
01	To find out the PA_2 or PD_2 value of given drugs using suitable isolated tissue preparation. (Minimum 03 exercises)
02	Irwin's Functional observation for neurobehavioral characterization of test drugs. (Caffeine/Diazepam/PTZ/haloperidol)
03	Basic concepts of statistics, its application and importance.
04	To determine the Mean, Mode and Median of the given data. (Minimum 02 exercises)
05	To determine the Standard deviation, Standard error of mean and coefficient of variation of the given data. (Minimum 02 exercises)
06	To determine the Analysis of Variance (ANOVA) of the given data. (Minimum 02 exercise)
07	To study the problems based on paired and unpaired Student 't' test. (Minimum 02 exercise)
08	To study the problems based on nonparametric test. (Minimum 02 exercise)
09	To solve statistical problems using suitable software. (Minimum 01 exercise)

Recommended Books:

1. Mahajan B.K. Methods in Biostatistics. Sixth edition. Jaypee Publishers Ltd. New Delhi.
2. Wayne W.D. “Biostatistics” basic concept and methodology for the health sciences. Ninth edition, 2010, Wiley India Publication.
3. Verma B.L, Shukala G.D, Shrivastava R.N. Biostatistics perspective in health care research and practice. CBS Publication and Distributors, New Delhi, India.
4. Shaik Y.I, Paradkar A.R, Dhayagude M.G., Introduction to Biostatistics and Computer Sciences. Nirali Prakashan.
5. Ghosh MN. Fundamental of Experimental Pharmacology, Hilton &Company, Calcutta.
6. Kulkarni SK. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
7. Goyal RK. Practicals in Pharmacology, B. S. Shah Prakashan, Ahemadabad.
8. Turner RA: Screening Methods in Pharmaocology.

4.8.6 T NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS (3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- Understand & realize the significance of natural products in daily life. He/she should be ableto classify different segments in market, demand & supply position; export & importpotential; position of Indian herbal drug industry in global contest; government organizations& policies for promotion; their regulation in India & other countries, various regulatoryguidelines, ethical issues etc.
- Realize the market potential of natural products & explore entrepreneurship skills to grabthese opportunities.
- Understand & explain safe use of natural products, possible toxicities &interaction, toxicitiesin most venerable group (elderly patients), need &significance of Pharmacovigilance systems; WHO guidelines in this regard.
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Sr.No.	Topic	Hrs
	SECTION-I	
01	**Commerce:** a. Global & domestic market size of various natural products in commerce i. Crude drugs ii. Phytopharmaceuticals iii. Drug leads/Biomarkers iv. Drug Intermediates/Precursors v. Neutraceuticals vi. Spices and Condiments vii. Herbal Cosmetics viii. Pharmaceutical Excipients ix. Biofuels b. Demand and Supply Status of above Mentioned Product Segment c. Import & Export	10
02	**Herbal Drug Industry:** a. Present Scope & Future Prospect b. OTC and TSM products c. Plant based industries and institutions working on medicinal and aromatic plants in India. d. Industry oriented R&D Institutes e. Technical and Funding assistance Schemes	07
03	**Regulation& Patenting:** a. Regulations i. Licensing requirements for production and scale of herbal drugs in India ii. Schedule T-GMP practices of Indian system of Medicine iii. Components of GMP and its objectives iv. Infrastructural requirements-working space, storage area, machinery and equipments, SOP, Health & Hygiene	10

	v. Documentation & Records b. Herbal Drug Patenting i. Intellectual Property Rights ii. Definition and Introduction of Patent iii. Farmers Right & Breeders Right iv. Biopyracy v. Trademark & Copyright	
	SECTION-II	
04	**Toxicity in herbals and their interaction:** Herbal-Drug & Herbal-Food interactions, General introduction to interaction and classification, Study of following drugs and their possible side effects and interactions a. Liquorice b. Cinnamon c. Amla d. Ginseng e. Garlic f. Digitalis g. Termeric h. Ephedra i. Cinchona	08
05	**Pharmacovigilance of herbal medicines:** a. Meaning, need & significance b. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems	06
06	**Plant Allergens:** a. Definition & classification (inhalants, injectants,contactants, infectants and infestants) b. Plants causing Hay fever, allergy, Idiosyncracy c. Applications of allergens in diagnosis & treatment d. Method of preparation of allergenic extracts.	04

Recommended Books:

1. Amitava Dasgupta, Catherine A. Hammtt-Stabler, Herbal supplements: Efficacy, toxicity, interactions with Western drugs, and effects on clinical laboratory tests. Wiley International,2011. ISBN: 978-0-470-43350-8.
2. Ashok D.B. Vaidya and Thomas P.A. Devasagayam, Current Status of Herbal Drugs inIndia: An Overview. J. Clin. Biochem.Nutr., 41, 1–11, 2007.
3. Brendler, Thomas; Phillips, L Denzil; Spiess, Stefan, A Practical Guide to Licensing HerbalMedicinal Products, Pharmaceutical Press. ISBN: 978 0 85369 784 8.
4. Drugs and Cosmetics Act 1940.
5. Duke James A. et al., Medicinal Herbs. 2nd Ed., CRC Press, 2002.ISBN 0-8493- 1284-1.
6. Entrepreneurship in Agriculture & Allied Sectors, Government of India.
7. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders, 2002. 16thEd. ISBN-10: 0702029335.
8. Gupta, SK. Textbook of Pharmacovigilance, Jaypee Brothers Medical Publishers (P) Ltd.2011. ISBN: 9789350252062
9. Iqbal Ahmad, FarrukhAqil, and Mohammad Owais, Modern Phytomedicine: Turning

Medicinal Plants into Drugs. WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim, 2006.ISBN-10: 3-527-31530-6.
10. Jon C Tilburt& Ted J Kaptchuk, Herbal medicine research and global health: an ethicalanalysis. Bulletin of the World Health Organization, 86 (8), 2008.
11. Kashi Anusuya R., S. Ramachandran & Bindu Sukumaran Textbook of Industrial Pharmacognosy, University Press, 2012. ISBN: 978-81-7371-754-3.
12. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, Nirali Prakashan, Pune, 2008, ISBN: 8185790094.
13. Lakshman Karalleidie & Indika Gawarammana Traditional Herbal Medicines: a Guide to Their Safer Use. Hammersmith Press, London, 2008.ISBN 978-1-905140- 04-6.
14. Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, World Health Organization, Geneva, 2001.
15. Leland J. Cseke et al., Natural Products from Plants, 2nd Ed., CRC Press, 2006. ISBN: 10:0-8493-2976-0.
16. Michael McGuffin, Art Tucker, Albert Y. Leung, John T. Kartesz, Herbs of Commerce, American Herbal Products Association, 2000. ISBN-10: 0967871905.
17. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals.Business Horizons, 2002.ISBN 8190078844.
18. Newall, C. A.; Anderson, L. A.; Phillipson, J. D., Herbal medicines. A guide for healthcareprofessionals.Pharmaceutical Press; 2nd Ed., 1996. ISBN: 0-85369- 289-0.
19. Rajpal V. & Kohli D. P. S., Herbal Drug Industry, Riddhi International, 2nd Ed., 2009. ISBN: 9788190646727.
20. Rangari V.D., Pharmacognosy & Phytochemistry (Vol I), Career Pub., Nashik, 2009, ISBN: 978-81-88739-45-5.
21. Rangari V.D., Pharmacognosy & Phytochemistry (Vol II), Career Pub., Nashik, 2009, ISBN: 978-81-88739-65-3.
22. Regulatory situation of herbal medicines: A worldwide review, WHO http://apps.who.int/medicinedocs/pdf/whozip57e/whozip57e.pdf
23. Roy Atul, Herbal Drug Industry, Oxford Book Company, 2012. ISBN 10: 9350300893.
24. Timothy S. Tracy & Richard L. Kingston, Herbal products: Toxicology and Clinical Pharmacology. Humana Press Inc. 2007.eISBN 10-digit: 1-59745-383-8.
25. Ved D.K. &Goraya, G.S. Demand & supply of medicinal plants in India, NMPB, New Delhi & FRLHT, Bangalore, India, 2008.
26.WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems, World Health Organization, Geneva, 2004.

4.8.7 T QUALITY ASSURANCE TECHNIQUES
(3hrs/week), CREDIT: 03

Learning Objectives:

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

Knowledge:

- Explain significance of quality in Pharmaceutical manufacturing, Role of Regulatory
- Agencies in deciding Quality Standards, significance of validation in quality assurance.
- Follow cGMP, GLP and GDP while working in Pharmaceutical industry.
- Explain the concept of QbD

Sr. No	Topic	Hrs
	SECTION-I	
01	**Introduction:** Concept of quality, quality assurance, quality control, IPQC in pharmaceutical industry, objectives, components of quality assurance, and responsibilities of QA Dept. Few documents such as BPCR and MPCR.	08
02	**Calibration & Qualifications**: Definition, purpose, Calibration Master Plan, Responsibility and Frequency of Calibration, Calibration of instruments such as P^H meter and Dissolution Test Apparatus. Equipment qualification, URS, DQ, IQ, OQ and PQ.	07
03	Introduction and Concept of Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Documentation Practices (GDP). Introduction to Pharmaceutical quality management system and quality risk management.	08
	SECTION-II	
04	**Pharmaceutical Validation:** Introduction, scope, objective, need, benefits, types of validation,documentation involved in validation	08
05	**Introduction to Regulatory Agencies** imparting quality standards such as WHO, ICH, USFDA, TGA, MHRA.	08
06	Introduction to QbD: Steps in QbD approach, significance and regulatory guidelines.	06

Recommended Books

1. M. A. Potdar, Pharmaceutical Quality Assurance, Nirali Prakashan, Pune.
2. FJ Carleton, J Agalloco, Validation of Pharmaceutical Process, Marcel Dekker Inc.
3. Ira R Ferry & Robert Nash Pharmaceutical process Validation, Second Ed, Marcel Dekker Inc.
4. Sidney Willing, Good Manufacturing Practices for Pharmaceutical, A Plan for Total Quality Control
5. Quality Assurance Guide by Organization of Pharmaceutical producer of India.
6. Pharmaceutical Master Validation plan, The Ultimate guide to FDA, GMP, & GLP Compliance, Sayed IH, Special Indian Ed.
7. How to Practice GMP by P. P. Sharma, 5th Ed, Vandana Publication Pvt. Ltd.
8. Facility Validation, Theory, Practice & Tool, Grahm C Wrigley
9. Indian Pharmacopoeia, 2014, Indian Pharmacopoeia Commission, Govt. of India.
10. United State Pharmacopeia, 2016, US Pharmacopoeial Convention, USA.