Programme Structure, Syllabi, Outline of Tests, and Course of Reading under the Faculty of Sciences – B. Pharmacy (4 Year)

						nacy (4 Year)		
S.		ar 1		ar 2		ar 3		ear 4
No.	Sem 1 Human	Sem 2 Human	Sem 3 Pharmace	Sem 4 Pharmaceu	Sem 5	Sem 6	Sem 7 Instrume	Sem 8
1	Anatomy and Physiology I-Theory (BP 101 T) [CU: 4, L- 3, T-1]	Anatomy and Physiology II-Theory (BP 201 T) [CU: 4, L- 3, T-1]	utical Organic Chemistry II-Theory (BP 301 T) [CU: 4, L-3, T-1]	tical Organic Chemistry III-Theory (BP 401 T) [CU: 4, L-3, T-1]	Medicinal Chemistry II – Theory (BP 501 T) [CU: 4, L- 3, T-1]	Medicinal Chemistry III – Theory (BP 601 T) [CU: 4, L-3, T-1]	Methods of Analysis - Theory (BP 701 T) [CU: 4, L-3, T-1]	Biostatistics and Research Methodology (BP 801 T) [CU: 4, L-3, T-1]
2	Pharmaceu tical Analysis I - Theory (BP 102 T) [CU: 4, L- 3, T-1]	Pharmaceut ical Organic Chemistry I - Theory (BP 202 T) [CU: 4, L- 3, T-1]	Physical Pharmace utics I— Theory (BP 302 T) [CU: 4, L-3, T-1]	Medicinal Chemistry I – Theory (BP 402 T) [CU: 4, L- 3, T-1]	Industrial Pharmacy I– Theory (BP 502 T) [CU: 4, L- 3, T-1]	Pharmacolo gy III – Theory (BP 602 T) [CU: 4, L-3, T-1]	Industria 1 Pharmac y II – Theory (BP 702 T) [CU: 4, L-3, T-1]	Social and Preventive Pharmacy (BP 802 T) [CU: 4, L-3, T-1]
3	Pharmaceu tics I – Theory (BP 103 T) [CU: 4, L- 3, T-1]	Biochemist ry – Theory (BP 203 T) [CU: 4, L- 3, T-1]	Pharmace utical Microbiol ogy – Theory (BP 303 T) [CU: 4, L-3, T-1]	Physical Pharmaceu tics II – Theory (BP 403 T) [CU: 4, L- 3, T-1]	Pharmacol ogy II – Theory (BP 503 T) [CU: 4, L- 3, T-1]	Herbal Drug Technology - Theory (BP 603 T) [CU: 4, L-3, T-1]	Pharmac y Practice - Theory (BP 703 T) [CU: 4, L-3, T-1]	Pharma Marketing Management (BP 803 ET) [CU: 4, L-3, T-1]
4	Pharmaceu tical Inorganic Chemistry Theory (BP 104 T) [CU: 4, L-3, T-1]	Pathophysi ology – Theory (BP 204 T) [CU: 4, L- 3, T-1]	Pharmace utical Engineerin g – Theory (BP 304 T) [CU: 4, L-3, T-1]	Pharmacol ogy I – Theory (BP 404 T) [CU: 4, L- 3, T-1]	Pharmacog nosy II – Theory (BP 504 T) [CU: 4, L- 3, T-1]	Biopharmac eutics and Pharmacoki netics – Theory (BP 604 T) [CU: 4, L-3, T-1]	Novel Drug Delivery System - Theory (BP 704 T) [CU: 4, L-3, T-1]	Pharmaceutic al Regulatory Science (BP 804 ET) [CU: 4, L-3, T-1]
5	Communic ation skills – Theory (BP 105 T) [CU: 2, L- 2]	Computer Application s in Pharmacy – Theory (BP 205 T) [CU: 3, L- 3]	Pharmace utical Organic Chemistry II- Practical (BP 305 P) [CU: 2, P-4]	Pharmacog nosy and Phytochem istry I— Theory (BP 405 T) [CU: 4, L- 3, T-1]	Pharmaceu tical Jurisprude nce – Theory (BP 505 T) [CU: 4, L- 3, T-1]	Pharmaceuti cal Biotechnolo gy – Theory (BP 605 T) [CU: 4, L-3, T-1]	Instrume ntal Methods of Analysis - Practical (BP 705 P) [CU: 2, P-4]	Pharmacovig ilance (BP 805 ET) [CU: 4, L-3, T-1]
6	Remedial Biology (BP 106 RBT)/ Remedial Mathemati cs - Theory (BP 106 RMT) [CU: 2, L- 2]	Environme ntal sciences – Theory (BP 206 T) [CU: 3, L- 3]	Physical Pharmace utics I— Practical (BP 306 P) [CU: 2, P-4]	Medicinal Chemistry I – Practical (BP 406 P) [CU: 2, P- 4]	Industrial PharmacyI – Practical (BP 506 P) [CU: 2, P- 4]	Quality Assurance – Theory (BP 606 T) [CU: 4, L-3, T-1]	Practice School (BP 706 PS) [CU: 6, P-12]	Quality Control and Standardizati on of Herbals (BP 806 ET) [CU: 4, L-3, T-1]
7	Human Anatomy	Human Anatomy	Pharmace utical	Physical Pharmaceu	Pharmacol ogy II –	Medicinal Chemistry		Computer Aided Drug

dit 21/25/36 25 24 26 26 36 24 Total Programme Credits							209 / 211 / 212	
Cre	27/29/30	29	24	28	26	30	24	(BP 813 PW) [CU: 6, P-12]
12	Remedial Biology- Practical (BP 112 RBP) [CU: 1, P-2]							Dietary Supplements and Nutraceutical s (BP 812 ET) [CU: 4, L-3, T-1] Project Work
11	Communic ation skills – Practical (BP 111 P) [CU: 1, P- 2]							Advanced Instrumentati on Techniques (BP 811 ET) [CU: 4, L-3, T-1]
10	Pharmaceu tical Inorganic Chemistry Practical (BP 110 P) [CU: 2, P-4]	Computer Application s in Pharmacy – Practical (BP 210 P) [CU: 1, P- 2]						Experimental Pharmacolog y (BP 810 ET) [CU: 4, L-3, T-1]
9	Pharmaceu tics I – Practical (BP 109 P) [CU: 2, P- 4]	Biochemist ry – Practical (BP 209 P) [CU: 2, P- 4]		Pharmacog nosy and Phytochem istry I— Practical (BP 409 P) [CU: 2, P- 4]		Herbal Drug Technology - Practical (BP 609 P) [CU: 2, P-4]		Cosmetic Science (BP 809 ET) [CU: 4, L-3, T-1]
8	Pharmaceu tical Analysis I - Practical (BP 108 P) [CU: 2, P- 4]	Pharmaceut ical Organic Chemistry I – Practical (BP 208 P) [CU: 2, P- 4]	Pharmace utical Engineerin g - Practical (BP 308 P) [CU: 2, P-4]	Pharmacol ogy I – Practical (BP 408 P) [CU: 2, P- 4]	Pharmacog nosy and Phytochem istry II – Practical (BP 508 P) [CU: 2, P- 4]	Pharmacolo gy III – Practical (BP 608 P) [CU: 2, P-4]		Cell and Molecular Biology (BP 808 ET) [CU: 4, L-3, T-1]
	and Physiology I- Practical (BP 107 P) [CU: 2, P- 4]	and Physiology II-Practical (BP 207 P) [CU: 2, P- 4]	Microbiol ogy – Practical (BP 307 P) [CU: 2, P-4]	tics II – Practical (BP 407 P) [CU: 2, P- 4]	Practical (BP 507 P) [CU: 2, P- 4]	III – Practical (BP 607 P) [CU: 2, P-4]		Design (BP 807 ET) [CU: 4, L-3, T-1]

Table-I: Course of study for semester I

Course code	Name of the course	No. of	Tuto	Credit
Course code	ivallie of the course	hours	rial	points
	Human Anatomyand Physiology I—	3	1	4
	Theory	J	_	_
	Pharmaceutical Analysis I – Theory		3	1
	Pharmaceutics I— Theory		4 3	1
	Pharmaceutical Inorganic Chemistry— Theory	_	_	4
	Communication skills – Theory	3	1	4
	Remedial Biology/	2	-	2
	Remedial Mathematics – Theory	2		2
	Human Anatomyand Physiology –		_	
	Practical	4		2
	Pharmaceutical Analysis I – Practical	4	_	
	Pharmaceutics I – Practical		4	-
	Pharmaceutical Inorganic Chemistry–		2 4	-
	Practical			2
	Communication skills – Practical	4		,
		4	_	2
		2	-	1
	Remedial Biology – Practical	2	_	11
	Total	32/34 ^{\$} /36	4	27/29 ^{\$} /30

Total 32/34^{\$}/36 4 27/29^{\$}/

^{*}Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearingfor RemedialBiology(RB)course.

^{\$}Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC andappearing for Remedial Mathematics(RM)course.

Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit points
	Human Anatomyand Physiology II – Theory	3 3 3 3	1	4 4
	Pharmaceutical Organic Chemistry I – Theory	3 3 4 4	1	4 4
	Biochemistry– Theory	4 2 32	1	3 3
	Pathophysiology– Theory		1	2 2
	Computer Applications in Pharmacy – Theory		-	2 1
	Environmental sciences – Theory		-	29
	Human Anatomyand Physiology II – Practical		-	
	Pharmaceutical Organic Chemistryl- Practical		-	
	Biochemistry– Practical		-	
	Computer Applications in Pharmacy– Practical		-	
	Total		4	

Table-III: Course of study for semester III

Course	Name of the course	Name of the course	Tutorial	Credit
code	Name of the course	hours	Tutoriai	points
	Pharmaceutical Organic Chemistry II – Theory	3333	1	4444
	Physical Pharmaceutics I – Theory	4444	1	2222
	Pharmaceutical Microbiology– Theory	28	1	24
	Pharmaceutical Engineering – Theory		1	
	Pharmaceutical Organic Chemistry II – Practical		-	
	Physical Pharmaceutics I – Practical		-	
	Pharmaceutical Microbiology – Practical		-	
	Pharmaceutical Engineering —Practical		-	
	Total		4	

Table-IV: Course of study for semester IV

Course	Name of the course	No. of	Tutorial	Credit
code	Name of the course		Tutoriai	points
	Pharmaceutical Organic Chemistry III– Theory	3 3 3 3	1	4 4
	Medicinal Chemistry I – Theory	3 4 4 4	1	4 4
	Physical Pharmaceutics II – Theory	4 31	1	4 2
	Pharmacology I – Theory		1	2 2
	Pharmacognosy and Phytochemistry I– Theory		1	2
	Medicinal Chemistry I – Practical		-	28
	Physical Pharmaceutics II – Practical			
	Pharmacology I – Practical		-	
	Pharmacognosyand Phytochemistry I – Practical		-	
	Total		5	

Table-V: Course of study for semester \boldsymbol{V}

Course	Name of the course	No. of	Tutorial	Credit
code	Nume of the course	hours	ratoriai	points
	Medicinal Chemistry II – Theory	3 3 3 3	1	4
	Industrial Pharmacy I– Theory	3 4 4 4	1	4
	Pharmacology II – Theory		1	4
	Pharmacognosy and Phytochemistry II– Theory	27	1	4
	Pharmaceutical Jurisprudence – Theory		1	4
	Industrial Pharmacy I – Practical		-	2
	Pharmacology II – Practical		-	2
	Pharmacognosyand Phytochemistry II –		-	2
	Practical			
	Total		5	26

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
	Medicinal Chemistry III – Theory	3 3 3	1	4
	Pharmacology III – Theory	2	1	4
	Herbal Drug Technology – Theory		1	4
	Biopharmaceutics and Pharmacokinetics –	3	1	4
	Theory	3		4
	Pharmaceutical Biotechnology – Theory	4	1	4
	Quality Assurance –Theory	4	1	4
	Medicinal chemistry III – Practical	4	-	2
	Pharmacology III – Practical		-	2
	Herbal Drug Technology – Practical		-	2
	Tota	I 30	6	30

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
	Instrumental Methods of Analysis – Theory	3333	1	4 4
	Industrial Pharmacy II – Theory	4 12	1	4 4
	Pharmacy Practice – Theory	28	1	<mark>2</mark> 6
	Novel Drug Delivery System – Theory		1	24
	Instrumental Methods of Analysis – Practical		-	
	Practice School		-	
	Total		5	

Table-VIII: Course of study for semester VIII

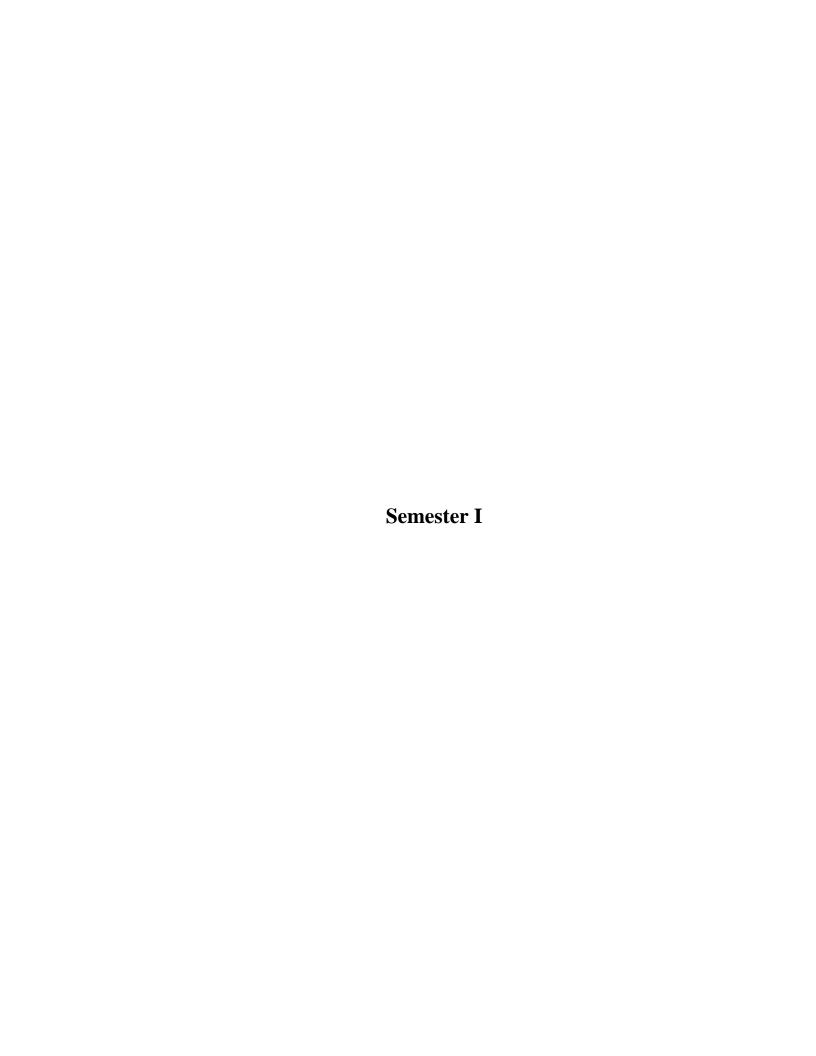
Course code	Name of the course	No. of hours	Tutorial	Credit points
	Biostatistics and Research Methodology	3 3	1	4
	Social and Preventive Pharmacy Pharma		1	4
	Marketing Management Pharmaceutical			
	Regulatory Science Pharmacovigilance	-		
	QualityControl and Standardization of			
	Herbals	3 + 3 =		
	Computer Aided Drug Design	6	1+1=2	4 + 4 =
	Cell and Molecular Biology	-	1+1=2	8
	Cosmetic Science-Theory			
	Experimental Pharmacology			
	Advanced Instrumentation Techniques			
	DietarySupplements and Nutraceuticals			
	Project Work	12		
	Total	24	-	6
			4	22

Table-IX: Semester wise credits distribution

Semester	Credit Points
I II III IV V	27/29 ^{\$} /30 [#]
VI	29 26 28 26
VII	26 24 22 01*
VIII	209/211 ^{\$} /212
Extracurricular/ Co curricular activities	#
Total credit points for the program	
*Thecredit points assigned for extracurricular and or	co-curricular activities shall be givenby the Principals
of the colleges and the same shall be submitted to the	e University. The criteria to acquire this credit point
shall be defined bythe colleges fromtime to time.	
^{\$} Applicable ONLY for the students studied Physics / C for Remedial Mathematics course.	hemistry / Botany / Zoology at HSC and appearing

^{*}Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for RemedialBiologycours





HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

- 1. Explain the gross morphology, structure and functions of various organs of the humanbody.
- 2. Describe the various homeostatic mechanisms and their imbalances.
- 3. Identifythe various tissues and organs of different systems of human body.
- 4. Perform the various experiments related to special senses and nervous system.
- 5. Appreciate coordinated working pattern of different organs of each system

Course Content:

Unit I 10 hours

• Introduction to human body

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

Cellular level of organization

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

• Tissue level of organization

Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

Unit II 10 hours

Integumentary system

Structure and functions of skin

• Skeletal system

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction,
neuromuscular junction

Joints

Structural and functional classification, types of joints movements and itsarticulation

Unit III 10 hours

Body fluids and blood

• Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.

• Lymphatic system

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

Unit IV 08 hours

Peripheral nervous system:

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

• Special senses

Structure and functions of eye, ear, nose and tongue and their disorders.

Unit V 07 hours

• Cardiovascular system

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

- 1. Studyof compound microscope.
- 2. Microscopic studyof epithelial and connective tissue
- 3. Microscopic studyof muscular and nervous tissue
- 4. Identification of axial bones
- 5. Identification of appendicular bones
- 6. Introduction to hemocytometry.
- 7. Enumeration of white blood cell (WBC) count
- 8. Enumeration of total red blood corpuscles (RBC) count
- 9. Determination of bleeding time
- 10. Determination of clotting time
- 11. Estimation of hemoglobin content
- 12. Determination of blood group.
- 13. Determination of erythrocyte sedimentation rate (ESR).
- 14. Determination of heart rate and pulse rate.
- 15. Recording of blood pressure.

Recommended Books (Latest Editions)

- 1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
- 2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
- 3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MIUSA
- 4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
- 5. Principles of Anatomy and PhysiologybyTortora Grabowski. Palmetto, GA, U.S.A.

- 6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
- 7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
- 8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

- 1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
- 2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
- 3. Human Physiology(vol 1 and 2) byDr. C.C. Chatterrje ,Academic Publishers Kolkata

PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives: Upon completion of the course student shall be able to

- understand the principles of volumetric and electro chemical analysis
- carryout various volumetric and electrochemical titrations
- develop analytical skills

Course Content:

UNIT-I 10 Hours

- (a) Pharmaceutical analysis Definition and scope
 - i) Different techniques of analysis
 - ii) Methods of expressing concentration
 - iii) Primaryand secondary standards.
 - iv) Preparation and standardization of various molar and normal solutions-Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate
- **(b) Errors:** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures
- (c) Pharmacopoeia, Sources of impurities in medicinal agents, limit tests.

UNIT-II 10 Hours

- Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, andveryweak acids and bases, neutralization curves
- **Non aqueous titration**: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT-III 10 Hours

- **Precipitation titrations**: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.
- **Complexometric titration**: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.
- **Gravimetry**: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.
- BasicPrinciples, methods and application of diazotisation titration.

UNIT-IV 08 Hours

Redox titrations

- (a) Concepts of oxidation and reduction
- (b) Types of redox titrations (Principles and applications)

 imetry, Jodimetry, Jodometry, Bromatometry, Dichrometry, Titration withnotassi

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration withpotassium iodate

UNIT-V 07 Hours

- Electrochemical methods of analysis
 - **Conductometry** Introduction, Conductivity cell, Conductometric titrations, applications.
 - Potentiometry Electrochemical cell, construction and workingof reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods todetermineendpointof potentiometric titration and applications.
 - Polarography Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Limit Test of the following

- (1) Chloride
- (2) Sulphate
- (3) Iron
- (4) Arsenic

II Preparation and standardization of

- (1) Sodium hydroxide
- (2) Sulphuric acid
- (3) Sodium thiosulfate
- (4) Potassium permanganate
- (5) Ceric ammonium sulphate

III Assay of the following compounds along with Standardization of Titrant

- (1) Ammonium chloride byacid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride byprecipitation titration

IV Determination of Normality by electro-analytical methods

- (1) Conductometric titration of strong acid against strong base
- (2) Conductometric titration of strong acid and weak acid against strong base
- (3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

- 1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
- 2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
- 3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
- 4. Bentleyand Driver's Textbook of Pharmaceutical Chemistry
- 5. John H. Kennedy, Analytical chemistryprinciples
- 6. Indian Pharmacopoeia.

PHARMACEUTICS- I (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatorypharmacywith arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the historyof profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional wayof handling the prescription
- Preparation of various conventional dosage forms

Course Content:

UNIT – I 10 Hours

- Historical background and development of profession of pharmacy: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, bodyweight and bodysurface area.

UNIT – II 10 Hours

- Pharmaceutical calculations: Weights and measures Imperial & Metric system,
 Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- Powders: Definition, classification, advantages and disadvantages, Simple & compound powders official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- Liquid dosage forms: Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III 08 Hours

• Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

- Biphasic liquids:
- **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV 08 Hours

- **Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V 07 Hours

 Semisolid dosage forms: Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

PHARMACEUTICSI (Practical)

3 Hours / week		

1. Syrups

- a) Syrup IP'66
- b) Compound syrup of Ferrous Phosphate BPC'68
- 2. Elixirs
- a) Piperazine citrate elixir b)

Paracetamol pediatric elixir

- 3.Linctus
- a) Terpin Hydrate Linctus IP'66
- b) Iodine Throat Paint (Mandles Paint)
- 4. Solutions
- a) Strong solution of ammonium acetate
- b) Cresol with soap solution
- c) Lugol's solution
- 5. Suspensions

- a) Calamine lotion
- b) Magnesium Hydroxide mixture
 - c) Aluminimum Hydroxide gel

- **6. Emulsions** a) Turpentine Liniment
 - b) Liquid paraffin emulsion
- 7. Powders and Granules

a) ORS powder (WHO) b)

Effervescent granules

c)Dusting powder

d)Divded powders

8. Suppositories

- a) Glycero gelatin suppository
 - b) Coca butter suppository
 - c) Zinc Oxide suppository

- 8. Semisolids
- a) Sulphur ointment
- b) Non staining-iodine ointment with methyl salicylate
- c) Carbopal gel
- 9. Gargles and Mouthwashes
 - a) lodine gargle
 - b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

- 1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
- 2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
- 3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
 - 4. Indianpharmacopoeia.
 - 5. Britishpharmacopoeia.
- 6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
- 7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
- 8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
- 9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
- 10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
- 11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
- 12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- •know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- •understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content:

UNIT I 10 Hours

• Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

General methods of preparation, assay for the compounds superscripted with **asterisk** (*), properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II 10 Hours

- Acids, Bases and Buffers: Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- Major extra and intracellular electrolytes: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- Dental products: Dentifrices, role offluoride in thetreatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III 10 Hours

Gastrointestinal agents

Acidifiers: Ammonium chloride* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium

Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boricacid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV 08 Hours

Miscellaneous compounds

Expectorants: Potassium iodide, Ammonium chloride*.

Emetics: Copper sulphate*, Sodium potassium tartarate

Haematinics: Ferrous sulphate*, Ferrous gluconate

Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium

nitrite333

Astringents: Zinc Sulphate, Potash Alum

UNIT V 07 Hours

• Radiopharmaceuticals: Radio activity, Measurement of radioactivity, Properties of α , β , γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I¹³¹, Storage conditions, precautions & pharmaceutical application of radioactive substances.

PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I Limit tests for following ions

Limit test for Chlorides and Sulphates Modified limit test for Chlorides and SulphatesLimit test for

Iron

Limit test for Heavymetals

Limit test for Lead

Limit test for Arsenic

| Identification test

Magnesiumhydroxide

Ferrous sulphate

Sodium bicarbonate

Calcium gluconate

Copper sulphate

III Test for purity

Swelling power of Bentonite

Neutralizing capacity of aluminum hydroxide gel

Determination of potassium iodate and iodine in potassium

IodideIV Preparation of inorganic pharmaceuticals

Boric acid Potash alum Ferrous sulphate

Recommended Books (Latest Editions)

- 1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical ChemistryVol I & II, Stahlone Press of University of London, 4th edition.
- 2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
- 3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
- 4. M.LSchroff, Inorganic Pharmaceutical Chemistry
- 5. Bentleyand Driver's Textbook of Pharmaceutical Chemistry
- 6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
- 7. Indian Pharmacopoeia

COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

- 1. Understand the behavioral needs for a Pharmacist to function effectively in theareas of pharmaceutical operation
- 2. Communicate effectively (Verbal and Non Verbal)
- 3. Effectivelymanage the team as a team player
- 4. Develop interview skills
- 5. Develop Leadership qualities and essentials

Course content:

UNIT – I 07 Hours

- Communication Skills: Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective Past Experiences, Prejudices, Feelings, Environment

UNIT – II 07 Hours

- Elements of Communication: Introduction, Face to Face Communication Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- Communication Styles: Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT – III 07 Hours

• Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations

- Effective Written Communication: Introduction, When and When Not to Use Written Communication Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV 05 Hours

- Interview Skills: Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V 04 Hours

• **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

COMMUNICATION SKILLS (Practical)

2 Hours / week

Thefollowing learning modules are to be conducted using wordsworth® English languagelab software

Basic communication covering the following topics **Meeting People Asking Questions Making Friends** What did you do? Do's and Dont's **Pronunciations covering the following topics** Pronunciation (Consonant Sounds) **Pronunciation and Nouns** Pronunciation (Vowel Sounds) **Advanced Learning** Listening Comprehension / Direct and Indirect Speech Figures of Speech EffectiveCommunication Writing Skills **Effective Writing Interview** Handling SkillsE-Mail etiquette Presentation

Skills

Recommended Books: (Latest Edition)

- 1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
- 2. Communication skills, SanjayKumar, Pushpalata, 1stEdition, Oxford Press, 2011
- 3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
- 4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
- 5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala SwamyRamesh, 5thEdition, Pearson, 2013
- 6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
- 7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals PHI, 2011
- 8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
- 9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
- 10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
- 11. Effective communication, John Adair, 4th Edition, Pan Mac Millan, 2009
- 12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

REMEDIAL BIOLOGY (Theory)

30 Hours

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives: Upon completion of the course, the student shall be able to

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiologyof plant
- know understand the basic components of anatomy & physiologyanimal withspecial reference to human

UNIT I 07 Hours

Living world:

- Definition and characters of living organisms
- Diversityin the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

- Morphology of different parts of flowering plants Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomyof Root, stem, leaf of monocotyledons & Dicotylidones.

UNIT II 07 Hours

Body fluids and circulation

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatorysystem
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

Digestion and Absorption

- Human alimentarycanal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

Breathing and respiration

- Human respiratorysystem
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratoryvolumes

UNIT III 07 Hours

Excretory products and their elimination

- Modes of excretion
- Human excretorysystem- structure and function
- Urine formation
 - Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted byendocrine glands

Human reproduction

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

UNIT IV 05 Hours

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

• Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affectingphotosynthesis.

UNIT V 04 Hours

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

 Phases and rate of plant growth, Condition of growth, Introduction to plant growthregulators

Cell - The unit of life

• Structure and functions of cell and cell organelles. Cell division

Tissues

• Definition, types of tissues, location and functions.

Text Books

- a. Text book of Biology byS. B. Gokhale
- b. A Text book of Biology byDr. Thulajappa and Dr. Seetaram.

Reference Books

- a. A Text book of Biology by B.V. Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d.Outlines of Zoologyby M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
- e. A manual for pharmaceutical biologypractical by S.B. Gokhale and C. K. Kokate

REMEDIAL BIOLOGY (Practical)

30 Hours

- 1. Introduction to experiments in biology
 - a) Studyof Microscope
 - b) Section cutting techniques
 - c) Mounting and staining
 - d) Permanent slide preparation
- 2. Studyof cell and its inclusions
- 3. Studyof Stem, Root, Leaf, seed, fruit, flower and their modifications
- 4. Detailed studyof frog byusing computer models
- 5. Microscopic study and identification of tissues pertinent to Stem, RootLeaf, seed, fruit and flower
- 6. Identification of bones
- 7. Determination of blood group
- 8. Determination of blood pressure
- 9. Determination of tidal volume

Reference Books

- 1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
- 2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
- 3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

REMEDIAL MATHEMATICS (Theory)

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

Objectives: Upon completion of the course the student shall be able to:-

- 1. Know the theory and their application in Pharmacy
- 2. Solve the different types of problems byapplying theory
- 3. Appreciate the important application of mathematics in Pharmacy

Course Content:

UNIT – I 06 Hours

• Partial fraction

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

Logarithms

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

• Function:

Real Valued function, Classification of real valued functions,

• Limits and continuity:

Introduction , Limit of a function, Definition of limit of a function (\in -

$$\delta$$
 definition), $\lim \frac{x^n - a^n}{n} = na^{n-1}$, $\lim \frac{\sin \theta}{n} = 1$,

$$x \rightarrow a$$
 X a $\theta \rightarrow 0$ θ

UNIT -II 06 Hours

• Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants , Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley—Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations

UNIT – III 06 Hours

• Calculus

Differentiation: Introductions, Derivative of a function, Derivative of aconstant, Derivative of a product of a constant and a function, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of $x^n w.r.tx$, where n is any rational number, Derivative of e^x , Derivative of $\log_e x$, Derivative of a^x , Derivative of trigonometric functions from first principles (without **Proof**), Successive Differentiation, Conditions for a function to be amaximum or a minimum at a point. Application

UNIT – IV 06 Hours

Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula,

Straight Line: Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line

Integration:

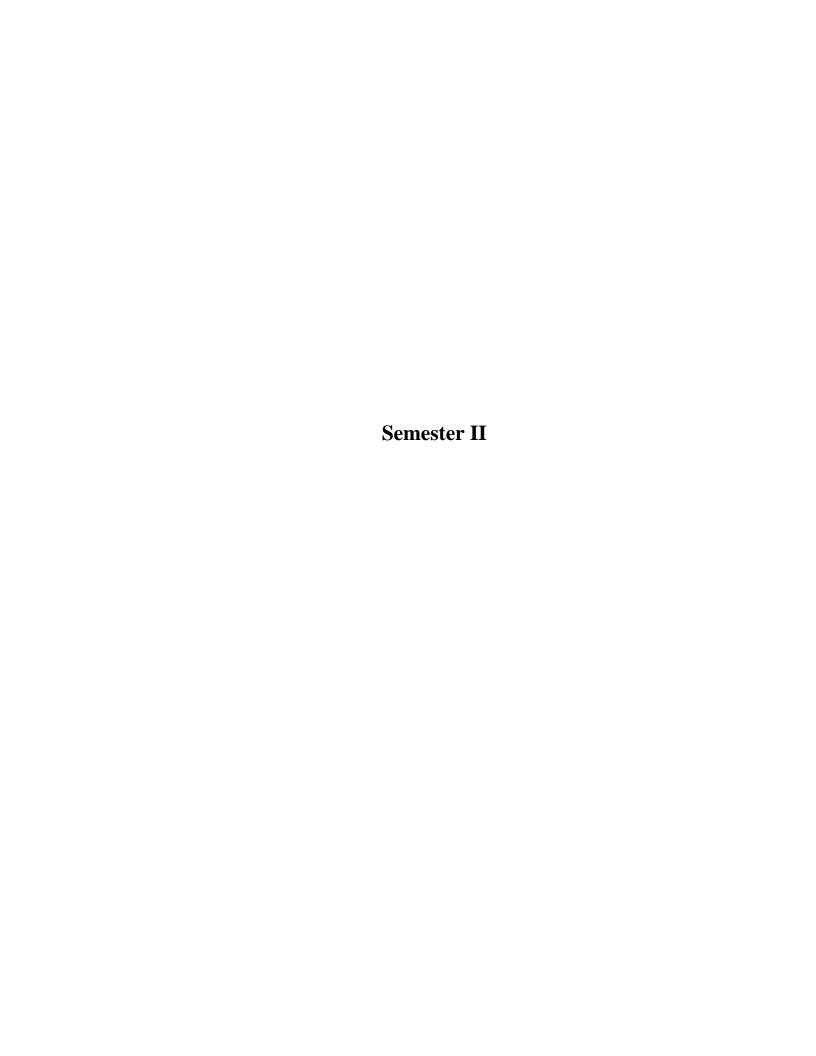
Introduction, Definition, Standard formulae, Rules of integration , Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

UNIT-V 06 Hours

- Differential Equations: Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, Application in solving Pharmacokinetic equations
- Laplace Transform: Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, Application in solving Chemical kinetics and Pharmacokinetics equations

Recommended Books (Latest Edition)

- 1. Differential Calculus by Shanthinarayan
- 2. Pharmaceutical Mathematics with application to Pharmacyby PanchaksharappaGowda D.H.
- 3. Integral Calculus by Shanthinarayan
- 4. Higher Engineering Mathematics by Dr.B.S.Grewal



HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to:

- 1. Explain the gross morphology, structure and functions of various organs of thehuman body.
- 2. Describe the various homeostatic mechanisms and their imbalances.
- 3. Identifythe various tissues and organs of different systems of human body.
- 4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratoryvolume.
- 5. Appreciate coordinated working pattern of different organs of each system
- 6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

Unit I 10 hours

• Nervous system

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid.structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

Unit II 06 hours

Digestive system

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

• Energetics

Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

• Respiratory system

10 hours

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

• Urinary system

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit IV 10 hours

• Endocrine system

Classification of hormones, mechanism of hormone action, structureand functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

Unit V 09 hours

• Reproductive system

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

• Introduction to genetics

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

- 1. To studythe integumentary and special senses using specimen, models, etc.,
- 2. To studythe nervous system using specimen, models, etc.,
- 3. To studythe endocrine system using specimen, models, etc
- 4. To demonstrate the general neurological examination
- 5. To demonstrate the function of olfactorynerve
- 6. To examine the different types of taste.
- 7. To demonstrate the visual acuity 8.

To demonstrate the reflex activity 9.

Recording of bodytemperature

- 10. To demonstrate positive and negative feedback mechanism.
 - 11. Determination of tidal volume and vital capacity.
 - 12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductivesystems with the help of models, charts and specimens.
 - 13. Recording of basal mass index
 - 14. Studyof familyplanning devices and pregnancy diagnosis test.
 - 15. Demonstration of total blood count bycell analyser
 - 16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

- 1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
- 2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
- 3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MIUSA

- 4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
- 5. Principles of Anatomy and PhysiologybyTortora Grabowski. Palmetto, GA, U.S.A.
- 6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
- 7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
- 8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

- 1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
- 2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
- 3. Human Physiology(vol 1 and 2) byDr. C.C. Chatterrje ,Academic Publishers Kolkata

PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives: Upon completion of the course the student shall be able to

- 1. write the structure, name and the type of isomerism of the organic compound
- 2. write the reaction, name the reaction and orientation of reactions
- 3. account for reactivity/stability of compounds,
- 4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I 07 Hours

Classification, nomenclature and isomerism

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds (up to

10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

UNIT-II10 Hours

Alkanes*, Alkenes* and Conjugated dienes*

SP³ hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

Stabilities of alkenes, SP² hybridization in alkenes

E₁ and E₂ reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E₁ verses E₂ reactions, Factors affecting E₁ and E₂ reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III10 Hours

Alkyl halides*

 SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN₁ versus SN₂ reactions, Factors affecting SN₁ and SN₂ reactions

Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

 Alcohols*- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

UNIT-IV10 Hours

Carbonyl compounds* (Aldehydes and ketones)

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT-V 08 Hours

Carboxylic acids*

Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids ,amide and ester

Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

• Aliphatic amines* - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

- 1. Systematic qualitative analysis of unknown organic compounds like
 - 1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturationand unsaturation, etc.
 - 2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
 - 3. Solubilitytest
 - 4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
 - 5. Melting point/Boiling point of organic compounds
 - 6. Identification of the unknown compound from the literature using melting point/ boiling point.
 - 7. Preparation of the derivatives and confirmation of the unknown compound bymelting point/ boiling point.
 - 8. Minimum 5 unknown organic compounds to be analysed systematically.
- 2. Preparation of suitable solid derivatives from organic compounds
- 3. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistryby Morrison and Boyd 2.

Organic Chemistryby I.L. Finar, Volume-I

- 3. Textbook of Organic Chemistryby B.S. Bahl & Arun Bahl.
- 4. Organic Chemistryby P.L.Soni
- 5. Practical Organic ChemistrybyMann and Saunders. 6.

Vogel's text book of Practical Organic Chemistry

- 7. Advanced Practical organic chemistrybyN.K.Vishnoi.
- 8. Introduction to Organic Laboratorytechniques byPavia, Lampman and Kriz. 9.

Reaction and reaction mechanism by Ahluwaliah/Chatwal.

BIOCHEMISTRY (Theory)

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shell able to

- 1. Understand the catalytic role of enzymes, importance of enzyme inhibitors indesign of new drugs, therapeutic and diagnostic applications of enzymes.
- 2. Understand the metabolism of nutrient molecules in physiological andpathological conditions.
- 3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Content:

UNIT I 08 Hours

• Biomolecules

Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

• Bioenergetics

Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

Energy rich compounds; classification; biological significances of ATPand cyclic AMP

UNIT II 10 Hours

Carbohydrate metabolism

Glycolysis - Pathway, energetics and significance Citric acid

cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase(G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathwayand its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

Biological oxidation

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT III 10 Hours

• Lipid metabolism

 β -Oxidation of saturated fattyacid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosisDe

novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol intobile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fattyliver and obesity.

• Amino acid metabolism

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders(Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV 10 Hours

• Nucleic acid metabolism and genetic information transfer

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functionsDNA

replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT V 07 Hours

• Enzymes

Introduction, properties, nomenclature and IUB classification of enzymesEnzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes –Structure and biochemical functions

BIOCHEMISTRY (Practical)

4 Hours / Week

- 1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
- 2. Identification tests for Proteins (albumin and Casein)
- 3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
- 4. Qualitative analysis of urine for abnormal constituents
- 5. Determination of blood creatinine
- 6. Determination of blood sugar
- 7. Determination of serum total cholesterol
- 8. Preparation of buffer solution and measurement of pH
- 9. Studyof enzymatic hydrolysis of starch
- 10. Determination of Salivaryamylase activity
- 11. Studythe effect of Temperature on Salivary amylase activity.
- 12. Studythe effect of substrate concentration on salivaryamylase activity.

Recommended Books (Latest Editions)

- 1. Principles of Biochemistry by Lehninger.
- 2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
- 3. Biochemistry byStryer.
- 4. BiochemistrybyD. Satyanarayan and U.Chakrapani 5.

Textbook of Biochemistry byRama Rao.

- 6. Textbook of Biochemistry by Deb.
- 7. Outlines of Biochemistry by Conn and Stumpf
- 8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
- 9. Introduction of Practical BiochemistrybyDavid T. Plummer. (3rd Edition) 10.

Practical Biochemistry for Medical students by Rajagopal and Ramakrishna. 11.

Practical Biochemistry by Harold Varley.

.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to -

- 1. Describe the etiologyand pathogenesis of the selected disease states;
- 2. Name the signs and symptoms of the diseases; and
- 3. Mention the complications of the diseases.

Course content:

Unit I 10Hours

• Basic principles of Cell injury and Adaptation:

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance

• Basic mechanism involved in the process of inflammation and repair:

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

Unit II 10Hours

• Cardiovascular System:

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

- Respiratory system: Asthma, Chronicobstructive airways diseases.
- Renal system: Acute and chronic renal failure

Unit II 10Hours

• Haematological Diseases:

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditaryacquired anemia, hemophilia

- Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- Gastrointestinal system: Peptic Ulcer •

Unit IV 8 Hours

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout
- Principles of cancer: classification, etiologyand pathogenesis of cancer
- Diseases of bones andjoints: Rheumatoid Arthritis, Osteoporosis, Gout
- Principles of Cancer: Classification, etiology and pathogenesis of Cancer

Unit V 7 Hours

• Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis

Urinary tract infections

• Sexually transmitteddiseases: AIDS, Syphilis, Gonorrhea

RecommendedBooks (Latest Editions)

- 1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
- 2. HarshMohan; Text bookof Pathology; 6th edition; India; Jaypee Publications; 2010.
- 3. Laurence B, Bruce C, Bjorn K.; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
 - 4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
- 5. Williamand Wilkins, Baltimore;1991 [1990 printing].
- 6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practiceof Medicine; 21stedition; London; ELBS/Churchill Livingstone; 2010.
- 7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
- 8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
- 9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
- 10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

- 1. The Journal of Pathology. ISSN: 1096-9896 (Online)
- 2. The American Journal of Pathology. ISSN: 0002-9440
- 3. Pathology. 1465-3931 (Online)
- 4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
- 5. Indian Journal of Pathologyand Microbiology. ISSN-0377-4929.

COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

- 1. know the various types of application of computers in pharmacy
- 2. know the various types of databases
- 3. know the various applications of databases in pharmacy

Course content:

UNIT – I 06 hours

Number system: Binary number system, Decimal number system, Octalnumber system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binarydivision

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT-II

06 hours

Web technologies:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and ServerProducts
Introduction to databases, MYSQL, MS ACCESS, PharmacyDrug database

UNIT – III 06 hours

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identificationandautomated dispensingofdrugs, mobile technologyandadherence monitoring

Diagnostic System, Lab-diagnostic System, Patient MonitoringSystem, Pharma Information System

UNIT – IV 06 hours

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics,Impact of Bioinformaticsin Vaccine Discovery

UNIT-V 06 hours

Computers as data analysis in Preclinical development: Chromatographic dada analysis(CDS), Laboratory Information managementSystem (LIMS) and Text Information Management System(TIMS)

COMPUTER APPLICATIONS IN PHARMACY (Practical)

- 1. Design a questionnaire using a word processing package to gather informationabout a particular disease.
- 2. Create a HTML web page to show personal information.
- Retrieve the information of a drug and its adverse effects using online tools
- 4 Creating mailing labels Using Label Wizard, generating label in MS WORD
- 5 Create a database in MS Access to store the patient information with the requiredfields Using access
- 6. Design a form in MS Access to view, add, delete and modify the patient record in the database
- 7. Generating report and printing the report from patient database
- 8. Creating invoice table using MS Access
- 9. Drug information storage and retrieval using MS Access
- 10. Creating and working with queries in MS Access
- 11. Exporting Tables, Queries, Forms and Reports to web pages
- 12. Exporting Tables, Queries, Forms and Reports to XMLpages

Recommended books (Latest edition):

- 1. Computer Application in Pharmacy William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
- 2. Computer Application in Pharmaceutical Research and Development –Sean Ekins Wiley-Interscience, A John Willeyand Sons, INC., Publication, USA
- 3. Bioinformatics (Concept, Skills and Applications) S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi 110 002(INDIA)
- Microsoft office Access 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope:Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to:

- 1. Create the awareness about environmental problems among learners. 2. Impart basic knowledge about the environment and its allied problems. 3. Develop an attitude of concern for the environment.
- 4. Motivate learner to participate in environment protection and environmentimprovement.
- 5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- 6. Strive to attain harmonywith Nature.

estuaries)

Course content:

Unit-I

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II

Ecosystems

Concept of an ecosystem.

Structure and function of an ecosystem.

Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans,

Unit- III 10hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

- 1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
- 2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
- 3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad 380 013, India,
- 4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
- 5. Clark R.S., Marine Pollution, Clanderson Press Oxford
- 6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
- 7. De A.K., Environmental Chemistry, WileyEastern Ltd.
- 8. Down of Earth, Centre for Science and Environment



PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives: Upon completion of the course the student shall be able to

- 1. write the structure, name and the type of isomerism of the organic compound
- 2. write the reaction, name the reaction and orientation of reactions
- 3. account for reactivity/stabilityof compounds,
- 4. prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I 10 Hours

Benzene and its derivatives

- **A.** Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
- **B.** Reactions of benzene nitration, sulphonation, halogenation-reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- **D.** Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II 10 Hours

- Phenols* Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- Aromatic Amines* Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts
- Aromatic Acids* Acidity, effect of substituents on acidity and important reactions of benzoic acid.

UNIT III

10 Hours

- Fats and Oils
 - a. Fattyacids reactions.

- b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
 - c. Analytical constants Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value significance and principle involved in their determination.

UNIT IV 08 Hours

• Polynuclear hydrocarbons:

- a. Synthesis, reactions
- b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V 07 Hours

• Cyclo alkanes*

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

- I Experiments involving laboratorytechniques
 - Recrystallization
 - Steam distillation
- II Determination of following oil values (including standardization of reagents)
 - Acid value
 - Saponification value
 - Iodine value

III Preparation of compounds

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide byhalogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid /Nitro benzene bynitration reaction.
- Benzoic acid from Benzyl chloride byoxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin byoxidation reaction.
- Dibenzal acetone from Benzaldehyde byClaison Schmidt reaction
- Cinnammic acid from Benzaldehyde byPerkin reaction
- P-lodo benzoic acid from P-amino benzoic acid

Recommended Books (Latest Editions)

- 1. Organic Chemistryby Morrison and Boyd 2. Organic Chemistryby I.L. Finar , Volume-I
- 3. Textbook of Organic Chemistryby B.S. Bahl & Arun Bahl.
- 4. Organic Chemistryby P.L.Soni
- 5. Practical Organic ChemistrybyMann and Saunders. 6.

Vogel's text book of Practical Organic Chemistry

7. Advanced Practical organic chemistrybyN.K.Vishnoi.

8. Introduction to Organic Laboratorytechniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physica and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon the completion of the course student shall be able to

- 1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
- 2. Know the principles of chemical kinetics & to use them for stabilitytesting nad determination of expiry date of formulations
- 3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I 10 Hours

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II 10Hours

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols

– inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III 08 Hours

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT-IV 08Hours

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stabilityconstants.

UNIT-V 07 Hours

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

- 1. Determination the solubility of drug at room temperature
- 2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
- 3. Determination of Partition co- efficient of benzoic acid in benzene and water
- 4. Determination of Partition co- efficient of Iodine in CCl₄ and water
- 5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
- 6. Determination of surface tension of given liquids bydrop count and drop weightmethod
- 7. Determination of HLB number of a surfactant by saponification method
- 8. Determination of Freundlich and Langmuir constants using activated char coal
- Determination of critical micellar concentration of surfactants
- Determination of stabilityconstant and donor acceptor ratio of PABA-Caffeine complex bysolubilitymethod
- 11. Determination of stability constant and donor acceptor ratio of Cupric-Glycinecomplex bypH titration method

Recommended Books: (Latest Editions)

- 1. Physical Pharmacy by Alfred Martin
- 2. Experimental Pharmaceutics by Eugene, Parott.
- 3. Tutorial Pharmacyby Cooper and Gunn.
- 4. Stocklosam J. Pharmaceutical Calculations, Lea & Febiger, Philadelphia.
- 5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
- 6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
- 7. Physical Pharmaceutics by RamasamyC and ManavalanR.
- 8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
- 9. Physical Pharmaceutics by C.V.S. Subramanyam
- 10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

 Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc..

Objectives: Upon completion of the subject student shall be able to;

- 1. Understand methods of identification, cultivation and preservation of various microorganisms
- 2. To understand the importance and implementation of sterlization inpharmaceutical processing and industry
- 3. Learn sterilitytesting of pharmaceutical products.
- 4. Carried out microbiological standardization of Pharmaceuticals. 5. Understand the cell culture technology and its applications in pharmaceuticalindustries.

Course content:

Unit I 10 Hours

Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

Unit II 10 Hours

Identification of bacteria using staining techniques (simple, Gram's & Acidfast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.

Evaluation of the efficiencyof sterilization methods.

Equipments employed in large scale sterilization.

Sterilityindicators.

Unit III 10 Hours

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterileproducts) according to IP, BP and USP.

Unit IV 08 Hours

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic.

Unit V 07Hours

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industryand research.

PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

- 1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
- 2. Sterilization of glassware, preparation and sterilization of media.
- 3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
- 4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration withpractical).
- 5. Isolation of pure culture of micro-organisms by multiple streak plate technique and othertechniques.
- 6. Microbiological assay of antibiotics bycup plate method and other methods
- 7. Motilitydetermination by Hanging drop method.
- 8. Sterilitytesting of pharmaceuticals.
- 9. Bacteriological analysis of water 10.

Biochemical test.

Recommended Books (Latest edition)

- 1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- 2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
- 3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- 4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 5. Rose: Industrial Microbiology.
- 6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan 7.

Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution. 8.

Peppler: Microbial Technology.

- 9. I.P., B.P., U.S.P.- latest editions.
- 10. Ananthnarayan: Text Book of Microbiology, Orient-Longman, Chennai
- 11. Edward: Fundamentals of Microbiology.
- 12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
- 13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and scienceof various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course student shall be able:

- 1. To know various unit operations used in Pharmaceutical industries.
- 2. To understand the material handling techniques.
- 3. To perform various processes involved in pharmaceutical manufacturing process.
- 4. To carry out various test to prevent environmental pollution.
- 5. To appreciate and comprehend significance of plant lay out design for optimumuse of resources.
- 6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course content:

UNIT-I 10 Hours

- Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- Size Reduction: Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Airseparator, Bag filter & elutriation tank.

UNIT-II 10 Hours

• **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

- Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economyof multiple effect evaporator.
- **Distillation:** Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT- III 08 Hours

- Drying: Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
- Mixing: Objectives, applications & factors affecting mixing, Difference between solid
 and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids
 mixing. Principles, Construction, Working, uses, Merits and Demeritsof Double
 cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary
 mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-IV 08 Hours

- Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- Centrifugation: Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V 07 Hours

Materials of pharmaceutical plant construction, Corrosion and its prevention:
 Factors affecting during materials selected for Pharmaceutical plant construction,
 Theories of corrosion, types of corrosion and there prevention. Ferrous and
 nonferrous metals, inorganic and organic non metals, basic of material handling
 systems.

Recommended Books: (Latest Editions)

- 1. Introduction to chemical engineering Walter L Badger & Julius Banchero, Latest edition.
- 2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
- 3. Unit operation of chemical engineering Mcabe Smith, Latest edition.
- 4. Pharmaceutical engineering principles and practices C.V.S Subrahmanyam et al., Latest edition.
- 5. Remington practice of pharmacy- Martin, Latest edition.
- 6. Theoryand practice of industrial pharmacyby Lachmann., Latest edition. 7.

Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.

8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

- I. Determination of radiation constant of brass, iron, unpainted and painted glass.
- II. Steam distillation To calculate the efficiencyof steam distillation.
- III. To determine the overall heat transfer coefficient byheat exchanger.
- IV. Construction of drying curves (for calcium carbonate and starch).
- V. Determination of moisture content and loss on drying.
- VI. Determination of humidity of air i) From wet and dry bulb temperatures –use of Dew point method.
- VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
- VIII. Size analysis by sieving To evaluate size distribution of tablet granulations Construction of various size frequency curves including arithmeticandlogarithmic probability plots.
- IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
- X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
- XI. Factors affecting Rate of Filtration and Evaporation (Surface area,

Concentrationand Thickness/ viscosity

- XII. To study the effect of time on the Rate of Crystallization.
- XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.



PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: At the end of the course, the student shall be able to

- 1. understand the methods of preparation and properties of organic compounds
- 2. explain the stereo chemical aspects of organic compounds and stereo chemicalreactions
- 3. know the medicinal uses and other applications of organic compounds

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT-I 10 Hours

Stereo isomerism

Optical isomerism -

Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute

UNIT-II 10 Hours

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for opticalactivity. Stereospecific and stereoselective reactions

UNIT-III 10 Hours

Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivativesPyrrole, Furan, and Thiophene

Relative aromaticityand reactivityof Pyrrole, Furan and Thiophene

UNIT-IV 8 Hours

Synthesis, reactions and medicinal uses of following compounds/derivativesPyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicityof pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V 07 Hours

Reactions of synthetic importance

Metal hydride reduction (NaBH₄ and LiAlH₄), Clemmensen reduction, Birchreduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

Recommended Books (Latest Editions)

- 1. Organic chemistry by I.L. Finar, Volume-I & II.
- 2. A text book of organic chemistry— Arun Bahl, B.S. Bahl.
- 3. Heterocyclic Chemistry by Raj K. Bansal
- 4. Organic Chemistry by Morrison and Boyd
- 5. Heterocyclic Chemistry by T.L. Gilchrist

MEDICINAL CHEMISTRY – I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importanceof physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

- 1. understand the chemistry of drugs with respect to their pharmacological activity
- 2. understand the drug metabolic pathways, adverse effect and therapeutic value ofdrugs
- 3. know the Structural ActivityRelationship (SAR) of different class of drugs
- 4. write the chemical synthesis of some drugs

Course Content:

Studyof the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I 10 Hours

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Proteinbinding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase land Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II 10 Hours

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,

Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III 10 Hours

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV 08 Hours

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*,Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital,

Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol. Aldehyde

& their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methabarbital. Hydantoins:

Phenytoin*, Mephenytoin, Ethotoin Oxazolidine diones:

Trimethadione, Paramethadione Succinimides:

Phensuximide, Methsuximide, Ethosuximide* Urea and

monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT – V 07 Hours

Drugs acting on Central Nervous System

General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbitutrates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I Preparation of drugs/intermediates 1 1,3-pyrazole 2 1,3-oxazole 3 Benzimidazole 4 Benztriazole 5 2,3- diphenyl quinoxaline 6 Benzocaine 7 Phenytoin 8 Phenothiazine 9 Barbiturate II Assay of drugs 1 Chlorpromazine Phenobarbitone 2 3 Atropine 4 Ibuprofen 5 **Aspirin** 6 Furosemide

Recommended Books (Latest Editions)

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1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.

Determination of Partition coefficient for any two drugs

- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design- Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.

- 6. Martindale's extra pharmacopoeia.
- 7. Organic Chemistryby I.L. Finar, Vol. II.
- 8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
- 9. Indian Pharmacopoeia.
- $10. \ {\it Text book of practical organic chemistry-} \ {\it A.I.Vogel}.$

PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

Scope: The course deals with the various physica and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon the completion of the course student shall be able to

- 1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
- 2. Know the principles of chemical kinetics & to use them for stabilitytesting nad determination of expiry date of formulations
- 3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I 07 Hours

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization& protective action.

UNIT-II 10 Hours

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III 10 Hours

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation byHLB method.

UNIT-IV 10Hours

Micromeretics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT-V 10 Hours

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

- 1. Determination of particle size, particle size distribution using sieving method
- 2. Determination of particle size, particle size distribution using Microscopic method
- 3. Determination of bulk density, true density and porosity
- 4. Determine the angle of repose and influence of lubricant on angle of repose
- 5. Determination of viscosity of liquid using Ostwald's viscometer
- 6. Determination sedimentation volume with effect of different suspending agent
- 7. Determination sedimentation volume with effect of different concentration of single suspending agent
- 8. Determination of viscosity of semisolid byusing Brookfield viscometer
- 9. Determination of reaction rate constant first order.
- 10. Determination of reaction rate constant second order
- 11. Accelerated stabilitystudies

Recommended Books: (Latest Editions)

- 1. Physical Pharmacyby Alfred Martin, Sixth edition
- 2. Experimental pharmaceutics by Eugene, Parott. 3. Tutorial pharmacyby Cooper and Gunn.
- 4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
- 5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
- 6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
- 7. Physical Pharmaceutics by RamasamyC, and Manavalan R.

45 Hrs

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives: Upon completion of this course the student should be able to

- 1. Understand the pharmacological actions of different categories of drugs
- 2. Explain the mechanism of drug action at organ system/sub cellular/macromolecular levels.
- 3. Apply the basic pharmacological knowledge in the prevention and treatment ofvarious diseases.
- 4. Observe the effect of drugs on animals bysimulated experiments
- 5. Appreciate correlation of pharmacologywith other bio medical sciences

Course Content:

UNIT-I 08 hours

1. General Pharmacology

- a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes ofdrug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT-II 12 Hours

General Pharmacology

- a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein—coupled receptors, ion channel receptor,transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discoveryphase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III 10 Hours

2. Pharmacology of drugs acting on peripheral nervous system

- a. Organization and function of ANS.
- b.Neurohumoral transmission,co-transmission and classification of neurotransmitters.
- c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

UNIT-IV 08 Hours

3. Pharmacology of drugs acting on central nervous system

- a. Neurohumoral transmission in the C.N.S.special emphasis on importance of variousneurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- **b.** General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrallyacting muscle relaxants.
- d. Anti-epileptics
- e. Alcohols and disulfiram

UNIT-V 07 Hours

3. Pharmacology of drugs acting on central nervous system

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.

- 1. Introduction to experimental pharmacology.
- 2. Commonlyused instruments in experimental pharmacology.
- 3. Studyof common laboratoryanimals.
- 4. Maintenance of laboratoryanimals as per CPCSEA guidelines.
- 5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
- 6. Studyof different routes of drugs administration in mice/rats.
- 7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleepingtime in mice.
- 8. Effect of drugs on ciliarymotility of frog oesophagus 9.

Effect of drugs on rabbit eye.

- 10. Effects of skeletal muscle relaxants using rota-rod apparatus.
- 11. Effect of drugs on locomotor activityusing actophotometer.
- 12. Anticonvulsant effect of drugs byMES and PTZ method.
- 13. Studyof stereotype and anti-catatonic activity of drugs on rats/mice.
- 14. Studyof anxiolytic activityof drugs using rats/mice.
- 15. Studyof local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
- 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
- 3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
- 5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

- 6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- 8. Modern Pharmacology with clinical Applications, by Charles R. Craig& Robert,
- 9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
- 10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and theirmedicinal properties.

Objectives: Upon completion of the course, the student shall be able

- 1. to know the techniques in the cultivation and production of crude drugs
- 2. to know the crude drugs, their uses and chemical nature
- 3. know the evaluation techniques for the herbal drugs
- 4. to carryout the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I 10 Hours

Introduction to Pharmacognosy:

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums andmucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II 10 Hours

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications.

Polyploidy, mutation andhybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III 07 Hours

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in

pharmacognosy. Edible vaccines

UNIT IV 10 Hours

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathyand Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V 08 Hours Study

of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primarymetabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids(Waxes, fats, fixed oils): Castor oil, Chaulmoogra oil, Wool Fat, Bees

Wax Marine Drugs:

Novel medicinal agents from marine sources

PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

- 1. Analysis of crude drugs by chemical tests: (i)Tragaccanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey(vii) Castor oil
- 2. Determination of stomatal number and index
- 3. Determination of vein islet number, vein islet termination and paliside ratio. 4.

Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer

- 5. Determination of Fiber length and width
- 6. Determination of number of starch grains by Lycopodium spore method
- 7. Determination of Ash value
- 8. Determination of Extractive values of crude drugs 9.

Determination ofmoisture content ofcrude drugs 10.

Determination of swelling index and foaming

Recommended Books: (Latest Editions)

- 1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
- 3. Text Book of Pharmacognosyby T.E. Wallis
- 4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 5. Text book of Pharmacognosyby C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 6. Herbal drug industryby R.D. Choudhary(1996), Ist Edn, Eastern Publisher, New Delhi.
- 7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
- 9. Anatomyof Crude Drugs by M.A. Ivengar



BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importanceof physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

- 1. Understand the chemistry of drugs with respect to their pharmacological activity
- 2. Understand the drug metabolic pathways, adverse effect and therapeutic value ofdrugs
- 3. Know the Structural ActivityRelationship of different class of drugs
- 4. Studythe chemical synthesis of selected drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I 10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H₁-antagonists: hydrochloride*, Dimenhydrinate, Diphenhydramine Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate. Triprolidine hydrochloride*, Phenidamine Promethazine tartarate, hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H₂-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan,

Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine,

Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II 10 Hours

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbidedinitrite*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.Osmotic

Diuretics: Mannitol

Anti-hypertensiveAgents:Timolol,Captopril, Lisinopril,Enalapril,Benazeprilhydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT- III 10 Hours

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine andCholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

UNIT-IV 08 Hours

Drugs acting on Endocrine system

Nomenclature, Stereochemistryand metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione,

Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Cortisone, Hydrocortisone, Prednisolone, **Corticosteroids:** Betamethasone,

Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil,

Methimazole.

07 Hours UNIT - V

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine,

Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Recommended Books (Latest Editions)

- 1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design- Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.
- 6. Martindale's extra pharmacopoeia.
- 7. Organic Chemistryby I.L. Finar, Vol. II.
- 8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
- 9. Indian Pharmacopoeia.
- 10. Text book of practical organic chemistry- A.I. Vogel.

Industrial Pharmacy I (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives: Upon completion of the course the student shall be able to

- 1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
- 2. Know various considerations in development of pharmaceutical dosage forms
- 3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

3 hours/ week

UNIT-I 07 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

- a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubilityprofile (pKa, pH, partition coefficient), polymorphism
- **b. Chemical Properties:** Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II 10 Hours

Tablets:

- Introduction, ideal characteristics of tablets, classification of tablets. Excipients,
 Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Qualitycontrol tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNIT-III 08 Hours

Capsules:

a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV 10 Hours

Parenteral Products:

- a. Definition, types, advantages and limitations. Preformulation factors and essentialrequirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls, aseptic processing
- c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Qualitycontrol tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V 10 Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stabilityaspects of packaging materials, qualitycontrol tests.

Industrial Pharmacy I (Practical)

4 Hours/week

- 1. Preformulation studies on paracetamol/asparin/or any other drug
- 2. Preparation and evaluation of Paracetamol tablets
- 3. Preparation and evaluation of Aspirin tablets
- Coating of tablets- film coating of tables/granules 5.
 Preparation and evaluation of Tetracycline capsules
- 6. Preparation of Calcium Gluconate injection
- 7. Preparation of Ascorbic Acid injection
- 8. Qulaity control test of (as per IP) marketed tablets and capsules
- 9. Preparation of Eye drops/ and Eye ointments
- 10. Preparation of Creams (cold / vanishing cream)
- 11. Evaluation of Glass containers (as per IP)

Recommended Books: (Latest Editions)

- 1. Pharmaceutical dosage forms Tablets, volume 1 -3 byH.A. Liberman, Leon Lachman &J.B.Schwartz
- 2. Pharmaceutical dosage form Parenteral medication vol- 1&2 by Liberman & Lachman
- 3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
- 4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
- 5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
- 6. Theoryand Practice of Industrial Pharmacyby Liberman & Lachman
- 7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
- 8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea & Febiger, Philadelphia, 5thedition, 2005
- 9. Drug stability Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

Objectives: Upon completion of this course the student should be able to

- 1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
- 2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- 3. Demonstrate the various receptor actions using isolated tissue preparation
- 4. Appreciate correlation of pharmacologywith related medical sciences

Course Content:

UNIT-I 10hours

1. Pharmacology of drugs acting on cardio vascular system

- a. Introduction to hemodynamic and electrophysiologyof heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

UNIT-II 10hours

1. Pharmacology of drugs acting on cardio vascular system

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT-III 10hours

3. Autocoids and related drugs

- a. Introduction to autacoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatoryagents
- f. Anti-gout drugs
- g. Antirheumatic drugs

UNIT-IV 08hours

5. Pharmacology of drugs acting on endocrine system

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitaryhormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT-V 07hours

5. Pharmacology of drugs acting on endocrine system

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

6. Bioassay

- a. Principles and applications of bioassay.
- b.Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamineand 5-HT

- 1. Introduction to *in-vitro* pharmacologyand physiological salt solutions.
- 2. Effect of drugs on isolated frog heart.
- 3. Effect of drugs on blood pressure and heart rate of dog.
- 4. Studyof diuretic activityof drugs using rats/mice.
- 5. DRC of acetylcholine using frog rectus abdominis muscle.
- 6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
- 7. Bioassayof histamine using guinea pig ileum by matching method. 8.

Bioassayof oxytocin using rat uterine horn by interpolation method. 9.

Bioassayof serotonin using rat fundus strip bythree point bioassay.

- 10. Bioassayof acetylcholine using rat ileum/colon byfour point bioassay.
- 11. Determination of PA₂ value of prazosin using rat anococcygeus muscle (by Schilds plot method).
- 12. Determination of PD₂ value using guinea pig ileum.
- 13. Effect of spasmogens and spasmolytics using rabbit jejunum.
- 14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
- 15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
- 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
- 3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 4. MarryAnne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
- 5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
- 6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- 8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert.
- 9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
- 10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how thesecondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives: Upon completion of the course, the student shall be able

- 1. to know the modern extraction techniques, characterization and identification of theherbal drugs and phytoconstituents
- 2. to understand the preparation and development ofherbal formulation.
- 3. to understand the herbal drug interactions
- 4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I 7 Hours

Metabolic pathways in higher plants and their determination

- a) Brief study of basic metabolic pathways and formation of different secondary metabolitesthrough these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b) Studyof utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II 14 Hours

General introduction, composition, chemistry& chemical classes, biosources, therapeuticuses and commercial applications of following secondarymetabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium, Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

JNIT-III 06 Hours

Isolation, Identification and Analysis of Phytoconstituents

a) Terpenoids: Menthol, Citral, Artemisin

b) Glycosides: Glycyrhetinic acid & Rutin

c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine

d) Resins: Podophyllotoxin, Curcumin

UNIT-IV 10 Hours

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V 8 Hours

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crudedrugs.

PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

- 1. Morphology, histologyand powder characteristics & extraction & detection of:Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
- 2. Exercise involving isolation & detection of active principles
 - a. Caffeine from tea dust.
 - b. Diosgenin from Dioscorea
 - c. Atropine from Belladonna
 - d. Sennosides from Senna
- 3. Separation of sugars by Paper chromatography
- 4. TLC of herbal extract
- 5. Distillation of volatile oils and detection of phytoconstitutents by TLC
- 6. Analysis of crude drugs bychemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony(iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

- 1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 3. Text book of Pharmacognosyby C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 4. Herbal drug industryby R.D. Choudhary(1996), Ist Edn, Eastern Publisher, New Delhi.
- 5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 6. Herbal Cosmetics by H. Pande, Asia Pacific Business press, Inc, New Delhi.
- 7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005
- 8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
- 9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
- 10. The formulation and preparation of cosmetic, fragrances and flavours.
- 11. Remington's Pharmaceutical sciences.
- 12. Text Book of Biotechnology by Vyas and Dixit.
- 13. Text Book of Biotechnology by R.C. Dubey.

PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacyin India.

Objectives: Upon completion of the course, the student shall be able to understand:

- 1. The Pharmaceutical legislations and their implications in the development andmarketing of pharmaceuticals.
- 2. Various Indian pharmaceutical Acts and Laws
- 3. The regulatoryauthorities and agencies governing the manufacture and sale ofpharmaceuticals
- 4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I 10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act andRules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II 10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs -

Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III 10 Hours

Pharmacy Act -1948: Objectives, Definitions, Pharmacy Council of India; its
constitution and functions, Education Regulations, State and Joint state pharmacy
councils; constitution and functions, Registration of Pharmacists, Offences and

Penalties

- Medicinal and Toilet Preparation Act -1955: Objectives, Definitions, Licensing,
 Manufacture In bond and Outside bond, Export of alcoholic preparations,
 Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
 Offences and Penalties.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives,
 Definitions, Authorities and Officers, Constitution and Functions of narcotic &
 Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse,
 Prohibition, Control and Regulation, opium poppy cultivation and production of
 poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV 08 Hours

- Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013.
 Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

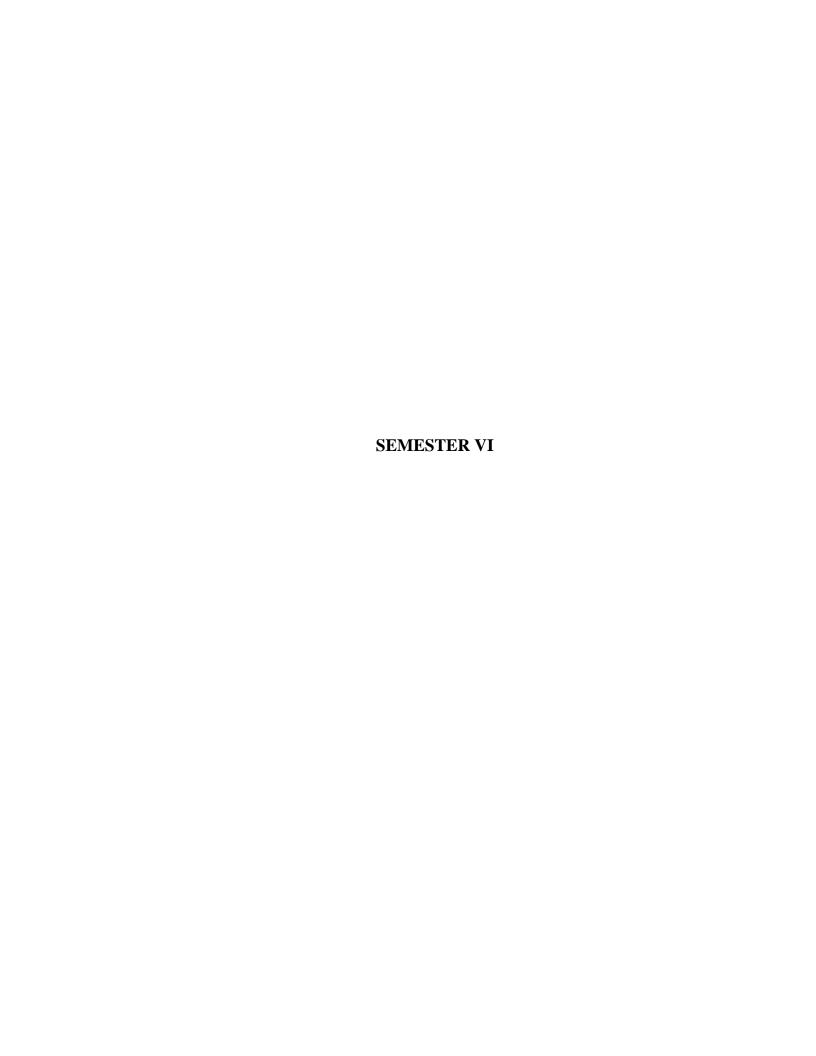
UNIT-V 07 Hours

- Pharmaceutical Legislations A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- Medical Termination of Pregnancy Act
- Right to Information Act
- Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

1. Forensic Pharmacyby B. Suresh

- 2. Text book of Forensic Pharmacyby B.M. Mithal
- 3. Hand book of drug law-by M.L. Mehra
- 4. A text book of Forensic Pharmacyby N.K. Jain
- 5. Drugs and Cosmetics Act/Rules byGovt. of India publications.
- 6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
- 7. Narcotic drugs and psychotropic substances act byGovt. of India publications
- 8. Drugs and Magic Remedies act byGovt. of India publication
- 9.Bare Acts of the said laws published by Government. Reference books (Theory)



MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives: Upon completion of the course student shall be able to

- 1. Understand the importance of drug design and different techniques of drugdesign.
- 2. Understand the chemistryof drugs with respect to their biological activity.
- 3. Know the metabolism, adverse effects and therapeutic value of drugs.
- 4. Know the importance of SAR of drugs. Course

Content:

Studyofthedevelopment of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT – I 10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II 10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III 10 Hours

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin,
Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV 08 Hours

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V 07 Hours

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

II Assay of drugs

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin
- III Preparation of medicinally important compounds or intermediates by Microwaveirradiation technique
- IV Drawing structures and reactions using chem draw®
- V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

- 1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design-Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.
- 6. Martindale's extra pharmacopoeia.
- 7. Organic Chemistryby I.L. Finar, Vol. II.
- 8. The Organic Chemistryof Drug Synthesis by Lednicer, Vol. 1-5.
- 9. Indian Pharmacopoeia.
- 10. Text book of practical organic chemistry- A.I. Vogel.

PHARMACOLOGY-III (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

Objectives: Upon completion of this course the student should be able to:

- 1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- 2. comprehend the principles of toxicology and treatment of various poisonings and
- 3. appreciate correlation of pharmacologywith related medical sciences.

Course Content:

UNIT-I 10hours

- 1. Pharmacology of drugs acting on Respiratory system
 - a. Anti -asthmatic drugs
 - b. Drugs used in the management of COPD
 - c. Expectorants and antitussives
 - d. Nasal decongestants e.

Respiratorystimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

UNIT-II 10hours

3. Chemotherapy

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole.
- c.Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III 10hours

3. Chemotherapy

- a. Antitubercular agents
- b. Antileprotic agents

- c. Antifungal agents
- d. Antiviral drugs
- e.Anthelmintics
- f. Antimalarial drugs g.

Antiamoebic agents

UNIT-IV 08hours

3. Chemotherapy

- I. Urinarytract infections and sexuallytransmitted diseases.
- m. Chemotherapyof malignancy.

4. Immunopharmacology

a. Immunostimulants b.

Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V 07hours

5. Principles of toxicology

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercuryand arsenic poisoning.

6. Chronopharmacology

- a. Definition of rhythm and cycles.
- b. Biological clock and their significance leading to chronotherapy.

1. Dose calculation in pharmacological experiments 2.

Antiallergic activity by mast cell stabilization assay

- 3. Studyof anti-ulcer activityof a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
- 4. Studyof effect of drugs on gastrointestinal motility 5.

Effect of agonist and antagonists on guinea pig ileum

- 6. Estimation of serum biochemical parameters byusing semi- autoanalyser
- 7. Effect of saline purgative on frog intestine
- 8. Insulin hypoglycemic effect in rabbit
- 9. Test for pyrogens (rabbit method)
- 10. Determination of acute oral toxicity(LD50) of a drug from a given data
- 11. Determination of acute skin irritation / corrosion of a test substance
- 12. Determination of acute eye irritation / corrosion of a test substance
- 13. Calculation of pharmacokinetic parameters from a given data
- 14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
- 15. Biostatistics methods in experimental pharmacology (Chi square test, WilcoxonSigned Rank test)

Recommended Books (Latest Editions)

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
- 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
- 3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
- 5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
- 6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacologywith clinical Applications, byCharles R.Craig& Robert,
- 8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
- 9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
- 10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

^{*}Experiments are demonstrated by simulated experiments/videos

HERBAL DRUGTECHNOLOGY (Theory)

45 hours

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatoryissues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

- 1. understand raw material as source of herbal drugs from cultivation to herbal drugproduct
- 2. know the WHO and ICH guidelines for evaluation of herbal drugs
- 3. know the herbal cosmetics, natural sweeteners, nutraceuticals 4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I 11 Hours

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drugpreparation Source of Herbs

Selection, identification and authentication ofherbal materials Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation ofmedicinal plants includingOrganic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

- a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
- b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT-II 7 Hours

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III 10 Hours

Herbal Cosmetics

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscositybuilders, disintegrants, flavors & perfumes.

Herbal formulations:

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- IV 10 Hours

Evaluation of Drugs WHO & ICH guidelines for the assessment ofherbal drugs Stabilitytesting of herbal drugs.

Patenting and Regulatory requirements of natural products:

- a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation ofmanufacture of ASU drugs - Schedule Zof Drugs & Cosmetics Act for ASU drugs.

UNIT-V 07 Hours

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

- 1. To perform preliminary phytochemical screening of crude drugs.
- 2. Determination of the alcohol content of Asava and Arista
- 3. Evaluation of excipients of natural origin
- 4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
- 5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
- 6. Monograph analysis of herbal drugs from recent Pharmacopoeias
- 7. Determination of Aldehyde content
- 8. Determination of Phenol content
- 9. Determination of total alkaloids

Recommended Books: (Latest Editions)

- 1. Textbook of Pharmacognosy byTrease & Evans.
- 2. Textbook of Pharmacognosyby Tyler, Brady & Robber.
- 3. Pharmacognosyby Kokate, Purohit and Gokhale
- 4. Essential of Pharmacognosyby Dr.S.H.Ansari
- 5. Pharmacognosy & Phytochemistryby V.D.Rangari
- 6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
- 7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

Scope:This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein.

Objectives: Upon completion of the course student shall be able to:

- 1. Understand the basic concepts in biopharmaceutics and pharmacokinetics andtheir significance.
- 2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- 3. To understand the concepts of bioavailability and bioequivalence of drugproducts and their significance.
- 4. Understand various pharmacokinetic parameters, their significance & applications.

Course Content:

UNIT-I 10 Hours

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volumeof drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II 10 Hours

Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- III 10 Hours

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartmentmodels, Non compartment models, physiological models, One compartment openmodel. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E,t1/2,Vd,AUC,Ka, Clt andCL_R- definitions methods of eliminations, understanding of their significance and application

UNIT- IV 08 Hours

Multicompartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

UNIT- V 07 Hours

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example ofdrugs.

Recommended Books: (Latest Editions)

- 1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
- 2. Biopharmaceutics and Pharmacokinetics; ByRobert F Notari
- 3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Inernational edition. USA
- 4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- 5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- 6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 7. Biopharmaceutics; By Swarbrick
- 8. Clinical Pharmacokinetics, Concepts and Applications: ByMalcolm Rowland and
- 9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- 10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- 11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- 12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvni

PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

- Biotechnology has a long promise to revolutionize the biological sciences andtechnology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technologymakes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- It is basically a research-based subject.

Objectives: Upon completion of the subject student shall be able to;

- 1. Understanding the importance of Immobilized enzymes in PharmaceuticalIndustries
- 2. Genetic engineering applications in relation to production of pharmaceuticals
- 3. Importance of Monoclonal antibodies in Industries
- 4. Appreciate the use of microorganisms in fermentation technology

Unit I 10 Hours

- a) Brief introduction to Biotechnologywith reference to Pharmaceutical Sciences.
- b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d) Brief introduction to Protein Engineering.
- e) Use of microbes in industry. Production of Enzymes- General consideration Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f) Basic principles of genetic engineering.

Unit II 10 Hours

- a) Studyof cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technologyand genetic engineering in the production of:
- i) Interferon ii) Vaccines- hepatitis- Biii) Hormones-Insulin.
- d) Brief introduction to PCR

Unit III 10 Hours

Types of immunity- humoral immunity, cellular immunity

- a) Structure of Immunoglobulins
- b) Structure and Function of MHC
- c) Hypersensitivityreactions, Immune stimulation and Immune suppressions.
- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- e) Storage conditions and stability of official vaccines
- f) Hybridoma technology- Production, Purification and Applications
- g) Blood products and Plasma Substituties.

Unit IV 08Hours

- a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b) Genetic organization of Eukaryotes and Prokaryotes
- c) Microbial genetics including transformation, transduction, conjugation, plasmids andtransposons.
- d) Introduction to Microbial biotransformation and applications.
- e) Mutation: Types of mutation/mutants.

Unit V 07 Hours

- a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- b) Large scale production fermenter design and its various controls.
- c) Study of the production of penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,
- d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.

Recommended Books (Latest edition):

- 1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applicationsof RecombinantDNA: ASM Press Washington D.C.
- 2. RA Goldshyet. al., : Kuby Immunology.
- 3. J.W. Goding: Monoclonal Antibodies.
- 4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

Societyof Chemistry.

- 5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
- 6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
- 7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delh

PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course dealswith thevariousaspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, qualitycertifications and regulatory affairs.

Objectives: Upon completion of the course student shall be able to:

- •understand the cGMP aspects in a pharmaceutical industry
- •appreciate the importance of documentation
- understand the scope of quality certifications applicable to pharmaceuticalindustries
- •understand the responsibilities of QA & QC departments

Course content:

UNIT – I 10 Hours Quality

Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stabilitytesting guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools **ISO 9000 & ISO14000**: Overview, Benefits, Elements, steps for registration **NABL accreditation**: Principles and procedures

UNIT - II 10 Hours

Organizationand personnel: Personnelresponsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III 10 Hours

Quality Control: Quality control test for containers, rubber closures and secondary packing

materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV 08 Hours

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling andwaste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

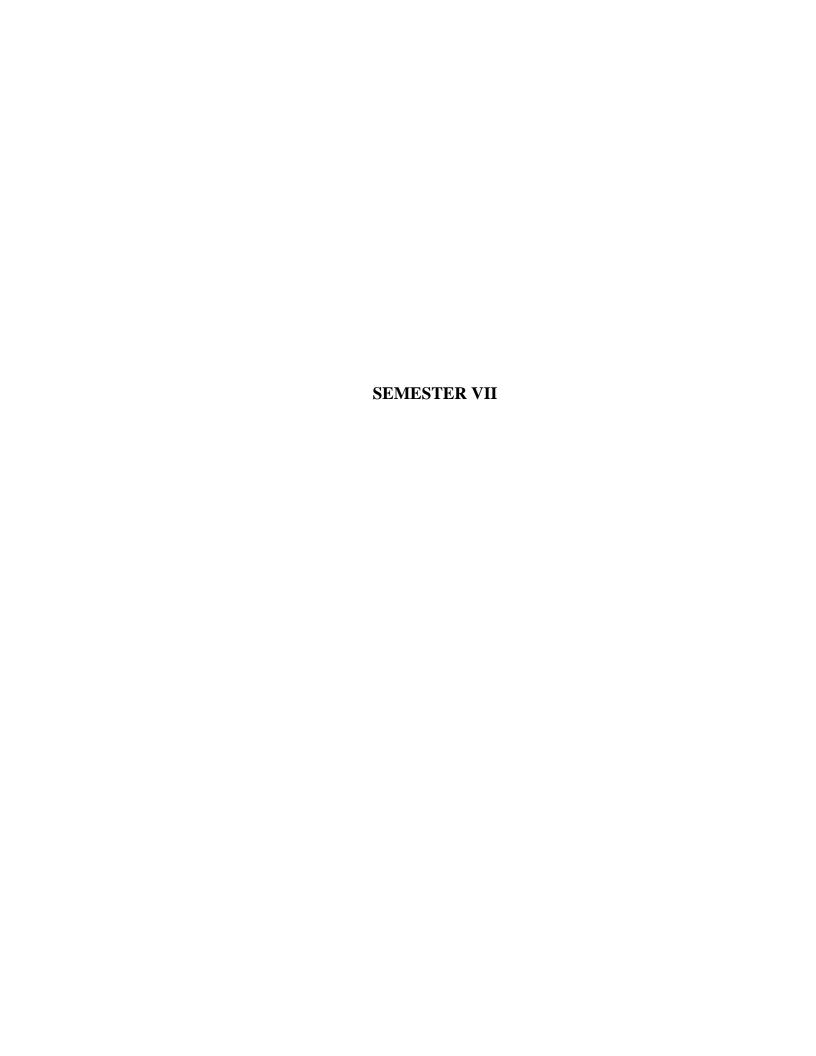
UNIT – V 07 Hours

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

- 1. QualityAssurance Guide byorganization of Pharmaceutical Products of India. 2. Good LaboratoryPractice Regulations, 2nd Edition, SandyWeinberg Vol. 69.
- 3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
- 4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh
- 5. How to Practice GMP's P P Sharma.
- 6. ISO 9000 and Total QualityManagement Sadhank G Ghosh
- 7. The International Pharmacopoeia Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
- 8. Good laboratoryPractices Marcel Deckker Series
- 9. ICH guidelines, ISO 9000 and 14000 guidelines



INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

- 1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
- 2. Understand the chromatographic separation and analysis of drugs.
- 3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I 10 Hours

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect onabsorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi componentanalysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT –II 10 Hours

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, samplehandling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT -III 10 Hours

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis—Introduction, factors affecting electrophoretic mobility, Techniquesof paper, gel, capillaryelectrophoresis, applications

UNIT -IV 08 Hours

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory,instrumentation, advantages and applications.

UNIT -V 07 Hours

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

- Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide bycolorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Studyof quenching of fluorescence
- 8 Determination of sodium byflame photometry
- 9 Determination of potassium byflame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids bypaper chromatography
- 12 Separation of sugars bythin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

- 1. Instrumental Methods of Chemical Analysis by B.K Sharma
- 2. Organic spectroscopy by Y.R Sharma
- 3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
- 4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 5. Practical Pharmaceutical Chemistryby A.H. Beckett and J.B. Stenlake
- 6. Organic Chemistryby I. L. Finar
- 7. Organic spectroscopy by William Kemp
- 8. Quantitative Analysis of Drugs by D. C. Garrett
- 9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
- 10. Spectrophotometric identification of Organic Compounds by Silverstein

INDUSTRIAL PHARMACY II (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:

- 1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
- 2. Understand the process of technologytransfer from lab scale to commercial batch
- 3. Know different Laws and Acts that regulate pharmaceutical industry
- 4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I 10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II 10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API,excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE /SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III 10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV 08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Outof Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V 07 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

- 1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
- 2. International RegulatoryAffairs Updates, 2005. available at http://www.iraup.com/about.php
- 3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guidefor Prescription Drugs, Medical Devices, and Biologics' Second Edition.
- 4. RegulatoryAffairs brought bylearning plus, inc. available at http://www.cgmp.com/ra.htm.

PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the communityset up.

Objectives: Upon completion of the course, the student shall be able to

- 1. know various drug distribution methods in a hospital
- 2. appreciate the pharmacystores management and inventorycontrol
- 3. monitor drug therapy of patient through medication chart review and clinical review
- 4. obtain medication history interview and counsel the patients
- 5. identifydrug related problems
- 6. detect and assess adverse drug reactions
- 7. interpret selected laboratory results (as monitoring parameters in therapeutics) ofspecific disease states
- 8. know pharmaceutical care services
- 9. do patient counseling in communitypharmacy; 10. appreciate the concept of Rational drug therapy.

Unit I: 10 Hours

a) Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Unit II: 10 Hours

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication historyinterview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III: 10 Hours

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stoporder, and emergencydrug list preparation.

Drug

information services

Drug and Poison information centre, Sources of drug information, Computerisedservices, and storage and retrieval of information.

c) Patient

counseling

Definition of patient counseling; steps involved in patient counseling, and Specialcases that require the pharmacist

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and communityhealth education.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

Unit IV 8 Hours a) Budget

preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

c) Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over the counter medications.

Unit V 7 Hours

a) Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

b) Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospitalpharmacist, advisorycommittee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

- 1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
- 2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills,* 1st ed. Chennai: Orient Longman Private Limited; 2004.
- 3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
- 4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008. 5.
- Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.
- 6. Parmar N.S. *Health Education and Community Pharmacy,* 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

- 1. Therapeutic drug monitoring. ISSN: 0163-4356
- 2. Journal of pharmacypractice. ISSN: 0974-8326
- 3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
- 4. Pharmacytimes (Monthly magazine)

NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drugdelivery systems.

Objectives: Upon completion of the course student shall be able

- 1. To understand various approaches for development of novel drug deliverysystems.
- 2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I 10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug deliverysystems.

Unit-II 10 Hours

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal deliverysystems

Implantable Drug Delivery Systems:Introduction, advantages and disadvantages,concept of implants and osmotic pump

Unit-III 10 Hours

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS — Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV 08 Hours

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V 07 Hours

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminarystudy, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

- 1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- 2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
- 3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wileyand Sons, Inc, New York. Chichester/Weinheim
- 4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- 5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

- 1. Indian Journal of Pharmaceutical Sciences (IPA)
- 2. Indian Drugs (IDMA)
- 3. Journal of Controlled Release (Elsevier Sciences)
- 4. Drug Development and Industrial Pharmacy(Marcel & Decker)
- 5. International Journal of Pharmaceutics (Elsevier Sciences)



BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understandthe applicationsofBiostaticsinPharmacy. Thissubject dealswith descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Objectives: Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

Course content:

Unit-I 10 Hours

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

Unit-II 10 Hours

Regression: Curve fitting bythe method of least squares, fitting the lines y=a+bx and x=a+by, Multiple regression, standard error of regression—Pharmaceutical Examples **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) -Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired), ANOVA, (One wayand Two way), Least Significance difference

Unit-III 10 Hours

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallistest, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Reportwriting and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV 8 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels **Introduction to Practical components of Industrial and Clinical Trials Problems**: Statistical Analysis Using Excel, SPSS, MINITAB*, DESIGN OF EXPERIMENTS, R -Online Statistical Software's to Industrial and Clinical trial approach

Unit-V 7Hours

Design and Analysis of experiments:

Factorial Design: Definition, 2², 2³design. Advantage of factorial design **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

- 1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
- 2. Fundamental of Statistics Himalaya Publishing House-S.C.Guptha
- 3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
- 4. Design and Analysis of Experiments Wiley Students Edition, Douglas and C. Montgomery

SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

Scope:

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives:

After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the countryand worldwide.
- Have a critical wayof thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related tohealth andpharmaceutical issues

Course content:

Unit I: 10 Hours

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Povertyand health

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II: 10 Hours

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: 10 Hours

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for preventionand control of deafness, Universalimmunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV: 08 Hours

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V: 07 Hours

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Recommended Books (Latest edition):

- 1. ShortTextbookof Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
- 2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
- 3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
- 4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
- 5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011,ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
- 6. CommunityPharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit I 10 Hours

Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Roleof market research.

Unit II 10 Hours

Product decision:

Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III 10 Hours

Promotion:

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit IV 10 Hours

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V 10 Hours

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

- 1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
- 2. Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
- 3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
- 4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
- 5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
- 6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
- 7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
- 8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT Excel series) Excel Publications.

PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to;

- 1. Know about the process of drug discoveryand development
- 2. Know the regulatory authorities and agencies governing the manufacture and saleof pharmaceuticals
- 3. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I 10Hours

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II 10Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III 10Hours

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical

Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV 08Hours

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safetymonitoring in clinical trials

Unit V 07Hours

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

- 1. Drug RegulatoryAffairs bySachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
- 2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185. Informa Health care Publishers.
- 3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
- 4. Guidebook for drug regulatorysubmissions / SandyWeinberg. ByJohn Wiley & Sons. Inc.
- 5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
- 6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
- 7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By FayA. Rozovskyand RodneyK. Adams
- 8. Principles and Practices of Clinical Research, Second Edition Edited by John I.Gallin and Frederick P. Ognibene
- 9. Drugs: From Discoveryto Approval, Second Edition ByRick Ng

PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- 1. Why drug safety monitoring is important?
- 2. Historyand development of pharmacovigilance
- 3. National and international scenario of pharmacovigilance
- 4. Dictionaries, codingand terminologies used in pharmacovigilance
- 5. Detection of new adverse drugreactions and their assessment
- 6. International standardsfor classification of diseases and drugs
- 7. Adverse drugreaction reportingsystems and communication in pharmacovigilance
- 8. Methods to generate safety data during pre clinical, clinical and post approval phases ofdrugs' life cycle
- 9. Drugsafety evaluation in paediatrics, geriatrics, pregnancy and lactation
- 10. Pharmacovigilance Programof India (PvPI) requirement for ADR reporting in India
- 11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
- 12. CIOMS requirements for ADR reporting
- 13. Writingcase narratives of adverse events and their quality.

Course Content

Unit I 10 Hours

Introduction toPharmacovigilance

- Historyand development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drugmonitoringprogramme
- Pharmacovigilance Programof India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severityand seriousness assessment
- Predictability and preventability assessment
- Management of adverse drugreactions

Basic terminologies usedin pharmacovigilance

- Terminologies of adversemedication related events
- Regulatoryterminologies

Unit II 10 hours

Drug and disease classification

- Anatomical, therapeuticand chemical classification ofdrugs
- International classification of diseases
- Daily defined doses
- International Non proprietaryNames for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Informationresources inpharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishinga national programme

Unit III 10 Hours

Vaccinesafety surveillance

- VaccinePharmacovigilance
- Vaccination failure
- Adverse events followingimmunization

Pharmacovigilance methods

- Passive surveillance Spontaneous reports and case series
- Stimulated reporting
- Active surveillance Sentinel sites, drugevent monitoringand registries
- Comparative observational studies Cross sectional study, case control study and cohort study
- Targetedclinical investigations

Communicationin pharmacovigilance

- Effective communicationinPharmacovigilance
- Communication in DrugSafetyCrisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV 8 Hours

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safetyreports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilanceplanning
- Good clinical practice in pharmacovigilance studies

Unit V 7 hours

Pharmacogenomics of adverse drugreactions

• Genetics related ADR with example focusing PK parameters.

Drug safety evaluation inspecial population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences inIndian and global pharmacovigilance requirements

Recommended Books (Latest edition):

- 1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
- 2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
- 3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
- 4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, WileyPublishers.
- 5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
- 6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
- 7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
- 8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen, Milap C. Nahata

- 9. National Formularyof India 10. Text Book of Medicine by Yashpal Munjal

- 11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
- 12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&m n 3=7297
- 13. http://www.ich.org/
- 14. http://www.cioms.ch/
- 15. http://cdsco.nic.in/
- 16. http://www.who.int/vaccine_safety/en/
- 17. http://www.ipc.gov.in/PvPI/pv_home.html

QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

- 1. know WHO guidelines for qualitycontrol of herbal drugs
- 2. know Quality assurance in herbal drug industry
- 3. knowtheregulatoryapprovalprocessandtheirregistrationin Indian and international markets
- 4. appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I 10 hours

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosageforms WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

Unit II 10 hours

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP intraditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal MedicinesWHO Guidelines on GACP for Medicinal Plants.

Unit III 10 hours

EU and ICH guidelines for qualitycontrol of herbal drugs.

Research Guidelines for Evaluating the Safetyand Efficacyof Herbal Medicines

Unit IV 08 hours Stability

testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registrationGMP requirements and Drugs & Cosmetics Act provisions.

Unit V 07 hours

Regulatoryrequirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systemsComparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions 1.

PharmacognosybyTrease and Evans

- 2. Pharmacognosy byKokate, Purohit and Gokhale
- 3. Rangari, V.D., Text book of Pharmacognosyand Phytochemistry Vol. I, Carrier Pub., 2006.
- 4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
- 5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products.
- 6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
- 7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
- 8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
- 9. WHO. The International Pharmacopeia, Vol. 2: QualitySpecifications, 3rd edn. World Health Organization, Geneva, 1981.
- 10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
- 11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
- 12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand

- Design and discovery of lead molecules
- The role of drug design in drug discoveryprocess
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course Content:

UNIT-I 10 Hours

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design:Bioisosterism, Classification, Bioisosteric replacement. Anythree case studies

UNIT-II 10 Hours

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III 10 Hours

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, **Molecular docking:** Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

UNIT-IV 08 Hours

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V 07 Hours

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

- 1. Robert GCK, ed., "Drug Action at the Molecular Level" UniversityPrak Press Baltimore.
- 2. Martin YC. "Quantitative Drug Design" Dekker, New York.
- 3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
- 4. Foye WO "Principles of Medicinal chemistry'Lea & Febiger.
- 5. Koro Ikovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
- 6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley& Sons, New York.
- 7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
- 8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
- 9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

Scope:

- Cell biology is a branch of biology that studies cells their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

Objectives: Upon completion of the subject student shall be able to;

- Summarize cell and molecular biologyhistory.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Course content:

Unit I 10Hours

- a) Cell and Molecular Biology: Definitions theory and basics and Applications.
- b) Cell and Molecular Biology: Historyand Summation.
- c) Properties of cells and cell membrane.
- d) Prokaryotic versus Eukaryotic
- e) Cellular Reproduction
- f) Chemical Foundations an Introduction and Reactions (Types)

Unit II 10 Hours

- a) DNA and the Flow of Molecular Information
- b) DNA Functioning
- c) DNA and RNA
- d) Types of RNA
- e) Transcription and Translation

Unit III 10 Hours

- a) Proteins: Defined and Amino Acids
- b) Protein Structure

- c) Regularities in Protein Pathways
- d) Cellular Processes
- e) Positive Control and significance of Protein Synthesis

Unit IV 08 Hours

- a) Science of Genetics
- b) Transgenics and Genomic Analysis
- c) Cell Cycle analysis
- d) Mitosis and Meiosis
- e) Cellular Activities and Checkpoints

Unit V 07 Hours

a) Cell Signals: Introduction

b) Receptors for Cell Signals

c) Signaling Pathways: Overview

d) Misregulation of Signaling Pathways

e) Protein-Kinases: Functioning

Recommended Books (latest edition):

- 1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- 2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
- 3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- 4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 5. Rose: Industrial Microbiology.
- 6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan 7.

Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution. 8.

Peppler: Microbial Technology.

- 9. Edward: Fundamentals of Microbiology.
- 10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
- 11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
- 12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
- 13. RA Goldshy et. al., : Kuby Immunology.

COSMETICSCIENCE(Theory)

45Hours

UNIT I 10Hours

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticalsfrom cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients,

preservatives. Classification and application **Skin:** Basic structure and function of skin. **Hair:** Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II 10 Hours

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmecuticals. **Antiperspants & deodorants**- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioningshampoo, Hair conditioner, anti-dandruff shampoo. Hair oils.

Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III 10 Hours

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmericHair

care: Henna and amla.
Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-

cream and toothpaste.

UNIT IV 08 Hours.

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evolution and skin benfits.

UNIT V 07 Hours

Oilyand dryskin, causes leading to dryskin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat andbodyodor. Antiperspirants and Deodorants- Actives and mechanism of action

References

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies inexperimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinicalresearch
- Appreciate and demonstrate the importance of biostatistics and researchmethodology
- Design and execute a research hypothesis independently

Unit –I	08 Hours
Laboratory Animals:	
Study of CPCSEA and OECD guidelines for maintenance, breeding and	
conduct of experiments on laboratory animals, Common lab animals:	
Description and applications of different species and strainsof animals.	
Popular transgenic and mutant animals.	
Techniques for collection of blood and common routes of drug	
administration in laboratory animals, Techniques of blood collection	
and euthanasia.	
Unit -II	10 Hours
Preclinical screening models	
a. Introduction: Dose selection, calculation and conversions,	
preparation of drug solution/suspensions, grouping of animals and	
importance of sham negative and positive control groups.	
Rationale for selection of animal species and sex for the study.	
b. Study of screening animal models for	
Diuretics, nootropics, anti-Parkinson's, antiasthmatics,	
Preclinical screening models: for CNS activity- analgesic,	
antipyretic,anti-inflammatory, general anaesthetics, sedative	
andhypnotics, antipsychotic, antidepressant, antiepileptic,	
antiparkinsonism, alzheimer's disease	

Unit –III	
Preclinical screening models: for ANS activity, sympathomimetics,	
sympatholytics, parasympathomimetics, parasympatholytics,	
skeletal muscle relaxants, drugs acting on eye, local anaethetics	
skeletai illustie relakants, urugs acting on eye, local anaethetics	
Unit –IV	
Preclinical screening models: for CVS activity- antihypertensives,	
diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory,	
coagulants, and anticoagulants	
Preclinical screening models for other important drugs like antiulcer,	
antidiabetic, anticancer and antiasthmatics.	
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Research methodology and Bio-statistics	05Hours
Selection of research topic, review of literature, research hypothesis	
and studydesign	
Pre-clinical data analysis and interpretation using Students 't' test	
and One-wayANOVA. Graphical representation of data	

Recommended Books (latest edition):

- 1. Fundamentals of experimental Pharmacology-byM.N.Ghosh
- 2. Hand book of Experimental Pharmacology-S.K.Kulakarni
- 3. CPCSEA guidelines for laboratoryanimal facility.
- 4. Drug discovery and Evaluation by Vogel H.G.
- 5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
- 6. Introduction to biostatistics and research methods by PSS Sundar Rao and JRichard

ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
 - understand the calibration of various analytical instruments
 - know analysis of drugs using various analytical instruments.

Course Content:

UNIT-I 10 Hours

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications **Mass Spectrometry**- Principles, Fragmentation, Ionization techniques — Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II 10 Hours

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry(DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X- ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT-III 10 Hours

Calibration and validation-as per ICH and USFDA guidelines **Calibration of following Instruments**

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

UNIT-IV 08 Hours

Radio immune assay:Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques:General principle and procedure involved in the solidphase extraction and liquid-liquid extraction

UNIT-V 07 Hours

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

- 1. Instrumental Methods of Chemical Analysis by B.K Sharma
- 2. Organic spectroscopy by Y.R Sharma
- 3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
- 4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 5. Practical Pharmaceutical ChemistrybyA.H. Beckett and J.B. Stenlake
- 6. Organic Chemistryby I. L. Finar
- 7. Organic spectroscopy by William Kemp
- 8. Quantitative Analysis of Drugs by D. C. Garrett
- 9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
- 10. Spectrophotometric identification of Organic Compounds by Silverstein

DIETARY SUPPLEMENTS AND NUTRACEUTICALS

No. of hours :3 Tutorial:1 Credit point:4

Scope:

This subject covers foundational topic that are important for understanding the need and requirements of dietarysupplements among different groups in the population.

Objective:

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- 1. Understand the need of supplements bythe different group of people to maintainhealthy life.
- 2. Understand the outcome of deficiencies in dietary supplements.
- 3. Appreciate the components in dietary supplements and the application. 4.

Appreciate the regulatory and commercial aspects of dietary supplements includinghealth claims.

UNIT I 07 hours

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
- b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
- c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II 15 hours

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical naturemedicinal benefits) of following

- a) Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, leutin
- b) Sulfides: Diallyl sulfides, Allyl trisulfide.
- c) Polyphenolics: Reservetrol
- d) Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans g) Tocopherols
- h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III 07 hours

 a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b) Dietaryfibres and complex carbohydrates as functional food ingredients..

UNIT IV 10 hours

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxyToluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention

UNIT V 06 hours

- a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on FoodSafety. Adulteration of foods.
 - c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals

References:

1. Dietetics by Sri Lakshmi

- 2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
- 3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
- 4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
- 5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
- 6. G. Gibson and C.williams Editors 2000 Functional foods Woodhead Publ.Co.London.
- 7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
- 8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
- 9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
- 10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

Semester VIII – Elective course on Pharmaceutical Product Development

No of Hours: 3 Tutorial:1 Credit points:4

Unit-I 10 Hours

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

Unit-II 10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Solvents and solubilizers
- ii. Cyclodextrins and their applications
- iii. Non ionic surfactants and their applications
- iv. Polyethylene glycols and sorbitols
- v. Suspending and emulsifying agents
- vi. Semi solid excipients

Unit-III 10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Tablet and capsule excipients
- ii. Directlycompressible vehicles
- iii. Coat materials
- iv. Excipients in parenteral and aerosols products
- v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specificindustrial applications

Unit-IV 08 Hours

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and itsapplication in pharmaceutical product development.

Unit-V 07 Hours

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

Recommended Books (Latest editions)

- 1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.
- 2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition,Informa Healthcare publishers.
- 3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
- 4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
- 5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BIPublications Pvt. Ltd.
- 6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
- 7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
- 8. Aulton's Pharmaceutics The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
- 9. Remington The Science and Practice of Pharmacy, 20th Ed.
- 10. Pharmaceutical Dosage Forms Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz
- 11. Pharmaceutical Dosage Forms Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
- 12. Pharmaceutical Dosage Forms Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.
- 13. Advanced Review Articles related to the topics