SAVITRIBAI PHULE PUNE UNIVERSITY

Faculty of Pharmaceutical Science

Syllabus

Final Year B. Pharm. 2013 Course
(With effect from Academic Year 2016 - 17)

4.7.1 T STERILE PRODUCTS
(Theory) (3Hrs/Week)

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

A. Knowledge:
1. Describe the General requirements, routes of administration, significance of tonicity adjustment and sterility and Pre-formulation of sterile products
2. Describe various packaging materials used, types, choice of containers, official quality control tests and methods of evaluation.
3. 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.
4. 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.
5. 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.
6. Explain General requirements, formulation, types and evaluation of ophthalmic products.
7. Describe Blood Products and Surgical Dressings

B. Skills:
1. Formulation development and Pharmacopoeial evaluation and labeling of SVPs, LVPs, and ophthalmic preparations
2. Expertise in sealing of ampoules
3. Describe use of ingredients in formulation and category of formulation
4. Pharmacopoeial evaluation of packaging materials
5. Importance and validation of aseptic area
6. Evaluation of marketed preparations
7 Significance and Accelerated stability testing of marketed samples.

Sr. No.	Topic	Hrs
	SECTION-I	
1	Sterile formulations: Pre-formulation: Physicochemical properties of drug substances, General requirements, routes of administration, significance of tonicity adjustment and sterility.	05
2	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
3	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.	
4	Small Volume Parenterals (SVPs): Classification, formulation of solutions, types of vehicles, selection of vehicles and added substance, processing and manufacturing of SVPs, Pilot plant scale up for SVPs. Special types of SVPs: Formulation of peptides and proteins, freeze dried products, Parenterals suspensions, emulsions and Reconstituted products. Quality control for SVP and stability aspects	08
	SECTION-II	
5	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 Peritoneal dialysis fluid. Pilot plant scale up for LVPs. Quality control for LVP and stability aspects	05
6	Lyophilization basics: Introduction, Principle, steps involved and Application of Freeze drying process. Component, Parameters, Construction and Working of Lyophilizer/ Freeze dryer	04
7	Ophthalmic Products: General requirements, formulation, types of dosage forms, evaluation of ophthalmic product. Contact lens and lens care products,	05
8	Blood Products: Collection and storage of whole human blood, fractionation of plasma. Quality control of blood products. Plasma Volume Expanders.	05
9	Surgical Products: Definition Sutures and Ligatures of different types, Primary wound dressing, absorbents, surgical cotton, surgical gauzes bandages, advances (Superporous hydrogels) absorbent foam (polyurethane) dressings, Quality control testing.	03

4.7.1 P STERILE PRODUCTS
Practical (3Hrs/Week)

1) Validation of aseptic area.
2) Pharmacopoeial evaluation of glass and plastic containers and rubber closures used for injectable.
3) Formulation and quality control of SVPs as per Indian pharmacopoeia. Any 3 (at least two ampoule sealing)
4) Formulation and quality control of LVPs as per Indian pharmacopoeia. Any 2
5) Accelerated stability testing of a SVP or LVP marketed samples.
6) Formulation, packaging and quality control of ophthalmic: Eye drop and Eye ointment
7) 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 behaviour using Brookfield viscometer.

Recommended books

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

4.7.2 T PHARMACEUTICAL ANALYSIS –V

(Theory) (3 Hrs/Week)

Learning objectives:

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

A. Knowledge:

1. Understand principles, instrumentation of Infra red (FTIR, NIR) Raman, Gas Chromatography, Flash Chromatography, Super critical fluid chromatography Atomic Emission spectroscopy, and their applications in Pharmaceutical industry.
2. Know about electron microscopy.

B. Skills:

1. Independently operate and calibrate various analytical instruments for the separation/isolation and 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.

Topic No	Topics	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	
	SECTION-I	
1	**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	14
2	Introduction to Near Infrared (NIR) & Raman spectroscopy with respect to theory, instrumentation and applications.	04
3	Introduction, principle, and applications of Scanning Electron Microscopy (SEM) Travelling Electron Microscopy (TEM)	04
	SECTION-II	
4	**Gas Chromatography:** Theory, instrumentation, sample handling, columns, detectors, derivatisation and quantitation (area normalization, percent area, Internal standard, and External standard method) and applications.	10
5	**Flash Chromatography**: Theory, instrumentation and applications.	03
6	**Super Critical Fluid Extraction and Super Critical Fluid Chromatography**: Theory, instrumentation and applications.	05
7	**Atomic Emission Spectroscopy**: Theory, instrumentation and applications.	05

4.7.2 P PHARMACEUTICAL ANALYSIS -V
(Practical) (3 Hrs/Week)

1. Spectrophotometric estimation of two-component formulations by simultaneous analysis. (minimum three)
2. Spectrophotometric analysis of two components by Q-Method. (minimum two)
3. Recording of IR spectra of compounds with different functional groups (-COOH, -COOR, - CONHR, -NH2,-NHR, -OH, -CHO, -CO etc.) (minimum two)
4. IR-Spectral interpretation of aliphatic and aromatic compounds (minimum two)
5. Demonstration experiments: Gas Chromatograph/Atomic Absorption Spectrophotometer / 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. 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

4.7.3 T MEDICINAL CHEMISTRY-III

(Theory) (3 Hrs/Week)

Learning objectives:

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

A. Knowledge:

Know general aspects of the design & development of drugs including history, classification, nomenclature, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses and recent developments in therapeutic categories such as NSAIDs, steroidal anti-inflammatory drugs, narcotic & non-narcotic analgesics, antipyretics, autacoids and drugs acting on respiratory & GI tract.

B. Skills:

1. Make correct use of various equipments & take safety measures while working in medicinal chemistry laboratory.
2. Develop skills involved in thin layer chromatography techniques and purification of synthesized compounds by column chromatography.
3. Synthesize, recrystallize and understand reaction mechanisms involved in synthesis of medicinally important organic compounds.
4. To interpret the spectral characterizations made by IR and ^{1}H-NMRs of synthesized compounds.

Sr. No	Topic	No. of hrs
	History and general aspects of the design & development of drugs including classification, nomenclature, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses, scheme of synthesis of drugs mentioned in bracket and recent developments of following categories.	
	SECTION-I	
1	**Narcotic analgesics:** Opiods, receptor subtypes and opioid antagonists (Methadone, Propoxyphen, Dextromethorphan)	07
2	NSAIDs, steroidal anti-inflammatory agents, analgesics & antipyretics (Ibuprofen, Diclofenac, Paracetamol, Piroxicam, Nambutone)	10
3	**Autacoids** 3.1 Antihistaminic agents: Structural features of Histamine receptor and its Subtypes and their structural features, H1 blockers and H2 blockers. 3.1 Eicosanoids: history and discovery, eicosanoids biosynthesis, drug action mediated by eicosanoids, eicosanoids approved for human clinical use 3.2 Prostaglandin analogs (Prolidine, Ranitidine, Diphenhydramine, Cetrizine, Chlorpheniramine, Promethazine)	08
	SECTION-II	
4	**Drugs Acting on Respiratory Tract** 1.1 Antiasthamatics	

	1.2 Expectorants 1.3 Antitussive agents 1.4 Mucolytics 1.5 Decongestants (Guaifensin)	08
5	**Drugs Acting on Gastrointestinal Tract** a. Antisecretory agents b. Proton pump inhibitors c. Antiemetics d. Antidiarrheals e. Laxatives f. Prokinetics g. Antispasmodics and drugs modifying intestinal motility h. Drugs Used for Irritable Bowel Syndrome (Omeprazole)	12

4.7.3 P MEDICINAL CHEMISTRY-III

(Practical) (3 Hrs/Week)

I. Synthesis of following medicinally important compounds/drug intermediates with recrystallization of each compound and motoring reactions over TLC.

1. Ibuprofen
2. 4-Fluoro acetophenone
3. Methyl benzoate
4. 2-Methyl benzimidazole
5. Biginelli Reaction
6. Caprolactam
7. Benzyl alcohol

II. Techniques in synthesis

1. Purification of above synthesized compounds by Column chromatography (Any two)
2. Interpretation of IR spectra of synthesized compounds (Any three)
3. Interpretation of ^{1}H-NMRs Standard spectra of organic 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)

4.7.4 T PHARMACOLOGY-IV
(Theory) (3Hrs/Week)

Learning objectives:

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

1. Get in-depth knowledge about pharmacology and pharmacotherapy of drugs used in infectious diseases, cardiovascular disorders etc.
2. Understand the involvement of oxidative stress and role of antioxidants along with some safety issues in pharmacology.

Skill:

1. Understand the importance of isolated preparation, mechanism of action of drugs on isolated tissues, expertise in performing bioassay of drugs.
2. Analyze the rational and irrational fixed dose combinations based on various parameters.
3. Understand the prescription pattern and rational use of drugs by performing case study or doing hospital visit.

Sr. No	Topic	No. of 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 principles of chemotherapy of infections.**	01
	Drug resistance: Introduction, types, mechanism and its importance in chemotherapy	
2	**Classification, mechanism of action, antibacterial spectrum, resistance, therapeutic uses, adverse effects and contraindications of:**	16
	• Penicillins, cephalosporines and β-lactamase Inhibitors • Sulfonamides and cotrimoxazole • Amino glycosides and macrolides • Quinolones and treatment of urinary tract infection. • Tetracycline and chloramphenicol • Tuberculosis and leprosy including National TB programmes (DOTS) • Antimalarials, anthelmintics and antiamoebics • Antiviral drugs including treatment of HIV	
3	Antineoplastic agents	03
4	Immunomodulators	02
	SECTION-II	
5	Pharmacology of Drugs acting on blood & blood forming organs	02
	• Haemopoeitics • Coagulants and anticoagulants	
6	**Diuretics and anti-diuretics**	03

7	**Pharmacotherapy of Cardiovascular disorders**	14
	Congestive heart failure, Hypertension, Angina, Myocardial infarction, Atherosclerosis and Arrhythmia	
8	**Oxidative stress and Antioxidants**	02
	Reactive oxygen intermediates, antioxidants and there therapeutic implications	
9	**Safety Pharmacology** Introduction, scope and study design of safety pharmacology	02

Recommended Books:

1. Goodman and Gillman: Pharmacological Basis of Therapeutics, McGraw-Hill, Medical Publishing Division, NewYork.
2. Barar F.S.K.: Essentials of Pharmacotherapeutics, S. Chand & Co., New Delhi.
3. Bevan J.A. and Thompson J.H.: Essentials of Pharmacology, Harper and Row Publishers, Philadelphia.
4. Bowman W.C. and Rand M.J.: Textbook of Pharmacology, Blackwell Scientific Publications, Oxford.
5. Butterworth S.: Modi' s Textbook of Medical Jurisprudence and Toxicology.
6. Craig C.R. and Stitzel R.E.: Modern Pharmacology, Little Brown and Co., Boston.87
7. Das M.M. and Dutta S.K.: Ghosh' s Modern Concepts on Pharmacology & Therapeutics, Hilton & Co., Calcutta.
8. DiPiro J.T.: Encyclopedia of Clinical Pharmacology, Marcel Dekkar, New York.
9. DiPiro J.T.: Pharmacotherapy: A Pathophysiological Approach. Elsevier Publications, London.
10. Hansten P.D.: Drug Interactions, Lea & Febiger, Philadelphia.
11. Harisons: Principles of Internal Medicine, McGraw Hill Publications, Singapore.
12. Herfindal E.: Clinical Pharmacy and therapeutics, Williams and Wilkins Publications, New York.
13. Katzung B.G.: Basic and Clinical Pharmacology, Lange Medical Publications, California.
14. Krantz and Carr: Pharmacology Principle of Medical Practice, Williams & Wilkins Co, Baltimore.
15. Laurence D.R. and Bennett P.N.: Clinical Pharmacology, Churchill Livingstone, Edinburgh.
16. Parikh C.K.: Parikh' s Text Book of Medical Jurisprudence and Toxicology. CBS Publishers and Distributors, Mumbai.
17. Rang H.P. and Dale M.M.: Pharmacology, Churchill Livingstone, Edinbergh.
18. Satoskar R.S. and Bhandarkar S.D.: Pharmacology & Pharmacotherapeutics, Popular Prakashan, Bombay.
19. Tripathi K.D.: Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, New Delhi.
20. Vyawahare N. S., Pawar A. T. and Takawale R. V., Pharmacology – I, Tech-Max Publuication, Pune
21. Walker R. and Edwards C.: Clinical Pharmacy and Therapeutics. Churchill Livingstone, London

4.7.4 P PHARMACOLOGY- IV

(Practical) (3Hrs/week)

Sr. No	Title of the Experiment
1	To find out the concentration of give drugs using three point bioassay method on suitable isolated tissue preparation (Minimum 02 exercise)
2	To find out the concentration of give drugs using four point bioassay method on suitable isolated tissue preparation (Minimum 02 exercise)
3	To study the drug antagonism using suitable isolated tissue preparation (minimum 02 exercise)
4	**Critical appraisal of fixed dose drug combinations of marketed preparations** with respect to comments on prescriptions of some proprietary preparations and multiple drug therapy (rational/irrational) mentioning possible indications, dose, route of drug administration, justification of inclusion of each ingredient, adverse reactions, contraindications, precautions and special instruction to patients. (Minimum 03 rational and 02 irrational combinations to be discussed)
5	**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 03 prescriptions to be discussed)
6	**Demonstration of any one of the following:** Study antioxidant activity of standard drugs by any method (DPPH), Superoxide anion, hydrogen peroxide and hydroxyl radical scavenging activity.

Recommended Books*:*

1. Burn J.H.: 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 M.N.: Fundamentals of Experimental Pharmacology, Scientific Book Agency. Bombay.
5. Jaju B.P.: Pharmacological Practical Exercise Book, Jaypee Brothers, New Delhi.
6. Kulkarni S.K.: Hand Book of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
7. Laurence D.R. and Bacharach A.L.: Evaluation of Drug Activity: Pharmacometritics, Academic Press, London.
8. Patil C.R.: X-Cology (Software), Pragati Book Co. Pvt. Ltd., Pune.
9. Perry W.L.M.: Pharmacological Experiments on Isolated Preparations. E&SP Livingstone, London.
10. Ravindran R.: X-Pharm (Software), Indian Journal of Pharmacology, JIPMER, Pondicherry.
11. Sheth U.K., Dadkar N.K. and Kamat U.G.: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Bombay.
12. Turner R.A.: Screening Methods in Pharmaocology.

4.7.5 T NATURAL DRUG TECHNOLOGY
(Theory) (3 Hrs/Week)

Learning objectives:

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

1. Understand & explain various difficulties in standardization of herbal material, new approaches evolved, and steps in development of plant monograph.
2. Understand & explain need & significance of plant material authentication, new approaches used with their merits & demerits.
3. 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 various guidelines issued by WHO in relation with cultivation, collection, storage etc.
4. 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 drug delivery of natural products; herbs used in cosmetic preparation & methods of their formulations.
5. Compare & contrast nutraceuticals & functional foods & understand & explaintheir significance. Explain & classify natural products used as dietary supplements.
6. Understand & explain significance of natural pesticides & explain source, chemistry & applications.
7. Explain source, extraction, processing, chemistry & applications of natural products used in pharmaceutical & allied industry such as bioavailability & skin permeation agents; wound healing agents, biofuels.

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

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

Sr. No.	Topic	No. of Hours
	SECTION-I	
1	***Standardization of herbal drugs:*** Current approaches, difficulties & their limitations, overview of new approach such as system biology approach; steps in development of crude drug monograph.	04
2	***Authentication of plant material:*** Need, significance, approaches used; DNA fingerprinting in plants: Principle and applications.	03
3	***Cultivation & harvesting technology:*** meaning & currently practiced approaches; role in quality assurance; factors influencing the level of plant metabolites; WHO guidelines on 'Good Agricultural and Collection Practices' (GACP).	06
4	***Post-harvesting storage of crude drugs:*** Overview of modifications during storage**,** deterioration of crude drugs due to excessive moisture, higher temperature, exposure to light & oxygen; mould& bacterial attack, insect & rodent-mediated deterioration; methods to control of infestation; other approaches to preserve crude drugs; WHO Guide to good storage practices for pharmaceuticals	03
5	***Traditional systems of medicine (AYUSH):*** Historical background, concept of health & pathogenesis, philosophical background, diagnosis & treatment aspects of Ayurveda, Unani, Siddha & Homoepatic system of medicine; Ayurvedic dosage forms: types & meaning; methods of preparation & evaluation of Vatika, Avleha, Asava, Arista, Taila, Bhasma & Churna.	08
	SECTION-II	
6	***Overview of novel drug delivery systems for herbal drugs.***	02
7	***Herbal dietary supplements:*** Definitions, classification, inorganic mineral supplements, digestive enzymes, probiotics, prebiotics, omega-3-polyunsaturated fatty acids, dietary fibers, Carotenoids, soya products, Spirulina, *Ginkgo biloba*, garlic, turmeric, grape seed proanthocyanidins, Resveratrol.	05
8	***Cosmecuticals:*** overview of herbs used in cosmetics for skin & hair care, general method of preparation & evaluation.	06
9	***Natural pesticides:*** Methods of pest control, classification, pesticides & environment; pharmacognostic account of Pyrethrum, Neem, Rotenone & Citronella	03
10	***Natural products as*** a] Oral bioavailability enhancers b] Skin permeation enhancers c] Radiation protection agents d] Natural products used in wound management [Hyaluronic acid; Corn protein (Zein); Hide glue derived from gelatin] e] Biofuels: Overview of biofuels (bioethanol, biodiesel), general method of preparation, significance of biofuels in national economy.	05

Recommended Books (Theory):

1. Agarwal S.S. & Paridhavi M., **Herbal drug technology**, Universities Press, 2007. ISBN-10: 8173715793.

2. Alessandro Burian*i et al.,* **Omic techniques in systems biology approaches to traditional Chinese 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. 16th Ed. 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. Gokhale S.B., Gaud R.S., Surana S.J., **Natural Excipients**, Nirali Publications, 2008. ISBN 978-81-85790-60-2.

11. Joshi Kalpana., Warude P.C. and Bhushan Patwardhan. **Molecular markers in herbal drug technology**. Cur. Sci., 87(2): 159-165, 2004.

12. Kang M. J. et al., **Bioavailability enhancing activities of natural compounds from medicinal plants.** J. Med. Plants Res., 3(13), 1204-1211, 2009.

13. Kesarwani K., & Gupta R., **Bioavailability enhancers of herbal origin: An overview**. Asian Pac J Trop Biomed, 3(4): 253-266, 2013.

14. Kokate C. K., Gokhale S.B. and Purohit A.P., **Textbook of Pharmacognosy**, Nirali Prakashan, Pune, 2008, ISBN: 8185790094.

15. Leo M.L. Nollet**,** Fidel Toldra, **Handbook of Analysis of Active Compounds in Functional Foods**, CRC Press, 2012**.**ISBN: 978-1-43-981588-5.

16. Mei Wang *et. al*., **Metabolomics in the Context of Systems Biology: Bridging Traditional Chinese Medicine and Molecular Pharmacology**.*Phytother. Res.* 19, 173–182 (2005).

17. 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.

18. Mukherjee Pulok K., **Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals**. Business Horizons, 2002.ISBN 8190078844.

19. NIIR Board of Consultants and Engineers, **Cultivation and Processing of Selected Medicinal Plants.**Asia Pacific Business Press Inc. 2006. ISBN: 8178330032.

20. Nikolaus J. Sucher, Maria C. Carles, **Genome-Based Approaches to the Authentication of Medicinal Plants**. Planta Med., 74: 603–623; 2008.

21. Panda H., **Herbal Cosmetics Hand Book**, Vedic Books Sales Rank, 2004. ISBN: 8178330806.

22. Purohit, S.S. & Vyas, S.P. **Medicinal Plant Cultivation: A Scientific Approach, Eastern Book Corporation,** 2007. ISBN: 8177542141.

23. Rajpal V. & Kohli D. P. S., **Herbal Drug Industry**, Riddhi International, 2nd Ed., 2009. ISBN: 9788190646727.

24. Rangari V.D., **Pharmacognosy & Phytochemistry** (Vol I), Career Pub., Nashik, 2009, ISBN: 978-81-88739-45-5.

25. Rangari V.D., **Pharmacognosy & Phytochemistry** (Vol II), Career Pub., Nashik, 2009, ISBN: 978-81-88739-65-3.

26. Robert E.C. Wildman, **Handbook of Nutraceuticals and Functional Foods**, 2nd Ed., CRC Press, 2006. ISBN-10: 0849364094.

27. Sharma Ravindra, **Agro Techniques of Medicinal Plants**. Riddhi International 2004. **ISBN:** 9788170353461.

28. 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.

29. V. Kusum Devi, Nimisha Jain, Kusum S Valli, **Importance of novel drug delivery systems in herbal medicines**, Pharmacog. Rev., 4(7), 27-31, 2010.

30. Wallis T. E., **Textbook of Pharmacognosy.** CBS Publisher & Distributors, 1985.ISBN:81-239-0886-5.

31.**WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants,** World Health Organization, Geneva, 2003.

32.**WHO monographs on selected medicinal plants**. World Health Organization, Geneva, 1999.

33.WHO Technical Report Series, No. 908, **Guide to good storage practices for Pharmaceuticals**. World Health Organization, Geneva, 2003.

4.7.5 P NATURAL DRUG TECHNOLOGY (Theory) (3 Hrs/Week)

1. Preparation of Ayurvedic formulations (Min 2 Exp.)
2. Evaluation of prepared/marketed Ayurvedic formulations (Min 2 Exp.)
3. Preparation of herbal formulations (Min 2 Exp.)
4. Evaluation of prepared/marketed herbal formulations (Min 2 Exp.)
5. Preparation of skin/hair care cosmetic products (Min 1 Exp.)
6. Evaluation of prepared/marketed skin/hair care cosmetic products (Min 2 Exp.)
7. Evaluation of marketed nutraceutical product
8. Preformulation study of isolated compounds
9. Determination of free radical scavenging acidity by spectrophometric 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. Kadbadi S.S., Deore S.L. &Baviskar B.A., **Experimental Phytopharmacognosy**, Nirali Publication, Pune, 2011. ISBN 9381237131.

5. Khandelwal K. R., **Practical Pharmacognosy**, Pragati Books Pvt. Ltd. ISBN 8185790302.

6. Kokate C. K., **Practical Pharmacognosy**, Vallabh Prakashan, 1993.

7. Krishnaswamy N. R., **Chemistry of Natural Products: A Laboratory Handbook**.

8. Leo M.L. Nollet**,** Fidel Toldra, **Handbook of Analysis of Active Compounds in Functional Foods**, CRC Press, 2012**.**ISBN: 978-1-43-981588-5.

9. Mukherjee Pulok K., **Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals**. Business Horizons, 2002.ISBN 8190078844.

10. Panda H., **Herbal Cosmetics Hand Book**, Vedic Books Sales Rank, 2004. ISBN: 8178330806.

11. **The Ayurvedic Pharmacopoeia of India**, Government of India, Ministry of Health and Family Welfare, Department of AYUSH.

4.7.6 T BIO-PHARMACEUTICS & PHARMACOKINETICS (Theory) (3Hrs/Week)

Learning objectives:

- 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 bioequivalence studies.
- Learning various compartmental models and non compartmental analysis methods.
- Understanding concept and mechanisms of dissolution and in vitro in vivo correlation.

Sr. No.	Topic	No of Hrs
	SECTION-I	
1	Introduction to biopharmaceutics and its importance in dosage form design.	02
2	**Absorption**: Factors affecting , mechanisms **Distribution**: physiological barriers, factors affecting, apparent volume of distribution. **Metabolism**: Phase I & phase II, factors affecting. **Elimination**: Routes renal & non renal, factors affecting, clearance concept.	10
3	**Non-Linear Pharmacokinetics**: Detection of non-linearity (saturation mechanism). Michaeles Menten equation. Definition of V_{max} and K_m. Determination of V_{max} and K_m. Significance of non-linear pharmacokinetics	03
4	Biopharmaceutical classification system, theories of dissolution, dissolution test apparatus, in vitro in vivo co-relation.	08
	SECTION-II	
5	**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.	08
6	**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 compartment model.	14

Recommended books:

- Rowland M, Tozer T, Clinical Pharmacokinetics and Pharmacodynamics Concepts and Applications, Ed 4, Wolter Kluwers – Lippincott,Williams and Wilkins.

- Niazi S, Textbook of biopharmaceutics and clinical pharmacokinetics, Appleton-century-crofts.
- Remington: The science and practise of Pharmacy, Ed 22 , Pharmaceutical press.
- Milo Gibaldi,Biopharmceutics and clinical pharmacokinetics, Ed 4.
- Venkateshwarulu V. Biopharmaceutics and pharmacokinetics, Ed 2, Pharmamed Press, Hyderabad.
- Bramhankar D. M, Jaiswal S. B, Biopharmaceutics and pharmacokinetics: A Treatise, Vallabh Prakashan.

4.7.7 T PHARMACEUTICAL JURISPRUDENCE
(Theory) (3Hrs/Week)

Learning objectives:

1) To understand .Basic principles, purpose and dimensions of the laws
2) Tounderstand the significance and relevance of Pharmaceutical laws in India
3) Important rules and regulations and procedures made to execute the laws
4) To discuss the purpose of the Board
5) To explain the definitions in the Act;
6) To describe the qualifications for membership and the make-up of the Board
7) To explain the rule-making authority of the Board;
8) To discuss the responsibilities of the Board;
9) To discuss inspections by the Board or its representative;
10) To learn the various laws governing the manufacturing, sale, research & usage of drugs
11)To understand significance of Schedule M and Schedule Y related Manufacturing & clinical t rials
12) Identify potential fraud and abuse legal issues of narcotic & psychotropic substance.
13) To study quality & prices of essential medicine
14) Learner knowledge about Patents, procedure for patent application and IPR.
15) To understand the regulatory system for safety and effectiveness of medicine and quality of product

Sr. No.	Topic	No of Hrs.
	SECTION-I	
1	**History of Pharmaceutical Legislation in India** **Code of Pharmaceutical Ethics**	**02**
2	**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 and Rules.	**09**
3	**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**
4	**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.	**03**
5	**Narcotic Drugs & Psychotropic substances act 1985**: Definition. Prohibited and controlled operation. Cultivation of poppy plants,	**03**

	sale of opium. Import and export of narcotics as amended to date. Offences and corresponding penalties	
6	**The prevention of cruelty to Animals Act, 1960**	**01**
7	**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	
8	**Intellectual Property Rights(IPR)** Introduction of IPR &Overview of Patents, Design, Trademarks, Copyrights, Geographical Indications etc.	**04**
9	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 case study,	**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 and Para-IV)	**05**
11	An Introduction to Standard Institutions and Regulatory Authorities such as ICH, WHO, USFDA, MHRA, TGA, BIS, ASTM, ISO.	**05**

Recommended books:

- Kuchekar B.S.,Forensic pharmacy, 9th edition. Nirali Prakashan.
- Education Regulations, Pharmacy Council of India, New Delhi
- The Drugs and Cosmetics Act and the rules by IDMa Publications, Mumbai
- Pharmaceutical regulatory affairs. Subrahmanyam C.V.S, Thimmasetty J. Vallabh Prakshan.
- What everyone should know about patents. Subbaram. 2nd edition. Pharmabook Syndicate.
- Forensic Pharmacy & Ethics. Mahajan J, Narang B.K. JPB Prakashan.
- A Textbook of forensic pharmacy. Mithal B.M. Vallabh Prakashan
- A Textbook of forensic pharmacy. Jain N.K. Vallabh Prakashan.
- Pharmaceutical Jurisprudence. Girish K, Jani. 4th edition. Atul Prakashan.
- Pharmaceutical Jurisprudence. Agarwal S.B. Tata Publishers.
- www.fda.gov

SAVITRIBAI PHULE PUNE UNIVERSITY

Faculty of Pharmaceutical Science

Syllabus

Final Year B. Pharm. 2013 Course
(With effect from Academic Year 2016 - 17)

4.8.1 T ADVANCED DRUG DELIVERY SYSTEM
(Theory) (3Hrs/Week)

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

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

B. Skills:
1. Formulation development and evaluation of sustained release, transdermal, gastro retentive formulations
2. Micro encapsulation techniques
3. Evaluation of marketed preparations
4. Optimization studies using 2^3 factorial design

Sr. No.	Topic	Hrs
	SECTION-I	
1	**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.	04
2	**Polymers-** introduction to polymers, classification (biodegradable /nonbiodegradable), types, environment responsive polymers, parameters affecting selection of polymers for modified release systems, application and examples.	04
3	**Novel Drug Delivery Systems:**Introduction, formulation, merits, demerits, application and evaluation of following— Mucosal drug delivery system, Transdemal drug delivery system (TDDS), Parenteral implants, Ophthalmic inserts, Intrauterine drug delivery system (IUDs), Liposomes, Probiotics and Prebiotics. Grastro retentive drug delivery system, Colon targeted drug delivery system, Externally modulated devices and delivery; iontophoresis and sonophoresis	15
	SECTION-II	
4	**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	10

	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	
5	**Microencapsulation**: Introduction, concept of microencapsulation, merits, demerits and application. Types of Microencapsulation: chemical encapsulation processes, complex, coacervation, polymer-polymer incompatibility, interfacial polymerization, and in-situ polymerization. Mechanical encapsulation process: Pan coating, spray drying, spray congealing, fluidized bed coaters, extrusion, and Spheronization techniques, rotational suspension separation, solvent evaporation. Evaluation of microcapsules	10
6	**Optimization Techniques in Pharmaceuticals** : Basic concept of optimization, factors variable and design of experiment, introduction to two level factorial design with suitable pharmaceutical samples.	02

4.8.1 P ADVANCED DRUG DELIVERY SYSTEM
(Practical) (3hrs/Week)

1) Evaluation of polymers – DSC, XRD, FTIR, viscosity, swelling index.(atleast 2)
2) Micro encapsulation (using one solid and one liquid drug) by coacervation evaluation of microcapsules
3) Formulation & Evaluation of sustained release formulations tablet
4) Evaluation of marketed sustained release tablets/capsules.
5) Formulation and evaluation of matrix type transdermal drug delivery system.
6) Formulation & Evaluation of Enteric coated tablet formulations
7) Evaluation of marketed sustained release tablets/capsules.
8) Preparation of beads using ionic gelation.
9) Formulation and evaluation of Effervescent gastro retentive tablet
10) Formulation and evaluation of swellable gastro retentive tablet
11) Optimisation of any one formulation using 2^3 factorial designs.

Recommended books:

- Y. W. Chien ; Controlled drug delivery, Fundamentals and Applications,, 2nd Ed. Marcel Dekker.
- P. Tyle; Drug Delivery System, 1st ed, Marcel Decker, 1988.
- Modern Pharmaceutics,Banker,Giberts S.Marcel Dekker,2nd edition,1990.
- Novel Drug Delivery System,Chien Yie.W.Marcel Dekker,2005.
- Targeted and Controlled Drug Delivery Novel carrier Systems,Vyas S.P. Khar R.k.CBS publication,2012.
- Hadgraf & Guy; Transdermal Drug Delivery, 1st Ed, Vol-35, Marcel Dekker, 1989.
- Benita; Microencapsulation- methods & Industrial Applications, 2nd Ed, vol-158, Taylor &Francis Publication, 2006.
- Peter.J.Tarcha; Polymers for Controlled drug delivery, 1st Ed,CRC Press,1991.
- J. Hickey; Pharmaceutical Inhalation Aerosol Technology; 1st ed, Marcel Decker, 2004.
- N. K. Jain; Advances in controlled and novel drug delivery, 1st Ed., CBS Publication, 2001
- Encyclopedia of Pharmaceutical technology, 2nd ed.,vol.III, 1999.
- Controlled drug delivery system - Vicent H.L., Marcel Dekker Second Edition, Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol- 29.

4.8.2 T COSMETIC SCIENCE
(Theory) (3 Hrs/Week)

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 in cosmetics.
- Explain formulation of cosmetics for skin, manufacturing, equipments &evaluation of creams like cold cream, vanishing cream etc. & powder cosmetics.
- Explain formulation of cosmetics for hair, manufacturing & evaluation of hair shampoos, tonics etc.
- Describe formulation of cosmetics for eyes, manufacturing & evaluation of eye mascara, shadow etc.
- Understand formulation of manicure products like nail lacquer, remover etc.
- Learn formulation, manufacture & evaluation of baby cosmetics like baby oils, powders etc.
- Explain the concept of cosmeceuticals, history, difference between cosmetics & cosmeceuticals & cosmeceutical agents.

Skills:

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

Unit	Topic	Hrs
	SECTION-I	
1	**Fundamentals and Scope of Cosmetic Science** • **Additives in Cosmetics:** emollients, waxes, oils, humectants, preservatives, binders, surfactants, colours and perfumes. • Cosmetics v/s drug formulation. Anatomy and composition of skin and hair. Types of cosmetics. • Quality of Water in cosmetic Industry • Packaging, Cleanliness, Hygiene and Microbial control in Cosmetic manufacturing • Perfumes- Source, classification, blending and fixation	**08**
2	**Formulation, manufacturing & evaluation of following cosmetics**	
A)	**Skin care Products** **a) Cosmetics for skin:** Moisturising 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 and packs** **d)Face make up:** Face powder, compact powders, Cake makeup, Liquid makeup, Stick preparation	**10**

	e) Coloured makeup preparations: Lipsticks, Lip balm, Rouge **f) 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, shaving preparations.	**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. Cosmeceutical Agents- retinoids, hydroxyl acids, beta hydroxyl acids, Antioxidants and others.	**05**

4.8.2 P COSMETIC SCIENCE
(Practical0 (3 Hrs/week)

Formulation and evaluation of following cosmetics:

Sr. No.	Cosmetic preparation
1	Cold cream
2	Vanishing cream
3	Moisturising cream
4	Sunscreen cream/lotion
5	Lip stick
6	Shampoo
7	Shaving cream
8	After shave lotion
9	Face pack
10	Face powder
11	Eye cosmetics: Eye shadow, Eye liner, Eye Mascara
12	Tooth powder
13	Baby products - Baby powders, lotions
14	Nail lacquer

Recommended Books:

- Barel Andre O., Paye Marc, Maibach Howard I., Handbook of Cosmetic Science and Technology. Marcel Dekker, Inc.
- Harry'sCosmeticology. By J.B. Wilkinson and R.J. Moore, Longman Scientific and Technical, England.
- Poucher W.A., Perfumes, Cosmetics and Soaps by, Vol. I, II, III
- J. B. Wilkinson, R. J. Moore, "Harry's Cosmetology", 7th edition, Longman Scientific and Technical, 1994.

- Sharma P. P., “Cosmetic Formulation, Manufacturing and Quality Control” 7th edition, Vandana publication, 2001.
- E.G.Thosmssen” Modern cosmetics Universal Publishing Corporation.
- Elsner Peter, Howard I. Maibach, Cosmeceuticals. Marcel Dekker, Inc.
- Dr. Laba “Rheological properties of cosmetics and toiletries” Marcel Dekker.
- Appell L.“The formulation and preparation of cosmetics, fragrance and flavours” Micelle press
- J.Knowlton and S.Rearce “ Handbook of cosmetic science and technology” 1st edition; Elsevier science publisher; oxford, UK, 1993
- Mithal BM, Saha RN, A handbook of Cosmetics. VallabhPrakashan, Delhi.

4.8.3 T PHARMACEUTICAL ANALYSIS-VI
(Theory) (3 Hrs/Week)

Learning objectives:
On successful completion of following theory topics & laboratory experiments, a learner should get the

Knowledge:

1. Understand principles, instrumentation of NMR and ESR spectroscopy, HPLC and their applications in Pharmaceutical research, quality control of APIs & formulations.
2. Understand the basic principle, instrumentation of Mass Spectrometry.

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. Take appropriate safety measures while handling instruments, chemicals and apparatus.

Sr. No.	Topics	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	
	SECTION-I	
1	**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 C^{13} NMR	15
2	**ESR:** Introduction, principle & instrumentation	02
3	Ion Exchange Chromatography: Theory, instrumentation and applications. Capillary electrophoresis: Theory, instrumentation and applications	04
	SECTION-II	
4	**High performance Liquid Chromatography (HPLC):** Theory, instrumentation and applications, Isocratic & Gradient types, Pumps, Columns, Detectors, Tubings, Degassing techniques, Quantitation techniques, Trouble shooting in brief and System suitability testing, **UPLC:** Introduction and advantages over HPLC	12
5	**Mass spectrometry:** Introduction, theory, instrumentation, resolution, different methods/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
(Practical) (3 Hrs/Week)

1. Validation of analytical methods (Spectrophotometry & HPLC) as per USP or ICH guidelines (minimum two)
2. Study of system suitability parameters as per IP/BP/USP protocol for HPLC methods.
3. Study of Quantitation Techniques in HPLC (% Area / Area Normalization, Internal Standard addition)
4. Interpretation of UV, IR, NMR, MS spectras of simple organic compounds for structure elucidation (minimum four compounds)

Recommended books for Theory and Practicals

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. 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

4.8.4 T MEDICINAL CHEMISTRY-IV

(Theory) (3 Hrs/Week)

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

A. Knowledge:

Know general aspects of the design & development of drugs including history, classification, nomenclature, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses and recent developments in categories such as chemotherapeutic agents, antibiotics, hormones & anti-fertility agents.

B. Skills:

1. Make correct use of various equipments & take safety measures while working in medicinal chemistry laboratory.
2. Understand and develop skills in various demonstrated experiments such as High Vacuum distillation, recrystallization and pH based amino acid separation.
3. Develop skills involved in thin layer chromatography techniques and purification of synthesized compounds by column chromatography.
4. Synthesize, recrystallize and understand reaction mechanisms involved in synthesis of medicinally important organic compounds.
5. Interpret the spectral characterizations made by IR and ^{1}H-NMRs of synthesized compounds.

Sr. No	Topic	No. of hrs
	SECTION-I	
	History and general aspects of the design & development of drugs including classification, nomenclature, structure activity relationship (SAR) and recent developments of following categories, therapeutic uses, scheme of synthesis of drugs given in bracket.	
1	a. Synthetic antibacterial agents eg. Sulfonamides, Quinolones, Nitrofurans etc. b. Antitubercular & Antileprotic agents c. Antifungal agents d. Antimalarials e. Antiamebic agent f. Trypanosomicidal drugs, drugs acting against leishmaniasis. g. Anthelmintics h. Antiviral agents including antiretroviral i. Antineoplastic agents including recent drugs and monoclonal antibodies (Metronidazole, Ciprofloxacin, Proguanil, Amodiaquine, PAS, Isoniazid, Clotrimazole, 5-Flocytosine, Nevirapine, Saquinavir, Albendazole, Melphalan,	25

	Chlorambucil, Methotrexate)	
	SECTION-II	
2	Antibiotics: β-lactam antibiotics: (Penicillins and Cephalosporins, oxopenams, carbapenams, monobactams and beta lactamase inhibitors) The aminoglycosides The tetracycline The macrolides The Lincomycins The Polypeptides Unclassified antibiotics (Amoxycillin Trihydrate, Cephadroxil)	10
3	Hormones: Thyroid and antithyroidal agents, GnRH, FSH agonists and antagonists	04
4	Steroids a. Sex hormones and their synthetic analogs b. Antifertility agents	06

4.8.4 P MEDICINAL CHEMISTRY-IV
(Theory) (3 Hrs/Week)

I. Synthesis of following medicinally important compounds/drug intermediates with recrystallization of each compound and monitoring reactions over TLC.
   1. 4-Methyl quinoline
   2. Isoniazide
   3. Metronidazole/Albendazole
   4. Sulphamethoxazole
   5. Methyl Salicylate
   6. O-Iodo benzoic acid from Phalimide

II. Techniques in synthesis:
   1. Purification of above synthesized compounds by Column chromatography (Any two)
   2. Preparative TLC (Any Two)
   3. Interpretation of IR spectra of synthesized compounds (Any three)

III. Demonstration Experiments (Any one)
   1. High Vacuum Distillation
   2. pH based amino acid separations

Recommended Books

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Co. Philadelphia.

2. Foye's Principles of Medicinal Chemistry by Lemke, 6th edition, Lippincott William Wilkins.
3. Burger's Medicinal Chemistry by Wolff ME, John Wiley & Sons, New York.
4. Introduction to Medicinal Chemistry', How Drugs Act and Why by Alex Gringauz, Willey-VCH Publication 1997.
5. Comprehensive Medicinal Chemistry by Hansh C, Vol IV, Elsevier Pergamon.
6. An Introduction to Drug Design by SN Pandeya & IR Dimmock, 1st edition, New Age International Publishers.
7. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
8. Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II, 10th Edition, Nirali Prakashan.
9. Drug Design by Bothara KG & Kulkarni VM, 3rd edition, Nirali Prakashan.
10. Pharmaceutical Substances by Kleeman & Engel, 4th edition, Thieme Publications.
11. The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 by Lednicer Daniel, 1st edition, John Wiley & Sons INC..
12. Textbook of Practical Organic Chemistry, The ELBS Longman, London.
13. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language Book Society and Longman Group Limited, London.
14. Vogel' s A Text book of Practical Organic Chemistry by Vogel, 3rd edition, The English language book society and Longman group limited, London.
15. Advanced practical Medicinal Chemistry by Ashutosh Kar, 1st edition, New Age International Publications.
16. Vogel's Elementary Practical Organic Chemistry Small Scale Preparation by Arthur I., 2nd Edition, Part-I, CBS Publication.
17. Spectrometric identification of organic compounds by R. M. Silverstein, John Wiley and sons USA.
18. A Textbook of Pharmaceutical Chemistry by Chatten LG, Vol I & II, Marcel Dekker New York.
19. Analytical profiles of drug substances by Klaus Florey(All Volumes)

4.8.5 T PHARMACOLOGY-V (INCLUDING BIOSTATISTICS)

(Theory) (3 Hrs/Week)

Learning objectives:

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

1. Understand various methods of drug-drug interaction inside the body.
2. Understand the mechanism of adverse drug reactions and pharmacovigilance.
3. Get knowledge about recent development in pharmacology

Skill:

1. Understand the in vivo and in vitro experiments, use of software for the study of preclinical experiments.
2. Brief idea about statistics, its applications and how to solve problems using various statistical tests.

Sr. No	Topic	No of Hrs
	SECTION I	
1	**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.	04
2	**Adverse Drug reactions (ADR):** Epidemiology, Classification, Risk factors, Monitoring, Detecting and reporting of ADR. Introduction to Pharmacovigilance.	04
3	**Bioavailability, bioequivalence and Therapeutic Drug Monitoring:** Concept, organization, advantages, special issues, applications.	04
4	**Introduction and recent development in:** Gene therapy Stem cell biology Tissue Engineering	04
5	Drug abuse and misuse, Drug induced diseases. Interpretation of clinical laboratory tests.	04
	SECTION II	
6	**Hospital Pharmacy:** Introduction, Hospital and therapeutic committee, hospital formulary, role of hospital pharmacist in hospital committees and practice of rational drug therapy.	04
7	Outpatient and inpatient services, drug distribution system in hospital, floor ward stock system, satellite pharmacy services, bed side pharmacy, distribution of control drugs.	05
8	Methods of assessment of compliance, Reason for patient noncompliance, strategies to improve compliance	02
9	**Clinical Trials:** History, important terminologies, Types of clinical research, Phases of clinical research, role of clinical trial in new drug developments	04
10	**Ethical issues in clinical trials-** Principle of regulatory requirements, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing),	06

	The Nuremberg Code, The Declaration of Helsinki, The Belmont Report	
11	**Good Clinical Practice**-Concept, importance, and cGCP guidelines including ICH guidelines and schedule Y	04

Recommended Books:

1. Hansten P.D.: Drug Interactions, Lea & Febiger, Philadelphia.
2. Barar F.S.K.: Essentials of Pharmacotherapeutics, S. Chand & Co., New Delhi.
3. Speight T.M. and Holford N.H.G.: Avery' s Drug Treatment, Blackwell Publishing, New York.
4. Stockley I.H.: Drug Interactions, Pharmaceutical Press, London.
5. Bauer L.A.: Applied Clinical Pharmacokinetics, McGraw-Hill Professional, Singapore.
6. Bowman W.C. and Rand M.J.: Textbook of Pharmacology, Blackwell Scientific Publications,Oxford.
7. Craig C.R. and Stitzel R.E.: Modern Pharmacology, Little Brown and Co., Boston.87
8. Das M.M. and Dutta S.K.: Ghosh' s Modern Concepts on Pharmacology & Therapeutics, Hilton & Co., Calcutta.
9. Goodman and Gillman: Pharmacological Basis of Therapeutics, McGraw-Hill, Medical Publishing Division, NewYork.
10. Harisons: Principles of Internal Medicine, McGraw Hill Publications, Singapore.
11. Katzung B.G.: Basic and Clinical Pharmacology, Lange Medical Publications, California.
12. Parthasarathy G.: A textbook of Clinical Pharmacy Practice- Essential Concepts and Skills, Orient Longman, Hongkong.
13. Rang H.P. and Dale M.M.: Pharmacology, Churchill Livingstone, Edinbergh.
14. Rodrignes A.D.: Drug-drug Interactions, Vol. 116, Marcel Dekkar, New York.
15. Satoskar R.S. and Bhandarkar S.D.: Pharmacology & Pharmacotherapeutics, Popular Prakashan, Bombay.
16. Tripathi K.D.: Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, New Delhi.
17. Rakesh Kumar Rishi. Regulation of clinical Trials. Kangpos Publication Pvt. Ltd., New Delhi.
18. Allwood M.C., Fell J.T. Textbook of hospital Pharmacy. CBS Publication and distributers Pvt.Ltd.
19. Vyawahare N. S., Pawar A. T. and Takawale R. V., Pharmacology – I, Tech-Max Publuication, Pune
20. Vyawahare N. S., and Vora S., General Pharmacology, Nirali Publication, Pune
21. Martin Stephens. Hospital Pharmacy. Pharmaceutical Press, London.

4.8.5 P PHARMACOLOGY-V (INCLUDING BIOSTATISTICS)

(Practical) (3 hrs/Week)

Minimum 15 Experiment to be conducted

Sr. No	Title of the Experiment
1	To study the preclinical pharmacological experiments using suitable computer based program (Minimum 02 exercise).
2	To find out the PA_2 or PD_2 value of given drugs using suitable isolated tissue preparation. (Minimum 02 exercise)
3	Basic concepts of statistics, its application and importance.
4	To determine the Mean, Mode and Median of the given data (Minimum 02 exercise)
5	To determine the Standard deviation, Standard error of mean and coefficient of variation of the given data (Minimum 02 exercise)
6	To determine the Analysis of variance (ANOVA) of the given data (Minimum 02 exercise)
7	To study the problems based on paired and unpaired Student 't' test. (Minimum 02 exercise)
8	To study the problems based on non parametric test. (Minimum 02 exercise)
9	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.

4.8.6 T NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS (Theory) (03 Hrs/Week)

Learning objectives:

On completion of theory, learner should be able to:

1. Understand & realize the significance of natural products in daily life. He/she should be able to classify different segments in market, demand & supply position; export & import potential; position of Indian herbal drug industry in global contest; government organizations & policies for promotion; their regulation in India & other countries, various regulatory guidelines, ethical issues etc.
2. Realize the market potential of natural products & explore entrepreneurship skills to grab these opportunities.
3. Understand & explain safe use of natural products, possible toxicities &interaction, toxicities in most venerable group (elderly patients), need &significance of pharmacovigilance systems; WHO guidelines in this regard.

Sr. No.	Topic	No. of Hours
1	***Commerce:*** Global & domestic market size/volume of various natural product segments in commerce (crude drugs, phytopharmaceuticals, herbal drug formulations, drug leads, drug intermediates, traditional medicinal products, nutraceuticals, health drinks & beverages, essential oils, flavor, fragrance, perfumes, spices & condiments, cosmetics, colorants, sweeteners, Pharmaceutical excipients, pesticides& insect repellents, veterinary medicinal products, biofuels; demand & supply position; export & import.	7
2	***Industry:*** Indian herbal drug industry: Size, turnover, domestic & international share, export potential, domestic & global market for prescription, OTC & TSM products, important plants used in indigenous systems of medicine & in modern medicine; major herbs/extracts exported from India, government agencies involved in development & promotion, promotional policy for entrepreneurship development: technical& funding assistance schemes, Industry oriented R & D institutes, leading manufacturer of herbal drugs, bottlenecks of plant based drug industry.	8
3	***Regulation:*** Herbal drug regulation in India, licensing requirements for production & sale of herbal drugs in India; documentation; global regulatory status; ethical issues, WHO guidelines for regulation, The International Conference on Harmonization (ICH) guidelines, concepts of Quality by Design (QBD), GMP; Other issues related to export of natural products (such as CITES Certificate, DGFT Notification, Negative list of herbs, TRAFFIC)	12
	SECTION - II	
4	***Toxicity in herbals and their interaction:*** Different ways by which herbal preparations cause toxicity, pharmacokinetic & pharmacodynamic interactions, herbal drug interaction of commonly used herbs (Liquorice, Cinchona, Cannabis, Garlic, Digitalis, St John's wort); special precautions in geriatric patients.	8
5	***Pharmacovigilance of herbal medicines:*** Meaning, need, significance; WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems	6
6	***Plant Allergens:*** definition & classification (inhalants, injectants, contactants, infectants and infestants), plants causing Hay fever, allergy.	4

	Applications of allergents in diagnosis & treatment, method of preparation of allergenic extracts.	

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 in India: An Overview**. J. Clin. Biochem.Nutr., 41, 1–11, 2007.

3. Brendler, Thomas; Phillips, L Denzil; Spiess, Stefan, **A Practical Guide to Licensing Herbal Medicinal 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. http://business.gov.in/agriculture/aromatic_herbal_plantation.php

7. Evans W. C., Trease G. E., **Trease and Evan's Pharmacognosy.** W.B. Saunders, 2002. 16th Ed. 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 ethical analysis.** 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 health-care professionals.** 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 (Theory) (3 Hrs/Week)

Learning Objectives:

On completion of following theory topics learner should be able to:

- Describe the significance of quality in pharmaceutical manufacturing
- Explain Current Good Manufacturing Practices
- Describe various aspects of documentation, SOPs and records
- Elaborate on the role of validation in assurance of quality in pharmaceutical industry
- Explain about quality by design
- Explain about ICH guidelines in stability testing and QMS

Sr. No.	Name of the topic	No of Hrs
	SECTION-I	
1	**Quality assurance:** Importance of QA, Concept of quality control, Organization of Quality Assurance department, Quality assurance & total quality controls. Sources of variation, Quality control of raw materials & pharmaceutical process & finished products. Documentation, concepts of statistical quality control. Quality Audits.	09
2	**Validation:** Introduction. Basic concepts, types and stages of validation, validation master plan (VMP), equipment validation. Concept of URS, DQ, IQ, OQ & PQ and process-types. Prospective, concurrent and retrospective validation & revalidation. Validation of steam sterilization, membrane filters, tray dryers, compression machine and cleaning method.	10
3	**Introduction to QBD**	02
	SECTION-II	
4	**Current good manufacturing practices:** Personnel, surrounding, building, equipment.	09
5	**Documentation and records:** Introduction, specifications, importance and types. Master Production and Control Record, Batch Production and Control Record. Importance of SOPs and records. Change control. Site Master File.	10
6	**ICH guidelines for stability testing.** Introduction to Quality management System as per ICH.	05

Recommended Books:

1) MA Potdar. Pharmaceutical Quality Assurance. Nirali Prakashan, Pune.
2) FJ Carleton, J Agalloco. Validation of Pharmaceutical Process. Mercel Dekker Inc.
3) Ira R Ferry and Robert Nash. Pharmaceutical Process Validation, Second Ed, Mercel Dekker Inc.
4) Sidney Willing. Good Manufacturing Practices for Pharmaceutical, A Plan for Total Quality Control
5) Quality Assurance Guide by Organization of Pharmaceutical Producers of India.
Pharmaceutical Master Validation Plan, The Ultimate Guide to FDA, GMP & GLP Compliance. Sayed IH, Special Indian Ed
6) Pharmaceutical Process Validation, 2nd Ed, Ira R Berry, Robert A Nash
7) Facility Validation, Theory, Practice and Tools, Grahm C Wrigley