SEMESTER-VI

SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
B601T	Dosage Form Development Theory	4	--	3	--
B601P	Dosage Form Development Practical	--	3	--	3
B602T	Pharmacology-IV Theory	3	--	3	--
B602P	Pharmacology-IV Practical	--	3	--	3
B603T	Pharmacognosy-IV Theory	3	--	2	--
B603P	Pharmacognosy-IV Practical	--	3	--	3
B604T	Biochemistry-II Theory	4	--	2	--
B604P	Biochemistry-II Practical	--	3	--	3
B605T	Medicinal Chemistry-I Theory	4	--	3	--
B605P	Medicinal Chemistry-I Practical	--	3	--	3
B606T	Elective Theory	3	--	2	--
	Total	36		30	

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)		MARKS			
				THEORY		PRACTICAL	
		T	P	University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
B601T	Dosage Form Development Theory	3	--	80	20	--	--
B601P	Dosage Form Development Practical	--	6	--	--	80	20
B602T	Pharmacology-IV Theory	3	--	80	20	--	--
B602P	Pharmacology-IV Practical	--	3	--	--	80	20
B603T	Pharmacognosy- IV Theory	3	--	80	20	--	--
B603P	Pharmacognosy- IV Practical	--	3	--	--	80	20
B604T	Biochemistry-II Theory	3	--	80	20	--	--
B604P	Biochemistry-II Practical	--	3	--	--	80	20
B605T	Medicinal Chemistry-I Theory	3	--	80	20	--	--
B605P	Medicinal Chemistry-I Practical	--	3	--	--	80	20
B606T	Elective Theory	3	--	80	20	--	--
TOTAL		36		480	120	400	100

SUBJECT : Dosage Form Development
SUBJECT CODE : B601T & B601P

RATIONALE : Developing a dosage form is an art but it also includes the basic science, without which it is not possible to create the presently available dosage form. The student here learns the basic principles governing the development of dosage forms. Also he/she learns the factors affecting the efficacy, utilization and stability of these dosage forms.

COURSE OBJECTIVES :

1. To learn the various factors which have to be considered while developing the dosage form.
2. To apply these basic understandings for development of formulations.

LEARNING OUTCOMES: The student should be able to

1. Describe the basic principles of biopharmaceutics.
2. Explain the various factors encompassing formulation of dosage forms
3. Demonstrate the techniques for studying the effect of various excipients.
4. Conduct the stability studies for drug formulations

PREREQUISITES: Physical pharmaceutics

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS		EVALUATION SCHEME				TOTAL MARKS
							INTERNAL		EXTERNAL		
		T	P	TOTAL HRS	T	P	T	P	T	P	
B601T & B601P	Dosage Form Development	4	3	7	3	3	20	20	80	80	200

CONTENTS:

1	**Preformulation** : Study of physical properties of drug like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution & organoleptic property and their effect on formulation, stability and bioavailability Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization etc. and their influence on formulation and stability of products	20
2	**Pharmaceutical Necessities**: Ideal requirements, Function, Classification (Functional and Dosage form wise) and Evaluation of: Stabilizers, Colors, Flavours, Suspending agents, Emulsifying agents, Solvents, Diluents, Binders, Disintegrants, Antifrictional agents, Superdisintegrants, Ointment and Suppository Bases, Solubilizer, Solvents. etc	15
3	**Stability of Pharmaceuticals**: Kinetic principles & stability testing: Reaction rate and order, acid base catalysts, decomposition reaction, stabilization, stability test parameters , Product Stability : Requirements, Shelf life, overages, containers, Stability testing and guidelines like US FDA, Indian FDA, Pharmacopoeial, ICH etc	15
4	**Biopharmaceutics :** Introduction to biopharmaceutics and pharmacokinetics and their role in formulation development and clinical setting. Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion & pinocytosis—Mechanisms and importance. Factors influencing absorption: Physicochemical, physiological and pharmaceutical.	15

5	**Pharmacokinetics:** Significance of plasma drug concentration measurement, Compartment model: Definition & scope Pharmacokinetic and drug absorption: zero order and first order absorption rate constant using Wagner Nelson and Loo Reigelman method, Volume of distribution and distribution coefficient Compartment kinetics: One compartment and two compartments models, Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intravascular and oral route. Clearance concept: mechanism of renal clearance, clearance ration, determination of renal clearance. Non-linear pharmacokinetics with special reference to one compartment model after I.V. drug administration, Michalis-Menton equation, detection of non linearity (saturation mechanism)	20
6	**Bioavailability & Bioequivalence**: Measurement of bioavailability, Cmax, Tmax, and area under curve (AUC) Design of single dose bioequivalence study and relevant statistics Regulatory requirements for conduction of bioequivalent studies In vitro dissolution studies: Methods, interpretation of data. IVIVC	15

B601P Dosage Form Development Practical

1	Evaluation of different excipients and their effect on formulation of pharmaceuticals, like: Suspending agents, Emulsifying agents, Diluents, Binders, Lubricants, Disintegrating agents,
2	Preformulation studies including drug excipient compatibility studies.
3	Stability evaluation of various dosage forms and their expiration dating

BOOKS RECOMMENDED:

1. Text Book Of Biopharmaceutics And Pharmacokinetics", Hiremath Shobha Rani R., Prism Books Publication
2. "Pharmaceutics The Science Of Dosage From Design", Aulton Michael E., Elbs Publication
3. "Applied Biopharmaceutics And Pharmacokinetics", Leon Shargel, Mc Graw-Hill Publication
4. "Bioavailability and Bioequivalence in Pharmaceutical Technology", Tapan Kumar, CBS Publication.
5. "Biopharmaceutics And Clinical Pharmacokinetics : An Introduction", Notary Robert E., Marcel Dekker Publication
6. "Ansel's Pharmaceutical Dosage Forms And Drugs Delivery System", Lloyd V Allen, B I Publication
7. "Drug Stability : Principles And Practices", Carstensen Jens T., Marcel Dekker Publication
8. "Handbook of Pharmaceutical Excipients", Raymond C Rowe, American Pharmaceutical Association
9. "Modern Pharmaceutical Vol-121", Gilbert S Banker, Marcel Dekker Publication
10. "Clinical Pharmacokinetics : Concepts And Applications", Rowland Malcolm, B I Waverly Publication
11. "Manual Of Laboratory Pharmacokinetics", Curry Stephen H., John Wiley Publication
12. "Pharmacokinetic Principles Of Dosing Of Dosing Adjustments", Schoenwald Ronald D, Technomic Publishing.
13. "The Drug Development Process Vol-76", Welling Peter G, Marcel Dekker Publication

SUBJECT : Pharmacology-IV
SUBJECT CODE : B602T & B602P
RATIONALE : This is one of the core subjects of Pharmacy field where student learns the biological effects of drugs. The subject has direct application to the profession as it teaches the student about how the drug produce effect, what effects are produced, what side effects are produced, where and when it should be used etc. The subject is an extension of Pharmacology learnt in previous semesters

COURSE OBJECTIVES:
To learn the mechanism of action, pharmacological effects, pharmacokinetics, adverse effects, therapeutic application of various classes of drugs with special attention to chemotherapeutic drugs and drugs acting on endocrine system.

LEARNING OUTCOMES: The student should be able to:

1. Narrate the principles involved in measurement of drug effects
2. Classify the drugs according to pharmacological classes
3. Explain the mechanism of action, pharmacodynamics and pharmacokinetic effects of drugs, adverse effects, contraindications and therapeutic application of various classes of drugs.
4. Conduct some simple *in vivo* experiments to demonstrate the pharmacological actions of the drugs.

PREREQUISITES:
Knowledge of Human Anatomy Physiology, Health Education, Biochemistry and basic physics and chemistry. Fundamentals of pharmacology learnt in previous semesters.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS		EVALUATION SCHEME				TOTAL MARKS
							INTERNAL		EXTERNAL		
		T	P	TOTAL HRS	T	P	T	P	T	P	
B602T & B602P	Pharmacology-IV	3	3	6	3	3	20	20	80	80	200

CONTENTS:

1. Endocrine and Metabolic Disorders:	**40**
Pharmacology of Pituitary, Hypothalamic& Thyroid hormones	07
Drugs affecting Calcium homeostasis	03
Corticosteroids	04
Androgens and anabolic steroids	04
Pharmacology of drugs acting on reproductive system	07
Pathophysiology of Diabetes mellitus obesity; Drugs used in the same	15
2. Chemotherapy	**60**
Pathophysiology of following communicable diseases, their causative agents, modes of transmissions and prevention	
Viral diseases : Chicken pox, Measles, Mumps, Rubella, Influenza, Dengue , Chikun gunia, Poliomyelitis, Hepatitis, AIDS, Rabies, Rubella	06

	Bacterial Diseases: Diphtheria, Whooping cough, Tuberculosis, Cholera, Typhoid, Leprosy, Syphilis, Gonorrhea, Food poisoning, Plague, Tetanus, Anthrax	06
	Protozoal Disease: Malaria, Amoebiasis, Leishmaniasis	04
	Helmenthiasis: Filariasis, Ascariasis, Schistosomiasis	06
	General principles of Chemotherapy.	02
	Sulphonamide, co-trimoxazole, Quinolones, nitrofurans.	06
	Antibiotics:- Betalactams, Macrolides	06
	Tetracycline, Aminoglycosides, Chloramphenicol, and Miscellaneous Antibiotics.	06
	Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, urinary tract infections and sexually Transmitted diseases	06
	Chemotherapy of the parasitic diseases:- Helmenthiasis, malaria, amoebiasis and other protozoal infections	06
	Chemotherapy of malignancy and Immunosuppressive agents.	06

B602P Pharmacology-IV Practical

1.	To study the estrus cycle of Rat (Smear).
2.	To perform the Oral Glucose Tolerance Test.
3.	To find out Total Cholesterol, Triglycerides and HDL.
4.	To study the effect of Oxytocin on Rat Uterus.
5.	To study the effect of Spironolactone on Urinary Sodium and Potassium levels.
6.	To study the effect of thyroid hormone on body weight, food intake and Basal Metabolic Rate (BMR)
7.	To study the antibacterial effect of given unknown drug using Agar plate method.
8.	To study the skeletal muscle relaxant effect of Aminoglycoside antibiotics.
9.	To determine antibacterial spectrum of given unknown drug.
10.	To study the effect of combination of antibiotics to understand the mechanism of action.

BOOKS RECOMMENDED

1.	Pharmacological Basis Of Therapeutics By Goodman & Gillman
2.	Pharmacology And Pharmacotherapeutics By Satoskar & Bhandarkar
3.	Essentials Of Pharmacotherapeutics By F.S.K. Barare
4.	Essentials Of Medical Pharmacology By K.D. Tripathi
5.	Pharmacology By Rang & Dale
6.	Fundamentals Of Experimental Pharmacology By M.N. Ghosh
7.	Handbook Of Experimental Pharmacology By S.K. Kulkarni
8.	P'cology Exp by R.K. Goyal
9.	Introduction To General Toxicology By Aries Simonsis & Offermeier
10.	Toxicology: The Basic Science Of Poisons By Casorett & Doull
11	Principles Of Drug Action By Goldstein Aronow & Kalaman
12.	Pharmacological Experiments on Isolated Preparation By Perry
13.	Medical Pharmacology By Goth
14.	Pharmacology By Gaddum
15.	Lewis Pharmacology By Crosland
16.	Textbook Of Pharmacology By Bowman & Rand
17.	Elements Of Pharmacology By Dr. Derasari & Dr. Gandhi
18.	Drug Interactions By Hansten
19.	Clinical Pharmacology By Lawrence
20.	Drug Treatment By Averey

SUBJECT : Pharmacognosy- IV
SUBJECT CODE : B603T & B603P
RATIONALE : It provides knowledge of drugs of natural origin. Since ages humans have been using drugs from natural origin. Many of the allopathic drugs also have herbal origin. Learning these drugs is of great value for pharmacy professionals as these drugs have important place in treatment of diseases.

COURSE OBJECTIVES :

1) To learn general morphological and microscopical characters of crude drugs
2) To understand general methods of checking purity of herbal drugs.

LEARNING OUTCOMES: The student should be able to:

1) Identify the crude drugs belonging to different classes based on morphological, microscopical and chemical properties.
2) Narrate the therapeutic and pharmaceutical uses of these drugs

PREREQUISITES: Biology and Pharmacognosy of semester-III, IV and V

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS		EVALUATION SCHEME				TOTAL MARKS
							INTERNAL		EXTERNAL		
		T	P	TOTAL HRS	T	P	T	P	T	P	
B603T & B603P	Pharmacognosy- IV	3	3	6	2	3	20	20	80	80	200

CONTENTS:

1.	Study of traditional drugs: II Brahmi, Nagarmotha, Palash, Rasna, Tylophora, Vaj, Phyllanthus, Bhringraj, Galo, Kalmegh, Karen, Neem, Shankhapuspi, Punarnava, Ashoka.	40
2.	Historical development of plant tissue culture, types of cultures, nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacy.	20
3.	Phytochemical screening of crude drugs	10
4.	Plant bitters and sweeteners	10
5.	Herbs as health foods	10
6.	Herbal cosmetics	10

B603P Pharmacognosy-IV Practical

1.	Evaluation of Neem leaf, Tylophora
2.	Evaluation of Brahmi
3.	Evaluation of Galo Stem young/Old
4.	Evaluation of Kalmegh
5.	Evaluation of Shankhapuspi
6.	Evaluation of Karen leaf, Bhringraj
7.	Evaluation of Punarnava,

8.	Evaluation of Nagarmotha root
9.	Evaluation of Vaj
10.	Evaluation of Rasna Stem
11.	Evaluation of Ashok bark
12.	Phytochemical Screening of Sample 1,2
13.	Phytochemical Screening of Sample 3,4
14.	Phytochemical Screening of Sample 5,6
15.	Phytochemical Screening of Sample 7,8
16.	Phytochemical Screening of Sample 9,10

BOOKS RECOMMENDED:

1. MG Chauhan, Microscopy Of Bark Drug, Jamnanagar Ayurved University
2. MG Chauhan, Microscopy Of Leaf Drug, Jamnanagar Ayurved University
3. Anasari, Pharmacognosy Textbook Of Natural Products, Latest Edition.
4. Ashutosh Kar, Pharmacognosy And Pharmacobiotechnology, New Age International
5. Jackson Betty P., Atlas Of Microscopy Of Medicinal Plants, Culinary Herbs And Spices, CBS Publication
6. Kokate C.K. Practical Pharmacognosy, Vallabh Prakashan, Delhi
7. Kokate C.K, Purohit A.P. And Gokhale S.B. Pharmacognosy (Degree) Nirali Prakashan,
8. Wagner, Plant Drug Analysis, Springer Verlag Publication
9. Bruneton Jean, Pharmacognosy : Phytochemistry Medicinal Plants, Lavoisier Publishing
10. Harborne J B, Phytochemical Methods, Champan And Hall, International Edition, London
11. Ayurvedic Pharmacopoeia Of India
12. Herbal Pharmacopeia 1-2 (IDMA)
13. The Wealth of India, Raw Materials (All Volumes) Council of Scientific and Industrial Research (CSIR), New Delhi.
14. The Wealth Of India – First Supplement Series (Row Materials) Vol- 1to 10
15. Who Monographs On Selected Medicinal Plants Vol-1-2
16. Indian Medicinal Plants (Plate) Vol-1-4, Kirtikar K. R
17. Indian Medicinal Plants (Text) Vol-1-4, Kirtikar K. R.
18. Quality standards of Indian medicinal plants Vol I-IV(ICMR)
19. Rangari & Rangari, Text Book Of Pharmacognosy
20. Phytochemical Methods: A Guide to Modern Techniques Of Plant Analysis, Harborne J.B.
21. Medicinal Natural Products, Paul And Devick
22. Kumar U., Methods In Plant Tissue Culture, Agro Botanica Publication
23. Plant Cell And Tissue Culture And Bio-Technology By Siddhiverasan

SUBJECT : Biochemistry-II
SUBJECT CODE : B-604T and B-604P
RATIONALE : Understanding the chemistry of life is fundamentally required for studying the effect of drugs on human body. The course will enable student to learn the basic chemical reactions occurring in the human body. Also the various factors which can regulate this chemical processes will be taught. This subject is an extension of what has been learnt in previous semester

COURSE OBJECTIVES :

1. To learn the structure and function of various biochemical and its contribution to function of body.
2. To learn the basic metabolic processes occurring within the human body and factors regulating the same.

LEARNING OUTCOMES:

1. Describe the structure and functions of various biochemical
2. To understand role of various metabolism in body.
3. To learn biosynthesis of lipid and protein
4. To understand metabolism disorders.

PREREQUISITES: Physics, chemistry, human anatomy physiology

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS		EVALUATION SCHEME				TOTAL MARKS
							INTERNAL		EXTERNAL		
		T	P	TOTAL HRS	T	P	T	P	T	P	
B604T & B604P	Biochemistry-II	4	3	7	2	3	20	20	80	80	200

CONTENTS:

1	Bioenergetics and biological oxidation 1.1 Basic thermodynamic concepts. The first law: heat, work, internal energy, enthalpy. The second law and entropy. Free energy 1.2 The physical significance of thermodynamic properties. 1.3 The effect of pH on standard state free energies. 1.4 The effect of concentration on net free energy changes. 1.5 The high energy biomolecules. 1.6 ATP is an intermediate energy shuttle molecule, its production, daily requirement effect of concentration and metal ions on the free energy of hydrolysis of ATP. 1.7 Redox potential. 1.7.1 Nernst equation. 1.7.2 Biological significance. 1.8 Enzymes and coenzymes involved in oxi-red potential. 1.8.1 Biological significance 1.8.2 Regulation of the oxi-red potential in biological system.	20

	1.9 The electron transport chain. 1.9.1 Bio macromolecules fate and ETC 1.9.2 Regulation of ETC 1.9.3 Oxidative phosphorylation. 1.9.4 Inhibitors of oxidative phosphorylation 1.9.5 P/O ratio fir ETC and oxidative phosphorylation.	
2	Carbohydrate metabolism. 2.1.7 Introduction to metabolism. 2.1.7.1 Definition of metabolism. 2.1.7.2. Classification of metabolism. 2.1.7.3 Role of ATP in metabolism 2.1.8 Glycolysis (conversion of glucose from polysaccharides.) 2.1.8.1 Conversion in to glucose-1 phosphate. 2.1.8.2 Glycolysis enzyme involved in it. Fate of pyruvate. Regulation of Glycolysis. 2.1.9 Gluconeogenesis and its role 2.1.10 Glycogenolysis. 2.3 Pentose phosphate pathway and its regulation. 2.4 The citric acid cycle. 2.4.1 Site of TCA cycle. 2.4.2 LDH (lactate dehydrogenase) pathway. 2.4.3 Role of various enzymes involved in TCA 2.4.4 Regulation of TCA cycle. 2.4.5 The entry and exit of various intermediate. 2.4.6 The Glyoxylate cycle.	25
3	Lipid Metabolism 3.2 Oxidation of fatty acids. 3.2.1 Discovery of β-oxidation. 3.2.2 –oxidation of fatty acids and role of coenzyme A. 3.2.3 –oxidation of odd carbon fatty acids. 3.2.3 –oxidation of unsaturated fatty acids. 3.2.4 α-oxidation of branched- chain fatty acids. 3.2.5 ω-oxidation of fatty acids yields small amount of dicarboxylic acids. 3.2.6 Ketone bodies biosynthesis and its utilization. 3.2.7 Regulation of lipid metabolism. 3.2.7.1 Role of allosteric modifiers. 3.2.7.2 Role of phosphorylation and dephosphorylation cycles. 3.2.7.3 Hormonal Regulation. 3.2.8 Eicosanoids biosynthesis (prostaglandins and thromboxanes) 3.2.9 Phospholipids and Sphingolipids biosynthesis and regulation. 3.3 Cholesterol biosynthesis. 3.3.1 Synthesis from Squalene. 3.3.2 Squalene from mevalonate. 3.3.3 Conversion of lanosterol to cholesterol	20
4	Protein Metabolism 4.4 Nitrogen fixation and the nitrogen cycle overview. 4.5 Assimilation of ammonia. 4.6 Biosynthesis of amino acids. 4.7 Catabolism of amino acids.	20

	4.8 Amino acid conversion to specialized product. 4.9 The urea cycle 4.9.1 Enzymes involved in urea cycle 4.9.2 Ancillary reaction of urea cycle 4.9.3 Disorders of urea cycle 4.10 Metabolism of Sulphur containing amino acids. 4.10.1 Methionine, Cysteine	
5	Nucleotides, structure, function and metabolism 5. Nucleotides, structure, function and metabolism 5.1 Pyrimidine and Purine 5.2 Nucleotides 5.3 Nucleosides 5.4 Purine biosynthesis and its metabolism 5.4.1 Precursor for biosynthesis 5.4.2 Regulation 5.4.3 Disorders of Purine metabolism 5.5 Pyrimidine biosynthesis and its metabolism 5.5.1 Precursor for biosynthesis 5.5.2 Regulation and disorder of Pyrimidine metabolism 5.6 Deoxy-ribonucleotides. 5.6.1 Formulations 5.6.2 Regulations.	15

B604P Biochemistry-II Practical

1. Introduction to Carbohydrates.
2. To perform chemical test of a given carbohydrate sample.
3. To find out % w/v of glucose by Benedict's quantitative method.
4. To find out % w/v glucose by Cole's ferricyanide – Methylene Blue method.
5. To find out blood glucose by Folin-Wu method.
6. Introduction to protein and its test for identification.
7. To identify the given unknown protein sample.
8. To study the biochemistry of food stuffs.
9. To find out % w/v of Ascorbic acid (Vitamin C) in the given sample.
10. To perform separation of amino acids by two dimensional paper
11. To perform experiments of Chromatography.
12. Isolation of RNA from yeast.
13. Determination of glucose by means of the enzyme glucose oxidase.
14. To study the Folin-Lowry method for protein assay.
15. To study Poly acrylamide – gel electrophoresis.
16. To study SDS – gel electrophoresis.
17. To perform estimation of serum phosphorous in the given sample.

BOOKS RECOMMENDED:

1. Dr. U. Satyanarayana, Biochemistry, 2nd edition, Books and allied (P) Ltd., 2004.
2. P.C. Champe, R.A. Harvey, Biochemistry, 2nd edition, Lippincott – Raven publishers, 1994.
3. R. K. Murray, D.K. Granner, P.A. Mayes, V.W. Rodwell, Harper's Illustrated Biochemistry, 26th edition, McGraw Hill Publishers, 2003.
4. White, Philip Handler, E.L. Smith, R.L. Hill, I.R. Lehman, Principles of Biochemistry, 6th edition, Tata McGraw Hill Publishing Company Ltd., 2004.
5. R.C. Gupta, S. Bhargava, Practical Biochemistry, 4th edition, CBS Publishers & Distributors, 2006.
6. D.T. Plummer, An Introduction to Practical Biochemistry, 3rd edition, Tata McGraw Hill Publishing Company Ltd., 1996.
7. S. K. Sawhney, Randhir Singh, Introductory Practical Biochemistry, 1st edition, Narosa Publishing House, 2000.
8. W. H. Elliott, D. C. Elliott, Biochemistry & Molecular Biology, 1st edition, Oxford University Press, 1997.
9. G. L. Zubay, W. W. Parson, D.E. Vance, Principles of Biochemistry, 1st edition, WCB publishers, 1995.
10. E.E. Conn and P.K. Stumpf, G. Bruening, R. H. Doi, Outlines of Biochemistry, 5th edition, John Wiley & Sons, New York, 1999.
11. J. Jayaraman, Laboratory Manual in Biochemistry, New Age International Publishers, 2000.
12. D. L. Nelson, M. M. Cox, Lehninger Principles of Biochemistry, 4th edition, W. H.
13. Freeman & Company, 2005.
14. R. H. Garrett, C. M. Grisham, Principles of Biochemistry with A Human Focus, 1st edition, Harcourt College Publishers, 2002.
15. M. Cohn, K.S. Roth, Biochemistry and Disease, 1st edition, William and Wilkins Co., Baltimore.
16. H. R. Horton, L. A. Moran, R. S. Ochs, J. D. Rawn, K. G. Scrimgeour, Principles of Biochemistry, 2nd edition, Prentice-Hall International Inc., 1996.
17. S. Ramakrishnan, K.G. Prasanan, R. Rajan, Textbook of Medical Biochemistry, Latest Edition, Orient Longman, Madras,
18. R. K. Switzer, L. F. Garrity, Experimental Biochemistry, 3rd edition, W. H. Freeman & Company, 1999.
19. A.M. Lesk, Introduction to Protein Science, 1st Indian edition, Oxford University Press, 2004.
20. F.K. Rodriguez, Carbohydrate Biochemistry, 1st edition, New Age International Publishers, 1997.
21. R. Montgomery, T. W. Conway, A. A. Spector, Biochemistry A Case-Oriented Approach, 5th edition, The C.V. Mosby Company, 1990.
22. T. D. Pollard, W. C. Earnshaw, Cell Biology, 1st edition, Elsevier Science (USA), 2002.
23. G. M. Cooper, R. E. Hausman, The Cell A Molecular Approach, 3rd edition, ASM Press Washington D.C., 2004.

SUBJECT **: Medicinal Chemistry-I**
SUBJECT CODE **: B605T and B605P**
RATIONALE **:** The basic chemistry learnt till previous semester is now getting extended to medicinal chemistry where the student learns the chemistry of complex drug molecules and how a chemical structure and alter the body functions.
COURSE OBJECTIVES **:**
To learn the structure, Structure activity relationship, physicochemical properties and therapeutic uses of drugs belonging to various therapeutic classes

LEARNING OUTCOMES:

1. Draw correct chemical structure of drugs
2. Give scientific name of drugs
3. Narrate physicochemical properties and Structure activity relationship.
4. Cary out synthesis of certain drugs.

PREREQUISITES: Knowledge of Pharmacology and Organic Chemistry

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS		EVALUATION SCHEME				TOTAL MARKS
							INTERNAL		EXTERNAL		
		T	P	TOTAL HRS	T	P	T	P	T	P	
B605T & B605P	Medicinal Chemistry-I	4	3	7	3	3	20	20	80	80	200

CONTENTS:

1	**Basic principles of Medicinal Chemistry** Physico-chemical aspects (Optical, geometric, and bioisosterism) of drug molecules and biological action, Drug-receptor interaction including transduction mechanisms Principles of Drug Design (Theoretical Aspects): Traditional analog (QSAR) and mechanism based approaches (Introduction to graph theory, applications of quantum mechanics, Computer Aided Drug Designing (CADD) and molecular modeling.	30
2	**Drugs acting on Cardiovascular System** Synthetic procedures of selected drugs, modes of action, uses, structure activity relationship including physicochemical properties of the following classes of drugs: Diuretics, Cardiovascular drugs (antihypertensive, antianginal, antihyperlipidemic, cardiotonic etc.) anticoagulant and antiplatelet drugs	35
3	**Drugs acting on Autocoids** Synthetic procedures of selected drugs, modes of action, uses, structure activity relationship including physicochemical properties of the following classes of drugs: Autocoids (Antihistamines, Analgesic, antipyretics, anti-inflammatory (Non-steroidal) agents), Anti-ulcer drugs.	20
4	**Drug metabolism and concept of prodrug.**	15

B605P Medicinal Chemistry-I Practical

1. Introduction to separation and Identification of organic binary mixtures and importance of solubility in separation of mixture.

2-10. To separate and identify the nature of the organic binary mixture.

11. Synthesis of Aspirin from salicylic acid.
12. To study absorption of drug from GIT.
13. Synthesis of benzocaine.
14. Measurement of partition coefficient of salicylic acid in various solvent at different pH.
15. Synthesis of benzil from benzoin.
16. Synthesis of benzilic acid from benzil.

BOOKS RECOMMENDED:

1. Block, J. and Beale, J. M. Eds., Wilson and Giswold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams & Wilkins, Philadelphia, 2004
2. Lemke, L. T., Williams, D. A., Victoria F Roche, V. F. Principles of Medicinal Chemistry, Lippincott Williams & Wilkins, Philadelphia, 2007.
3. Furniss, B.S. Hannaford, A.J., Smith, P.W.G., Tatchell, A.R., Vogel's Textbook of Practical Organic Chemistry, Pearson Education (ELBS/Longman group), London, 1989.
4. Mann, F. G. & Saunder, B. C., Introduction to Practical Organic Chemistry, 1st Edition, Longmans, Green, London, 1941.
5. Shriner, R. L., Hermann, C. K. F., Morrill, T. C., The Systematic Identification of Organic Compounds, John Wiley & Sons, USA, 2003.
6. Thomas, G., Fundamentals of Medicinal Chemistry, 1st Edition, John Wiley & Sons, 2003.
7. Abraham, D. J., Ed., Burger's Medicinal Chemistry and Drug Discovery, Vol. 1-6, 6th Edition, John Wiley & Sons, New Jersey, 2003. Lednicer, D., Strategies for Organic Drug Synthesis & Design, John Wiley & Sons, USA, 1998.
8. Kar, A., Medicinal Chemistry, New Age International Publishers, New Delhi, 2007.
9. Ladu, B. N., Mandel H.G. & E. L.Way, Fundamentals of Drug Metabolism & Disposition,William & Wilkins Co., Baltimore.
10. Finar, I. L., Organic Chemistry, Vol. I & II, 6th Edition, Pearson Education (ELBS/Longman group), London, 2004.
11. Nogradey, T., Medicinal Chemistry: A Molecular and Biochemical Approach, Oxford University Press, New York, Oxford, 2005.
12. Silverstein, R. M., Basseler, G. C., Morrill, T.C., Spectrometric Identification of Organic Compounds, John Wiely & Sons, USA, 1967.
13. Kemp, W., Organic Spectroscopy, 3rd Edition, W.H. Freeman & Company/ELBS, London, 1991.
14. Taylor, J. B and Triggle, D. J., Comprehensive Medicinal Chemistry II, Vol. 1-8, Quantitative Drug Design, Elsevier Ltd., 2007
15. Martin, Y. C. Quantitative Drug Design- A Critical Introduction (Medicinal Research Monograph, Vol. 8) Marcel Dekker Inc., New York, 1978.
16. Lednicer, D. Strategies for Organic Drug Synthesis & Design, Vol 1-6, John Wiley & Sons, USA, 2002.
17. Jurs, P. C. Computer Software Application in Chemistry, 2nd Edition, John Wiley & Sons, New York, 1996.

SUBJECT : Elective
SUBJECT CODE : B606 T

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		T	P	T	P	
B606T	Elective	3	-	3	2	20	--	80	--	100

LIST OF SUBJECTS FOR SELECTION

SPECIALIZATION	SUBJECT CODES:	SUBJECTS
A. Pharmacology	606T-A1	Preclinical Toxicology
	606T-A2	Good Clinical Practice in Clinical Research
B. Pharmaceutical Chemistry	606T-B1	Validation in Pharmacy
	606T-B2	Advanced Organic Chemistry
C. Pharmaceutics & Pharmaceutical Technology	606T-C1	Stability Study of Pharmaceuticals
	606T-C2	Cosmetic Technology
D. Pharmacognosy	606T-D1	Standardization of crude drugs and their herbal formulations
	606T-D2	Phytochemical Screening of Herbal Drugs
E. Entrepreneurship Development	606T-E	Entrepreneurship Development

Pharmacology
606T-A1 Preclinical Toxicology

1	Single dose and Repeat dose toxicity studies, Schedule Y and OECD guidelines	15
2	Data Evaluation and Regulatory requirements	5
3	ICH guidelines for evaluating efficacy and safety of drugs	10
4	Reproductive toxicology, maternal and developmental toxicology	10
5	Mutagenicity– mechanisms, point mutation, individual chromosomes and whole genome mutations, somatic cell mutations,	10
6	Test systems: in vitro for gene mutations in bacteria, chromosome damage, gene mutation, in vivo micro nucleus tests in rodents, metaphase analysis.	10
7	Carcinogenicity- Principles of carcinogenicity, prechronic studies for dose setting, chronic study, trans placental carcinogenesis/tumor promotion, estimation of carcinogenicity of complex mixtures	10
8	Toxicokinetic methods	10
9	Preclinical toxicological requirements for biologicals and biotechnological products, safety analysis, problems specific to recombinant products- secondary pharmacology, antibodies, transmissions of viral infections, residual DNA etc.	20
	Reference: Recent amendments 1) Schedule Y, Drug and Cosmetic Act. (Latest Amendments) 2) OECD Guidelines. (Latest Amendments) 3) ICH Guidelines. (Latest Amendments)	

606T-A2 Good Clinical Practice in Clinical Research

Learning Objectives Understanding of GCPs requirements for Sponsors, Monitors, and Investigators. Significance of protocol and case report form development for all phases of clinical research. Information regarding in-field and in-house auditing. Investigational Review Boards (IRBs) and Informed Consent (IC) as required by regulations.	
Course Description The roles and responsibilities of key players, as well as regulatory requirements. The elective subject consists of lecture and exercises. Participants will be placed in several real life situations such as reviewing pre-study documents and informed consent forms for completeness and compliance; conducting drug accountability; reviewing case report forms for accuracy and adherence to protocol and performing source document verification. It is designed to provide the attendee with thorough knowledge of the following topics:	
How drugs are discovered and developed for marketing approval	10
The purpose for an IND and its composition, How INDs are filed, reviewed, approved & amended The IND reporting requirements, The purpose and composition of the NDA /ANDA, How NDAs /ANDA are filed, reviewed and approved	05
The four different study phases of clinical research	10
What constitutes Good Clinical Practices (GCP), **The principles of GCP,** The IRB/IEC's composition and role/responsibilities , The IRB study review & approval process	10
The role and responsibilities of the investigator & study site staff , The role and responsibility of the sponsor, The role and responsibilities of Monitor	15
The requirements for Informed Consent , How to review an Informed Consent form for compliance, The process for Informed Consent review & approval, The administration of subjects Informed Consent	05
ADR, SAE, Adverse Events - the types and reporting requirements	05
Essential Documents (Before, During, After study), Clinical Research study Protocol, ICF and CRF content and importance, How to review Case Report Forms and determine adherence to protocol	20
How to perform Source Document Verification, How to perform Drug Accountability & compliance ,	10

How to manage study supplies , How to detect and deal with Fraud , How to review study documents & determine compliance, Auditor and audit report	
Latest Amendments and Information in Clinical Research	10

REFERENCE:

1. ICH-GCP Guidelines (ICH, CDSCO etc.,)
2. Gupta S K, Basic Principles of Clinical Research & Methodology (2007). Jaypee Brothers Publication.
3. Woodin K E, Schneider J C, The CRA's Guide to monitoring Clinical Research (2003), Thomson Center Wath, Boston, USA.
4. Stephen Beny, Crossover trial in Clinical Research (2002), John Wiley Pub, USA
5. Gallin John, Principles and Practice of Clinical Research (2002), Academic Press pub, USA.

B. Pharmaceutical Chemistry
606T-B1 Validation in Pharmacy

1	Validation and calibration of equipments and instruments	15
2	Elements of Validation, benefits, types of process validation, validation protocol, process characterization, and optimization	15
3	Validation of process: Mixing, granulation, drying, compression, filtration, filling.	15
4	Validation of water supply systems (demineralized, distilled and water for injection)	15
5	Validation of sterilization methods and equipments: Dry heat sterilization, autoclaving, membrane filtration, gaseous sterilization and sterilization by radiation	15
6	Validation of Air-handling equipments and facilities in sterile-non-sterile areas, cleaning Validation	10
7	Validation of system and validation of analytical procedures (as per ICH guidelines)	15

BOOKS RECOMMENDED:

1. B.T Lofters, R. A. Nash, Pharmaceutical Process Validation, Marcel Dekker, lnc. New York, Volume 23, second edtition.
2. Carleton & Agalloco, (Marcel & Dekker), Validation of Asceptic Pharmaceutical Processes, second edition.
3. E. Joachim, Method Validation in Pharmaceutical Analysis, Wiley-Vch Verlag Gmbh & Co, Kga, First edition, 2005.

606T-B2 Advanced Organic Chemistry

1	Purification techniques Distillation, Chromatography, Crystallization	20
2	Advance synthetic approaches Microwave techniques, solvent free synthesis	30
3	Newer approaches for the synthesis of drug intermediates Hypnotics & Sedatives, Anti-inflammatory and Analgesic, Sulphonamide, Antiepileptic, Antifungal and Antibacterial	20
4	Green Chemistry	10
5	Reagents and Name reaction in organic chemistry Aldol Condensation, Baeyer-villiger oxidation, Benzoin condensation, Friedal craft reaction, Grignard Reaction, Canizzaro Reaction, Claisen Smith Reaction, Villsmeier- Haack Reaction, Skraup Quinoline Synthesis, Beckmann rearrangement	20

REFERENCES

1. March's advanced organic chemistry: reactions, mechanisms, and structure By Michael Smith, Michael B. Smith, Jerry March
2. Name reactions: a collection of detailed reaction mechanisms By Jie jack Li Journal of Organic Chemistry ACS Publication
3. Microwave methods in organic synthesis Mats Larhed, Kristofer Olofsson, Prasad Appukkuttan
4. Vogel's textbook of practical organic chemistry By Vogel
5. Annual Reports in Organic Synthesis By Philip M. Weintraub

C. Pharmaceutics and Pharmaceutical Technology

606T-C1 Stability Study of Pharmaceuticals

1	Introduction	**20**
	Objectives and scope of stability study. Stability study requirement at different stages of drug Development.	
2	Instability and products Types of instability in different dosage forms, Causative factors, Methods of stabilization.	**20**
3	Stability kinetics and Mathematical representations of data.	**10**
4	Assessment of stability Manifestations of different instabilities, Qualitative and Quantitative estimation of instability: Accelerated conditions of Temperature, Light and Moisture. Detailed study design, Stability protocols for all types of dosage forms (Including Biopharmaceuticals and Phytopharmaceuticals), test parameters, Result interpretations. Stability study with respect to different packaging materials.	**30**
5	Regulatory requirements ICH guidelines, WHO & USFDA requirements, State FDA requirements. Documentation.	**10**
6	Future requirements of stability testing.	**10**

BOOKS RECOMMENDED:

1. Lechman, Lieverman & Kenig, “the Theory & Practice of Industrial Pharmacy”, Third Edition, Varghese Publishing House.
2. M. E. Aulton, “Pharmaceutics”, ELBS Publication.
3. Edited by James T. Cartensen, C. T. Rhodes,”Drugs Stability Principles and Practices” Third Edition, Marcel Dekker Inc.

606T-C2 Cosmetic Technology

1.	Definition of cosmetics as per D&C Act, Differentiation between Drug and Cosmetics with examples.	05
2.	Structure of skin, hair and nail, skin barrier functions.	05
3.	Classification of cosmetic products and factors affecting choice of cosmetic products. As per body parts used: Cosmetics for Hair, Face, Hand and Body, Nail, Foot care, Oral care, etc. As per functions: Skin care products, Hair care products, Skin and body cleansers, Antiperspirants, Depilatories, Nail care products, Baby products, Decorative cosmetics etc.	10
4.	Skin disorders: Definition, causes and symptoms of Dermatitis, Acne, Psoriasis, Pigmentation, Tanning, Burning, Dry skin, Ageing etc.	10
5.	Principles of F & D, special excipients (Emollients, Viscosity modifiers, Preservatives, Emulsifiers, Suspending agents, etc.), characterization methods and manufacturing Equipments for: • Skin creams-Cold cream, Vanishing cream, Barrier cream, Hand and body lotions. • Skin Moisturizers, • Skin cleansers-Lotion, Face wash gels, Body wash gels, Scrubs. • Sunscreen products and Skin lighteners. • Antiaging products. • Baby care products. • Antiperspirants and Deodorants. • Color cosmetics - Foundation make up, Compact powder, Lipstick and Nail polish. • Dentifrices • Shampoo and conditioners. • Shaving preparations	45
6.	In vitro, *Ex-vivo* and *In-vivo* testing methods of cosmetic products. Various models used.	05
7.	Performance testing methods for Cleansers, Moisturizers, Sunscreens, Skin lightners.	05
8.	Marketing of cosmetics.	05
9.	Regulatory requirements of cosmetics.	05
10.	Cosmetic drug delivery systems.	05

BOOKS RECOMMENDED:

1.	Harry's Cosmeticology, 8th edition, by Martin M. Rieger, Kindle Publication.
2.	Lechman, Lieverman & Kenig, "The Theory & Practice of Industrial Pharmacy", Third Edition, Varghese Publishing House.
3.	Perfumes, Flowers and Essential Oil Industries S. B. Srivastava
4.	Manufacture of Perfumes, Cosmetics and Detergents. Giriraj Prasad.
5.	Poucher's Soaps Perfumery and Cosmetics Vol. I, II & III.
6.	Editated by Richard J. Hadgraft "Transdermal Drug Delivery", Second Edition, Marcel Dekker.
7.	Edited by Kenneth A Walters., "Dermatological and Transdermal formulations," Marcel Dekker. Inc.
8.	Z. D. Draelos, "Cosmetics in Dermatology", Second edition, Churchill Livingstone.
9.	Editated by N.J. Lowe, N. A. Shaath, M. A. Pathak, "Sunscreens: Development, Evaluation & Regulatory aspects" 2nd Edition, Marcel Dekker, Inc.
10.	Cosmetic and Drug Preservation: Principles and Practice, edited by Jon, J. Kabara
11.	Edited by Norman F. Estrin, "The cosmetic Industry: Scientific and Regualtory Foundations"
12.	Howard R. Moskowitz, "Cosmetic Product Testing: A modern Psychophysical Approach".
13.	Edited by P. Bore, "Cosmetic Analysis: Selective Methods and Techniques".
14.	Edited by James H. Whittam, "Cosmetic Safety: A Primer for Cosmetic Scientists".
15.	Morton Padar, "Oral Hygiene Products and Practice".
16.	Edited by Karl Laden and Carl B., "Felger Antiperspirants and Deodorants ".
17.	Edited by William C. Waggoner Clinical Safety and Efficacy Testing of Cosmetics".
18.	Edited by Robert L. Rietschel and Thomas S. Spencer, "Methods for Cutaneous Investigation".
19.	Edited by Eric Jungermann and Norman O. V. Sonntag, "Glycerin: a Key Cosmetic Ingredient".
20.	Donald S. Orth, "Handbook of Cosmetic Microbiology"
21.	Edited by Dennis Laba, "Rheological Properties of Cosmetics and Toiletries".
22.	Howard R. Moskowitz, "Consumer Testing and Evaluation of Personal Care Products".
23.	Edited by Jon J. Kabara and Donald S. Orth, "Preservative-Free and self-preserving cosmetics and Drugs: Principles and Practice".
23.	Alsner Peter, "Cosmeceuticals: Drugs v/s Cosmetics" Marcel Dekker Inc.

D. Pharmacognosy
606-D1 Standardization of crude drugs and their herbal formulations

1	What is a standardized herbal drug? Herbal Medicines as per WHO, Factors affecting standardization, WHO Guidelines for Herbal Industry	25
2	Reasons for the difficulty in developing quality control standards for herbal drugs, The general protocol for the standardization, Production of herbal drugs, Quality control of raw (plant) material, Quality control of finished product	25
3	Validation of the manufacturing process and in-process quality control, Modern analytical tools in quality control of herbal drugs	25
4	Current good manufacturing practices for herbal medicines (schedule T), Standardization of modern herbal formulations.	25

606-D2 Phytochemical Screening of Herbal Drugs

a)	General methods of extraction, isolation and purification of plant constituents of following class alkaloids, glycosides, flavonoids, tannins, volatile oils, fixed oils, etc., Classification of medicinally active constituents and phytochemical study including general chemical tests to identify plant constituents such as alkaloids, glycosides, flavonoids, tannins, volatile oils, fixed oils, steroids.	25
b)	Review of various Phytoconstituents used as prototypes for therapeutically active constituents.	25
c)	What is herbal marker, Selection of herbal marker compound, Classification of herbal marker compound, Assay for active constituents/markers, how do active compounds differ from marker compounds, Analysis of marker compounds, Application of herbal marker compound.	25
d)	Application of chromatographic techniques: Column chromatography, paper chromatography, TLC, HPTLC, GLC, HPLC and DCCC in the isolation and purification of Phytopharmaceuticals.	25

REFERENCES:

1. Quality Control Methods for Medicinal Plant Materials, WHO
2. Pulok Mukherjee, Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals
3. Paridhavi, Herbal Drug Technology,
4. Wagner, Plant Drug Analysis, Springer Verlag Publication.
5. E. Stahl, Thin layer chromatography
6. Ayurvedic Pharmacopoeia of India
7. Ayurvedic Formulary of India (Formulations)
8. Herbal Pharmacopeia 1-2 (IDMA)
9. Quality control of Indian Medicinal Plants by ICMR

606T-E Entrepreneurship Development

Course Overview:
The primary objective of this elective subject is to provide an understanding of the Worldviews and life-worlds of entrepreneurs. Develop you into a curious, confident, Competent, and creative entrepreneurial thinker. To encourage you to explore concepts Related to a problem from a multi-disciplinary perspective and inculcate the attitudes, Values and psychological mindsets and strategic practices of entrepreneurial actors.
1 Conceptual Frame Work **20**
Evolution of the concept of entrepreneur, Definition of entrepreneur, Entrepreneur and Enterprise, Entrepreneur and managers, Qualities of entrepreneur, Types of Entrepreneurs, Functions of entrepreneur, meaning of entrepreneurial culture Barriers to Entrepreneurship Socio-economics origins of entrepreneurship Behavioral patterns Affecting entrepreneurship Entrepreneurial structures Nature and characteristics of Entrepreneurship Intrapreneurs – Conceptual model of entrepreneurship. Entrepreneurship culture.
2 Idea generation **20**
Theories of Creativity, Creative Characteristics, Different Kinds of Intelligence, Left Brain and Right Brain Issues, The Creative Process Brainstorming, Mind mapping and its Role in the Creative Process, Being Professionally Creative, Creativity on Demand or by Necessity, Convergence and Divergence, Creating Value, Personal Creativity, Organizational Creativity, Strategies for Leading and Working with Groups to Maximize Creative Output; Management Styles and Managing Creative People. Idea generation, processing and Selection.
3 Strategic and financial management: **15**
Basic ideas on meaning, sources and importance of risk management, venture capital, fixed capital and working capital. Basic awareness of financial services. Alternative growth Strategies-meaning and importance. Basic understanding of various growth strategies.
4 Motivation and communication: **10**
Internal and external motivating factors to entrepreneur. Role of industrial fairs. 7 C's of Communication. Basic format for letter and e-mail writing.
5 Project management **15**
Meaning of project, Projects classification, Project identification, Internal and External Constraints, Project objectives, Techno-economic survey, Project life cycle, Project Formulation and significance, Elements of project formulation, Project selection, Project design, Basic concepts of in network analysis, CPM, PERT.
6 Business plan: **20**
Meaning, importance-elements in business plan-Feasibility reports to start large, small and service organizations-essential for report writing.

REFERENCE BOOKS:

1. Entrepreneurial Development by C.B Gupta & N.P Sr Entrepreneurship Development by CB Gupta and P Srinivasan, Sultan Chand and Sons, New Delhi
2. Desai, V. (1999), Dynamics of Entrepreneurial Development and Management, 3rd ed., Himalaya Publishing House, Mumbai.
3. Balu V. Entrepreneurial Development, Venkateswaran Publication, Chennai - 4.
4. A Handbook of Entrepreneurship, Edited by BS Rathore and Dr. J S Saini; Aapga Publications, Panchkula (Haryana)