North Maharashtra University, Jalgaon

Syllabus of

Final Year B. Pharmacy (Sem VII & Sem VIII)

W.E.F. Academic Year 2015-2016

T- 4.7.1 Pharmaceutical Technology II (Pharmaceutics –VIII)

(Theory)(3Hrs/week)

Sr. No.	Topics	Hrs.
	Section- I	
1.	**Parenteral Preparations:** **A} General requirements: -** Concept of sterile products**.** Definition and Introduction of Parenteral Preparation. Historical background, Ideal Requirements, Advantages, Disadvantages, Classification, Precautions, Brief discussion on preformulation factors for parenterals. Routes of Administration {Primary and Secondary}, Water for Injection (WFI) and its preparation methods, Sterile Water for Injection (SWFI), and Bacteriostatic Water for Injection (BWFI), Pharmacopoeial evaluation of SWFI and WFI. Non aqueous solvents used in parenteral formulations. Pyroginicity, sources & removal of pyrogens. Isotonicity. Formulation additives for Parenterals. Preparation of sterile powders {Liophilization}. Long acting parenteral formulations such as suspensions, emulsions, and depot preparations. Effect of route of administration. **B} Packing of Parenterals: -** Containers- Glass- Introduction, advantages and disadvantages, composition of glass. Types of glass. Problems encountered with glass containers such as leaching and flaking. Evaluation of glass containers {Powdered glass test, Water attack test and light transmission test for colored glass}. Containers- Plastic- Introduction, advantages and disadvantages, classification of plastics {thermoplastic and thermosetting type- brief explanation} evaluation of plastic containers for parenteral preparations. Closures- Rubber- Introduction, excipients or additives used in rubber closures, Ideal characteristics of rubber, types of rubbers. Evaluation of rubber closures. Aseptic packaging via Form Fill Seal Technology. Sealing of Ampoules. **C} Design of facilities and environmental control: -** Basic design, environmental control, class 100 and other areas. HEPA filters, HVAC system. Laminar Flow Rooms {Horizontal & Vertical}. Validation of Environment. Validation of HEPA filters {Hot & Cold DOP test}. Concept of CIP {Clean in Place} & SIP {Steam in Place}. **D} Personnel factors: -** Contamination in pharmaceutical parenteral plant, selection of clean room personnel, training programs for clean room employees, motivation of employees. **E} Processing of Parenteral Products: -** Processing of parenteral products by terminal sterilization, filtration sterilization. Validation of sterilization equipments, Biological & Chemical Indicators. **F} Quality control and Quality Assurance of Parenterals: -** Evaluation of Parenteral Products by Pyrogen test, Clarity test, Leaker test and sterility test.	**12**
2.	**Ophthalmic Products:** Definition, Introduction, Types of Ophthalmic Products. Anatomy and Physiology of the eye. General requirement / safety consideration. Formulation, isotonicity	**05**

	adjustment. Sodium chloride equivalent method {Calculation of dissociation factor and sodium chloride equivalent}. Problems on Isotonicity calculation. Sterilization of ophthalmic products {Steam sterilization, filtration, gaseous and radiation}. Composition of Tears, Artificial Tears. Mechanism of ocular drug absorption {Corneal & Non corneal}. Glaucoma and its management. Packing of eye drops. Evaluation of ophthalmic products.	
3.	**Drug Stability: -** Introduction, Definition of stability, Concept of expiry date or shelf life, Reasons for stability, Advantages. Kinetic studies versus stability studies. Physical degradation of Pharmaceutical Products with their preventive measures. Chemical decomposition of drugs with their preventive measures such as – Hydrolysis {Ester and amide hydrolysis with examples}, Oxidation {Auto oxidation kinetics of ascorbic acid}. Miscellaneous reactions with their preventive measures such as optical isomerisation, epimerization, geometrical isomerisation, polymerization, and decarboxylation. Effect of light {Photochemical decomposition}, pH, and temperature on drug decomposition. Brief introduction to ICH guidelines for stability testing.	**06**
	Section- II	
4.	**Oral sustained and controlled drug delivery system:** Definition, Introduction, rationale, advantages, and disadvantages. Comparison of sustained and controlled drug delivery system. Model drug selection criteria for sustained and controlled drug delivery system. Classification – details of matrix and diffusion control systems. Biopharmaceutical aspects –concept of maintenance dose & loading dose. Evaluation of SR & CR Tablets only.	**07**
5.	**Polymers used sustained and controlled drug delivery system:** Brief introduction to polymers, linear polymers, branched polymers, cross linked polymers, classification of polymers based on method of polymerization, properties of polymers, characterization of polymers. Examples of polymers such as celluloses, chitosan, Polylactide – coglycolide {PLGA}.	**04**
6.	**Microencapsulation:** Definition, Introduction, Typical shapes of Microcapsules, Types of microcapsules, importance of microcapsulation in pharmacy, Core and Coating materials, Formulation of microcapsules by coacervation phase separation, air suspension technique, multiorifice centrifugal process, solvent evaporation, spray drying and spray congealing, pan coating. Introduction of a relatively new technique "Polymerization,". Brief discussion on magnetic microspheres, evaluation of microcapsules.	**07**
7.	**Optimization:** Definition, Introduction, Optimization parameters – Problem type {Constrained & Unconstrained} and Variable type {Independent and Dependent Variables}, surface response, Classical optimization. Statistical design and optimization methods. Applications of optimization in Pharmacy.	**04**

Total Hours: 45

P - 4.7.1 Pharmaceutical Technology II (Pharmaceutics –VIII)

(Practical) (3Hrs/week)

Note: Conduct any 15 experiments from following list. A) Products may be assayed to evaluate accuracy in regular practical. Assays are not to be given to students in University examinations.

B) Formulation of different dosage forms should give stress on raw material specifications, preformulation, process controls, and documentation.

1) Introduction to Parenterals.
2) To prepare & evaluate ampoule containing SWFI.
3) To prepare & evaluate ampoule containing ascorbic acid injection.
4) To prepare & evaluate ampoule containing calcium gluconate injection.
5) To prepare & evaluate sodium chloride and dextrose injection.
6) To prepare & evaluate ampoule containing atropine sulphate injection.
7) To prepare & evaluate ampoule containing sodium thiosulphate injection.
8) Introduction to Ophthalmic Products.
9) To prepare & evaluate zinc sulphate eye drop.
10) To prepare & evaluate sulphacetamide sodium eye drop.
11) To prepare & evaluate chloramphenicol eye ointment.
12) To prepare & evaluate sulphacetamide sodium eye ointment.
13) To perform powdered glass test.
14) To perform water attack test.
15) To evaluate plastic containers used for parenteral products.
16) To evaluate rubber closures used for glass containers containing parenteral products.
17) Accelerated stability testing of an injection.
18) Preparation and evaluation of microspheres.
19) Formulation and evaluation of one controlled release/sustained release formulation.

Book Recommended for Theory & Practical's:-

1. Leon Lachman. The Theory and Practice of Industrial Pharmacy. Third edition. Varghese publication.
2. Ansel-- P'ceutical dosage forms and drug delivery system. Eight edition.Indian edition by B. I. publications.
3. Alfanso R. Gennaro-- Remington's Pharmaceutical Sciences. 21st Edition, Vol. I & II.
4. Rawling-- Bentleys T.B. of Pharmaceutics.
5. Lockhart-- Packaging of Pharmaceuticals and healthcare products
6. D A Dean, E R Evans --Pharmaceutical Packaging Technology
7. Swarbrick & Boyan -- Encyclopedia of Pharm. Tech.
8. Banker & Rhodes-- Modern pharmaceutics.
9. S J Turco-- Sterile dosage forms
10. Liberman H. A. and Leon Lachman. Pharmaceutical dosage forms: - Parenteral Medications. Vol. 1, 2 and 3. Second edition, Marcel Dekker.
11. C. V. S. Subrahmanyam. Text Book of Physical Pharmaceutics. Second edition, Vallabh prakashan.
12. B. M. Mithal. A text book of Pharmaceutical Formulation. Sixth edition, Vallabh prakashan.
13. Official Books such as I.P., B.P., B.P.C., U.S.P.
14. Niazi. Handbook of Pharmaceutical manufacturing formulations. (Vol. 1-6)
15. Deasy. Microencapsulation and related drug processes.
16. E.A. Rawlin. Bentley's textbooks of Pharmaceutics. Eighth edition. Elsevier publication.
17. Michael E. Aulton. Aulton's Pharmaceutics. The design and manufacture of medicines. Third edition. Elsevier publication.

T - 4.7.2 Pharmaceutical Chemistry – VIII (Medicinal Chemistry – III)

(Theory) (3Hrs/week)

Discussion of the following classes of drugs including, classification, chemical nomenclature, structure including stereochemistry, generic names, chemistry, physicochemical properties, SAR. Metabolism, molecular mechanism of action, and synthesis, introduction to rational development if any of the class of drugs:

Sr. No.	Topic	Hour
	Section- I	
1	**Sedatives and hypnothics** (mephobarbital, Phenobarbital, pentobarbital, secobarbital, diazepam, nitrazepam*. Oxazepam. Alprazolam. Midazolam, cholorodiazepoxide, choral hydrate, gluthethimde*, zolpidem, zopiclone)	**4**
2	**Anticonsulvants** (Phenobarbital, chlordizepoxide, diazepam, clonazepam*, phenytoin, trimethadione, paramethadione, ethosuximide*, phenosuximide, primidone, sodium valproate, carbamazepine*, progabide, lamotrigine, vigbatrin)	**5**
3	**Antipyschotics** (chlorpromazine*, triflupromazine, thioridazine, fluphenazine, chlorprothixene, loxapine, clozapine, haloperidol*,droperiodol, risperidone*, pimozide, molindone)	**5**
4	**Antidepressants** (imipramine, chlorimipramine, amitryptyline, nortriptyline, doxepine*, fluoxetine*, paroxetine, trazodone, iproniazid, pargline, isocarboxazide, tranylcypromine)	**4**
5	**Antiparkinsons** (carbidopa*, levodopa, selegiline, amantadine, bromocriptine, benzotropine*, procyclidine, trihexyphenidyl, orphenadrine)	**4**
	Section- II	
6	**General Anesthetics** Ketamine hydrochloride, Diazepam	**2**
7	**Local Anesthetics** a. Amino esters – procaine, tetracaine, benzocaine b. Amino amides – lidocaine*, mepivacaine, bupivacaine c. Amino ethers – pramoxine d. Alcohols – Benzyl alcohol, eugenol	**3**
8	**Drugs for Alzheimer's Diseases:** Pharmacological,Psychological, Care giving treatment including Aricept, Exelon, Namenda, Donepezil ,Galantamine ,Rivastagmine , Tacrine ,Memantine and other drugs	**4**
9	**Antiviral agents including HIV** Indoxuridine*, amantadine*,acyclovir, ganciclovir and ribavirin, HIV agents –both nonnucleosides like nevirapine & delaviridine and nucleosides	**6**

	like AZT and protease inhibitors like indinavir, saqvunavir, ritonavir (only highlights of structure). Combination therapy	
10	**Vitamins and Related Compounds** Water soluble & lipid soluble vitamins	**6**
11	**CNS Stimulant** Caffeine, theophylline, Pentoxifyllin, amphetamine*, Dextroamphetamine, methamphetamine, methyphenidate, doxapram, alitrine, phenteramine*	**2**

Total Hours: 45

Reference Books:

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

P - 4.7.2 Pharmaceutical Chemistry – VIII (Medicinal Chemistry – III)

(Practical) (3Hrs/week)

Minimum Twelve numbers of Experiments should be performed.

***Minor **Major Experiments**

1. Purification techniques of solvents/liquids by Fractional distillation and distillation under vacuum
2. Synthesis of benzil from benzoin*
3. Synthesis of hydantoin from benzil*
4. Toluene –p-sulphonate from toluene –p-sulphonil chloride
5. Dichloramine –T From Toluene –p-sulphonate
6. Chloramine – T from Dichloramine –T **
7. Preparation of Iso-Nicotinic acid (oxidation of picoline with potassium permanganate)*
8. Cyclization reactions: 2-Phenylindole*
9. Benzophenone**(Friedal craft acylation)
10. Acetoacetanilide*
11. 1, 2, 4-triazole**
12. Benzimedazole from o-phenylenediamine*
13. 3H-quinazolin-4-one
14. Esterification (synthesis of nbutylacetatefrom n-butanoland acetic acid)
15. 4-methylcarbostyril from Acetoacetanilide.
16. Reduction reaction: PABA from p nitrobenzoic acid.

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

Fluorescein*

Ethyl benzoate*

Phenytoin**

Book Recommended

1. Text Book of Practical Organic Chemistry - A.I. Vogel
2. Practical Organic Chemistry - Mann and Sanders
3. Systematic Identification of Organic Composition, Shriner and Fuson
4. Indian Journal of Pharmaceutical Education and Research, 39 (4) Oct-Dec. 2005, 188-190
5. Organic Synthesis Special techniques V. K. Ahluwalia, Renu Aggrawal, Nerosa publishing house , p. no. 90 - 114
6. Sharma S. V., Badamis S. et al. Indian Drug 40(8) August 2003, 450 – 454

T - 4.7.3 PHARMACOLOGY – III

(Theory) (3Hrs/week)

Sr. No.	Topic	Hour
	Section- I	
01	**CVS: -** a) Diuretics. Types and pharmacology of diuretics and antidiuretics b) Antihypertensives. c) Antianginal. d) Cardiotonics. e) Antiarrhythmics f) Antihyperlipidemics. Drugs acting on blood and blood forming agents g) Coagulants and anticoagulants. h) Hemopoietics. i) Thrombolytics and antiplatelets	**15**
02	**Bioassays: -** a) Concept, merits and demerits, methods, types, bioassay of insulin, digitalis as per official books. b) Biostatics with reference to bioassay.	**05**
03	**Immunopharmacology: -** a) Pharmacology of immunosuppressants. b) Pharmacology of immunostimulants.	**02**
	Section II	
04	**Chemotherapy: -** a) Introduction and molecular basis of chemotherapy. b) Sulphonamides and cotrimoxazole. c) Penicillins and cephalosporins. d) Tetracyclines and chloramphenicol. e) Macrolides, aminoglycosides, polyenes and polypeptids. f) Quinolones and fluoroquinolones. g) Chemotherapy of T. B and leprosy. h) Antifungal antibiotics. i) Antiviral agents and anti HIV agents. j) Chemotherapy of protozoal infections (malaria). k) Chemotherapy of amoebiasis and giardiasis. l) Pharmacology of anthelmintics drug. m) Chemotherapy of cancer.	**23**

Total Hours: 45

P - 4.7.3 Pharmacology - III

(Practical) (3Hrs/week)

MINOR EXPERIMENTS

1. T-test for comparing difference in means between groups by student's t test.
2. To study effects of drugs on dog-blood pressure using EP-DOG software / www.animalsimulator.com
3. Case presentations for any one non-communicable and one communicable disease
4. Cost analysis of prescriptions and concept of Pharmacoeconomics
5. Semi-quantitative determination of C-reactive protein or Rheumatoid factor or any other protein by serial dilution and agglutination method
6. Calculation of sample size using any free online software package and concept of randomization (types with advantages and disadvantages)
7. Detection of sickle cell anemia using solubility test

MAJOR EXPERIMENTS

1. Determination of Na^+ and K^+ concentrations in urine samples using flame photometry or any other suitable technique
2. Determination of effect of anti-cholineasterases on DRC of acetylcholine using any suitable isolated tissue preparation like rat ileum, goat ileum, chick ileum
3. Determination effect of atropine on DRC of Acetylcholine using suitable isolated preparation like rat ileum, goat ileum, chick ileum
4. DNA electrophoresis / protein electrophoresis using pre-extracted / ready samples
5. Micronucleus assay using blood smear microscopy (in cyclophsophamide/ acrolein treated mice)
6. Irwin's Functional observational battery testing for neurobehavioural characterization of test drugs (caffeine/ diazepam/ pentylene tetrazole/ haloperidol)

Demonstration:

1. Determination of glucose absorption through inverted rat/ chick/ goat ileum segment and effect of acarbose on it.

Books Recommended

1. Ghosh M.N. Fundamentals of Experimental pharmacology. Hilton & Company Kolkata 2005 3rd edition
2. Vogel G.H. Drug discovery and evaluation. Springer Germany 2002 2nd edition
3. Goyal R.K. Practicals in pharmacology. B.S. Shah Prakashan Ahmedabad 2005 5th edition
4. Kulkarni S.K. Handbook of Experimental Pharmacology. Vallabh Prakashan. New Delhi, 5th edition
5. Perry W. L. M. Pharmacological Experiments on Isolated preparations.E.&S. LivingstoneLondon 1970,2nd edition
6. Kasture S.B.Text book of Experimental Pharmacology, Career Publication Nashik.1 st edition, 2006

T - 4.7.4 Pharmaceutical Analysis –III

(Theory) (3hrs/week)

Sr. No.	Topic	Hours
	Section-I	
1.	**Basic concepts related to Chromatography :** Introduction, history, Chromatographic selection of methods, classification.	**02**
2.	**Planer chromatography:** **i. Paper chromatography**: Theory, development techniques and applications. **ii. Thin-layer chromatography**: Theory, selection of adsorbent, preparation of plates, spotting, development of chromatogram, detection of compounds, recovery of Components, and applications. **iii. HPTLC:** Introduction, theory and applications	**04** **06** **04**
3.	**Electrophoresis**– Principle, Instrumentation, Various types of Developments	**03**
4.	**Radioimmunoassay and related immunoassay techniques**: ELISA techniques, theory, Instrumentation and applications.	**04**
	Section-II	
5.	**Basic Concepts in Spectroscopy :** Introduction – Electromagnetic radiation, Wavelength, wave number, frequency, absorbance, transmittance, photometers, Spectrophotometers, classification of Spectroscopy, atomic Spectra, molecular spectra.	**03**
6.	**UV – Visible absorption spectroscopy:** Introduction, origin and theory of UV spectra, bathochromic & hypsochromic shift, choice of solvents, Beers Lambert's law, Deviations of Beers law, Single component analysis, use of absorptive value , multiple Component analysis, simultaneous equation method. Difference spectroscopy, derivative spectroscopy, Chemical Derivatization (Colorimetric) Reactions – diazotization, Condensation, acid dye, oxidation. Determination of lambda Max. by Woodward-Fischer rule.	**10**
7.	**Fluorescence spectroscopy :** Introduction, fluorescence spectra, excitation & emission spectra, Instrumentation, Factors affecting fluorescence intensity, quantitative aspects, application of spectroflurimetry and photofluorimetry.	**03**
8.	**Atomic emission and atomic absorption spectrophotometry:** Principle, difference between atomic absorption spectroscopy and flame emission spectroscopy, advantages of AAS over flame emission spectroscopy, limitation, instrumentation of atomic emission and atomic absorption spectroscopy, single and double beam spectrophotometer , pharmaceutical applications of atomic emission and atomic absorption spectroscopy	**06**

Total Hours: 45

Books Recommended:

1. IP, USP, BP, European Pharmacopoeia, International pharmacopoeia
2. Pharmaceutical analysis-Higuchi and brochmann
3. The quantitative analysis of drugs- Garrat
4. Analytical chemistry- Meites H.B.
5. Analytical chemistry- Garry Chrisian
6. Principles of instrumental analysis- Skoog
7. Vogel textbook of quantitative chemical analysis
8. Instrumental methods of analysis- Willard, Dean
9. Instrumental methods of analysis-Ewing.
10. Instrumental methods of analysis- Chatwal and Aanand
11. Practical Pharmaceutical chemistry Vol. II Beckett &Stenlake

P - 4.7.4 Pharmaceutical Analysis –III

(Practical) (3hrs/week)

Sr. No.	Experiments
1.	Identification of Sample by Ascending Paper Chromatography (Minimum Exp. 02)*
2.	Identification of Sample by Radial Paper Chromatography(Minimum Exp. 02)*
3.	Identification of Sample by Thin layer Chromatography (Minimum Exp. 02)*
4.	Calibration of Visible spectrophotometer / Colorimeter and determination of lambda max of drug **
5.	Colorimetric analysis of Excipient/Finished products (At least Three expt.for each)**
6.	Determination of Quinine Sulfate / Riboflavin using Fluorimeter. **
7.	Determination of Na+ and K+ by flame photometry after preparation of calibration curve**
8.	H.P.T.L.C (DEMONSTRATION ONLY)

Minimum 12 experiments should be covered

*** Indicate Minor experiments ** Indicate Major experiments**

Books Recommended:

1. IP, USP, BP, European Pharmacopoeia, International pharmacopoeia
2. Vogel textbook of quantitative chemical analysis
3. Practical pharmaceutical chemistry, Vol II by Beckett and Stenlake
4. Practical Hand Book of Pharmaceutical Analysis- Dr. S.B. Bari, Dr. L. V. Sonawane Nirali Prakashan

T - 4.7.5 Pharmaceutical Biotechnology

(Theory) (3Hrs/week)

Sr. No.	Topic	Hrs.
	Section- I	
1	Biotechnology-Definition, scope and potential (01)	**01**
2	Fermentation technology and industrial microbiology	**02**
	Fermentation as a biochemical process	**03**
	Construction, working and types of fermenter, fermentation monitoring, Downstream processing.	**02**
	Industrial production of Penicillin, Dextran and Vit B12. Waste discharge & effluent treatment	**02**
3	Plant cell and tissue culture Cellular Totipotency, Laboratory and media requirements for establishing in vitro culture.	**02**
	Cell culture techniques –organ, callus, single cell, cell suspension and Protoplast Culture	**03**
	Somatic hybridization and Cybridisation-isolation and fusion of protoplast, selection of hybrids and cybrids and their applications	**03**
	Production of secondary metabolites using hairy root culture, immobilized cell culture and elicitor-induced accumulation. Introduction to germplasm conservation	**03** **02**
	Number of lectures	**23**
	Section- II	
4	Animal cell culture Introduction to animal cell culture, media, Culture techniques and Types of animal cell culture, Application of animal cell culture.	**05**
5	Genetic recombination of animal cells Steps in genetic recombination, Endonucleases, Vectors, Strain construction and Gene transfer methods.	**04**
6	Biotechnological production of-(1) human Insulin,(2) Human growth hormone and (3)Interferons. Impurities in bioproducts.	**05**
7	Principle and applications of polymerase chain reaction (PCR), gel electrophoresis, peptide mapping, protein sequencing, HPLC and Immunoassays(RIA and ELIZA)	**05**
8	Principle and application of Blotting techniques Northern blotting, Southern blotting, Dot blotting, Colony and plaque hybridization.	**03**
	Number of lectures	**22**

Total Hours - 45

Books:

Books Recommended

1. U.Satyanarayana,Biotechnology, Books and Allied (P) Ltd Ist Edition, 2006,Kolkatta.
2. Bainse William, Biotechnology from A to Z, 2nd Edition, 2002, Oxford University Press.
3. Casida L. E., Industrial Microbiology, 2000, New Age International, Delhi.
4. P.H.Agarkar et al ,Biochemistry, Basic and Applied, Nirali Prakashan, IVth Edition,Pragati B**ooks** Pune.
5. De Kalyan Kumar, Plant Tissues Culture, 1st Edition, 1997, New Central Book Agency (P) Ltd.
6. Disouza J. I., Killedar S. G., Biotechnology and Fermentation Process, Nirali Prakashan
7. Freifelder David, Molecular Biology, 2nd Edition, 1998, Narosa Publishing House.
8. Gupta P. K., Elements of Biotechnology, 1st Edition, 2001, Rastogi Pub., Meerut.
9. Higgins, Best D.J. and Jones J., Biotechnology: Principles and Applications, Blackwell Scientific Publications, Boston, MA 1985.
10. Hugo W. B., Russell A. D., Pharmaceutical Microbiology, 6th Edition, 1998
11. Razdan M.K., An introduction to plant tissue culture, Oxford & IBH Pub., Co. Pvt. Ltd, New Delhi
12. Badlsametal: cosmetics science & technology Vol. I, II, III, ED: Willey Intervcine.
13. W. A. Poucher: Perfumes, cosmetics, & soaps Vol. I. II. III. Ed: Champman & Hall.
14. Indian standard Institution booklets.
15. Booklet: Pharmaceutical analysis.
16. A. H. Backett & J. B. Stanlake: Practical pharmaceutics Chemistry
17. www.chemist corner.com
18. www.specialchem.com

T - 4.7.6. Pharmaceutical Industrial Management

(Theory) (3 hrs/week)

Sr. No.	Topics	Hrs.
	Section- I	
1.	**Introduction to Management** Types of management, Basic concepts of management, Management process , function and principles, Levels of management, Pharmaceutical Management –Art , science or profession Social responsibilities of management, Functions of management	**05**
2.	**Planning , and Forecasting** Planning - Nature, process and types of planning, Steps in planning process, Planning premises, Advantages and limitations of planning. Management by Objective Meaning ,objective ,features , advantages and limitations Forecasting - Meaning , nature importance limitations Techniques of forecasting	**06**
3.	**Organization** Definition , nature , Theories , functions, Line and staff organization concepts	**04**
4.	**Communication** Nature, Types of communication Process, channels and barriers of communication, Importance in pharmaceutical industries, Limitations of communications.	**03**
5.	**Leadership and Motivation** Leadership: Meaning, nature , leadership styles , theories of leadership, Motivation Meaning, nature , importance , theories of motivation	**04**
	Section- II	
6.	**GATT** (General Agreement on Tariff and Trade) and its impact on pharmaceutical industry: History of GATT, Its impact on pharmaceutical industry, Pharmaceutical market in India.	**03**
7.	**World Trade Organization (WTO) and Trade Related Intellectual Property Rights (TRIPS)** Introduction to WTO, Types of intellectual property rights: Industrial property and copy rights. Indian Patent Acts, 1970 with amendment -2002 Definition, types of patents, Patentable invention, Patent Application process., Complete and provisional specifications,	**07**
8.	**Quality Assurance-** GMP, CGMP, GLP, TQM, Quality review and quality documentation Validation: Validation of process, equipments and validation of analytical procedure.	**05**
9.	**Statistics & statistical quality control:-** Statistics in Q.C., definition of terms, normal. Statistics in Q.C., definition of terms, normal distribution, *t*-test, *f*-test, linear regression, correlation coefficient. Methods of statistical analysis as applied to sampling & interpretation of results, regression lines, sampling procedures .	**03**

10.	**Standard Institutions and Regulatory Authorities** Bureau of Indian standards (BIS) International Organization for Standardization (ISO). United States of Food and Drug Administration (USFDA) Central Drug Standard Control Organization (CDSCO) International Conference on Harmonization (ICH); World Health Organization (WHO) Ministry of Health, Labour and Welfare(MHLW)	**05**

Total Hrs: - 45

Books:-

1. Management a Global Perspective by Heinz Weihrich and Harold Koontz; 10th edition; Mc Graw Hills, New Jersey 1994.
2. Management Theory and Practice by C.B. Gupta ; 9th edition ; Sultan Chand and Sons Educational publishers , New Delhi 2006.
3. What everyone should know about patents? by N. Subbaram ; 2nd edition Pharma Book syndicate , Hyderabad 2003
4. Human Resource management A contemporary Perspective by Ian Beardwell , lenHolden ,1st edition Mac Millan Indian Ltd New Delhi 2001.
5. Forensic Pharmacy by B.S. Kuchekar et.al; Nirali Prakashan, Pune 4th edition 2004.
6. Pharmaceutical Quality Assurance by M.A.Potdar; Nirali Prakashan, Pune 2nd edition 2007.

Semester VIII

T - 4.8.1 Pharmaceutics –IX

(Theory) (3Hrs/week)

Sr. No.	Topics	Hrs.
	Section- I	
1.	**Introduction to Targeted drug delivery systems:** Introduction, Advantages, disadvantages, classification, pharmaceutical applications, Stability, and storage of following systems such as - **Nanoparticles**: concept of polymeric nanoparticles, solid lipid nanoparticles {SLNs}, Nanostructured lipid carriers {NLCs}, and Lipid drug conjugate nanoparticles {LDC}. **Liposomes, Niosomes, Resealed erythrocytes. Dendrimers, Parenteral implants, and osmotic pumps.** (No details to be taught)	**12**
2.	**Ocular drug delivery system:** Definition, Introduction. Anatomy and Physiology of the eye. Conventional ocular drug delivery. Composition of tears. Mechanism of ocular drug absorption {Corneal & Non corneal}.Role of polymers in ocular drug delivery system. Mucoadhesives, Ocular Inserts – objective, non erodible {ocuserts and contact lens} and erodible inserts {lacriserts, SODI, minidisc}. Evaluation of inserts.	**05**
3.	**Transdermal drug delivery system:** Definition, Introduction, advantages and disadvantages, anatomy and physiology of skin, Percutaneous absorption, basic components, drug selection criteria for transdermal drug delivery system, approaches, evaluation of adhesives and *in vitro, ex vivo* and *in vivo* evaluation of transdermal patches.	**06**
	Section- II	
4.	**Gastroretentive drug delivery system:** Anatomy and Physiology of GIT, Advantages and disadvantages Model drug selection criteria. Formulation approaches for GRDDS {effervescent and non effervescent systems}, *in vitro* and *in vivo* evaluation techniques.	**04**
5.	**Colon-specific drug delivery system:** Introduction. Anatomy and Physiology of colon. Model drug selection criteria for colonic drug delivery system. Formulation approaches of colon specific drug delivery. Evaluation of colonic drug delivery system.	**04**
6.	**Mucosal drug delivery system:** Anatomy and Physiology of oral human mucosa, Trans and Para cellular permeation, Permeability enhancers. Brief discussion on buccal and sublingual drug delivery systems, *in vitro* and *in vivo* evaluation techniques.	**04**
7.	**Pulmonary drug delivery system: -** Structure and function of pulmonary system, Dosage forms: Nebulizers, pressurized inhalation aerosols, aerosol powder.	**03**
8.	**Nasal:** Anatomy and physiology of nasal mucosa, penetration Enhancers, formulation development, *in vitro, ex vivo* and *in vivo* methods of evaluation.	**04**
9.	**Intrauterine and Intravaginal drug delivery system**: Physiology, Development of intrauterine devices (IUDs), copper IUDs. Vaginal rings.	**03**

Total Hours: 45

P - 4.8.1 Pharmaceutics –IX

(Practical) (3Hrs/week)

Note: Conduct any 15 experiments from following list. A) Products may be assayed to evaluate accuracy in regular practical. Formulation and evaluation should consider as separate experiment. Many times evaluation is not completed in 3 hrs, conduct evaluation in slots of 3 hrs and designate each experiment as separate experiment. All evaluation aspects are not to be given to the students in University examinations by considering time.

B) Formulation of different dosage forms should give stress on raw material specifications, preformulation, process controls, and documentation.

C}Concerned faculty members are requested to take the help of various recently published research papers from national & international well reputed journals in designing and evaluating following listed experiments.

1. Introduction to Novel drug delivery system.
2. Formulation of nanoparticles by suitable technique.
3. Evaluation of prepared nanoparticles.
4. Formulation of ocular inserts.
5. Evaluation of prepared ocular inserts.
6. Formulation of transdermal patch.
7. Evaluation of prepared transdermal patch.
8. Formulation of floating tablets.
9. Evaluation of prepared floating tablets.
10. Dissolution study of marketed sustained release tablets.
11. Dissolution study of marketed enteric coated tablets.
12. Formulation of gels.
13. Diffusion study of gels.
14. Rheological study of gels. {Viscosity determination}
15. Effect of concentration of effervescent agents on floating lag time.
16. Effect of polymer concentration on drug release in floating tablets.
17. Effect of polymer concentration on swelling in floating tablets.
18. Formulation of gel by ion induced gelation technique.
19. Evaluation of gel prepared by ion induced gelation technique.
20. Formulation of gel by temperature induced gelation technique.
21. Evaluation of gel prepared by temperature induced gelation technique.
22. Formulation of gel by pH induced gelation technique.
23. Evaluation of gel prepared by pH induced gelation technique.

Book Recommended for Theory & Practical's:-

1. Dr. D. T. Baviskar. Novel drug delivery system. First edition. Nirali Prakashan.
2. Alfanso R. Gennaro-- Remington's Pharmaceutical Sciences. 21st Edition, Vol. I & II.
3. Yie W. Chien. Novel drug delivery systems. Second edition. Marcel Dekker Vol. 50.
4. Vicent H.L. Controlled drug delivery system. Second edition. Marcel Dekker. Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol- 29.
5. E.A. Rawlin. Bentley's textbooks of Pharmaceutics. Eighth edition. Elsevier publication.
6. Michael E. Aulton. Aulton's Pharmaceutics. The design and manufacture of medicines. Third edition. Elsevier publication.
7. N.K. Jain. Controlled and novel drug delivery. First edition. CBS publishers.
8. N.K. Jain. Advances in Controlled and novel drug delivery. First edition. CBS publishers.
9. Vyas S P & Khar R K: Targeted & controlled drug delivery. Novel carrier systems. First edition. CBS publishers.
10. Robinson, J.R. & Lee, V.H.I.: Controlled and Novel Drug Delivery Marcel Dekker, New York.
11. Morton Rosoff; Controlled release of drugs; VCH Publishers.
12. Osborne, and Amann; Topical drug delivery formulations; Marcel Dekker.
13. Barry: Dermatological formulation; Marcel Dekker
14. Robinson; Novel Drug Delivery systems; Marcel Dekker
15. P. Johnson and J. G. Lloyd – Jones; Drug delivery systems; VCH Publisher
16. P. Tyle and B. P. Ram; Targeted therapeutics systems; Marcel Dekker.
17. C.G. Wilson & N. Washington; Physiological Pharmaceutics; Ellis Horwood Limited.
18. H.S. Bean, A.H. Beckett, and J.E. Carless; Advances in Pharmaceutical Sciences; Vol. 5, Academic Press.
19. R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivry; Marcel Dekker
20. T.J. Roseman and S.Z. Mansdorf; Contolled release delivery systems; Marcel Dekker
21. A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology; Marcel Dekker.
22. J. Kreuter; Controlled drug delivery system; Marcel Dekker
23. Pharmaceutical Dissolution Testing, U.V.Bankar, Mercel Decker Inc.
24. Kydonieus Agis. Treatise on Controlled drug delivery. Fundamentals. Optimization. Applications. Marcel Dekker.

T - 4.8.2 Pharmaceutical Analysis –IV

(Theory) (3hrs/week)

Sr. No.	Topic	Hours
	Section-I	
1.	**Column Chromatography:** Principle, Column packing, techniques, application, theory, Efficiency of column, Capacity factor and other Performance parameters	**02**
2.	**Gas chromatography :** Introduction, carrier gases , columns, injection system, detectors, thermal conductivity detectors (TCD), electron capture detector(ECD),thermo-ionic detector(TID), flame ionization detector(FID), nitrogen phosphorus Detector (NPD), photo-ionization detector(PID), head space analysis, applications, programmed temperature gas chromatography(PTGC)	**06**
3.	**HPLC:** Instrumentation, pumps (reciprocating pumps, displacement & pneumatic pumps), mobile phase reservoirs, solvent treatment systems, isocratic elution, gradient elution, injection system. Detectors, photometric detectors (single wavelength, multi wavelength, variable wavelength, diode array, fluorescence detectors), refractive index detectors, electrochemical detectors. Columns: analytical columns, guard columns, column thermostats, types of column packaging, Introduction of UPLC (Ultra Pressure Liquid Chromatography)	**06**
4.	**Ion exchange and Ion Pair chromatography:** Principle, Ion exchange resins, applications.	**03**
5.	**Gel permeation chromatography: -** Introduction, apparatus & techniques.	**03**
6.	**Flash Chromatography**	**01**
7.	**Hyphenated Techniques GCMS, LCMS (Interfaces and Applications only).**	**02**
	Section-II	
8.	**Infrared spectroscopy:** Introduction, range of IR radiation, Requirements of IR radiation, correct wavelength of radiation, electric dipole, theory of IR absorption spectroscopy, modes of vibration of atoms in polyatomic molecules-stretching vibration, bending vibration, types of stretching and bending vibration, interpretation of IR spectra, quantitative analysis, routine maintenance – dispersive and FT-IR instruments, instrumentations-single beam, double beam spectrophotometer, applications to pharmaceuticals, limitations of IR spectrophotometry.	**06**
9.	**NMR spectroscopy: -** Introduction to NMR, basic principles involved, instrumentation, chemical shift, Factors affecting Chemical shift spin-spin coupling, applications, quantitative analysis.	**06**
10.	**Mass spectroscopy: -** Principles & theory, instrumentation, application of mass spectroscopy, Mass spectroscopy-mass spectroscopy (MS-MS).	**05**

11.	**X- ray diffraction** Laue photographic method, Bragg's X-ray spectrophotometry, Rotating crystal methods, Powder method.	**02**
12.	**Structural elucidation problems based on IR, NMR, Mass spectroscopy (simple problems with molecular formula given)**	**03**

Total Hours: 45

Books Recommended:

1. IP, USP, BP, European Pharmacopoeia, International pharmacopoeia

2. Pharmaceutical analysis-Higuchi and brochmann

3. The quantitative analysis of drugs- Garrat

4. Analytical chemistry- Meites H.B.

5. Analytical chemistry- Garry Chrisian

6. Principles of instrumental analysis- Skoog

7. Vogel textbook of quantitative chemical analysis

8. Instrumental methods of analysis- Willard, Dean

9. Instrumental methods of analysis-Ewing.

10. Instrumental methods of analysis- Chatwal and Aanand

11. Practical Pharmaceutical chemistry Vol. II Beckett &Stenlake

P - 4.8.2 Pharmaceutical Analysis –IV

(Practical) 3hrs/week

Sr. No.	Experiments
1.	Calibration of UV- spectrophotometer and determination of lambda max of drug *
2.	UV-Spectrophotometric analysis of Raw materials / Finished products (At least Three expt. each)**
3.	To determine the effect of pH upon the Absorption Spectrum of Sulphanilamide.*
4.	To determine the effect of Solvent upon the Absorption Spectrum of Phenol.*
5.	To show the typical Pyridine absorption in Nicotinamide comparing with benzoic acid*
6.	Separation and identification of sample by Column Chromatography **(At least Two expt.)
7.	Assay of caffeine and sodium benzoate injection by simultaneous equation method And absorbance ratios method.
8.	To determine the structure of compounds by F.T.I.R (At least Two compounds)
9.	H.P.L.C (DEMONSTRATION ONLY)
10.	G.C. (DEMONSTRATION ONLY)

Minimum 12 experiments should be covered

*** Indicate Minor experiments ** Indicate Major experiments**

Books Recommended:

1. IP, USP, BP, European Pharmacopoeia, International pharmacopoeia
2. Vogel textbook of quantitative chemical analysis
3. Instrumental methods of analysis-Ewing
4. Instrumental methods of analysis- Chatwal and Aanand
5. Practical pharmaceutical chemistry, Vol II by Beckett and Stenlake

T - 4.8.3 Pharmaceutical Chemistry –IX (Medicinal Chemistry- IV)

(Theory) (3Hrs/week)

Sr. No.	Topic	Hour
	Section- I	
1	**Quantitative approaches to structure–activity Relationships** Introduction, Descriptors: Biological and physicochemical descriptors; Topliss tree and Craig plot, Determining relationships between chemical and biological data (QSAR methods): The Hansch approach, Free-Wilson analysis and related methods, Partial least squares (PLS),Linear discriminant analysis (LDA) Principal component analysis (PCA), Cluster analysis. Introduction to 3D-QSAR, Introduction to CADD: energy minimization, Quantum Mechanics, Molecular Mechanics.	**7**
2	**Designing Prodrugs And Bioprecursors** General Introduction, The Carrier-Prodrug Principle, The Bioprecursor-Prodrug Principle, Practical Applications of Prodrug Design, Carrier Prodrugs: Improvement of the bioavailability and the biomembrane passage, Site-specific delivery, Prolonged duration ofaction, Use of Cascade Prodrugs and Soft Drugs Bioprecursor Prodrugs: Oxidative Bioactivations, Reductive Bioactivations, Mixed Bioactivation Mechanisms.	**4**
3	**Diureties** a) Site 1 Carbonic: anhydrate inhibitors acetazolamide*,methazolamide. b) Site 2 High ceiling or loop diuretics is sulfamoylanthranilicacids like furosemide*, azosemide and bumetanideinphenoxyacetic acids ethacrynic acid* c) Site 3 Thiazideand Thiazide like diuretics d) Site 4 Potassium sparing diuretics such as spironoloactone triamterene and amiloride	**4**
4	Steroids – Configuration 5 α and 5 β cholestane, conventional formula and conformational representation. Reactions in ring A & B of steroids – conformation and chemical reactivity, addition, elimination, epoxide opening, relative rates of esterification and oxidation of epimeric alcohols and reduction of ketones, rearrangement reactions, Medicinal chemistry of steroids: Sex hormones (androgens like testosterone and its esters: estrogens like estradiol, ethinyl estradiol and mestranol: progestines like medroxy progesterone acetate, megesterolacetate, norethindrone and norgestrel), anabolic steroids like danazol, stanozolol and androizoxazole: non steroidal estrogens like diethylstilbestrol and cholotrianisene, antiestrogens like tamoxifen and clomiphene, corticoids and steroidal anti iflammatory like cortisone, hydrocortisone, prednisolone, dexamethasone, betamethasone and triameinolone.	**08**

	Section- II	
5	**Antihistaminics, Antiemetics and antiulcer drugs** Antihistamines H1, H2 receptors. Emphasis to be on the secondgeneration H1 antagonists such as fexofenidine, astemazole, loratidinecetrizine and acrivastine, H2 receptor antagonist like cimetidine*, ranitidine, famotidine, nizatidine, proton pump inhibitors like omeprazole and lansoprazole.	**5**
6	Analgesics (opioids) (morphine, codeine, levophanol, dextromethorphan, phenazocine, pentazocine, meperidine*, α and β prodine, pheniridine, anileridine, fentanyl, methadone*, phenadoxone, racemoramide, dextropropoxyphene*, nalorphine, naloxone, naltrexone)	**6**
7	NSAID's (aspirin, paracetamol, phenylbutazone*, oxyphenbutazone, indomethacine, sulindac, mefenamic acid, ibuprofen, naproxen*, ketoprofen, nabumetone, diclofenac*, nimesulide, celecoxib, rofecoxib, piroxicam*, colchicines, sulfinpyrazone, allopurinol).	**6**
8	Hypoglycemics (Insulin not to be discussed) 1. Biguanides e.g. metformin b. Sulfonylurea's 1st Generation like tolbutamide *, cholorpropamide, tolazamide and acetohexamide: 2nd Generation like glyburide, glypizide, 3 rd Generation like glimepride and repaglimide. 2. Thiazolidinediones such as troglitazone, ciglitazone, rosiglitazone and pioglitazone 3. β – Glycosidase inhibitors like acarbose, voglibose and miglitol.	**5**

Total Hours: 45

Reference Books:

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

P - 4.8.3 Pharmaceutical Chemistry –IX (Medicinal Chemistry- IV)

(Practical) (3Hrs/Week)

Minimum Twelve numbers of Experiments should be performed.

***Minor **Major Experiments**

1. Determination of partition coefficient, dissociation constant, molar refractivity of compound from QSAR analysis (DEMONSTRATION)
2. Methyl Salicylate**
3. Paracetamol*
4. Phenacetin*
5. Aspirin*
6. Acetylglycine*
7. 4-benzylidene-2-methyloxazole-5-one**
8. Benzoglycine form Benzoyl chloride*
9. 4-benzlidene -2-phenyloxazole- 5-one**
10. Phthalaldehydic acid from Naphthalene**
11. *p*-Methylacetophenone*
12. 3,5-dinitrobenzoic acid from benzoic acid**
13. Benzanilide from Benzophenone**
14. m-nitrophenol from m-nitro aniline

Book Recommended

1. Text Book of Practical Organic Chemistry - A.I. Vogel
2. Practical Organic Chemistry - Mann and Sanders
3. Systematic Identification of Organic Composition, Shriner and Fuson
4. Indian Journal of Pharmaceutical Education and Research, 39 (4) Oct-Dec. 2005, 188-190
5. Organic Synthesis Special techniques V. K. Ahluwalia, Renu Aggrawal, Nerosa publishing house , p. no. 90 - 114
6. Sharma S. V., Badamis S. et al. Indian Drug 40(8) August 2003, 450 – 454

T- 4.8.4 Pharmacognosy – VI

(Theory) (3Hrs/Week)

Sr. No.	Topic	Hour
	Section- I	
01	World-wide trade in medicinal plants and their derived products with special reference to diosgenin (dioscorea), Taxol (Taxus sps) ,digitalis, tropane alkaloid containing plants, Papain, cinchona, Ipecac, Liquorice, Ginseng, Aloe, Valerian, Rauwolfia and plants containing laxatives. Role of medicinal and aromatic plants in national economy.	**08**
02	A brief account of plant based industries and institutions involved in work on Medicinal and aromatic plants in India. Utilization and production of phytoconstituents such as caffeine, quinine, calcium sennoside, podophyllotoxin, diosgenin, solasodine, and tropane alkaloids.	**10**
03	**Indian trade in aromatic plants-** Utilization of aromatic plants and derived products with special reference to Sandalwood oil, mentha oil, lemon grass oil, vetiver oil, geranium oil and Eucalyptus oil.	**05**
	Section-II	
04	**Herbal cosmetics-** Brief study of Phytocosmetics of industrial significance. Herbs used for different cosmetic preparations	**04**
05	**Quality control & standardization of herbal drugs** a. Quality control of herbal drugs as per AYUSH and Pharmacopoeial standards. b. WHO Guidelines for the assessment of Crude Drugs and extract including Pharmacognostical, Physical and chemical analysis. c. WHO Guidelines for the assessment of herbal formulation by chemical and spectral analysis. d. Study of different chromatographic methods and their applications in evaluation of Herbal drugs and formulation. e. Qualitative and Quantitative estimation of active principles from herbal Extracts by HPTLC and HPLC). f. Analysis of heavy metals & microbial contamination.	**15**
06	**Global Regulatory Status and Patenting of herbal Medicines.**	**03**

Total Hours: 45

Book recommended

1. Horborn J. B. Phytochemical methods, Chapman and Hall, International Edition, London.
2. Kokate C. K. Purohit A. P. and Gokhale S. B. , Pharmacognosy (degree) Nirali Prakashan
3. Kokate C. K. Practical Pharmacognosy, Vallabh Prakashan, Delhi.
4. Brain K. R. and Turner T. D., The practical Evaluation of phytopharmaceuticals, Wright-Scientechnica, Bristil.
5. Guenther, E, Me, Essential oils-4 D Van Nostrand CO Inc, New York.
6. Pulok Mukharji, Quality control of Herbal drugs.
7. Pharmacopoeia of India, 1985,1996, Govt. of India, Ministry of Health and Family Welfare.
8. Trease, G.E. and Evans, W.C. Pharmacognosy, 12th Edition, Bailliere Tindall, Eastbourne, U.K.
9. Tyler, V.E., Brady, R., Pharmacognosy
10. Wagner, S.B., Zgainsky, Plant drug Analysis.
11. V.D.Rangari, Pharmacognosy and Phytochemistry Volume I & II.

P - 4.8.4 Pharmacognosy – VI

(Practical) (3Hrs/Week)

*** Minor experiments**

**** Major experiments**

1. Isolation of some selected phytoconstituents studied in theory**.
2. Analysis of volatile oils *(estimation of Phenols OR and aldehyde, OR and ketone etc.) and their chromatographic profiles**.
3. Preparation of herbal skin and hair care cosmetics**
4. Standardization of herbal crude drugs & extract by physical *& chemical parameters** (Estimation of total tannins, OR and total phenolics, OR and flavonoid, OR and carbohydrates OR and alkaloids OR and sterols OR and triterpenoid, content etc.)
5. Preparation & Standardization of different Herbal formulation** (Ex. Tablet or syrup).

Book recommended

1. Horborn J. B. Phytochemical methods, Chapman and Hall, International Edition, London.
2. Kokate C. K. Purohit A. P. and Gokhale S. B. , Pharmacognosy (degree) Nirali Prakashan
3. Kokate C. K. Practical Pharmacognosy, Vallabh Prakashan, Delhi.
4. Brain K. R. and Turner T. D., The practical Evaluation of phytopharmaceuticals, Wright-Scientechnica, Bristil.
5. Guenther, E, Me, Essential oils-4 D Van Nostrand CO Inc, New York.
6. Pulok Mukharji, Quality control of Herbal drugs.
7. Pharmacopoeia of India, 1985,1996, Govt. of India, Ministry of Health and Family Welfare.
8. Trease, G.E. and Evans, W.C. Pharmacognosy, 12th Edition, Bailliere Tindall, Eastbourne, U.K.
9. Tyler, V.E., Brady, R., Pharmacognosy
10. Wagner, S.B., Zgainsky, Plant drug Analysis.
11. V.D.Rangari, Pharmacognosy and Phytochemistry Volume I & II.
12. British Herbal Pharmacopoeia
13. Herbal Pharmacopoeia, IDMA, Mumbai
14. A.N. Kalia, A textbook of Industrial Pharmacognosy, CBS Publishers and Distributors
15. Herbal drugs industry by R.D. Chaudari.
16. Natural Products, A Laboratory Guide – Raphael Ikan – Academic Press
17. Quality Control Methods for Medicinal Plants – WHO, AITBS Publication.
18. Raphael Ikon, Natural products a laboratory Guide, Academic Press
19. Clarke ECG, Isolation and Identification of Drugs, The Pharmaceutical Press, London
20. Export potential of selected medicinal plants, prepared by basic chemicals pharmaceuticals and cosmetic export promotion council, Bombay, and other reports.
21. Martindale, the extra pharmacopoeia, pharmaceutical society of great Britain London.
22. Kokate C. K. Practical Pharmacognosy, Vallabh Prakashan, Delhi.
23. Official Methods of Analysis, Association of Official Analytical Chemists publication, Washington.
24. Pharmacopoeia of India, 1985, 1996, Govt. Of India, Ministry Of Health and Family Welfare.
25. Peach K, and Tracey M. V., Modern methods of plant analysis, 1-4, Narosa Publishing house, New Delhi

T - 4.8.5 Pharmacology – IV (Clinical Pharmacy and Drug Interactions)

(Theory) (3Hrs/Week)

Sr. No.	Topic	Hour
	Section- I	
01	**Drug development process: -** a) Introduction b) Various approaches to drug discovery. c) Preclinical evaluation (acute, sub acute, chronic toxicity, ADME, Therapeutic index). d) Clinical evaluation. **e)** IND application	**05**
02	**Drug interactions: -** a) Introduction, types, classification, basic concept of mechanism. b) Drug interactions and role of pharmacist in minimizing drug interactions.	**04**
03	**Drug induced diseases: -** a) Introduction b) Drug induced diseases by systems and various categories of drug lead to diseases and disorder- dermatological, hepatic, gastrointestinal, haematological, ototoxicity, ocular, pulmonary, renal, and teratogenecity effect.	**04**
04	**Therapeutic drug monitoring:** a) Introduction, definition, indications, protocol, pharmacokinetic/ pharmacodynamic correlation in drug therapy. b) TDM of drugs used in following disorders- CVS, seizure, psychiatric, organ transplantation. c) Role of clinical pharmacist in TDM	**04**
05	**Adverse drug reaction monitoring: -** a) Introduction, definition, types of ADR, predisposing factors lead to ADR, detection, management, reporting and role of clinical pharmacist in preventing ADR. b) Pharmacovigilance: Introduction, definition, reporting of ADR to pharmacovigilance centres.	**05**
	Section II	
06	**Medication errors: -** a) Introduction, definition, types, documentation and publication, causes, identification, reduction/prevention, role of clinical pharmacist in reducing medication errors.	**05**
07	**Drug utilisation evaluation:** a) Introduction, definition, types, objectives, establishment, phases and steps involved in conducting DUE study, Importance, example of any one category of drug for improvement in its safer use, role of clinical pharmacist in DUE.	**05**

08	**Essential and rational drug used:** a. Introduction, definition, Essential drug concept. b. irrational use of drug, reasons and hazards, rational drug use and prescribing, obstacles and steps for improvement, guidelines for rational prescribing for antibiotics, injections and OTC drugs, the pharmacist role in rational drug use.	**05**
09	**Pharmacoeconomics:** Introduction, definition, history, misconceptions, scope and need, types, advantages and disadvantages, guidelines for conduction or evaluation.	**04**
10	**Pharmacoepidemiology:** Introduction, definition, history, different models, scope and need, types, advantages and disadvantages, guidelines for conduction or evaluation.	**04**

Total Hrs: - 45

Books Recommended:

1. Bennett P.N, Brown M.J. Clinical Pharmacology Churchill living stone New Delhi 2003 9th edition
2. Melmon & Morrelli's Clinical Pharmacology. Mc-Graw Hill. New Delhi 2000 4th edition
3. Craig C.R, Stitzel R.E. Modern Pharmacology with Clinical application, Lippincott Williams & Wilkins, New York 2004 6th edition
4. Raymond J.M. Niesink, John de vries. Hollinger M.A. Toxicology- Principle and applications, CRC, Florida
5. Klaassen C.D, Casarett & Doull's. Toxicology. The basic science of poison Mc-Graw Hill, New Delhi 6th ed
6. Remington's Pharmaceutical Science and practice pharmacy .Lippincott Williams and Wilkins, New Delhi
7. 2004, 20th edition
8. Katzung B.G. Basic & Clinical Pharmacology. Mc-Graw Hill, New Delhi 2001 8th edition
9. Clinical pharmacy practice - C. W. Blissit
10. Therapeutic drug monitoring - B. Widdop
11. TDM & Clinical biochemistry – Mike Hallworth
12. Textbook of therapeutics, Drug & disease management - 7th edition - Eric T. Herfindel, Dick. R. Gourley
13. Recent developments in TDM & Clinical toxicology – I. Sunshine - Marcel – Dekker 1992
14. Handbook of TDM. – Simkin
15. Parrthsarthi G, Hansen Kavin Nytort & Nahata Milap C. A Textbook of Clinical Practice: Essential Concepts & skills, Orient Longman.
16. Roger walker, Clive Edwards, Clinical Pharmacy & therapeutics, 3rd International Edition, Churchill Livingstone.
17. Dr. Tipnis H. P, Dr. Bajaj Amrita, Clinical Pharmacy, Career Publication

T - 4.8.6.1 Pharma Marketing (Elective)

(Theory) (3 hrs/week)

Sr. No.	Topics	Hrs.
	Section- I	
1.	**Marketing:** Meaning, concepts, importance and emerging trends; Marketing environment; Industry and competitive analysis, Indian Pharmaceutical Industry; Analysing consumer buying behaviour; industrial buying behaviour, Pharmaceutical market segmentation & targeting.	**09**
2.	**Product Decision-** Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.	**09**
3.	**Pricing-** Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).	**09**
4.	**Pharmaceutical marketing channels:** Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.	**07**
5.	**Promotion-** meaning and methods, determinants of promotional mix, promotional budget; an overview - personal selling, advertising, sales promotion and public relations.	**06**
6.	**Strategic marketing planning; Marketing implementation and evaluation.**	**05**

Total Hrs: - 45

Books :

1) Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi

2) Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.

3) Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill

4) Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India

5) Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)

6) Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, Indian Context,Macmilan India, New Delhi.

7) Shanker, Ravi: Service Marketing, Excell Books, New Delhi

8) Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

T - 4.8.6.2 Medicinal Plant Biotechnology (Elective)

(Theory) (3hrs/week)

Sr. No.	Topics	Hours
	Section - I	
1.	Emerging Trends in Medicinal Plant Biotechnology	**02**
2.	Plant Biotechnology- Introduction and Applications	**04**
3.	Plant Tissue culture-Principle and methodology, Culture techniques, Concept of Totipotency, Protoplast culture, protoplast fusion, somatic cell hybridisation, organogenesis, embryogenesis, somoclonal variation	**08**
4.	Plant cell immobilisation and Micropropagation in plants- Principle, methodology and applications.	**05**
5.	Biomedicines from plant tissue culture	**03**
Section-II		
6	Genetic engineering of plants-Gene transfer in Plants, Introduction, transgenic plants, methods used in gene identification. Gene transfer using DNA mediated gene transfer electroporation, micro projectile, macro & micro injection, liposomes, Ultra-sonication & chemical mediated gene transfer, Localization of transfer gene in genetically modified plants, Use of radio isotopes & molecular markers etc Applications of transgenic plants. Germ plasm storage, Gene storage bank.	**08**
7.	Methods of improving quality of plants and their applications- plant breeding, chemodemes, hybridisation, mutation, polyploidy.	**06**
8.	Germ Plasm conservation- **a**. In-situ conservation **b**. Invitro methods of conservation. Cytopreservation and cryopreservation in plant bitechnology-preparation and materials.	**05**
9.	Biotransformation in Medicinal plants-Prospects and challenges.	**04**

Total Hours 45

Books recommended:

1. Vyas S. P. and Dixit V. K., Pharmaceutical Biotechnology, CBS publishers and distributors, New Delhi, First edition (Reprint), 2008.
2. Kumar H. D. A textbook on Biotechnology, Rajkamal electric press, 2nd edition Reprint, 2003.
3. Purihit S.S., Biotechnology fundamentals and applications, Student edition, Jodhour, 2007.
4. Giriraj Kulkarni J, Biotechnology and its application in pharmacy, Jaypee Brothers, New Delhi, first edition, 2007.
5. Ashutosh Kar, Pharmacognosy and pharmacobiotechnology, New age international publishers, 2nd edition, New Delhi.
6. Disouza J. I., Killedar S. G., Biotechnology and Fermentation Process, Nirali Prakashan
7. Gupta P. K., Elements of Biotechnology, 1st Edition, 2001, Rastogi Pub., Meerut.
8. Higgins, Best D.J. and Jones J., Biotechnology: Principles and Applications, Blackwell Scientific Publications, Boston, MA 1985.
9. Kori S. S., Halkai M. A. Pharmaceutical Biotechnology-Fundamentals and applications, First edition Reprint, Vallabh Prakashan, 2003.

T - 4.8.6.3 Quality Assurance (Elective)

(Theory) (3 hrs/week)

Sr. No.	TOPICS	Hrs.
	Section- I	
1.	Introduction to Concepts of quality, quality assurance, GMP & cGMP, QC, IPQC and QA as applied to the pharmaceutical industry.	**04**
2.	**Documentation-** Pharmaceutical Manufacturing documentation (MFR, BMR, Quality control documentation) Quality assurance documentation (SOP, Protocols, reports etc). Storage, retention and retrieval of documents.	**05**
3.	**Good Laboratory Practices (GLP)** :- Regulations, biological evaluation of microbiological limit tests, sterility tests for effectiveness of antimicrobial preservatives, LD50, ED50, teratogenicity, mutagenecity, clinical trials, bioassays, pyrogens and pyrogen testing.	**05**
4.	**Process Validation-** Introduction, Concept of validation, objectives and functions of validation. **Process Validation and its types.** Prospective, concurrent, Retrospective and revalidation. **Sterilization process validation**	**04**
5.	**Equipment Validation**: - Installation qualifications and operational qualification, performance qualification of different equipments like autoclave, oven, and dissolution test apparatus.	**05**
	Section- II	
6.	**Analytical method validation-** Accuracy, precision, linearity, range, LOD, LOQ, Ruggedness, Robustness, Specificity determination for analytical techniques for assay, impurity detection and bioanalysis.	**05**
7	**Cleaning validation-** Introduction, cleansing agents, methods of cleaning, CFR requirements for cleaning validation, factors in cleaning validation, sampling techniques.	**03**
8.	Pilot plant scale up techniques and Technology transfer	**03**
9.	**Regulatory authorities**: TGA, MHRA, USFDA, WHO, ICH	**05**
10.	**Quality by Design -** Design of Experiments, Design space, factorial design, response surface methodology	**06**

Total Hours:-45

Books :

1. Pharmaceutical Quality Assurance, M.A. Potdar, Nirali Prakashan, Pune.
2. Current Good Manufacturing Practices, M.A. Potdar, Pharma-Med Press, Hyderabad.
3. GMP for Pharmaceuticals, 5th Edition, Sidney H. Willing, Marcel Decker Series
4. Regulatory guidelines related to GMP by
    a. Australian code of GMP for medicinal products,16th Aug. 2002.
    b. 21 Code of Federal Regulation, parts 210, 211 & 58. (USFDA guidelines)
    c. MHRA, UK Guidelines on GMP
    d. GMP Guidelines by Medicines Control Council of South Africa Schedule M of D & C Act
5. Assurance of Quality, Pharmaceutical Total Quality Approach, M. S. P. Khan, Chitgaon, Bangladesh, Signet Press-1990
6. Packaging of Pharmaceuticals & Healthcare Products, Lockhard,
7. Pharmaceutical Packaging, F.A.Paine,
8. Quality Control of Packaging Materials in the Pharmaceutical Industry, Kenneth & Harburn, Mercel Decker Inc.
9. Validation of active Pharmaceutical Ingredients by, I.R. Berry and Danie Harpar.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Guidelines on cGMP and Quality of Pharmaceuticals product by S. Iyer
12. Quality Control of Packaging materials in the Pharmaceutical Industry by Kenneth and Hanbinn, M. Dekker. Inc.

T - 4.8.6.4 Drug Design and Lead Identification (Elective)

(Theory) (3Hrs/Week)

Sr. No.	Topic	Hrs.
1	**Introduction to The Drug Discovery/Development** A. Drug Discovery B. Drug Development C. Source of Drugs D. Structural effects on drug action	06
2	**Approaches to New Drug Discovery** A. Drugs Derived from Natural Products B. Existing Drugs as a Source for New Drug Discovery C. Using Disease Models as Screens for New Drug Leads D. Physiological Mechanisms: the Modern "Rational Approach" to Drug Design E: Approaches to Lead Optimization 1. Bioisosteric replacement 2. Conformation restriction : a) Increase selectivity b) Increase affinity 3. Pharmacophore 4. Molecular dissection 5. Metabolic stabilization	06
3	**Enzymes as Targets of Drug Design** A. Enzyme kinetics (Kimball) B. Enzyme inhibition and activation (Kimball) C. Approaches to the Rational Design of Enzyme Inhibitors	04
4	**Receptors as Targets of Drug Design** A. Receptor Theory B. Receptor Complexes and Allosteric Modulators C. Second and Third Messenger Systems D. Molecular Biology of Receptors F. Receptor Models and Nomenclature G. Receptor Binding Assays H. Lead Compound Discovery of Receptor agonists and antagonists	06
	Section II	
5	**Prodrug Design and Applications (Hu)** A. Definition B. Applications C. Prodrug Design Considerations D. Prodrug Forms of Various Functional Groups 1. Ester prodrugs of compounds containing –COOH or –OH 2. Prodrugs of compounds containing amides, imides, and other acidic NH	07

	3. Prodrugs of Amines 4. Prodrugs for compounds containing carbonyl groups E. Drug release and activation mechanisms 1. Simple one-step activation 2. Cascade release/activation systems F. Prodrugs and intellectual property rights – two court cases	
6	**Computer-Aided Drug Design** A. Docking and virtual screening B. Molecular Dynamics and binding free energy methods	**06**
7	**Combinatorial Chemistry and Microwave Chemistry** A. Introduction: Concepts and Terms B. Solid-phase Strategies C. Solution Phase Strategies D. Microwave Chemistry	**06**
8	**Introduction of Peptides in Drug discovery.** Reactivity of proteins and peptides	**04**

Total 45 Hrs

Reference Textbooks:

1) Kerns, E.H.; Di, L. Drug-Like Properties: Concepts, Structure Design and Methods: from ADME toToxicity Optimization, Academic Press, Oxford, **2008**

2) Burger's Medicinal Chemistry and Drug Discovery, 5th Edition, Vol. 1. Principles and Practice, edited by M. E. Wolff, John Wiley & Sons: New York, **1995.**

3) Principles of Medicinal Chemistry, 4th Edition, edited by W.O. Foye, T.L. Lemke, and D. A.

4) Williams, Williams and Wilkins: Philadelphia, **1995**.

5) Medicinal Chemistry: Principles and Practice, edited by F.D. King, Royal Society of Chemistry: Cambridge, **1994**.

6) A Practical Guide to Combinatorial Chemistry, edited by A. W. Czarnik and S. H. DeWitt, American Chemical Society: Washington DC, **1997**.

T - 4.8.6.5 Bioavailability and TDM (Elective)

(Theory) (3hrs/week)

Sr. No.	Topic	Hrs.
1	**Introduction:** Definition of Bioavailability, bioequivalence, generic drugs, types of BA, methods to determine BA, Hatch max-man act 1971.	04
2	**Application of Biopharmaceutics in BA/BE:** Biopharmaceutical aspects of absorption, distribution, metabolism and elimination, factors influencing bioavailability of dosage forms, methods to determine BA/BE. Bioavailability of highly variable drugs, narrow therapeutic index drugs and poorly soluble drugs. Methods for enhancement of BA.	10
3	**Protocol in BA/BE studies**: Designing of protocol, rationale of the research, selection of subjects. Construction, role and responsibilities of IRB/IEC	03
4	**Conduct of Study:** Design of the study, inclusion and exclusion criteria, sampling point, sampling volume, treatment groups. Documentation in BA/BE -Formation of investigator's information brochure, Case Record Form (CRF), presentation of Results and conclusion.	06
5	**Introduction To Therapeutic Drug Monitoring:** Definition & introduction. Indication for TDM & clinical applications. Monitoring plasma drug levels. Role of Clinical pharmacist in TDM.	05
6	**Techniques Used In TDM** a) Physical methods HPLC, HPTLC, GC b) Immuno assays. RIA, ELISA, EMITH, NIIA	04
7	**Variation of clinical laboratory tests due to drugs : -** Serum Creatinine, blood urea, nitrogen, plasma, glucose, creatine kinase, phosphatase, amylase, bilirubin, serum proteins, globulines, complete blood count & differential blood count	05
8	**Importance of TDM with reference to Adverse Drug Reaction (ADR)**	02
9	**TDM of specific drugs** Clinical pharmacokinetics, general guidelines, sample collection, time of sample collection, clinical comments, clinical monitoring parameters, usual dosing parameters, common toxicities, adverse drug reactions & drug interactions, techniques used for estimation, importance of 1. Digoxin 2. Lithium 3. Phenobarbitone 4. Gentamicin. 5. Theophylline 6. Carbamazepine 7. Lidocaine 8. Phenytoin 9. Valproic acid	06

Total Hours - 45

Reference Books:

1. Dr. Tapan Kumar Pal, M. Ganeshan. Bioavailability and Bioequivalence in Pharmaceutical Technology. CBS Publishers and Distributors
2. Llyod r. Snyder, J. J. Kirkland, J. L. Glajch. Practical HPLC method development. JohnWiley & Sons
3. Peter G. Welling, Francis L. S. Tse, Shrikant V. Dighe. Pharmaceutical Bioequivalence.Marcel Dekker Inc.
4. Jerry L. Hamelink, Peter F. Landrum, Harold L. Bergman, William H. Benson. Bioavailability. Physical, chemical, and biological interactions. Lewis publishers
5. Clinical pharmacy practice - C. W. Blissit.
6. Therapeutic drug monitoring - B. Widdop
7. TDM & Clinical biochemistry – Mike Hallworth
8. Textbook of therapeutics, Drug & disease management - 7th edition - Eric T. Herfindel,Dick. R. Gourley.
9. Recent developments in TDM & Clinical toxicology – I. Sunshine - Marcel – Dekker –1992.
10. Handbook of TDM. – Simkin
11. Therapeutic drug monitoring
12. Clinical pharmacology

T - 4.6.4.6 Cosmoceutics (Elective)

(Theory) (3hrs/week)

Sr. No.	Topics	Hrs.
	Section- I	
1.	Introduction To Cosmaceutics: Introduction, Advantages, Disadvantages, Cosmaceuticals And Pharmaceutical Applications, Stability, Evaluation Testing And Storage Of Following Systems Such As – Emulsion, Suspension, Creams, Lotion, Shampoo ,Face Mask And Packs ,Gels, Bath Product ,Sunscreen,	**08**
2.	Cosmetic Serum-Introduction, Definition Of Serum, Serums Effects , Use Of Serum, Cosmetic Serum Application, Recommendation, Advantages, Disadvantages, Various Cosmetic Formulation And Stability Testing Of Serum For Eye, Skin Care And Hair Care Products.	**05**
3	Latest Technology Advances In Cosmaceuticals- Introduction, Cosmaceuticals And Pharmaceutical Applications Of Vesicular Delivery System, Emulsion Delivery System	**04**
4	Effervescent Bath Tablet Formulation Technology. (Bath & Spa Beauty Products)- The Chemistry Of Effervescence, No Reactive Components, Processing Considerations, Quality Control	**06**
	Section- II	
5	Use of botanicals in cosmoceutics: Botanicals as natural products, available sources, extracts, plant additives that are reputed to benefit skin, formulation aspects, standardisation	**04**
6	Most commonly used cosmetics raw material: water, preservatives, humectants, surfactants, oils, fats, perfumes, colors, silicones, functional raw material, development of new raw material.	**08**
7	Processes used in manufacture of cosmetics: emulsification, mixing, compaction, moulding, packaging, product packaging material compatability, cosmetic labeling.	**07**
8	Cosmaceutics in new drug delivery systems: Phytosomes: New Cosmetic Delivery System- Benefits Of Phytosomes, Physical And Chemical Properties Of Phytosomes, Method Of Preparation, Evaluation Of Phytosomes, Difference Between Phytosomes And Liposome's, Herbal Drugs And Their Phytosomes	**03**

Total Hours: 45

References-

1- Cosmetics Formulation Manufacturing & Quality Control 4/Ed
By P P Sharma

2- The Complete Beauty Bible: The Ultimate Guide to Smart Beauty -
By Paula Begoun

3- Dermatologic, Cosmoceutics, and Cosmetic Development: Therapeutic and Novel.
Edited By Kenneth A. Walters, Michael S. Roberts

4- Vesicular & Particulate Drug Delivery Systems
By Prof.R.S.R.Murthy.

5- Healthy Healing: A Guide to Self-Healing For Everyone
By Linda R. Page

6- Cosmetic and Clinical Applications of Botox and Dermal Fillers, Second Edition
By William J. Lipham

7- Handbook of Cosmetic Science and Technology By A. O. Barel, Marc Paye, Howard I. Maibach

T - 4.8.6.7 Packaging Technology (Elective)

(Theory) (3Hrs/week)

Sr. No.	Topics	Hrs.
	Section- I	
1.	**An introduction to pharmaceutical packaging:** Characteristics of packaging, Properties of pack, Types of packaging – primary, secondary and repackaging.	**05**
2.	**Regulatory aspect of pharmaceutical packaging:** Introduction, cost of development, FDA packaging guideline, the package as a contaminator of the environment.	**05**
3.	**Glass containers:** Comparison and types of glass, properties, manufacturing processes, design and decoration, production line handling, quality control and quality assurance, filling, closuring, labeling etc., special pharmaceutical containers – ampoules, vials etc., closures, caps, seals and stoppers.	**05**
4.	**Plastic containers:** Types of plastics – thermosets, thermoplastics, properties of plastic containers, constitutes in plastics, moulding processes, sterilization of plastic containers.	**04**
5.	**Film, foils and laminates:** single ply material, shrink wrapping, stretch wrapping, regenerated cellulose films, special individual film and their uses, collapsible tubes, coatings, Foils- aluminium, Lamination and lamination processes.	**04**
	Section- II	
6.	**Metal containers:** metal containers, tinplate and associated materials, aluminium, types of metal containers, built up containers.	**04**
7.	**Paper and board based materials:** sources of cellulose fibers, manufacturing processes, machine conversion into paper and board, leaflets, folding or collapsible cartons, carton erection and filling, rigid boxes, solid and corrugated boards for casing, paper and board based containers.	**05**
8.	**Closures and closure systems:** basis of closure system, closure assessment and control, prethreaded screw caps, specific closures for containers, non-reclosables, membrane seal, adhesive sealing, specials aspect of closures and their assessment.	**05**
9.	**Blister, strip and sachet packaging:** blister packs, strip packs, sachets, recent development in blister and strip packaging.	**04**
10.	**Printing and decoration:** decoration- features and terms, print terminology, graphic reproduction, mechanical contact printing, printing machines and processes, other printing processes, printing inks, recent trends in printing.	**04**

Total Hours: 45

References:

1. DA Dean, ER Evans, IH Hall. Pharmaceutical Packaging Technology. Taylor and Francis.
2. AJ Winfield, RME Richards. Pharmaceutical practice. Churchill livingstone.
3. Lachman, Lieberman. The Theory and Practice of Industrial Pharmacy.
4. Bentley's Textbook of Pharmaceutics. Elsevier.
5. H Lockhart, FA Paine. Packaging of pharmaceuticals and health care products. Blackie academic and professionals.