C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmaceutics & Pharmaceutical Technology
Semester: VIII
Name of Subject: Pharmaceutical Technology II (Theory)
Subject Code: 4PS08PTE1

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				
									Theory				Total
									Sessional Exam		University Exam		
				Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	04	4PS08PTE1	Pharmaceutical Technology II	3	0	0	3	3	20	1	70	3	100
									10 (CEC)	--			

Objective of Course:-

- Pharmaceutical Technology provides students with the chemical, pharmacological, technological and regulative knowledge and competences required to work, in all sectors directly or indirectly connected with the design, development, manufacture, evaluation and commercialisation of medications and health products.

Prerequisites:-

- To have a more thorough theoretical background in many of the topics covered in this course; students should have basic knowledge of dispensing pharmacy.

Course outline:-

Sr. No.	Course Contents	Hours
1	**Tablet:** Definition, Advantages and disadvantages, Introduction to types of tablets**,** formulation of different types of tablets; excipients, granulation techniques, Directly compressible excipients, machinery for large scale granulation and compression, physics of tablet making, compression and compaction, In process controls, processing problems and remedies, evaluation and equipments for evaluation. Brief outline on manufacturing method and evaluation of conventional tablets and modified release tablets. **Coating of Tablets:** Objectives, types of coating, film forming materials, formulations of coating solution, equipments for coating, coating process, evaluation of coated tablets, coating defects, specialized coating processes. **Pharmaceutical Tablet Compression Tooling:** Terminology, tablet design, specification and information required, use and care of the tooling, problem solving.	13
2	**Capsules** • **Hard Capsules:** Definitions, advantages, disadvantages, Ideal requirements, Production of Hard capsules, Capsule storage, size of capsules, formulation and methods of capsule filling, problems and remedies, quality control, climatic control in capsule department, I.P capsules. • **Soft Gelatin Capsules:** Formulation of shell and capsule coat, manufacturing and quality control, marketed products.	12

	• **Microcapsules:** Importance of microcapsule and microsphere in pharmacy, methods of preparation, evaluation of microcapsules, Applications of Microcapsules.	
3	**Extrusion and Pelletization:** Factors affecting pellet properties, Cold extrusion, Melt extrusion, Applications of extrusion in pharmacy (including preparation of solid solution), selective equipments used for extrusion and pelletization, Use of polyethylene oxide and Eudragit in melt extrusion, Use of MCC in pelletization.	6
4	**Pharmaceutical Packaging:** Definition, Packaging components, types, specifications and methods of evaluation, stability aspects of packing. Primary and secondary packaging, packaging materials, containers and closures; and tamper-evident packaging, packaging equipments. Regulatory requirements in pharmaceutical packaging.	4
5	**Good Manufacturing Practice for Pharmaceuticals and validation** Brief Introduction to GMP and quality assurance, practice of GMP Procedure, Building, Equipment, Personnel, Components, Documentation, Containers, Labelling, Laboratory Control, Distribution Records, and Recovery. Introduction to validation, validation of selective unit operations (Mixing, Granulation) used in tablet manufacturing, validation of hot air oven and steam sterilizer.	10
	Total	**45**

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmaceutics & Pharmaceutical Technology
Semester: VIII
Name of Subject: Pharmaceutical Technology II (Practical)
Subject Code: 4PS08PTEP

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				Total
				Th	Tu	Pr	Total		Practical				
									Sessional Exam		University Exam		
									Marks	Hrs	Marks	Hrs	
1	04	4PS08PTEP	Pharmaceutical Technology II Practical	0	0	3	3	1.5	20	3	70	3	100
									10 (CEC)	--			

The students would perform the experiments related to the topics mentioned under theory.

- Filling of powder/ granules/ pellets in hard gelatin capsule and its evaluation.
- Preparation of gelatin microcapsules by simple coacervation method.
- Preparation of pellets by extrusion and spheronization
- Formulation and evaluation of controlled release pellets
- Preparation and evaluation of tablets employing direct compression
- Preparation and evaluation of tablets employing wet granulation.
- Preparation and evaluation of tablets employing dry granulation.
- Preparation and evaluation of Soluble Aspirin Tablet.
- Preparation and evaluation of Paracetamol tablet or any NSAID tablet.
- Preparation and evaluation of any calcium supplement tablet
- Preparation and evaluation of any antibiotic tablet.
- Preparation and evaluation of iron supplement tablet.
- Preparation and evaluation of Chewable Antacid tablet.
- Preparation and evaluation of Fast Dispersible tablet using Effervescent agent.
- Preparation and evaluation of Fast Dispersible tablet using super disintegrant.

Learning Outcomes:-

- The course would help the student to achieve more confidence in manufacturing different dosage forms.

Teaching & Learning Methodology:-

- Lectures will be conducted with the aid of multimedia projector, black board etc
- Assignments based on course content will be given to the students at the end of each
- Unit/topic and will be evaluated at regular interval.
- Specific discussion questions will be assigned each week.

Books Recommended:-

Text Book

1. The Theory and Practice of Industrial Pharmacy by L Lachman, H Lieberman and J Kanig.
2. Gennaro, Alfonso R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York
3. Pharmaceutical Dosage Forms and Drug Delivery Systems by Ansel & others.
4. Pharmaceutics: The Science of Dosage Form Design by Michael E. Aulton

Reference Book

1. Pharmaceutical Dosage Forms: Disperse systems: Vol.1, Vol. 2 and Vol.3, Ed. by Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker Inc., New York.
2. Pharmaceutical Dosage Forms: Parenteral Medication: Vol.1, Vol. 2 and Vol.3, Ed. by Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker Inc., New York
3. GMP for Pharmaceuticals by S. H. Willig and J. R. Storker.
4. Latest editions of IP, BP, USP.
5. Pharmaceutical Packaging Handbook by Edward Bauer
6. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes, Marcel Dekker, Inc., New York.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmaceutics & Pharmaceutical Technology
Semester: VIII
Name of Subject: Pharmaceutical Dosage Form Design II (Theory)
Subject Code: 4PS08DFD1

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				
									Theory				Total
									Sessional Exam		University Exam		
				Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	04	4PS08DFD1	Pharmaceutical Dosage Form Design II	3	0	0	3	3	20	1	70	3	100
									10 (CEC)	--			

Objective of Course:-

- Pharmaceutical Dosage Form Design provides students with the physical, chemical, pharmacological, technological and regulative knowledge and competences required to work in the design, development, manufacture, evaluation and commercialization of medications and health products.

Prerequisites:-

- To have a more thorough theoretical background in many of the topics covered in this course; students should have basic knowledge of Physical Pharmacy.

Course outline:-

Sr. No.	Course Contents	Hours
1	**Sustained and Controlled Release Drug Delivery System:** Introduction, Biological factors, Physicochemical factors, Dissolution controlled system, Diffusional systems, Bioerodible and Combination of diffusion and dissolution system	8
2	**Novel drug delivery system** • Modified drug delivery systems: Fundamentals, rational of modified release drug delivery, factors influencing the design and performance, pharmacokinetic and pharmacodynamic basis for modified drug delivery systems, estimation of loading and maintenance dose. • Design and development of oral modified release dosage forms: Matrix tablets, microspheres, hydrogels, osmotic pressure controlled systems, gastro retentive systems. • Fabrication of parenteral drug delivery systems: Parenteral emulsions and parenteral suspensions, microspheres, liposomes, niosomes, nanoparticles. • Formulation and evaluation of Transdermal drug delivery systems. • A brief study of site specific and targeted drug delivery systems, transmucosal, colon targeted and ocular drug delivery systems.	22
3	**Pharmacokinetics:** • Definition and scope, significance of plasma drug concentration measurement. • Compartment model: Phamacokinetics of drug absorption, Zero	10

	order and first order absorption rate constant using Wagner-Nelson and Loo-Riegelman method. • Volume of distribution and distribution coefficient. • Compartment kinetics-one compartment and two compartment models. Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intra vascular and oral route. • Curve fitting (Method of Residuals), regression procedures. • Clearance concept, mechanism of renal clearance, clearance ratio, determination of renal clearance. • Hepatic elimination of drugs, first pass effect, extraction ratio, hepatic clearance, biliary excretion, extrahepatic circulation. • Non-linear pharmacokinetics with special reference to one compartment model after I.V. drug administration, Michaeles Menten Equation, detection of nonlinearity • Numericals related to pharmacokinetic parameters using one compartmental model.	
4	**Clinical Pharmacokinetics:** Definition and scope, Dosage adjustment in patients with and without renal and hepatic failure, Pharmacokinetic drug interactions and their significance in combination therapy	5
	Total	**45**

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmaceutics & Pharmaceutical Technology
Semester: VIII
Name of Subject: Pharmaceutical Dosage Form Design II (Practical)
Subject Code: 4PS08DFDP

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				Total
				Th	Tu	Pr	Total		Practical				
									Sessional Exam		University Exam		
									Marks	Hrs	Marks	Hrs	
1	04	4PS08DFDP	Pharmaceutical Dosage Form Design II Practical	0	0	3	3	1.5	20	3	70	3	100
									10 (CEC)	--			

The students would have to perform the experiments related to the topics mentioned under theory.

- Preparation and evaluation of matrix tablet of BCS class I drug with erosion and diffusion based mechanisms.
- Preparation and evaluation of tablet coating.
- Preparation and evaluation of osmotic drug delivery system .
- Preparation and evaluation of floating drug delivery system.
- Preparation and evaluation of buccal tablet.
- Preparation and evaluation of buccal film.
- Preparation and evaluation of transdermal patch.
- Preparation and evaluation of colon drug delivery system.
- Preparation and evaluation of Sodium alginate beads.
- Preparation and evaluation of *in situ* gel.
- Preparation and evaluation of microparticles by solvent change method.
- Calculation of absorption rate by residual method.
- Calculation of absorption rate by Wagner Nelson method.
- Calculation of elimination rate by urinary excretion method.

Learning Outcomes:-

- The course would help the student to achieve more confidence in manufacturing different dosage forms.

Teaching & Learning Methodology:-

- Lectures will be conducted with the aid of multimedia projector, black board, etc
- Assignments based on course content will be given to the students at the end of each
- Unit/topic and will be evaluated at regular interval.
- Specific discussion questions will be assigned each week.

Books Recommended:-

Text Book

1. Gennaro, Alfonso R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York
2. Pharmaceutical Dosage Forms and Drug Delivery Systems by Ansel & others.
3. Pharmaceutics: The Science of Dosage Form Design by Michael E. Aulton

4. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu.
5. Pharmacokinetics by Milo Gibaldi and Donald Perrier.
6. Novel Drug Delivery Systems by N.K. Jain latest edition.

Reference Book

1. Clinical Pharmacokinetics: Concepts and Applications by Rowland and Tozar, Lippincott Williams & Wilkins.
2. Controlled Drug delivery, Fundamentals and Applications by J.R. Robinson & Uinvent Lee, Marcel Dekkar Inc.
3. Noval Drug Delivery Systems by Y. W. Chian Ed. James Swarbrick, Marcel Dekker.
4. Hanbook of Pharmaceutical excipients, Royal society of Great Britain, U.K. Stability Studies, Marcel Dekker.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmaceutical Chemistry & Pharmaceutical Analysis
Semester: VIII
Name of Subject: Pharmaceutical Analysis-III (Theory)
Subject Code: 4PS08PHA1

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				
									Theory				Total
									Sessional Exam		University Exam		
				Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	04	4PS08PHA1	Pharmaceutical Analysis-III	3	0	0	3	3	20 10 (CEC)	1 --	70	3	100

Objective:-

- To Design and application of analytical method to obtain analysis data with high precision and accuracy.
- To Introduce various analytical techniques and their applications.
- To make students familiar with the principles of pharmaceutical analysis and its application in pharmacy

Prerequisites:-

- Student must have under gone the theory and practicals related to pharmaceutical analysis of titrimetric methods and simple electro-chemical methods and simple chromatographic methods of analysis in previous semesters of B. Pharmacy.

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Course outline:-

Sr. No.	Course contents	Hours
1	**UV-VIS spectroscopy:** Theory, Beer and Lambert's law, Terminologies associated with absorption measurements, Types of transitions, Factors affecting spectral characteristics, Wood ward Fischer rule, Instrumentation, applications, advantages and limitations of UV Visible spectroscopy, calibration of U.V. spectrophotometer.	6
2	**Fluorescence spectroscopy:** Theory of Fluorescence and Phosphorescence, Jablonski diagram, Factors affecting fluorescence intensity, Instrumentation, applications, advantages and limitations of fluorescence spectroscopy.	4
3	**IR spectroscopy:** Theory of IR, Molecular vibrations, Factors influencing vibrational frequencies, Calculation of vibrational frequencies (Hooke's law), Sample handling techniques; Instrumentation and applications of IR Spectroscopy, calibration of IR.	4
4	**Atomic spectroscopy:** Principle of atomic absorption and atomic emission spectroscopy, Interferences in atomic spectroscopy, Factors affecting atomic spectroscopy. **Flame Photometry:** Instrumentation and applications, **Atomic Absorption Spectroscopy**: Instrumentation and applications	4
5	**Mass spectrometry:** Theory; Ionization techniques, Ion separating techniques; Different types of ions and their significance in mass	4

	spectra, Fragmentation rules and rearrangements; Instrumentation and applications of mass spectrometry.	
6	**Nuclear Magnetic Resonance spectroscopy:** Fundamental Principles - nuclear spin, magnetic moment; Proton NMR spectroscopy - theory, chemical shift and factors affecting chemical shift, spin-spin coupling, coupling constant, relaxation process, Instrumentation and applications Brief overview of C13 NMR.	5
7	**Gas Chromatography:** Theory and Principle of Gas - Chromatography, Mobile Phase and Stationary Phase for GSC and GLC, Instrumentation, Application of GC.	5
8	**High Performance Liquid Chromatography & HPTLC:** Theory, Classification and principle of HPLC, Instrumentation and Application of HPLC, Overview of LC-MS, LC-MS/MS. Principle of HPTLC, Instrumentation, Applications, advantages and Limitations of HPTLC, Comparison with HPLC, calibration of HPLC.	8
9	Overview of RIA and ELISA	2
10	Analytical Method Validation, Validation Parameter and GLP	3
	Total	45

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmaceutical Chemistry & Pharmaceutical Analysis
Semester: VIII
Name of Subject: Pharmaceutical Analysis-III (Practical)
Subject Code: 4PS08PHAP

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				
									Practical				Total
									Sessional Exam		University Exam		
				Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	04	4PS08PHAP	Pharmaceutical Analysis-III Practical	0	0	3	3	1.5	20	3	70	3	100
									10 (CEC)	--			

Detailed Syllabus (Practical):
The practical exercises are based on topics described under theory. The practicals should broadly cover the following

1. Two experiments: Colorimetric assay of colored drug (e.g. Vitamin B_{12}) & non-colored drug (e.g. Sulpha - BMR, Nitration of Paracetamol)
2. Calibration of UV spectrophotometer.
3. Determination of λ_{max}, A(1cm1%), Detection - Quantitation Limit and preparation of calibration curve (Verification of Beer's law) for any drug by UV-visible spectrophotometer.
4. Two experiments on Spectrophotometric estimation of drugs in marketed formulations (e.g. Paracetamol /Ibuprofen / sulphadiazine).
5. To perform QC testing of tablets.
6. Determination of vitamin C in fruit juice.
7. Two experiments - Fluorimetric estimation of drug (quinine sulphate / riboflavin / Thiamine).
8. Flame photometric estimation of sodium/potassium ions in urine/ORS.
9. To determine total glucose in different brands of honey.
10. Content Uniformity of any drug as per Pharmacopoeia.
11. Quantitative analysis of market formulations by HPLC (Demo)

Learning Outcomes: -

- At the end of the course, the student will be able to understand the concept of pharmaceutical analysis, which is important for qualitative as well as quantitative analysis of drug substances and drug product.
- Understand and be able to apply the fundamental principles of analytical chemistry.
- Demonstrate an understanding of the application of and use of different methods of analysis.
- Competently undertake advanced qualitative and quantitative laboratory tasks, including the operation of advanced analytical instrumentation.
- Demonstrate the ability to follow the analytical approach to the solution of problems in chemical analysis and adhere to good laboratory practice.
- Be able to understand and follow standard documented methods of analysis.

Teaching & Learning Methodology:-

- Lectures will be conducted with the aid of multimedia projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each Unit/topic and will be evaluated at regular interval.
- Specific discussion questions will be assigned each week.

Books Recommended:-

Text Books

1. Quantitative chemical analysis – Vogel A.I, Pearson Education.
2. Instrumental Methods of Analysis H. H. Willard (CBS Publishers, Delhi).
3. Fundamentals of Analytical Chemistry – Skoog, Harcourt College Publishers.
4. Instrumental method of Analysis by P.S. Kalsi.

Reference Books

1. The Quantitative analysis of drugs Garratt.
2. Quantitative chemical analysis by Gilbert H. Ayers. Harper and Row New York.
3. A Textbook of pharmaceutical analysis by Kenneth A. Connors. Jon Wiley and sons.
4. Analysis chemistry by Gary D. Cheristian, John Wiley and sons N.Y.
5. Quantitative analysis by V. Alexeyev. Mir publishers, Moscow.
6. Pharmaceutical Analysis by T. Higuchi etc. CBS Publishers, New Delhi.
7. Quantitative Analysis R. A. Day and A. L. Underwood Prentice Hall of India.
8. Pharmacopoeia: USP, B.P., I.P
9. Analytical Chemistry by R. M. Verma CBS Publishers.
10. Text Book of Pharmaceutical Analysis by kasture, wadodkar, Vol II Nirali Publication.
11. Pharmaceutical analysis by Ravishankar.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmacology
Semester: VIII
Name of Subject: Pharmacology V (Theory)
Subject Code: 4PS08COL1

Teaching & Evaluation Scheme:-

Sr. No	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				Total
								Theory				
								Sessional Exam		University Exam		
			Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	4PS08COL1	Pharmacology V	3	0	0	3	3	20	1	70	3	100
								10 (CEC)	--			

Objective of Course:-

- Exploration and analysis of selected topics in Clinical Pharmacy with a specific theme indicated by course title listed in a syllabus. This subject will take three times for credit as long as different topics are selected. (3 lecture per week)

Prerequisites:-

- Clinical Pharmacy studies required in a sixth semester, it is the base (core) of the major subjects in pharmaceutical studies like Pharmacology and Bio pharmaceutics.

Course Content:-

Sr. No	Course Contents	Hours
1	**Drug interactions:** Prescription monitoring, documentation and methods for minimizing clinically relevant drug interactions	01
2	Drug induced diseases, adverse drug reactions and Pharmacovigilance	02
3	**Pathophysiology, risk factors, diagnosis, complications, treatment & prognosis of the following diseases/conditions:**	
	Respiratory: Bronchial asthma, COPD	02
	Gastrointestinal: Peptic Ulcer Disease, Inflammatory Bowel Disease, and Hepatitis	05
	Endocrine: Diabetes mellitus, Thyroid disorders, Parathyroid disorders, Osteoporosis, Hormone Replacement Therapy	06
	Rheumatoid arthritis and gout	02
	Neoplastic: Leukemia, Lymphomas, Breast Cancer, Cervical Cancer, Prostrate Cancer	07
	Infections: Tuberculosis, Urinary Tract Infections, Enteric Infections, Meningitis, Respiratory Tract Infections, Septicemia, Skin and Soft Tissue Infections (Cellulites, Bed Sores, Diabetic Foot Infection), Leptospirosis, Syphilis, Nosocomial Infection, Filariasis, Leishmaniasis, Gonorrhea, Viral Infections (AIDS, Bird Flu, Swine Flu, Congo Fever, Chickenguniya, SARS (Severe Acute Respiratory Syndrome), Surgical Antibiotics, Prophylaxis.	16
	Obesity	01
	Glaucoma	01
	Pharmacoeconomics	02
	Total	**45**

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmacology
Semester: VIII
Name of Subject: Pharmacology V (Practical)
Subject Code: 4PS08COLP

Teaching & Evaluation Scheme:-

Sr. No	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				Total
								Practical				
								Sessional Exam		University Exam		
			Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	4PS08COLP	Pharmacology V Practical	0	0	2	2	1	20	2	70	3	100
								10 (CEC)	--			

Detailed Syllabus (Practical):-

Case studies (questions based on history, etiology, symptoms, investigations, medication, adverse effects, drug interactions, pharmacists' advice)	
1.	To evaluate case study of bacterial infection (minimum 3 cases)
2.	To evaluate case study of viral infection (minimum 3 cases)
3.	To evaluate case study of protozoal infections (2 cases)
	To evaluate case study of cancer (minimum 2 cases)
4.	To suggest appropriate parenteral nutrition for hospitalized patients after proper nutritional assessments in different conditions, and enlist importance of medications necessary in a pharmacy for Intensive Care Unit management.
5.	To evaluate cases for Interpretation of laboratory data: Hematological / Respiratory / Cancer / Infectious diseases (Min. two full cases with clinical and other relevant findings)
6.	Collecting information for a given drug (Preferably recently approved drugs) regarding adverse drug reactions, drug interactions and contraindications using authenticated sources (Recent text books, Latest Journals and online drug data bases such as medscape).

Learning Outcomes:-

- Define and correctly use scientific terminology in regard to human body and processes.
- Apply principles of scientific inquiry, differentiate a theory from a hypothesis, and differentiate fact from opinion in regard to use of drugs in different human system.
- Describe and practice laboratory safety guidelines relating to working with drugs, experimental animals and body fluids.
- Show proficiency in taking lab practical exams, responding to questions quickly and accurately, effectively handling the pressure of a timed exam.

Teaching & Learning Methodology:-

- Lectures will be conducted with the aid of multimedia projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each Unit/topic and will be evaluated at regular interval.
- Specific discussion questions will be assigned each week.

Books Recommended:-

Text Books:-

1. Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone Edinburgh / London.
2. Tripathi K.D., Essentials of medical pharmacology 6th ed, 2010, Jaypee brothers medical publishers pvt, ltd.
3. Pathology & Therapeutics for Pharmacists. Russell J. Greene and Norman F. Harris. Chapman & Hall, London / Glasgow / Madras.
4. Rang, H.P. and Dale, M.M. Pharmacology, 5th ed, 2010, Publisher: Churchil Livingstone.

Reference Books:-

1. Text Book of Therapeutics: Drug and Disease Management. 7th Ed. Editors: Eric T. Herfindal and Dick R. Gurley, Williams and Wilkins, 2000.
2. Davidson's Principle and Practice of Medicine, Eds. Christopher R.W. Edwards & Ian A.D. Boucher ELBS with Churchill Livingstone, Edinburgh.
4. Applied Therapeutics: The Clinical Use of Drugs Eds. Brian S. Katcher, Lloyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc.
5. Melmon and Morrelli's Clinical Pharmacology, 4th Edition. Authors: S.George Carrathers, Brian B. Hoffman, Kenneth L. Melmon and David W. Nierenberg. McGraw Hill, 2000.
6. Pharmacotherapy: A Pathophysiological Approach. J. T. Dipiro, R. L. Talbert etal, McGraw-Hill, New York.
7. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
8. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's the pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher McGraw Hill, Pergamon press.
9. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and Pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmacognosy
Semester: VIII
Name of Subject: Pharmacognosy-VII (Theory)
Subject Code: 4PS08COG1

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				
									Theory				Total
									Sessional Exam		University Exam		
				Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	04	4PS08COG1	Pharmacognosy-VII	3	0	0	3	3	20	1	70	3	100
									10 (CEC)	--			

Objectives: -

- To make students familiar with holistic concept of medication and drugs used in traditional system of medicine and understand the safety aspects of plants used as medicine.

Prerequisites:-

- The students should have a clear concept of Pharmacognosy.

Course outline:-

Sr. No.	Course Contents	Hours
1	Preparation of Herbal Extracts and their standardization: Introduction to different methods of preparation of plant extracts. Preparation of standardized plant extracts and principles of Garcenia, Garlic, Turmeric, Aswagandha and Amla.	7
2	Evaluation of Phytopharmaceuticals: Phytopharmaceutical evaluation and modern analytical techniques for analysis of herbal drugs.	6
3	Isolation, identification and analysis of phytoconstituents: 1. Terpenoids: Menthol, Citral, Artemisin 2. Glycosides: Sennosides, Diosgenin, Glycyrrhetinic acid and Rutin 3. Alkaloids: Atropine, Quinine, Reserpine, Morphine, Ephedrine, Caffeine 4. Resin: Podophyllotoxin, Curcumin 5. Antibiotic: Penicillin, Streptomycin	18
4	Herbal Drug Industry: Scope, Study of infrastructure, Staff requirement, Project profiles, Plant and equipment, Processing, Research and development and pilot scale up techniques. Quality assurance and concept of Schedule T, GMP and ISO-9000 in herbal drug industry.	7
5	Phytopharmacovigilance	2
6	Herbal drugs for modern diseases: Recent developments of natural products used as Anticancer agents, Antidiabetics, Hepatoprotectives, Antiasthematic, Hypolipidemic, Lythotryptic, Immunomodulators, Tranquilisers, Memory enhancer, Hypnotics.	5
	Total	**45**

C. U. SHAH UNIVERSITY

Department: Pharmacognosy
Semester: VIII
Name of Subject: Pharmacognosy VII (Practical)
Subject Code: 4PS08COGP

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				
									Practical				Total
									Sessional Exam		University Exam		
				Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	04	4PS08COGP	Pharmacognosy -VII Practical	0	0	3	3	1.5	20	3	70	3	100
									10 (CEC)	--			

The practical exercises are based on topics describe under theory. The practicals should broadly cover the following:

1. Isolation of Diosgenin from Fenugreek by preparative TLC and identification by TLC.
2. Isolation of Diosgenin from Fenugreek by column chromatography.
3. Estimation of Diosgenin by quantitive TLC.
4. Estimation of Diosgenin by colorimetric method.
5. Isolation of Ephedrine and identification by TLC.
6. Estimation of Glycyrrhizinic acid by colorimetric method.
7. Isolation of Triammonium Glycyrrhizinate from Glycyrrhiza.
8. Estimation of carbohydrates in crude drugs/ extracts.
9. TLC study of flavonoids of lemon peel, estimation of total flavonoids and isolation hesperidin.
10. Estimation of Total Phenolics and tannins from Harde.
11. Estimation of Total Phenolics and tannins in Triphala.
12. Preparation and evaluation of Amla extract.
13. Preparation and evaluation of Curcuma extract.
14. Preparation of Volatile oil using Clavenger apparatus.

Learning Outcomes:-

- The students are expected to understand Pharmacognostic aspects, uses and pharmacological properties of traditional plant drugs.
- To learn about uses of the herbal extracts in various cosmetic and herbal formulations.
- To learn about various poisonous plants.

Teaching Methodology:-

- Lectures will be conducted with the aid of multimedia projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each Unit/topic and will be evaluated at regular interval.
- Specific discussion questions will be assigned each week.

Books Recommended:

Text Book

1. A Text book of Pharmacognosy: Shah C. S., Quadry J. S., B. S. Shah Prakashan,
2. Ahmedabad. 15th Edition, 2009.

3. Pharmacognosy: Kokate C. K., Purohit A. P., Gokhale S. B., Nirali Prakashan Pune,
4. 42nd edition, 2008.
5. Trease and Evans Pharmacognosy. 16th Edition, William Charles Evans, W.
6. Textbook of Pharmacognosy: Wallis T. E., CBS Publishers and Distributors, New
7. Delhi, 5th Edition, reprinted, 2009.
8. Study of Crude drugs, Iyengar M. A. and Nayak S.G.K. Manipal Power Press, Manipal.
9. Practical Pharmacognosy, Technique and Experiment by Kokate C. K. and Gokhale S. B., Nirali Prakashan, Pune, 8th edition, 2005.

References Books

1. Cultivation and Utilization of Medicinal Plants, Atal C. K. and Kapur B. M., RRL Jammu, 1st Edition, 1989.
2. Supplement to Cultivation and Utilization of Medicinal Plants, Handa, S.S. and Kaul, M.K., 1996. RRL, CSIR Publication, Jammu Tawi.
3. Pharmacognosy: C. K. Kokate, A. P. Purohit, S. B. Gokhale, Nirali Prakashan Pune, 42nd edition, 2008.
4. Trease and Evans Pharmacognosy. 16th Edition, William Charles Evans, W. Saunders, Edinburg, London, New York, Philadelphia, St. Louis, Sydney, Toronto, 2013.
5. Natural Products, Vol I & II, 28th edi Agrawal O. P., Goel Publishing House, Meerut, 28th Edition, 2004.
6. Chemistry of Natural products. Bhat SV, Nagasampagi BA, Meenakshi S. Narosa Publishing House, New Delhi, 2005.
7. Medicinal Natural Products, A Biosynthetic Approach. Dewick Paul M, John Wiley and Sons, West Sussex, 2009.
8. The Organic Constituents of Higher Plants. Their chemistry and interrelationships. Trevor Robinson, Burges Publishing Company, Minneapolis, USA, 1963.
9. Quality Control, Herbal Drugs, An approach to evaluation of Botanicals. Mukherjee P K, Business Horizons Pharmaceutical Publishers; 2002
10. The Ayurvedic Pharmacopoeia of India, Part I, (Vol. I–V) , part II (I & II) Govt. of India, Ministry of Health and Family Welfare, Dept. of Indian Systems of Medicine and Homeopathy, New Delhi 2008.
11. The Ayurvedic Formulary of India, Vol. I, II and III, Published by Government of India, New Delhi, 1st Edition, 2000.
12. The Wealth of India (Raw Material & Industrial Product), Published by Council of Scientific Research, New Delhi, 1st Edition, 2005.
13. Indian Medicinal Plants, Kirtikar and Basu, 1st Edition, International Book Distributors, Dehradun, 1999.
14. Ayurveda Unravelled, Sharadini Dahanukar and Urmila Thatte, 1st Edition, 1996, National Book Trust, New Delhi.
15. Compendium of Indian Medicinal Plant Vol. 1 to 6, Rastogi R. P., Mehrotra B. N., CDRI & NISCOM, 1st Edition, New Delhi, 1998
16. Indian Herbal Pharmacopoeia, 1st revised Edition, Published by RRL, Jammu and IDMA, Mumbai, 2002.
17. Quality standards of Indian medicinal plants, Volume I to XI (2003 to 2013) Editor: Neeraj Tundon & Parul Sharma; By : Medicinal plant Unit, ICMR, New Delhi.
18. Malati G Chanhan & A. P.G Pillai, Microscopic profile of powdered drugs used in Indian system of medicine, Volume I, Bark drugs 2005, Institute of Ayurvedic medicinal plant science, Gujarat ayurved unit Jamnagar; CPTA.

19. Malati G Chauhan & A.P.G Pillai, "Microscopic profile of powdered drugs used in Indian systems of Medicine, Leaf Drugs, Vol 2, 2007, Institute of P.G Teaching & Reaearch in Ayurveda, Gujarat Ayurved University, Jamnagar.
20. Malati G Chauhan & A.P.G Pillai, " Microscopic profile of Drugs used in Indian system of Medicine, Seed drugs, Volume- 3, part- 1, 2011; Publisher: Prof Malati G Chauhan, P.G T- S.F C cell, I.P. G T. & R.A, Gujarat Ayurved University, Jamnagar.
21. Review on Indian Medicinal Plants, Vol I to XI (2004 to 2012) Editor: A K Gupta & Neeraj Tundon. By: Indian council of medicinal Research (ICMR), New Delhi.
22. R. D Chaudhry, Herbal Drug Industry, Eastern Publications, New Delhi.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmaceutics & Pharmaceutical Technology
Semester: VIII
Name of Subject: Drug Regulatory Aspects & IPR (Elective Subject)
Subject Code: 4PS08DRA1

Teaching & Evaluation Scheme:-

Sr. No	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				Total
								Theory				
								Sessional Exam		University Exam		
			Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	4PS08DRA1	Drug Regulatory Aspects & IPR	3	0	0	3	3	20 10 (CEC)	1 --	70	3	100

Objective:-

- To explore the regulatory provisions with respect to clinical trials, Investigational New Drug Application, New Drug Application, ANDA, market authorization of medicines, inspection of Pharmaceutical manufactures and product registration.
- To explore practical aspects repeated to patenting Students learning

Prerequisites:-

- To have a more thorough theoretical background in many of the topics covered in this course; students should have basic knowledge of law.

Course outline:-

Sr. No.	Course Contents	Hours
1	**Drug Regulatory Aspects (India)**: Indian drug regulatory authorities, Central and State regulatory bodies (FDA), Drugs and Cosmetics Act and Rules with latest Amendments., New Drugs – Importation, Registration, development, clinical trials, BE NOC & B.E. studies, Various licenses – Test lic., Import lic. For testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	10
2	**Approval of New drugs:** Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA**.**	8
3	**Drug Regulatory Aspects (International & highly regulated markets)** • US Requirements – (for Generic Drugs especially formulations). • CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, orphan Drugs, ANDA's, exhibit/pivotal batches, validation batches. • Various guidance issued by CDER, OGD, Orange Book (and patents), RLD (reference listed drug) for BE studies and the norms for US submission, bioequivalence and dissolution recommendations, packaging, stability studies and the product information leaflet, US FDA inspection (audits), pre-approval inspections and approvals. • European Union Requirements: All the aspects for European registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above.	17

	• A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. • GMP audits, role of quality assurance, product approvals and supplies.	
4	• Introduction to IPR & Patents – Development of IP law in India, IPR regime, introduction to IP laws in India, Introduction, patent legislation, Indian Patents Act 1970 and amendments, procedure for patent application, grant and opposition proceedings, patent licensing, patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP case laws. • American & European patent system – Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system in Europe. Patent search, patent analysis & patent drafting. • Allied Patents Related Issues: Exploitation of patent, abuse of patents, compulsory licensing, infringement analysis, drug-patent linkage.	6
5	International treaties and conventions on IPR - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO. Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003. Introduction to geographical indication / trademark / copyright: filing procedures.	4
	Total	45

Learning Outcomes:-

- To get familiar with regulatory aspects related to Research & Development as well as manufacturing and marketing of Pharmaceutical Products

Teaching & Learning Methodology:-

- The course employs lectures and class discussions. It also includes presentation by students on a specific topic assigned to them by the faculty.

Books Recommended:-

Text Book

1. GMPs by Mehra
2. The Drugs and Cosmetic Act, 1940 by Vijay Mallik
3. How to Practice GMP by P. P. Sharma.

Reference Book

1. EMEA Publications and Guidance.
2. Orange Book, ICH guidelines, Indian Patents Act
3. Country specific Regulatory Guidelines (available from internet)
4. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
5. J. D. Nally, “Good manufacturing Practice for Pharmaceuticals” Informa Healthcare.
6. Kanfer & L. Shargel, “Generic Product Development BE issued” Informa Healthcare.
7. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
8. USPTO and WIPO Guidelines.
9. Gnarino Richard A, New Drug Approval Process, 3rd Ed., Marcel Dekker Inc.
10. Latest update from the related web resources.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmaceutical Chemistry & Pharmaceutical Analysis
Semester: VIII
Name of Subject: Computer Applications in Drug Discovery (Elective Subject)
Subject Code: 4PS08CAD1

Teaching & Evaluation Scheme:-

Sr. No	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				Total
								Theory				
								Sessional Exam		University Exam		
			Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	4PS0CAD1	Computer Applications in drug discovery	3	0	0	3	3	20	1	70	3	100
								10 (CEC)	--			

Objective of Course:

- To Design and application of analytical method to obtain analysis data with high precision and accuracy.
- To Introduce various analytical techniques and their applications.
- To make students familiar with the principles of QSAR and CADD and its application in pharmacy.

Prerequisites:

- Student must have under gone the theory and practical related to medicinal chemistry and structure activity relationship of different class of drugs in previous semesters of B. Pharmacy.

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Course outline:-

Sr. No	Course Content	Hours.
1	A) Introduction to drug discovery concept / process and importance of drug design approaches in drug discovery. Various approaches to drug discovery B) Ligand Databases for Computer-Aided Drug Design 1. Preparation of Ligand Libraries for Computer-Aided Drug Design. 2. Representation of Small Molecules as "SMILES". 3. Small Molecule Representations for Modern Search Engines: InChIKey. C) Target Data Bases for Computer-Aided Drug Discovery/Design.	06
2	**Structure-Based Computer-Aided Drug Design (SBDD)** **A) Preparation of a Target Structure** 1. Comparative Modeling. Template identification and alignment; Model building; Model refinement and evaluation; Model data bases. 2. Binding Site Detection and Characterization. Geometric method; Energy-based approaches; Pocket matching; Molecular dynamics-based detection. **B) Representing Small Molecules and Target Protein for Docking** Simulations	20

	C) Sampling Algorithms for Protein - Ligand Docking Systematic Methods: Molecular Dynamics Simulations; Monte Carlo Search with Metropolis Criterion ; Genetic Algorithms; Incorporating Target Flexibility in Docking. **D) Scoring Functions for Evaluation Protein - Ligand Complexes** Force-Field or Molecular Mechanics-Based Scoring Functions; Empirical Scoring Functions; Knowledge-Based Scoring Function; Consensus-Scoring Functions. **E) Structure-Based Virtual High-Throughput Screening** **F) Atomic-Detail/High-Resolution Docking** **G) Binding Site Characterization** **H) Pharmacophore Model** Virtual Screening using a Pharmacophore Model; Multitarget Inhibitors using Common Pharmacophore Models; Dynamic Pharmacophore Models that account for Protein Flexibility.	
3	**Ligand-Based Computer-Aided Drug Design** **A. Molecular Descriptors/Features:** Functional Groups. Prediction of Psychochemical Properties : Electronegativity and partial charge; Polarizability; Octanol/water partition coefficient. Converting Properties into Descriptors; Binary molecular fingerprints; 2D description of molecular constitution; 3D Description of molecular configuration and conformation. **B. Quantitative Structure-Activity Relationship Models** Multidimensional QSAR: 4D and 5D Descriptors; Receptor-Dependent 3D/4D- QSAR; Linear Regression and Related Methods; Quantitative Structure- Activity Relationship Application in Ligand-Based Computer-Aided Drug Design. **C. Selection of Optimal Descriptors/Features** **D. Pharmacophore Mapping** Superimposing Active Compounds to Create a Pharmacophore, Pharmacophore Feature Extraction; Pharmacophore Algorithms and Software Packages.	12
4	Prediction and Optimization of Drug Metabolism and Pharmacokinetics Properties Including Absorption, Distribution, Metabolism, Excretion and the Potential for Toxicity Properties Compound Library Filters; Lead Improvement: Metabolism and Distribution; Prediction of Human Ether-a-go-go related Gene Binding; Drug Metabolism and Pharmacokinetics/Absorption, Distribution, Metabolism, and Excretion and the Potential for Toxicity Prediction Software Packages and Algorithms.	7
	Total	**45**

Learning Outcomes: -

- At the end of the course, the student will be able to understand the concept of CADD and QSAR, which is important for applications of CADD in large companies in the Pharmaceutical synthetic industries and new drug molecule discovery.

Teaching & Learning Methodology:-

- Lectures will be conducted with the aid of multimedia projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each Unit/topic and will be evaluated at regular interval.
- Specific discussion questions will be assigned each week.

Books Recommended:-

Text Books

1. H. Smith & H. J. William – Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
2. Burger Medicinal Chemistry – The Basis of Medicinal Chemistry by Manfred S. Wolff, Part – I, John Wiley & Sons.

References Books:

1. W. O. Foye – Principals of Medicinal Chemistry, Lipincott Williams and Wilkins.
2. C. Hansch and Leo – Comprehensive Medicinal Chemistry Vol. 4, Pergamon Press.
3. E. H. Kerns and L. Di – Drug like properties, concepts, structure design and methods, Academic Press.
4. Molecular Modeling in Drug Design by Cohen N. C.
5. D. C. Young – Computational Drug Design, John Wiley & Sons, Inc.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmacology
Semester: VIII
Name of Subject: Pharmacovigilance (Elective Subject)
Subject Code: 4PS08PCV1

Teaching & Evaluation Scheme:-

Sr. No	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				
								Theory				Total
								Sessional Exam		University Exam		
			Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	4PS08PCV1	Pharmacovigilance	3	0	0	3	3	20	1	70	3	100
								10 (CEC)	--			

Objective of Course:-

- Exploration and analysis of selected topics in Clinical Pharmacy with a specific theme indicated by course title listed in a syllabus. This subject will take three times for credit as long as different topics are selected. (3 lecture per week)

Prerequisites:-

- Clinical Pharmacy studies required in a sixth semester, it is the base (core) of the major subjects in pharmaceutical studies like Pharmacology and Bio pharmaceutics.

Course Content:-

Sr. No	Course Contents	Hours
1	Pharmacovigilance- Introduction, Scope, Definition, Purpose, Methods, History	3
2	Fundamental Clinical Aspects of ADRs- Definition, Types, Factors, Mechanisms, Seriousness and Severity, causality assessment, Markers, Management, Pharmacogenetic causes, ADR in Public Health	11
3	Important ADRs and 'Risk Driving' ADRs of Important Medicines, Serious and important ADRs in various organ class, ADR of various anti infective drugs	4
4	Individual Case Safety Reports (ICSRs)- Definition, Types, Contents, Structure, Validity and assessment of ICSRs reports, Role of ICSRs in Pharmacovigilance	6
5	Pharmacovigilance in Clinical Trials- Characterization, Pre and post authorization studies, observational studies	3
6	Counterfeiting, Quality Defects and Medication Errors- Definition of substandard/spurious/falsely labelled /falsified / counterfeit (SSFFC) medicines, Pattern and scale of counterfeiting, Medication error-Definition, types, detections	7
7	Spontaneous ICSR Reporting Systems (SRS) Definition, Potential and limitations of SRS, Forms and formats of ICSR transmission as per various regulatory bodies, descriptive statistics, access and confidentiality	6
8	Signal Detection and Management Definition, Sources, Validation, Assessment, Scope	2

9	Industry and Regulatory Authorities, Mandatory Procedures from Legislation, Pharmacovigilance system and SOPs, Benefit risk assessment, crisis management plan, WHO international drug monitoring programme, medDRA, Pharmacovigilance regulation in INDIA, USA, EUROPE, CANADA	3
	Total	**45**

Learning Outcomes:-

- Define and correctly use scientific terminology in regard to human body and processes.
- Apply principles of scientific inquiry, differentiate a theory from a hypothesis, and differentiate fact from opinion in regard to use of drugs in different human system.
- Describe and practice laboratory safety guidelines relating to working with drugs, experimental animals and body fluids.
- Show proficiency in taking lab practical exams, responding to questions quickly and accurately, effectively handling the pressure of a timed exam.

Teaching & Learning Methodology:-

- Lectures will be conducted with the aid of multimedia projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each Unit/topic and will be evaluated at regular interval.
- Specific discussion questions will be assigned each week.

Books Recommended:-

Text Books:-

1. Talbot J, Aronson JK (eds.) Stephen's detection and evaluation of adverse drug Reactions
2. Andrews E, Moore N (eds.) Mann's Pharmacovigilance
3. Van Boxtel CJ, Santoso B, Edwards IR (eds.) Drug benefits and risks
4. Rawlins MD Therapeutics, evidence and decision-making
5. Aronson JK (ed.) Meyler's side effects of drugs
6. Sweetman SC (ed.) Martindale - the complete drug reference
7. World Health Organization WHO model formulary
8. S. K. Gupta Text book of Pharmacovigilance
9. Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone Edinburgh / London.
10. Tripathi K.D., Essentials of medical pharmacology 6th ed, 2010, Jaypee brothers medical publishers pvt, ltd.
11. Pathology & Therapeutics for Pharmacists. Russell J. Greene and Norman F. Harris. Chapman & Hall, London / Glasgow / Madras.
12. Rang, H.P. and Dale, M.M. Pharmacology, 5th ed, 2010, Publisher: Churchil Livingstone.

Reference Books:-

1. Text Book of Therapeutics: Drug and Disease Management. 7th Ed. Editors: Eric T. Herfindal and Dick R. Gurley, Williams and Wilkins, 2000.
2. Davidson's Principle and Practice of Medicine, Eds. Christopher R.W. Edwards & Ian A.D. Boucher ELBS with Churchill Livingstone, Edinburgh.

3. Applied Therapeutics: The Clinical Use of Drugs Eds. Brian S. Katcher, Lloyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc.
4. Melmon and Morrelli's Clinical Pharmacology, 4th Edition. Authors: S.George Carrathers, Brian B. Hoffman, Kenneth L. Melmon and David W. Nierenberg. McGraw Hill, 2000.
5. Pharmacotherapy: A Pathophysiological Approach. J. T. Dipiro, R. L. Talbert etal, McGraw-Hill, New York.
6. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
7. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman andGilman's the pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher McGraw Hill, Pergamon press.
8. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and Pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences
Department: Pharmacognosy
Semester: VIII
Name of Subject: Commerce of herbs and Phytoconstitutents
(Elective Subject)
Subject Code: 4PS08CHP1

Teaching & Evaluation Scheme:-

Sr. No	Branch Code	Subject Code	Subject Name	Teaching hours/ week				Credit	Evaluation Scheme/ Semester				
									Theory				Total
									Sessional Exam		University Exam		
				Th	Tu	Pr	Total		Marks	Hrs	Marks	Hrs	
1	04	4PS08CHP1	Commerce of herbs and Phytoconstitutents	3	0	0	3	3	20	1	70	3	100
									10 (CEC)	--			

Objectives: -

- To make students familiar with holistic concept of medication and drugs used in traditional system of medicine, understand the importance of trade and commerce of phytoconstituents and plants used as medicine.

Prerequisites:-

- The students should have a clear concept of Pharmacognosy.

Course outline:-

Sr. No.	Course Contents	Hours
1	Contribution of natural products in modern drug discovery: overview of drug molecules discovered from natural products; detailed study of following in drug discovery: vinca alkaloids, morphine, atropine, δ-tubocurarine, ephedrine, artemisinin, campothecin, taxol, curcumin, diosgenin, papain etc.	5
2	World-wide trade in medicinal plants: withania, senna, liquorice, echinacea, ginseng, aloe, ipecac, boswellia, guggulu etc	5
3	Industrially important aromatic plants and their derived products	5
4	Herbal Drug Trade: WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants. Geneva; WHO guidelines on good manufacturing practices for the manufacture of herbal medicines; International trade, drug registration for export import.	5
5	Production, supply and distribution	5
6	Wild harvesting, cultivated material.	5
7	Constraints to the development of trade.	5
8	Herbal Drug/Intellectual Property Rights (IPR).	5
9	Medicinal plant based industries in indigenous system of medicine (ISM), standardization.	5
	Total	**45**

Learning Outcomes:-

- The students are expected to understand Commerce of herbal drugs of traditional plant drugs.
- To learn about uses of the WHO guidelines in various cosmetic and herbal formulations.

Teaching Methodology:-

- Lectures will be conducted with the aid of multimedia projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each Unit/topic and will be evaluated at regular interval.
- Specific discussion questions will be assigned each week.

Books Recommended:

Text Book

1. A Text book of Pharmacognosy: Shah C. S., Quadry J. S., B. S. Shah Prakashan, Ahmedabad. 15th Edition, 2009.
2. Pharmacognosy: Kokate C. K., Purohit A. P., Gokhale S. B., Nirali Prakashan Pune, 42nd edition, 2008.
3. Trease and Evans Pharmacognosy. 16th Edition, William Charles Evans, W.
4. Textbook of Pharmacognosy: Wallis T. E., CBS Publishers and Distributors, New Delhi, 5th Edition, reprinted, 2009.
5. Study of Crude drugs, Iyengar M. A. and Nayak S.G.K. Manipal Power Press, Manipal.

References Books

1. Pathak YV. Handbook of Nutraceuticals Volume I: Ingredients, Formulations, and Applications, CRC Press, 2009. Ed: 1st
2. Aluko RE. Functional Foods and Nutraceuticals, Springer Verlag GMBH, 2012
3. Hildebert Wagner and Sabine Bladt, Plant Drug Analysis: A Thin Layer Chromatography Atlas;, New Delhi: Springer (India) Pvt. Ltd., 2nd ed. 1996
4. D'Amelio, Frank S. Sr., Botanical: A Phytocosmetic Desk Reference; New York: CRC Press, I Llc, Boca Raton, Florida, U.S.A. 1999
5. Stephen J. Cutler and Horace G. Cutler, Biologically Active Natural Products: Pharmaceuticals; CRC Press, Boca Rotan London, New York. Washington DC 2000
6. Marc Paye, André O. Barel, Howard I. Maibach, Handbook of Cosmetic Sciences, Informa Press, Tylor and Francis, LLC, 2006
7. Vermeer BJ, Definition In: Peter Elsener, Howard I. Maibach, editors Cosmeceuticals: Drugs vs. Cosmetics, New York, Marcel Dekker, 2000.
8. Atal CK and Kapoor LD; CSIR, 1982, Cultivation and utilization of Medicinal plants.
9. Handa SS, 1996, CSIR, Supplement to cultivation and utilization of Medicinal plants.
10. Atal CK and Kapoor LD, CSIR, 1982, Cultivation and utilization of Aromatic plants.
11. Handa SS and Kaul CL; CSIR, 1998, Supplement to cultivation and utilization of Aromatic plants.
12. Chaudhary RD, Herbal Drug Industry, Eastern Publications, New Delhi.