VELS UNIVERSITY

VELS INSTITUTE OF SCIENCE, TECHNOLOGY & ADVANCED STUDIES (VISTAS)

(Deemed to be University Estd. u/s 3 of the UGC Act, 1956)

PALLAVARAM - CHENNAI - INDIA

NAAC ACCREDITED

PROGRAM OBJECTIVES-PHARMACY

To provide solid foundation in pharmacy possessing basic knowledge and comprehensive understanding of Profession of Pharmacy

To prepare student graduates for a successful career in Pharmacy Profession with effective planning skills, problem analyzing skills, leadership skills, communication skills, and professional ethics

To train student graduates in learning, selecting, and applying appropriate methods, procedures, and resources of modern tools in Pharmacy Profession

Create dynamic and proficient Pharmacists for their successful careers in Pharmaceutical industry, academia, government organization, hospitals, and other organizations and as an entrepreneur

To train the students to promote practice of Pharmacy for improving and sustaining quality of life

To shape pharmacy graduates equipped with knowledge and skill to cater to the health-care needs of the society

To create state of art facilities to upgrade the technical skills of the students

To inculcate in student graduates, ability to gain multidisciplinary knowledge through innovative projects, industrial training, industrial visits, visiting research institutions, health care communities, health promoters, employees and employers

To promote environmental consciousness, cultural heritage, social, spiritual, and human values

To promote and enhance the quality of Pharmacy education and make student globally competent

PROGRAM OUTCOMES-PHARMACY

PO1: Pharmacy knowledge: Apply the knowledge of pharmacy fundamentals and an pharmaceutical specialization to the solution of complex pharmaceutical problems

PO2: Problem analysis: Identify, formulate, research literature, and analyze complex pharmaceutical problems reaching substantiated conclusions using first principles of natural sciences, mathematical, and pharmaceutical sciences

PO3: Design/Development of solutions: Design solutions for complex pharmaceutical problems and design system components or processes that meet the specified needs with appropriate considerations for public health and safety, and the cultural, societal, and environmental considerations

PO4: Conduct investigations of complex problems: Use research-based knowledge and research methods including design of experiments, analysis and interpretation of data, and synthesis of the information to provide valid conclusions

PO5: Modern tool usage: Create, select, and apply appropriate techniques, resources, and modern pharmaceutical tools including prediction and modeling to complex pharmaceutical activities with an understanding of the limitations

PO6: The Pharmacy and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety, legal and cultural issues and the consequent responsibilities relevant to the professional pharmaceutical practice

PO7: Environment and sustainability: Understand the impact of the professional pharmaceutical solutions in societal and pharmaceutical contexts, and demonstrate the knowledge of, and need for sustainable development

PO8: Ethics: Apply ethical principles and commit to professional ethics and responsibilities and norms of pharmaceutical practice

PO9: Individual and team work: Function effectively as an individual, and as a member or leader in diverse teams, and in multidisciplinary settings

PO10: Communication: Communicate effectively on complex pharmaceutical activities with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports and design documentation, make effective presentations, and give and receive clear instructions

PO11: Project management and finance: Demonstrate knowledge and understanding of the pharmaceutical and management principles and apply these to one's own work, as a member and leader in a team, to manage projects and in multidisciplinary environments

PO12: Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change

PROGRAM SPECIFIC OUTCOMES-PHARMACY

To impart fundamental knowledge of structure and functions of various systems, their biochemical aspects, patho-physiological roles and the therapeutic management through pharmacological science

To inculcate among the students the knowledge and technical skills to carry out synthesis and analysis of drugs as well as develop, manufacture, market pharmaceuticals and cosmetics

To develop among the students the knowledge and technical skills of biopharmaceutical aspects and bioassays as well as screening of drugs for pharmacological actions

To inculcate the knowledge and technical skills of identification, standardization of drugs obtained from natural origin, herbal drugs as well as development of herbal formulations and cosmetics

To train the students and develop their technical skill knowledge for handling sophisticated analytical instruments

To create a talent pool by involving students in research projects and to make students undertake research projects under faculty guidance for publication

To foster ambitious desire among students to undertake higher studies and career growth

To establish industry institute partnership cell to bridge the gap between the industrial requirements and the academic curriculum

To improve patient care in performing medication history, interpretations of laboratory data of biological samples, identifying potential-drug related influences of Pharmacotherapy

To establish systems management as an entrepreneur through inventory control, distribution systems, documentation, analysis of financial resources, utilizing management theories, and information technology in industrial Pharmacy and Business Management

School of Pharmaceutical Sciences

BOS Members

UG Board of Studies

S.No	Name	Post	Contact Address
1	Dr.P.Shanmugasundaram	Chairman	Director, School of Pharmaceutical Sciences, Vels University Chennai
2	Dr.S.Jayakumari	Professor	Professor and Head, Department of Pharmacognosy School of Pharmaceutical Sciences Vels University
3	Dr. S. Sathesh Kumar	Professor	Professor and Head, Department of Pharmaceutics School of Pharmaceutical Sciences Vels University
4	Dr. M.Vijey Aanandhi	Professor	Professor and Head, Department of Pharmaceutical chemistry and Analysis School of Pharmaceutical Sciences Vels University
5	Dr. S.Santhosh Kumar	Professor	Professor and Head, Department of Pharmacology School of Pharmaceutical Sciences Vels University
6	Dr.T.S.Shanmugarajan	Professor	Professor, Department of Pharmaceutics School of Pharmaceutical Sciences Vels University

7	Mr.M.Ashok Kumar	Associate Professor	Department of Pharmacy Practice School of Pharmaceutical Sciences Vels University
8	Dr.A.Vijayalakshmmi	Associate Professor	Department of Pharmacognosy School of Pharmaceutical Sciences Vels University
9	Mr.I.Somasundaram	Assistant Professor	Department of Pharmaceutics School of Pharmaceutical Sciences Vels University
10	Mrs. V.Jayashree	Assistant Professor	Department of Pharmacology School of Pharmaceutical Sciences Vels University
Subject Experts			
11	Mr.C.Venkatasubramaniyan	Expert (Industry)	Senior Scientist, Formulation Development, Par Formulations Pvt. Ltd., Kelambakkam, Chennai
12	Dr.R.Sundhararajan	Expert (Academic)	Professor and Principal M.S.A.J College of Pharmacy, Sholinganallur.
13	Mr.M.Shivanandhaperumal	Alumni	Territory Sales Executive, Sun Pharma,3/4, Old Tower Block Street, 1st Extension, Nandanam, Chennai-35

CURRICULUM STRUCTURE

Table-I: Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills – Theory *	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical*	2	-	1
BP112RBP	Remedial Biology – Practical*	2	-	1
	Total	**32/34$/36#**	**4**	**27/29$/30#**

[#]Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course**.**

[$]Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course**.**

* Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II –Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
	Total	**32**	**4**	**29**

*Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology – Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology – Practical	4	-	2
BP 308P	Pharmaceutical Engineering –Practical	4	-	2
	Total	**28**	**4**	**24**

Table-IV: Course of study for semester IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4		2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4	-	2
	Total	**31**	**5**	**28**

Table-V: Course of study for semester V

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Formulative Pharmacy– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Formulative Pharmacy – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	**27**	**5**	**26**

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance –Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
	Total	**30**	**6**	**30**

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial Pharmacy – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School*	12	-	6
	Total	**28**	**5**	**24**

Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharmaceutical Marketing	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardizations of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812PW	Project Work	12	-	6
	Total	**24**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	**27/29$/30#**
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	**209/211$/212#**

Schemes for internal assessments and end semester examinations semester wise

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP101T	Human Anatomy and Physiology I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP103T	Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP105T	Communication skills – Theory *	5	10	1 Hr	15	35	1.5 Hrs	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP109P	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP111P	Communication skills – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
BP112RBP	Remedial Biology – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**70/75$/80#**	**115/125$/130#**	**23/24$/26# Hrs**	**185/200$/210#**	**490/525$/ 540#**	**31.5/33$/ 35# Hrs**	**675/725$/ 750#**

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$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

Non University Examination (NUE)

Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP201T	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP203T	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP204T	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP205T	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP206T	Environmental sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP209P	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP210P	Computer Applications in Pharmacy – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
Total		**80**	**125**	**20 Hrs**	**205**	**520**	**30 Hrs**	**725**

The subject experts at college level shall conduct examinations

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP302T	PhysicalPharmaceuticsI –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP307P	Pharmaceutical Microbiology – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP308P	Pharmaceutical Engineering – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**60**	**100**	**20**	**160**	**440**	**28Hrs**	**600**

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP401T	Pharmaceutical Organic Chemistry III– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP402T	Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP404T	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP405T	Pharmacognosy I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP406P	Medicinal Chemistry I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP407P	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP408P	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP409P	Pharmacognosy I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**70**	**115**	**21 Hrs**	**185**	**515**	**31 Hrs**	**700**

Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Formulative Pharmacy– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Formulative Pharmacy – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**

Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

Semester VII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP701T	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705 P	Instrumental Methods of Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP706 PS	Practice School*	25	-	-	25	125	5 Hrs	150
Total		**70**	**70**	**8Hrs**	**140**	**460**	**21 Hrs**	**600**

The subject experts at college level shall conduct examinations

Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardizations of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150

Total	**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table-XI:Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	**Maximum Marks**	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	**10**	**5**
Practical		
Attendance (Refer Table – XII)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	**5**	

Table- XII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

11.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

I. Multiple Choice Questions (MCQs)
(Answer all the questions) = 10 x 1 = 10
I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10
II. Short Answers (Answer 2 out of 3) = 2 x 5 = 10

Total = 30 marks

For subjects having Non University Examination

I. Long Answers (Answer 1 out of 2)		=	1 x 10 = 10
II. Short Answers (Answer 4 out of 6)		=	4 x 5 = 20

	Total	=	30 marks

Question paper pattern for practical sessional examinations

I. Synopsis		=	10
II. Experiments		=	25
III. Viva voce		=	05

	Total	=	40 marks

Question paper pattern for end semester theory examinations

For 75 marks paper

I. Multiple Choice Questions(MCQs)		
(Answer all the questions)	=	20 x 1 = 20
I. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
II. Short Answers (Answer 7 out of 9)	=	7 x 5 = 35

Total	=	75 marks

For 50 marks paper

I. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
II. Short Answers (Answer 6 out of 8)	=	6 x 5 = 30

Total	=	50 marks

For 35 marks paper

I. Long Answers (Answer 1 out of 2)	=	1 x 10 =10
II. Short Answers (Answer 5 out of 7)	=	5 x 5 = 25

Total	=	35 marks

Question paper pattern for end semester practical examinations

I. Synopsis	=	5
II. Experiments	=	25
III. Viva voce	=	5

Total	=	35 marks

SYLLABUS

BP101T. 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

Explain the gross morphology, structure and functions of various organs of the human body.
Describe the various homeostatic mechanisms and their imbalances.
Identify the various tissues and organs of different systems of human body.
Perform the various experiments related to special senses and nervous system.
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 its articulation

Unit III **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 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**

Endocrine system

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

BP107P. 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**.**

Study of compound microscope.

Microscopic study of epithelial and connective tissue

Microscopic study of muscular and nervous tissue

Identification of axial bones

Identification of appendicular bones

To study the integumentary and special senses using specimen, models, etc.,

To study the nervous system using specimen, models, etc.,

To study the endocrine system using specimen, models, etc

To demonstrate the general neurological examination

To demonstrate the function of olfactory nerve

To examine the different types of taste.

To demonstrate the visual acuity

To demonstrate the reflex activity

Recording of body temperature

To demonstrate positive and negative feedback mechanism.

Recommended Books (Latest Editions)

Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.

Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York

Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.

Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.

Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.

Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA

Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.

Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP102T. 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**

Pharmaceutical analysis- Definition and scope

Different techniques of analysis

Methods of expressing concentration

Primary and secondary standards.

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

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, and very weak 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

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.

UNIT-IV **08 Hours**

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT-V **07 Hours**

Electrochemical methods of analysis

Conductometry- Introduction, Conductivity cell, Conductometric titrations, applications.

Potentiometry - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.

Polarography - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

Preparation and standardization of

Sodium hydroxide
Sulphuric acid
Sodium thiosulfate
Potassium permanganate
Ceric ammonium sulphate

Assay of the following compounds along with Standardization of Titrant

Ammonium chloride by acid base titration
Ferrous sulphate by Cerimetry
Copper sulphate by Iodometry
Calcium gluconate by complexometry
Hydrogen peroxide by Permanganometry
Sodium benzoate by non-aqueous titration
Sodium Chloride by precipitation titration

Determination of Normality by electro-analytical methods

Conductometric titration of strong acid against strong base
Conductometric titration of strong acid and weak acid against strong base
Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
A.I. Vogel, Text Book of Quantitative Inorganic analysis
P. Gundu Rao, Inorganic Pharmaceutical Chemistry
Bentley and Driver's Textbook of Pharmaceutical Chemistry
John H. Kennedy, Analytical chemistry principles
Indian Pharmacopoeia.

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

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

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

Know the history of profession of pharmacy

Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations

Understand the professional way of 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, body weight and body surface 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 ofEmulsion, 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

BP109P. PHARMACEUTICSI (Practical)

3 Hours / week

1. Syrups a) Syrup IP

Paracetamol pediatric syrup

Elixirsa) Piperazine citrate elixir

Paracetamol pediatric elixir

3.Linctusa) Simple Linctus BPC

4. Solutions

Strong solution of ammonium acetate

Cresol with soap solution

Suspensions a) Calamine lotion

Magnesium Hydroxide mixture

Emulsions a) Turpentine Liniment

Liquid paraffin emulsion

Powders and Granules

ORS powder (WHO)

Effervescent granules

c)Dusting powder

Suppositories

Glycero gelatin suppository

Soap glycerin suppository

Semisolids

Sulphur ointment

Non staining iodine ointment with methyl salicylate

Bentonite gel

Gargles and Mouthwashes

Potassium chlorate gargle

Chlorhexidinemouthwash

Recommended Books: (Latest Editions)

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

BP104T. 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 of fluoride in the treatment 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, Boric acid, 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 I^{131}, Storage conditions, precautions & pharmaceutical application of radioactive substances.

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

Limit tests for following ions

Limit test for Chlorides and Sulphates
Modified limit test for Chlorides and Sulphates
Limit test for Iron
Limit test for Heavy metals
Limit test for Lead
Limit test for Arsenic

Identification test

Magnesium hydroxide
Ferrous sulphate
Sodium bicarbonate
Calcium gluconate
Copper sulphate

Test for purity

Swelling power of Bentonite
Neutralizing capacity of aluminum hydroxide gel
Determination of potassium iodate and iodine in potassium Iodide

IV **Preparation of inorganic pharmaceuticals**

Boric acid
Potash alum
Ferrous sulphate

Recommended Books (Latest Editions)

A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.

A.I. Vogel, Text Book of Quantitative Inorganic analysis

P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition

M.L Schroff, Inorganic Pharmaceutical Chemistry

Bentley and Driver's Textbook of Pharmaceutical Chemistry

Anand & Chatwal, Inorganic Pharmaceutical Chemistry

7. Indian Pharmacopoeia

BP105T.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

Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation

Communicate effectively (Verbal and Non Verbal)

Effectively manage the team as a team player

Develop interview skills

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

BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

Thefollowing learning modules are to be conducted using wordsworth® English language lab 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

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

Recommended Books: (Latest Edition)

Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011

Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011

Organizational Behaviour, Stephen .P. Robbins, 1st Edition, Pearson, 2013

Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011

The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5th Edition, Pearson, 2013

Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010

Communication skills for professionals, Konar nira, 2nd Edition, New arrivals – PHI, 2011

Personality development and soft skills, Barun K Mitra, 1st Edition, Oxford Press, 2011

Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011

Soft skills and professional communication, Francis Peters SJ, 1st Edition, Mc Graw Hill Education, 2011

Effective communication, John Adair, 4th Edition, Pan Mac Millan,2009

Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999

BP 106RBT.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 & physiology of plant

know understand the basic components of anatomy & physiology animal with special reference to human

UNIT I **07 Hours**

Living world:

Definition and characters of living organisms
Diversity in 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 Anatomy of 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 circulatory system
Structure of human heart and blood vessels
Cardiac cycle, cardiac output and ECG

Digestion and Absorption

Human alimentary canal and digestive glands
Role of digestive enzymes
Digestion, absorption and assimilation of digested food

Breathing and respiration

Human respiratory system
Mechanism of breathing and its regulation
Exchange of gases, transport of gases and regulation of respiration
Respiratory volumes

UNIT III **07 Hours**

Excretory products and their elimination

Modes of excretion
Human excretory system- 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 by endocrine 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 affecting photosynthesis.

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 growth regulators

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 by S. B. Gokhale

b. A Text book of Biology by Dr. 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 Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.

e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

Introduction to experiments in biology
- Study of Microscope
- Section cutting techniques
- Mounting and staining
- Permanent slide preparation

Study of cell and its inclusions
Study of Stem, Root, Leaf and its modifications
Detailed study of frog by using computer models
Microscopic study and identification of tissues
Identification of bones
Determination of blood group
Determination of blood pressure
Determination of tidal volume

Reference Books

Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.

A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.

Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

BP 106RMT.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:-

Know the theory and their application in Pharmacy

Solve the different types of problems by applying theory

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 ($\in$ - δ definition) , $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{\theta \to 0} \frac{\sin\theta}{\theta} = 1,$

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,Applicationof Matrices in solving Pharmacokinetic equations

UNIT – III **06 Hours**

Calculus

Differentiation : Introductions, Derivative of a function, Derivative of a constant, 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.t*x,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 a maximum 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)

Differential Calculus by Shanthinarayan

Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.

Integral Calculus by Shanthinarayan

Higher Engineering Mathematics by Dr.B.S.Grewal

Semester II

BP 201T. 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:

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

Course Content:

Unit I **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 II **10 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.

Unit III **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.

Respiratory system

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

Unit IV

- **Respiratory system** **10 hours**

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 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

BP 207 P. 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**.**

Introduction to hemocytometry.

Enumeration of white blood cell (WBC) count

Enumeration of total red blood corpuscles (RBC) count

Determination of bleeding time

Determination of clotting time

Estimation of hemoglobin content

Determination of blood group.

Determination of erythrocyte sedimentation rate (ESR).

Determination of heart rate and pulse rate.

Recording of blood pressure.

Determination of tidal volume and vital capacity.

Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.

13. Recording of basal mass index .

Study of family planning devices and pregnancy diagnosis test.

Demonstration of total blood count by cell analyser

Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.

Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York

Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.

Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.

Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.

Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA

Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.

Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP202T. 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

write the structure, name and the type of isomerism of the organic compound

write the reaction, name the reaction and orientation of reactions

account for reactivity/stability of compounds,

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*

SP^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

Stabilities of alkenes, SP^2 hybridization in alkenes

E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 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.

SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions

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

Alcohols*- Qualitative tests, Structure and uses of Ethyl 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

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

Systematic qualitative analysis of unknown organic compounds like

Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.

Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test

Solubility test

Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.

Melting point/Boiling point of organic compounds

Identification of the unknown compound from the literature using melting point/ boiling point.

Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.

Minimum 5 unknown organic compounds to be analysed systematically.

Preparation of suitable solid derivatives from organic compounds

Construction of molecular models

Recommended Books (Latest Editions)

Organic Chemistry by Morrison and Boyd

Organic Chemistry by I.L. Finar , Volume-I

Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.

Organic Chemistry by P.L.Soni

Practical Organic Chemistry by Mann and Saunders.

Vogel's text book of Practical Organic Chemistry

Advanced Practical organic chemistry by N.K.Vishnoi.

Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

Reaction and reaction mechanism by Ahluwaliah/Chatwal.

BP203 T. 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

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

Course Content:

UNIT I **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- Pathway and 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 II **10 Hours**

Lipid metabolism

β-Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

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

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver 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 III **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 functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT IV **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 ATP and cyclic AMP

UNIT V **07 Hours**

Enzymes

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme 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

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)

Identification tests for Proteins (albumin and Casein)

Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)

Qualitative analysis of urine for abnormal constituents

Determination of blood creatinine

Determination of blood sugar

Determination of serum total cholesterol

Preparation of buffer solution and measurement of pH

Study of enzymatic hydrolysis of starch

Determination of Salivary amylase activity

Study the effect of Temperature on Salivary amylase activity.

Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

Principles of Biochemistry by Lehninger.
Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
Biochemistry by Stryer.
Biochemistry by D. Satyanarayan and U.Chakrapani
Textbook of Biochemistry by Rama Rao.
Textbook of Biochemistry by Deb.
Outlines of Biochemistry by Conn and Stumpf
Practical Biochemistry by R.C. Gupta and S. Bhargavan.
Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
Practical Biochemistry by Harold Varley.

BP 204T.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 –

Describe the etiology and pathogenesis of the selected disease states;
Name the signs and symptoms of the diseases; and
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, Chronic obstructive 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, hereditary acquired 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

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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, etiology and pathogenesis of cancer
Diseases of bones and joints: 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 transmitted diseases:AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.

Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.

Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.

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;

William and Wilkins, Baltimore;1991 [1990 printing].

Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.

Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.

Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.

V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.

Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

The Journal of Pathology. ISSN: 1096-9896 (Online)

The American Journal of Pathology. ISSN: 0002-9440

Pathology. 1465-3931 (Online)

International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)

Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

BP205 T. 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

know the various types of application of computers in pharmacy
know the various types of databases
know the various applications of databases in pharmacy

Course content:

UNIT – I **06 hours**

Number system: Binary number system, Decimal number system, Octal number 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, binary division

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 **hours**

Web technologies:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III **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 identification and automated dispensing of drugs, mobile technology and adherence monitoring

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

UNIT – IV **06 hours**

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

UNIT-V **06 hours**

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

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

Design a questionnaire using a word processing package to gather information about a particular disease.

Create a HTML web page to show personal information.

Retrieve the information of a drug and its adverse effects using online tools

Creating mailing labels Using Label Wizard , generating label in MS WORD

Create a database in MS Access to store the patient information with the required fields Using access

Design a form in MS Access to view, add, delete and modify the patient record in the database

Generating report and printing the report from patient database

Creating invoice table using – MS Access

Drug information storage and retrieval using MS Access

Creating and working with queries in MS Access

Exporting Tables, Queries, Forms and Reports to web pages

Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.

Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA

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

BP 206 T. 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**:**

Create the awareness about environmental problems among learners.
Impart basic knowledge about the environment and its allied problems.
Develop an attitude of concern for the environment.
Motivate learner to participate in environment protection and environment improvement.
Acquire skills to help the concerned individuals in identifying and solving environmental problems.
Strive to attain harmony with Nature.

Course content:

Unit-I **10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

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 **10hours**

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, estuaries)

Unit- III **10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore

Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.

Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,

Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p

Clark R.S., Marine Pollution, Clanderson Press Oxford

Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p

De A.K., Environmental Chemistry, Wiley Eastern Ltd.

Down of Earth, Centre for Science and Environment

SEMESTER III

BP301T. 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

write the structure, name and the type of isomerism of the organic compound

write the reaction, name the reaction and orientation of reactions

account for reactivity/stability of compounds,

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

Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule

Reactions of benzene - nitration, sulphonation, halogenation-reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.

Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction

Structure and uses of DDT, Saccharin, BHC and Chloramine

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

UNIT III **10 Hours**

Fats and Oils

a. Fatty acids – reactions.

Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

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:

Synthesis, reactions

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

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

Experiments involving laboratory techniques

Recrystallization

Steam distillation

Determination of following oil values (including standardization of reagents)

Acid value

Saponification value

Iodine value

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 by halogenation (Bromination) reaction.

5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.

Benzoic acid from Benzyl chloride by oxidation 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 by oxidation reaction.

Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction

Cinnammic acid from Benzaldehyde by Perkin reaction

P-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

Organic Chemistry by Morrison and Boyd
Organic Chemistry by I.L. Finar , Volume-I
Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
Organic Chemistry by P.L.Soni
Practical Organic Chemistry by Mann and Saunders.
Vogel's text book of Practical Organic Chemistry
Advanced Practical organic chemistry by N.K.Vishnoi.

8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

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

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

Understand various physicochemical properties of drug molecules in the designing the dosage form

Know the principles of chemical kinetics & to use them in assigning expiry date for formulation

Demonstrate use of physicochemical properties in evaluation of dosage forms.

Appreciate physicochemical properties of drug molecules in formulation research and development

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, Dissolution & drug release, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions, azeotropic mixtures, fractional distillation. 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 **10Hours**

Micromeretics: Particle size and distribution, average 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-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 stability constants.

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.

BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

Determination the solubility of drug at room temperature

Determination of pKa value by Half Neutralization/ Henderson Hassel Balch equation.

Determination of Partition co- efficient of benzoic acid in benzene and water

Determination of Partition co- efficient of Iodine in CCl_4 and water

Determination of % composition of NaCl in a solution using phenol-water system by CST method

Determination of particle size, particle size distribution using sieving method

Determination of particle size, particle size distribution using Microscopic method

Determination of bulk density, true density and porosity

Determine the angle of repose and influence of lubricant on angle of repose

Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method

Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

Physical pharmacy by Alfred Martin
Experimental pharmaceutics by Eugene, Parott.
Tutorial pharmacy by Cooper and Gunn.
Stocklosam J. Pharmaceutical calculations, Lea &Febiger, Philadelphia.
Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
Physical pharmaceutics by Ramasamy C and ManavalanR.
Laboratory manual of physical pharmaceutics, C.V.S. Subramanyam, J. Thimma settee

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

In the broadest sense, scope of microbiology is the study of all organisms that are invisible to the naked eye- that is the study of microorganisms.

Microorganisms are necessary for the production of bread, cheese, beer, antibiotics, vaccines, vitamins, enzymes etc.

Microbiology has an impact on medicine, agriculture, food science, ecology, genetics, biochemistry, immunology etc.

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

Understand methods of identification, cultivation and preservation of various microorganisms
Importance of sterilization in microbiology. and pharmaceutical industry
Learn sterility testing of pharmaceutical products.
Microbiological standardization of Pharmaceuticals.
Understand the cell culture technology and its applications in pharmaceutical industries.

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 &Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of Physical, chemical and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III **10 Hours**

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

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 sterile products) 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 and testing of antimicrobial activity of a new substance.
General aspects-environmental cleanliness.

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 industry and research.

BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

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.

Sterilization of glassware, preparation and sterilization of media.

Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.

Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).

Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.

Microbiological assay of antibiotics by cup plate method and other methods

Motility determination by Hanging drop method.

Sterility testing of pharmaceuticals.

Bacteriological analysis of water

Biochemical test (IMViC reactions)

Revision Practical Class

Recommended Books (Latest edition)

W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.

Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.

Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.

Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.

Rose: Industrial Microbiology.

Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan

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

Peppler: Microbial Technology.

I.P., B.P., U.S.P.- latest editions.

Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai

Edward: Fundamentals of Microbiology.

N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi

Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

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

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

To know various unit operations used in Pharmaceutical industries.

To understand the material handling techniques.

To perform various processes involved in pharmaceutical manufacturing process.

To carry out various test to prevent environmental pollution.

To appreciate and comprehend significance of plant lay out design for optimum use of resources.

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, Air separator, Bag filter & elutriation tank.

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 Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-II **10 Hours**

Crystallization: Objectives, applications, & theory of crystallization. Solubility curves, principles, construction, working, uses, merits and demerits of Agitated batch crystallizer, Swenson Walker Crystallizer, Krystal crystallizer, Vacuum crystallizer. Caking of crystals, factors affecting caking & prevention of caking.

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& Economy of multiple effect evaporator.

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

UNIT- III **10 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.

Distillation: Objectives, applications & types of distillation. principles, construction, working, uses, merits and demerits of (lab scale and industrial scale) Simple distillation, preparation of purified water and water for injection BP by distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

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**

Plant location, industrial hazards and plant safety: Plant Layout, utilities and services, Mechanical hazards, Chemical hazards, Fire hazards, explosive hazards and their safety.

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.

Material handling systems: Objectives & applications of Material handling systems, different types of conveyors such as belt, screw and pneumatic conveyors.

Recommended Books: (Latest Editions)

Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.

Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.

Unit operation of chemical engineering – Mcabe Smith, Latest edition.

Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.

Remington practice of pharmacy- Martin, Latest edition.

Theory and practice of industrial pharmacy by Lachmann., Latest edition.

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

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

BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

Determination of radiation constant of brass, iron, unpainted and painted glass.
Steam distillation – To calculate the efficiency of steam distillation.
To determine the overall heat transfer coefficient by heat exchanger.

IV. Construction of drying curves (for calcium carbonate and starch).
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 arithmetic andlogarithmic 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.
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, Concentration and 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.

SEMESTER IV

BP401T. 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

understand the methods of preparation and properties of organic compounds

explain the stereo chemical aspects of organic compounds and stereo chemical reactions

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 optical activity.

Stereospecific and stereoselective reactions

UNIT-III **10 Hours**

Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene - Relative aromaticity, reactivity and Basicity of pyrrole

UNIT-IV **8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V **07 Hours**

Reactions of synthetic importance

Metal hydride reduction ($NaBH_4$ and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

Recommended Books (Latest Editions)

Organic chemistry by I.L. Finar, Volume-I & II.

A text book of organic chemistry – Arun Bahl, B.S. Bahl.

Heterocyclic Chemistry by Raj K. Bansal

Organic Chemistry by Morrison and Boyd

Heterocyclic Chemistry by T.L. Gilchrist

BP402T. 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, importance of 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

understand the chemistry of drugs with respect to their pharmacological activity

understand the drug metabolic pathways, adverse effect and therapeutic value of drugs

know the Structural Activity Relationship (SAR) of different class of drugs

write the chemical synthesis of some 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**

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

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

Drug metabolism

Drug metabolism principles- Phase I and 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.

BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I Preparation of drugs/ intermediates

1,3-pyrazole

1,3-oxazole

Benzimidazole

Benztriazole

2,3- diphenyl quinoxaline

Benzocaine

Phenytoin

Phenothiazine

Barbiturate

II Assay of drugs

Chlorpromazine

Phenobarbitone

Atropine

Ibuprofen

Aspirin

Furosemide

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.

Foye's Principles of Medicinal Chemistry.

Burger's Medicinal Chemistry, Vol I to IV.

Introduction to principles of drug design- Smith and Williams.

Remington's Pharmaceutical Sciences.

Martindale's extra pharmacopoeia.

Organic Chemistry by I.L. Finar, Vol. II.
The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
Indian Pharmacopoeia.
Text book of practical organic chemistry- A.I.Vogel.

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

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

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

Understand various physicochemical properties of drug molecules in the designing the dosage form
Know the principles of chemical kinetics & to use them in assigning expiry date for Formulation
Demonstrate use of physicochemical properties in evaluation of dosage forms.
Appreciate physicochemical properties of drug molecules in formulation research and Development

Course Content:

UNIT-I **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

UNIT-II **10 Hours**

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatants, 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 suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Physical stability of emulsions, preservation of emulsions, rheological properties of emulsions, phase equilibria and emulsion formulation.

UNIT-IV **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-V **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.

BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

Determination of surface tension of given liquids by drop count and drop weight method

Determination of HLB number of a surfactant by saponification method

Determination of Freundlich and Langmuir constants using activated char coal

Determination of critical micellar concentration of surfactants

Determination of viscosity of liquid using Ostwald's viscometer

Determination sedimentation volume with effect of different suspending agent

Determination sedimentation volume with effect of different concentration of single suspending agent

Determination of viscosity of semisolid by using Brookfield viscometer

Determination of reaction rate constant first order.

Determination of reaction rate constant second order

Accelerated stability studies

Recommended Books: (Latest Editions)

Physical Pharmacy by Alfred Martin, Sixth edition

Experimental pharmaceutics by Eugene, Parott.

Tutorial pharmacy by Cooper and Gunn.

Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.

Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.

Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.

Physical Pharmaceutics by Ramasamy C, and Manavalan R.

BP 404 T. PHARMACOLOGY-I (Theory)

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

Understand the pharmacological actions of different categories of drugs
Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
Observe the effect of drugs on animals by simulated experiments
Appreciate correlation of pharmacology with other bio medical sciences

Course Content:

UNIT-I **08 hours**

General Pharmacology

Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT-II **12 Hours**

General Pharmacology

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.

Adverse drug reactions.

Drug interactions (pharmacokinetic and pharmacodynamic)

Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III **10 Hours**

2. Pharmacology of 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 central nervous system

a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

General anesthetics and pre-anesthetics**.**

Sedatives, hypnotics and centrally acting muscle relaxants.

Anti-epileptics

Alcohols and disulfiram

UNIT-V **07 Hours**

3. Pharmacology of central nervous system

Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.

Drugs used in Parkinsons disease and Alzheimer's disease.

CNS stimulants and nootropics.

Opioid analgesics and antagonists

Drug addiction, drug abuse, tolerance and dependence.

BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

Introduction to experimental pharmacology.

Commonly used instruments in experimental pharmacology.

Study of common laboratory animals.

Maintenance of laboratory animals as per CPCSEA guidelines.

Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.

Study of different routes of drugs administration in mice/rats.

Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.

Effect of drugs on ciliary motility of frog oesophagus

Effect of drugs on rabbit eye.

Effects of skeletal muscle relaxants using rota-rod apparatus.

Effect of drugs on locomotor activity using actophotometer.

Anticonvulsant effect of drugs by MES and PTZ method.

Study of stereotype and anti-catatonic activity of drugs on rats/mice.

Study of anxiolytic activity of drugs using rats/mice.

Study of 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)

Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,.Churchil Livingstone Elsevier

Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill

Goodman and Gilman's, The Pharmacological Basis of Therapeutics

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

Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.

Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

BP 405 T.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 their medicinal properties.

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

to know the techniques in the cultivation and production of crude drugs
to know the crude drugs, their uses and chemical nature
know the evaluation techniques for the herbal drugs
to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I **10 Hours**

Introduction to Pharmacognosy:

Definition, history, scope and development of Pharmacognosy

Sources of Drugs – Plants, Animals, Marine & Tissue culture

Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, 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 and hybridization 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, Homeopathy and 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 Primary metabolites: **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

BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

Analysis of crude drugs by chemical tests: **(**i)Tragaccanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil

Determination of stomatal number and index

Determination of vein islet number, vein islet termination and paliside ratio.

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

Determination of Fiber length and width

Determination of number of starch grains by Lycopodium spore method

Determination of Ash value

Determination of Extractive values of crude drugs

Determination of moisture content of crude drugs

Determination of swelling index and foaming

Recommended Books: (Latest Editions)

W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.

Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.

Text Book of Pharmacognosy by T.E. Wallis

Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.

Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.

Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.

Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007

Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae

Anatomy of Crude Drugs by M.A. Iyengar

SEMESTER V

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, importance of 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

Understand the chemistry of drugs with respect to their pharmacological activity

Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs

Know the Structural Activity Relationship of different class of drugs

Study the 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

H_1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H_2-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, Isosorbide dinitrite*, 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-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, 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 and Cholestipol

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, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.
Drugs for erectile dysfunction: Sildenafil, Tadalafil.
Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol
Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone
Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V **07 Hours**

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)

Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
Foye's Principles of Medicinal Chemistry.
Burger's Medicinal Chemistry, Vol I to IV.
Introduction to principles of drug design- Smith and Williams.
Remington's Pharmaceutical Sciences.
Martindale's extra pharmacopoeia.
Organic Chemistry by I.L. Finar, Vol. II.

The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
Indian Pharmacopoeia.
Text book of practical organic chemistry- A.I.Vogel.

BP 502 T. FORMULATIVEPHARMACY (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

Know the various pharmaceutical dosage forms and their manufacturing techniques.

Know various considerations in development of pharmaceutical dosage forms

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, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation,

polymerization BCS classification of drugs

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.

Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

Quality control tests: In process and finished product tests

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

UNIT-III 08 Hours Capsules:

a. ***Hard gelatin capsules:*** Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules. 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 minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules

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 essential requirements, vehicles, additives, importance of isotonicity

Production procedure, production facilities and controls.

Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization.

Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.

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, stability aspects of packaging materials, quality control tests.

BP 506 P. FORMULATIVEPHARMACY (Practical)

4 Hours/week

Preformulation study for prepared granules

Preparation and evaluation of Paracetamol tablets

Preparation and evaluation of Aspirin tablets

Coating of tablets

Preparation and evaluation of Tetracycline capsules

Preparation of Calcium Gluconate injection

Preparation of Ascorbic Acid injection

Preparation of Paracetamol Syrup

Preparation of Eye drops

Preparation of Pellets by extrusion spheronization technique

Preparation of Creams (cold / vanishing cream)

Evaluation of Glass containers

Recommended Books: (Latest Editions)

Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz

Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman

Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman

Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition

Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)

Theory and Practice of Industrial Pharmacy by Liberman & Lachman

Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition

Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005

Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

BP503.T. PHARMACOLOGY-II (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 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

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

Course Content:

UNIT-I **10hours**

Pharmacology of drugs acting on cardio vascular system

Introduction to hemodynamic and electrophysiology of heart.
Drugs used in congestive heart failure
Anti-hypertensive drugs.
Anti-anginal drugs.
Anti-arrhythmic drugs.
Anti-hyperlipidemic drugs.

UNIT-II **10hours**

Pharmacology of drugs acting on cardio vascular system

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

Pharmacology of drugs acting on urinary system

Diuretics
Anti-diuretics.

UNIT-III **10hours**

Autocoids and related drugs

Introduction to autacoids and classification
Histamine, 5-HT and their antagonists.
Prostaglandins, Thromboxanes and Leukotrienes.
Angiotensin, Bradykinin and Substance P.
Non-steroidal anti-inflammatory agents
Anti-gout drugs
Antirheumatic drugs

UNIT-IV **08hours**

Pharmacology of drugs acting on endocrine system

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

UNIT-V **07hours**

Pharmacology of drugs acting on endocrine system

Androgens and Anabolic steroids.
Estrogens, progesterone and oral contraceptives.
Drugs acting on the uterus.

Bioassay

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

BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

Introduction to *in-vitro* pharmacology and physiological salt solutions.
Effect of drugs on isolated frog heart.
Effect of drugs on blood pressure and heart rate of dog.
Study of diuretic activity of drugs using rats/mice.
DRC of acetylcholine using frog rectus abdominis muscle.
Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
Bioassay of histamine using guinea pig ileum by matching method.
Bioassay of oxytocin using rat uterine horn by interpolation method.
Bioassay of serotonin using rat fundus strip by three point bioassay.
Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
Determination of PD_2 value using guinea pig ileum.
Effect of spasmogens and spasmolytics using rabbit jejunum.
Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
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)

Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
Goodman and Gilman's, The Pharmacological Basis of Therapeutics
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.
Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how the secondary 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

to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents

to understand the preparation and development of herbal formulation.

to understand the herbal drug interactions

to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I **7 Hours**

Metabolic pathways in higher plants and their determination

Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.

Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II **20 Hours**

General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, biosources, therapeutic uses and commercial applications of following secondary metabolites:

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

UNIT-III **10 Hours**

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

UNIT IV **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 crude drugs.

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander

Exercise involving isolation & detection of active principles

- Caffeine - from tea dust.
- Diosgenin from Dioscorea
- Atropine from Belladonna
- Sennosides from Senna

Separation of sugars by Paper chromatography

TLC of herbal extract

Distillation of volatile oils and detection of phytoconstitutents by TLC

Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.

Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.

Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.

Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.

Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007

Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.

A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.

R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.

Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.

The formulation and preparation of cosmetic, fragrances and flavours.

Remington's Pharmaceutical sciences.

Text Book of Biotechnology by Vyas and Dixit.

Text Book of Biotechnology by R.C. Dubey.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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

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

The Pharmaceutical legislations and their implications in the development and marketing
Various Indian pharmaceutical Acts and Laws
The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
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 and rules

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; its 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, 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 Pharmacy by B. Suresh

Text book of Forensic Pharmacy by B.M. Mithal

Hand book of drug law-by M.L. Mehra

A text book of Forensic Pharmacy by N.K. Jain

Drugs and Cosmetics Act/Rules by Govt. of India publications.

Medicinal and Toilet preparations act 1955 by Govt. of India publications.

Narcotic drugs and psychotropic substances act by Govt. of India publications

Drugs and Magic Remedies act by Govt. of India publication

9.Bare Acts of the said laws published by Government. Reference books (Theory)

SEMESTER VI

BP601T. 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

Understand the importance of drug design and different techniques of drug design.

Understand the chemistry of drugs with respect to their biological activity.

Know the metabolism, adverse effects and therapeutic value of drugs.

Know the importance of SAR of 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 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, Gatifloxacin, 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.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

Sulphanilamide

7-Hydroxy, 4-methyl coumarin

Chlorobutanol

Triphenyl imidazole

Tolbutamide

Hexamine

II Assay of drugs

Isonicotinic acid hydrazide

Chloroquine

Metronidazole

Dapsone

Chlorpheniramine maleate

Benzyl penicillin

Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

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)

Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.

Foye's Principles of Medicinal Chemistry.

Burger's Medicinal Chemistry, Vol I to IV.

Introduction to principles of drug design- Smith and Williams.

Remington's Pharmaceutical Sciences.

Martindale's extra pharmacopoeia.

Organic Chemistry by I.L. Finar, Vol. II.
The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
Indian Pharmacopoeia.
Text book of practical organic chemistry- A.I.Vogel.

BP602 T. 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:

understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
comprehend the principles of toxicology and treatment of various poisoningsand
appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hours**

Pharmacology of drugs acting on Respiratory system

Anti -asthmatic drugs
Drugs used in the management of COPD
Expectorants and antitussives
Nasal decongestants
Respiratory stimulants

Pharmacology of drugs acting on the Gastrointestinal Tract

Antiulcer agents.
Drugs for constipation and diarrhoea.
Appetite stimulants and suppressants.
Digestants and carminatives.
Emetics and anti-emetics.

UNIT-II **10hours**

Chemotherapy

General principles of chemotherapy.

Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III **10hours**

Chemotherapy

Antitubercular agents

Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08hours**

Chemotherapy

Urinary tract infections and sexually transmitted diseases.

Chemotherapy of malignancy.

Immunopharmacology

Immunostimulants

Immunosuppressant

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

UNIT-V **07hours**

Principles of toxicology

Definition and basic knowledge of acute, subacute and chronic toxicity.

Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

General principles of treatment of poisoning

Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology

Definition of rhythm and cycles.

Biological clock and their significance leading to chronotherapy.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

Dose calculation in pharmacological experiments
Antiallergic activity by mast cell stabilization assay
Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
Study of effect of drugs on gastrointestinal motility
Effect of agonist and antagonists on guinea pig ileum
Estimation of serum biochemical parameters by using semi- autoanalyser
Effect of saline purgative on frog intestine
Insulin hypoglycemic effect in rabbit
Test for pyrogens (rabbit method)
Determination of acute oral toxicity (LD50) of a drug from a given data
Determination of acute skin irritation / corrosion of a test substance
Determination of acute eye irritation / corrosion of a test substance
Calculation of pharmacokinetic parameters from a given data
Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
Goodman and Gilman's, The Pharmacological Basis of Therapeutics
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
Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (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 regulatory issues of herbal drugs

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

understand raw material as source of herbal drugs from cultivation to herbal drug product

know the WHO and ICH guidelines for evaluation of herbal drugs

know the herbal cosmetics, natural sweeteners, nutraceuticals

appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I **6 Hours**

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation
Source of Herbs
Selection, identification and authentication of herbal
materials Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming.
Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

UNIT-II **05 Hours**

Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

UNIT-III **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-IV **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, viscosity builders, disintegrants, flavors & perfumes.

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

UNIT- V **10 Hours**

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:
Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

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

UNIT-VI **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.

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

To perform preliminary phytochemical screening of crude drugs.

Determination of Ash value

Determination of moisture content of crude drugs

Determination of Extractive values of crude drugs

Determination of the alcohol content of Asava and Arista

Preparation of herbal cosmetics

Preparation and standardization of herbal formulation

Determination of swelling index and foaming index

Monograph analysis of herbal drugs from recent Pharmacopoeias

Analysis of fixed oils

Recommended Books: (Latest Editions)

Textbook of Pharmacognosy by Trease & Evans.

Textbook of Pharmacognosy by Tyler, Brady & Robber.

Pharmacognosy by Kokate, Purohit and Gokhale

Essential of Pharmacognosy by Dr.S.H.Ansari

Pharmacognosy & Phytochemistry by V.D.Rangari

Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

Scope: This subject is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of Biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

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

Understand the basic concepts in biopharmaceutics and pharmacokinetics.
Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
Critically evaluate biopharmaceutic studies involving drug product equivalency
Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

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 of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II **10 Hours**

Drug Elimination renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

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

UNIT- III **10 Hours**

Pharmacokinetics: Introduction to Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of Ka, K_E. From plasma and urinary excretion data

UNIT- IV **08 Hours**

Multicompartment models: Two compartment open model. IV bolus

Multiple – Dosage Regimens:

a). Repititive Intravenous injections – One Compartment Open Model

b). Repititive Extravascular dosing – One Compartment Open model

UNIT- V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Biotransformation of drugs

Recommended Books: (Latest Editions)

Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.

Biopharmaceutics and Pharmacokinetics; By Robert F Notari

Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA

Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi

Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.

Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.

Biopharmaceutics; By Swarbrick

Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.

Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.

Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.

Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

Biotechnology has a long promise to revolutionize the biological sciences and technology.

Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes 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;

Understanding the importance of Immobilized enzymes in Pharmaceutical Industries

Genetic engineering applications in relation to production of pharmaceuticals

Importance of Monoclonal antibodies in Industries

Appreciate the use of microorganisms in fermentation technology

Unit I **10 Hours**

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

Enzyme Biotechnology- Methods of enzyme immobilization and applications.

Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

Brief introduction to Protein Engineering.

Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

Basic principles of genetic engineering.

Unit II **10 Hours**

Study of cloning vectors, restriction endonucleases and DNA ligase.

Recombinant DNA technology. Application of genetic engineering in medicine.

Application of r DNA technology and genetic engineering in the products:

Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.

Brief introduction to PCR

Types of immunity- humoral immunity, cellular immunity

Unit III **10 Hours**

Structure of Immunoglobulins

Structure and Function of MHC

Hypersensitivity reactions, Immune stimulation and Immune suppressions.

General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.

Storage conditions and stability of official vaccines

Hybridoma technology- Production, Purification and Applications

Unit IV **08Hours**

Immuno blotting techniques- ELISA, Western blotting, Southern blotting.

Genetic organization of Eukaryotes and Prokaryotes

Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.

Introduction to Microbial biotransformation and applications.

Mutation.

Unit V **07 Hours**

Types of mutation/mutants

Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.

Large scale production fermenter design and its various controls.

Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

Recommended Books (Latest edition):

B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
RA Goldshy et. al., : Kuby Immunology.
J.W. Goding: Monoclonal Antibodies.
J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications 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 pharmaceutical industries

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 stability testing 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 procedure

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, 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: Equipments 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 and waste 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)

Quality Assurance Guide by organization of Pharmaceutical Products of India.
Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
How to Practice GMP's – P P Sharma.
ISO 9000 and Total Quality Management – Sadhank G Ghosh
The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
Good laboratory Practices – Marcel Deckker Series
ICH guidelines, ISO 9000 and 14000 guidelines

SEMESTER VII

BP701T. 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

Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis

Understand the chromatographic separation and analysis of drugs.

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 on absorption 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 component analysis

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, sample handling, 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, Techniques of paper, gel, capillary electrophoresis, 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

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
Estimation of dextrose by colorimetry
Estimation of sulfanilamide by colorimetry
Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
Assay of paracetamol by UV- Spectrophotometry
Estimation of quinine sulfate by fluorimetry
Study of quenching of fluorescence
Determination of sodium by flame photometry
Determination of potassium by flame photometry
Determination of chlorides and sulphates by nephelo turbidometry
Separation of amino acids by paper chromatography
Separation of sugars by thin layer chromatography
Separation of plant pigments by column chromatography
Demonstration experiment on HPLC
Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

Instrumental Methods of Chemical Analysis by B.K Sharma

Organic spectroscopy by Y.R Sharma

3. Text book of Pharmaceutical Analysis by Kenneth A. Connors

Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel

Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake

Organic Chemistry by I. L. Finar

Organic spectroscopy by William Kemp

Quantitative Analysis of Drugs by D. C. Garrett

Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

Spectrophotometric identification of Organic Compounds by Silverstein

BP 702 T. INDUSTRIAL PHARMACY (Theory)

45 Hours

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

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

Know the process of pilot plant and scale up of pharmaceutical dosage forms

Understand the process of technology transfer from lab scale to commercial batch

Know different laws and acts that regulate pharmaceutical industry in India and US

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: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing 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), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, 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, Six Sigma concept, Out of 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, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.

International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php

Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.

Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

BP 703T. 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 community set up.

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

know various drug distribution methods in a hospital
appreciate the pharmacy stores management and inventory control
monitor drug therapy of patient through medication chart review and clinical review
obtain medication history interview and counsel the patients
identify drug related problems
detect and assess adverse drug reactions
interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
know pharmaceutical care services
do patient counseling in community pharmacy;
appreciate the concept of Rational drug therapy.

Unit I: **10 Hours**

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.

Hospital pharmacy and its organization

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

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

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 controlled drugs.

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.

Therapeutic drug monitoring

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

Medication adherence

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

Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III: 10 Hours

Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

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

c) Patient counseling

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

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 community health education.

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.

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**

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

Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.

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.

William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.

Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.

Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.

Parmar N.S. *Health Education and Community Pharmacy,* 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

Therapeutic drug monitoring. ISSN: 0163-4356

Journal of pharmacy practice. ISSN : 0974-8326

American journal of health system pharmacy. ISSN: 1535-2900 (online)

Pharmacy times (Monthly magazine)

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

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

Objectives: Upon completion of the course student shall be able

To understand various approaches for development of novel drug delivery systems.
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 delivery systems.

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 delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implantsand 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**

Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, 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 –Preliminary study, ocular formulations and ocuserts

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

Recommended Books: (Latest Editions)

Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim

N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

Indian Journal of Pharmaceutical Sciences (IPA)

Indian Drugs (IDMA)

Journal of Controlled Release (Elsevier Sciences)

Drug Development and Industrial Pharmacy (Marcel & Decker)

International Journal of Pharmaceutics (Elsevier Sciences)

SEMESTER VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with 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 by the 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 way and Two way), Least Significance difference

Unit-III **10 Hours**

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, 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, Report writing 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, 2^2, 2^3design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.

Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha

Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,

4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

BP 802T 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 country and worldwide.
Have a critical way of thinking based on current healthcare development.
Evaluate alternative ways of solving problems related tohealth and pharmaceutical 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, Poverty and 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 prevention and control of deafness, Universal immunization 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)*:*

Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications

Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications

Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications

Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications

Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.

Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

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

BP803ET. PHARMACEUTICAL MARKETING (Theory)

45 Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemist, 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. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management.The career in product management starts from having hands on experience in sales and marketing only.

Course Objective: The course aim is to provide an understanding of marketing concepts and techniques and the application of the same 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;Role of market research.

Unit II **10 Hours**

Product decision:

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

Unit III **10 Hours**

Promotion:

Meaning and 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 appropriatechannel, conflict in channels, physical distribution management: Strategic importance, tasks in physicaldistribution 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, issuesin 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)

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

Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.

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

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

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

Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.

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

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

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

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

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

Know about the process of drug discovery and development

Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

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) in US. Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of 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 - safety monitoring in clinical trials

Unit V **07Hours**

Regulatory Concepts

Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.

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.

New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.

Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.

Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143

Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams

Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene

Drugs: From Discovery to Approval, Second Edition By Rick Ng

BP 805T: 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):

Why drug safety monitoring is important?
History and development of pharmacovigilance
National and international scenario of pharmacovigilance
Dictionaries, coding and terminologies used in pharmacovigilance
Detection of new adverse drug reactions and their assessment
International standards for classification of diseases and drugs
Adverse drug reaction reporting systems and communication in pharmacovigilance
Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
Pharmacovigilance Program of India (PvPI)
ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
CIOMS requirements for ADR reporting
Writing case narratives of adverse events and their quality.

Course Content

Unit I **10 Hours**

Introduction to Pharmacovigilance

History and development of Pharmacovigilance
Importance of safety monitoring of Medicine
WHO international drug monitoring programme
Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

Definitions and classification of ADRs
Detection and reporting
Methods in Causality assessment
Severity and seriousness assessment
Predictability and preventability assessment
Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

Terminologies of adverse medication related events
Regulatory terminologies

Unit II **10 hours**

Drug and disease classification

Anatomical, therapeutic and chemical classification of drugs
International classification of diseases
Daily defined doses
International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance

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)
Establishing a national programme

Unit III **10 Hours**

Vaccine safety surveillance

Vaccine Pharmacovigilance
Vaccination failure
Adverse events following immunization

Pharmacovigilance methods

Passive surveillance – Spontaneous reports and case series
Stimulated reporting
Active surveillance – Sentinel sites, drug event monitoring and registries
Comparative observational studies – Cross sectional study, case control study and cohort study
Targeted clinical investigations

Communication in pharmacovigilance

Effective communication in Pharmacovigilance
Communication in Drug Safety Crisis management
Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV **8 Hours**

Statistical methods for evaluating medication safety data

Safety data generation

Pre clinical phase
Clinical phase
Post approval phase

ICH Guidelines for Pharmacovigilance

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

Unit V **7 hours**

Pharmacogenomics of adverse drug reactions

Drug safety evaluation in special population

Paediatrics
Pregnancy and lactation
Geriatrics

CIOMS

CIOMS Working Groups
CIOMS Form

CDSCO (India) and Pharmacovigilance

D&C Act and Schedule Y
Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& Bartlett Publishers.
Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
National Formulary of India
Text Book of Medicine by Yashpal Munjal
Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
http://www.ich.org/
http://www.cioms.ch/
http://cdsco.nic.in/
http://www.who.int/vaccine_safety/en/
http://www.ipc.gov.in/PvPI/pv_home.html

BP 806 ET. 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;

know WHO guidelines for quality control of herbal drugs

know Quality assurance in herbal drug industry

know the regulatory approval process and their registration in Indian and international markets

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 dosage forms

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 in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

Unit II I **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of 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

registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

Regulatory requirements for herbal medicines.

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

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions

Pharmacognosy by Trease and Evans

Pharmacognosy by Kokate, Purohit and Gokhale

Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.

Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.

EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,

Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

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.

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.

WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.

WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.

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.

WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

BP 807 ET. 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 discovery process
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. Any three 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)

Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.

Martin YC. "Quantitative Drug Design" Dekker, New York.

Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.

Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.

Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.

Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.

Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.

Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.

Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

BP808ET: 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 organismssuch as humans, plants, and sponges.

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

Summarize cell and molecular biology history.
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**

Cell and Molecular Biology: Definitions theory and basics and Applications.
Cell and Molecular Biology: History and Summation.
Theory of the Cell? Properties of cells and cell membrane.
Prokaryotic versus Eukaryotic
Cellular Reproduction
Chemical Foundations – an Introduction and Reactions (Types)

Unit II **10 Hours**

DNA and the Flow of Molecular Structure
DNA Functioning
DNA and RNA
Types of RNA
Transcription and Translation

Unit III **10 Hours**

Proteins: Defined **and** Amino Acids
Protein Structure

Regularities in Protein Pathways
Cellular Processes
Positive Control and significance of Protein Synthesis

Unit IV **08 Hours**

Science of Genetics
Transgenics and Genomic Analysis
Cell Cycle analysis
Mitosis and Meiosis
Cellular Activities and Checkpoints

Unit V **07 Hours**

Cell Signals: Introduction
Receptors for Cell Signals
Signaling Pathways: Overview
Misregulation of Signaling Pathways
Protein-Kinases: Functioning

Recommended Books (latest edition):

W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.

Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.

Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.

Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.

Rose: Industrial Microbiology.

Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan

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

Peppler: Microbial Technology.

Edward: Fundamentals of Microbiology.

N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi

Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.

RA Goldshy et. al., : Kuby Immunology.

BP809ET. COSMETIC SCIENCE(Theory)

45Hours

UNIT I 10Hours Classification of cosmetic and cosmeceutical products

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 their relative skin sensory, advantages and disadvantages.Application of these products in formulation of cosmecuticals.
Principles of formulation and building blocks of Hair care products:
Conditioning shampoo, Hair conditioners,antidandruff 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 turmeric
Hair 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**

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.
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 beneits.

UNIT V **07 Hours**

Oily and dry skin, causes leading to dry skin, 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 and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

References

Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.

Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.

BP810 ET.EXPERIMENTAL PHARMACOLOGY

Suggested title:PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental 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 preclinical research

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 strains of 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. **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 and hypnotics, 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	
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.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data	**05 Hours**

Recommended Books (latest edition):

Fundamentals of experimental Pharmacology-by M.N.Ghosh
Hand book of Experimental Pharmacology-S.K.Kulakarni
CPCSEA guidelines for laboratory animal facility.
Drug discovery and Evaluation by Vogel H.G.
Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

BP 811 ET. 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,

Fluorimeter, Flame Photometer, HPLC and GC

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 solid phase extraction and liquid-liquid extraction

UNIT-V **07 Hours**

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

Recommended Books (Latest Editions)

Instrumental Methods of Chemical Analysis by B.K Sharma

Organic spectroscopy by Y.R Sharma

3. Text book of Pharmaceutical Analysis by Kenneth A. Connors

Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel

Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake

Organic Chemistry by I. L. Finar

Organic spectroscopy by William Kemp

Quantitative Analysis of Drugs by D. C. Garrett

Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

Spectrophotometric identification of Organic Compounds by Silverstein

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

Solvents and solubilizers
Cyclodextrins and their applications
Non - ionic surfactants and their applications
Polyethylene glycols and sorbitols
Suspending and emulsifying agents
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

Tablet and capsule excipients
Directly compressible vehicles
Coat materials
Excipients in parenteral and aerosols products
Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial 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 its application 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)

Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.

Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition,Informa Healthcare publishers.

Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman andLeon Lachman; Marcel Dekker, Inc.

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.

Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.

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.

Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40

Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.

Remington – The Science and Practice of Pharmacy, 20th Ed.

Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz

Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.

Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis andH.A. Libermann.

Advanced Review Articles related to the topics.