

SREE DATTHA INSTITUTE OF PHARMACY
(Approved by AICTE & PCI, New Delhi, Affiliated to JNTU, Hyderabad)
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EVALUATION SCHEME & SYLLABUS



BACHELOR OF PHARMACY

I, II, III & IV Year

On PCI Guidelines



(EFFECTIVE FROM THE SESSION 2023-24)

Bachelor of Pharmacy (B. Pharm.)
COURSE OF STUDY & SCHEME OF EVALUATION FOR INTERNAL AND END SEMESTER EXAMINATIONS
(W.E.F. Session 2019-20)

FIRST SEMESTER

Course Code	Name of the Course	No. of Hours/ week	Continuous Mode	Internal Assessment			End Semester Exams		Total Marks	Credit Points
				Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP101T	Human Anatomy and Physiology– Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP102T	Pharmaceutical Analysis I – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP103T	Pharmaceutics I – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP104T	Pharmaceutical Inorganic Chemistry– Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP105T	Communication Skills – Theory	2	20	30	2 Hrs	50	---	---	50	2
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory	2	20	30	2 Hrs	50	---	---	50	2
BP107P	Human Anatomy and Physiology – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP108P	Pharmaceutical Analysis I – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP109P	Pharmaceutics I – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP110P	Pharmaceutical Inorganic Chemistry– Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP111P	Communication Skills – Practical	2	10	15	2 Hrs	25	---	---	25	1
BP112RBP	Remedial Biology– Practical	2			2 Hrs	25	---	---	25	1
Total		38 [§] / 40 [#]	110 [§] / 110 [#]	175 [§] / 175 [#]	26 [§] /28 [#] Hrs	285 [§] / 310 [#]	440 [#]	28 [#] Hrs	725 [§] / 750 [#]	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.

SECOND SEMESTER

Course Code	Name of the Course	No. of Hours/ week	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP201T	Human Anatomy and Physiology II – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP203T	Biochemistry – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP204T	Pathophysiology– Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP205T	Computer Applications in Pharmacy – Theory	3	25	50	2 Hrs	75	---	---	75	3
BP206T	Environmental Sciences – Theory	3	25	50	2 Hrs	75	---	---	75	3
BP207P	Human Anatomy and Physiology II – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP208P	Pharmaceutical Organic Chemistry I – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP209P	Biochemistry – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP210P	Computer Applications in Pharmacy – Practical	2	10	15	2 Hrs	25	---	---	25	1
Total		36	115	205	22 Hrs	320	405	24 Hrs	725	29

THIRD SEMESTER*

Course Code	Name of the Course	No. of Hours/ week	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP301T	Pharmaceutical Organic Chemistry II – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP302T	Physical Pharmaceutics I – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP303T	Pharmaceutical Microbiology – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP304T	Pharmaceutical Engineering – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP306P	Physical Pharmaceutics I – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP307P	Pharmaceutical Microbiology– Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP308P	Pharmaceutical Engineering –Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
KVE301	Universal Human Values and Professional Ethics**	3	20	30	1 Hr	50	100	3 Hrs	150	3
Total		35	80	130	21 Hrs	210	540	31 Hrs	750	27

*The lateral entry students taking admission directly to second year shall compulsorily appear for and pass the Communications Skill Subject Examination in the Third Semester.

Human values & Professional Ethics will be offered as a **compulsory course for which passing marks shall be 30% in End Semester Examination and 40% in aggregate.

FOURTH SEMESTER*

Course Code	Name of the Course	No. of Hours/ week	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP401T	Pharmaceutical Organic Chemistry III – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP402T	Medicinal Chemistry I – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP403T	Physical Pharmaceutics II – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP404T	Pharmacology I – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP405T	Pharmacognosy I – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP406P	Medicinal Chemistry I – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP407P	Physical Pharmaceutics II – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP408P	Pharmacology I – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP409P	Pharmacognosy I – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
Total		36	70	115	21 Hrs	185	515	31 Hrs	700	28

*The lateral entry students taking admission directly to second year shall compulsorily appear for and pass the Computer Applications in Pharmacy Subject Examination in the Fourth Semester.

FIETH SEMESTER

Course Code	Name of the Course	No. of Hours/ week	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP501T	Medicinal Chemistry II – Theory	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP502T	Industrial Pharmacy I– Theory	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP503T	Pharmacology II – Theory	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP504T	Pharmacognosy and Phytochemistry	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP506P	Industrial Pharmacy I– Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP507P	Pharmacology II – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP509P	Report on Hospital Training-I	-	-	-	-	-	100	-	100	2
Total		27	65	105	17 Hrs	170	580	27 Hrs	750	28

SIXTH SEMESTER

Course Code	Name of the Course	No. of Hours/ week	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP601T	Medicinal Chemistry III – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP602T	Pharmacology III – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP603T	Herbal Drug Technology – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP605T	Pharmaceutical Biotechnology– Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP606T	Quality Assurance– Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP607P	Medicinal Chemistry III – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP608P	Pharmacology III – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP609P	Herbal Drug Technology – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP610P	Report on Industrial Training	-	-	-	-	-	100	-	100	2
Total		36	75	120	18 Hrs	195	655	30 Hrs	850	32

SEVENTH SEMESTER

Course Code	Name of the Course	No. of Hours/week	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP701T	Instrumental Methods of Anal ysis – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP702T	Industrial Pharmacy II – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP703T	Pharmacy Practice – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP704T	Novel Drug DeliveryS ystem (NDDS) – Theory	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP705P	Instrumental Methods of Analysis/ NDDS – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP706PS	Practice School	12	50	100	5 Hrs	150	---	---	150	6
BP707P	Report on Hospital Training-II	-	-	-	-	-	100	-	100	2
Total		32	95	170	13 Hrs	265	435	16 Hrs	700	26

EIGHTH SEMESTER

Course Code	Name of the Course	No. of Hours/	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP801T	Biostatistics and Research Methodology	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP802T	Social and Preventive Pharmacy	4	10	15	1 Hr	25	75	3 Hrs	100	4
BP803ET	Pharma Marketing Management*	4 + 4 = 8	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 =200	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science*									
BP805ET	Pharmacovigilance*									
BP806ET	QualityControl and Standardization of Herbal*									
BP807ET	Computer Aided Drug									
BP808ET	Cell and Molecular									
BP809ET	Cosmetic Science*									
BP810ET	Experimental									
BP811ET	Advanced Instrumentation Techniques*									
BP812ET	Dietary Supplements and Nutraceuticals*									
BP813ET	Pharmaceutical Product Development*									
BP814ET	LSSSDC Elective*									
BP815PW	Project Work (On Elective)	12	-	-	-	-	150	4 Hrs	150	6
BP816P	Report on Industrial Tour	-	-	-	-	-	100	-	100	2
Total		28	40	6	4 Hrs	10	550	16 Hrs	650	24

*(ET: Elective subject) Every candidate has to **opt for two** of the elective subjects, and has to carry out **project on any one** of them. The student has the choice to choose both the elective subjects from the already prescribed list of elective subjects by the PCI **or** choose one elective subject from the existing prescribed list of elective subjects of B. Pharm. programme by the PCI and the other (second subject) elective from list of skill pack/modules available with the LSSSDC from time to time.

Semester I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

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

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

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

Unit-IV

08 hours

Peripheral nervous system: Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves.

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

Unit-V

07 hours

Cardiovascular system

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

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/weeks

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

Recommended Books (Latest Editions)

- Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York.
- Physiological Basis of Medical Practice by Best and Taylor, Williams & Wilkins Co, Riverview, MI, USA.
- Textbook of Medical Physiology by Arthur C. Guyton and John, E. Hall, Miamisburg, Ohio, U.S.A.
- Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
- Human Anatomy and Physiology by Marieb E.N., Benjamin Cummings, Pearson Education Inc., San Francisco.
- Preventive and Social Medicine by Park K., Banarsidas Bhanot Publishers, Jabalpur.
- Anatomy and Physiology in Health and Illness by Ross & Wilson Churchill Livingstone, London.
- Essentials of Anatomy and Physiology by Seeley R.R., Stephens T.D. and Tate P. McGraw-Hill, New York.
- Health Education and Community Pharmacy by Parmar N.S., CBS Publishers, Delhi.
- Health Education and Community Pharmacy by Dandiya P.C., Zafer Z.Y.K., and Zafer A. Vallabh Prakashan, Delhi.
- Samson Wright's Applied Physiology by Keele C.A., Niel E. and Joels N., Oxford University Press, New York.
- Human Physiology - Volume 1 and 2 by Dr. C.C. Chatterjee, Academic Publishers, Kolkata.

BP102T. PHARMACEUTICAL ANALYSIS (Theory) 45 Hours

Course Content:

Unit-I

10 Hours

Pharmaceutical analysis: Definition and scope.

- i) Different techniques of analysis.
- ii) Methods of expressing concentration.
- iii) Primary and secondary standards.
- iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate.

Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures.

Pharmacopoeia, Sources of impurities in medicinal agents, limit tests.

Unit-II

10 Hours

Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, 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 Volhard's, Fajan's method, estimation of sodium chloride.

Complexometric titration: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.

Gravimetry: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate. Basic Principles, methods and application of diazotization titration.

Unit-IV

08 Hours

Redox titrations: Concepts of oxidation and reduction, Types of redox titrations (Principles and applications).

Cerimetry, Iodimetry, Iodometry, Bromometry, Dichrometry and 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

I Limit Test of the following:

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

II Preparation and standardization of

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

III Assay of the following compounds along with Standardization of Titrant:

- (1) Ammonium chloride by acid base titration.
- (2) Ferrous sulphate by Cerimetry.
- (3) Copper sulphate by Iodometry.
- (4) Calcium gluconate by Complexometry.
- (5) Hydrogen peroxide by Permanganatometry.
- (6) Sodium benzoate by non-aqueous titration.
- (7) Sodium Chloride by precipitation titration.

IV Determination of Normality by electro-analytical methods:

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

Recommended Books: (Latest Editions)

- Vogel's Textbook of Quantitative Chemical Analysis by Mendham J., Denny R.C., Barnes J.D., Thomas M, Jeffery G.H., Pearson Education Asia.
- A Textbook of Pharmaceutical by Connors K.A., Wiley Inter-science.
- Practical Pharmaceutical Chemistry by Beckett A.H., and Stenlake J.B., Vol. I & II. Athlone Press, University of London.
- British Pharmacopoeia, Her Majesty's Stationary Office, University Press, Cambridge.
- Quantitative Analysis by Alexeyev V., CBS Publishers & Distributors, New Delhi.
- The Pharmacopoeia of India, the Controller of Publications, Delhi.
- Bentley and Driver's Textbook of Pharmaceutical Chemistry, Oxford University Press, New Delhi.
- Analytical Chemistry Principles by John H. Kennedy, Cengage Learning, Delhi.

BP103T. PHARMACEUTICS-I (Theory)

45 Hours

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, allegation, 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

10 Hours

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

Biphasic liquids:

Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

Unit-IV

08 Hours

Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

Pharmaceutical incompatibilities: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

Unit-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 dosage forms.

BP109P. PHARMACEUTICS I (Practical)

3 Hours/week

- 1. Syrups**
 - a) Syrup IP'66.
 - b) Compound syrup of Ferrous Phosphate BPC'68.
- 2. Elixirs**
 - a) Piperazine citrate elixir.
 - b) Paracetamol pediatric elixir.
- 3. Linctus**
 - a) Terpen Hydrate Linctus IP'66.
 - b) Iodine Throat Paint (Mandl's Paint).
- 4. Solutions**
 - a) Strong solution of ammonium acetate.
 - b) Cresol with soap solution.
 - c) Lugol's solution.
- 5. Suspensions**
 - a) Calamine lotion.
 - b) Magnesium Hydroxide mixture.
 - c) Aluminum Hydroxide gel.
- 6. Emulsions**
 - a) Turpentine Liniment.
 - b) Liquid paraffin emulsion.
- 7. Powders and Granules**
 - a) ORS powder (WHO).
 - b) Effervescent granules.
 - c) Dusting powder.
 - d) Divided powders.
- 8. Suppositories**
 - a) Glycero -Gelatin suppository.
 - b) Cocoa butter suppository.
 - c) Zinc Oxide suppository.
- 9. Semisolids**
 - a) Sulphur ointment.
 - b) Non staining-iodine ointment with methyl salicylate.
 - c) Carbopol gel.
- 10. Gargles and Mouthwashes**
 - a) Iodine gargle.

b) Chlorhexidine mouthwash.

Recommended Books: (Latest Editions)

- Pharmaceutical Dosage Form and Drug Delivery System by H.C. Ansel et al., Lippincott Williams and Wilkins, New Delhi.
- Cooper and Gunn's Dispensing for Pharmaceutical Students by Carter S.J., CBS Publishers, New Delhi.
- A Practical Guide to Contemporary Pharmacy Practice by Judith E. Thompson, 1st ed., Lippincott Williams & Wilkins.
- Pharmaceutics, The Science & Dosage Form Design by M.E. Aulton, Churchill Livingstone, Edinburgh.
- Pharmacopoeia of India, The Controller of Publications, Delhi.
- British Pharmacopoeia, Her Majesty's Stationary Office, University Press, Cambridge.
- United States Pharmacopoeia (National Formulary).
- Theory and Practice of Industrial Pharmacy by Lachman, Lea & Febiger Publisher, the University of Michigan.
- Remington. The Science and Practice of Pharmacy by Alfonso R. Gennaro, Lippincott Williams and Wilkins, New Delhi.
- Cooper and Gunn's Tutorial Pharmacy by Carter S.J., CBS Publications, New Delhi.
- Bentley's Textbook of Pharmaceutics by E.A. Rawlins, English Language Book Society, Elsevier Health Sciences, USA.
- Pharmaceutical Palletization Technology by Isaac Ghebre Sellassie, Marcel Dekker Inc., New York.
- Handbook of Pharmaceutical Granulation Technology, Marcel Dekker Inc., New York.
- Pharmaceutical Emulsions and Suspensions, Francoise Nieloud and Gilberte Marti-Mestres Marcel Dekker, INC, New York.
- Textbook of Pharmaceutics, Volume - I & II by Aulton M.E., Churchill Livingstone, London.
- Modern Dispensing Pharmacy by Jain N.K., 2nd Ed, PharmaMed Press, Hyderabad.
- Calculations for Pharmaceutical Practice by A. Winfiled and I. Edafigho, Elsevier Churchill Livingstone, London.
- Elementary Pharmaceutical Calculations by Tripathi D.K., PharmaMed Press, Hyderabad.

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

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 tartrate.

Hematinics: 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

I 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

II Identification test

Magnesium hydroxide
Ferrous sulphate
Sodium bicarbonate
Calcium gluconate
Copper sulphate

III Test for purity

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

IV Preparation of inorganic pharmaceuticals

Boric acid
Potash alum
Ferrous sulphate

Recommended Books (Latest Editions)

- Pharmacopoeia of India, the Controller of Publications, Delhi.
- British Pharmacopoeia, Her Majesty's Stationary Office, University Press, Cambridge.
- United States Pharmacopoeia (National Formulary).
- Inorganic, Medicinal & Pharmaceutical Chemistry by Block J.H., Roche E., Soine, T. and Wilson, C., Lea & Febiger, Philadelphia.
- Bentley and Driver's Textbook of Pharmaceutical Chemistry by Atherden L.M., Oxford University Press, London.
- Inorganic Chemistry by Miessler, G.L. and Tarr, D.A., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education), New Delhi.
- Vogel's Qualitative Inorganic Analysis by Svehla, G. and Sivasankar, B. Dorling Kindersley (India) Pvt. Ltd. (Pearson Education), New Delhi.

- Pharmaceutical Inorganic Chemistry by Rao K.S. and Suresh C.V., PharmaMed Press, Hyderabad.
- Pharmaceutical Inorganic Chemistry: Theory and Practice by Chenchu Lakshmi, N. V., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education), New Delhi.
- Bentley and Driver's Textbook of Pharmaceutical Chemistry, Oxford University Press, New Delhi.
- Inorganic Pharmaceutical Chemistry by M.L. Schroff, National Book Centre, Kolkata.

BP105T. COMMUNICATION SKILLS (Theory)

30 Hours

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 Don'ts 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 Don'ts of group discussion.

BP111P. COMMUNICATION SKILLS (Practical)

2 Hours / Week

Course content:

The following learning modules are to be conducted using words worth[®] English language lab software.

Basic communication covering the following topics

Meeting People.

Asking Questions.

Making Friends.

What did you do?

Do's and Don'ts.

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 Behavior, 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 S.J., 1st Edition, McGraw Hill Education, 2011.
- Effective Communication, John Adair, 4th Edition, Pan MacMillan, 2009.
- Bringing Out the Best in People, Aubrey Daniels, 2nd Edition, McGraw Hill, 1999.

30 Hours

Course content:

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, Protista, 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 & Dicotyledons.

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, Renin-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.

BP112RBP. REMEDIAL BIOLOGY (Practical)

30 Hours

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

Textbooks:

- Textbook of Biology by S. B. Gokhale.
- A Textbook of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books:

- A Textbook of Biology by B.V. Sreenivasa Naidu.
- A Textbook of Biology by Naidu and Murthy.
- Botany for Degree Students by A.C. Dutta.
- Outlines of Zoology by M. Ekambaranatha Ayyer and T.N. Ananthkrishnan.
- A Manual for Pharmaceutical Biology Practical by S.B. Gokhale and C.K. Kokate.

Recommended Books (Latest Edition):

- 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. Shrivastava.
- Biology Practical Manual According to National Core Curriculum Biology Forum of Karnataka by Prof. M.J.H. Shafi.

BP106RMT. REMEDIAL MATHEMATICS (Theory)

30 Hours

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 ($\epsilon - \delta$

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

$$\lim_{x \rightarrow a} \frac{x^n - a^n}{x - a}$$

$$\lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta}$$

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 equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley-Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations.

Unit-III

06 Hours

Calculus Differentiation : Introductions, Derivative of a function, Derivative of 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

BP201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

Course Content:

Unit-I

10 hours

Nervous system

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

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

Unit II

06 hours

Digestive system: Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

Energetics: Formation and role of ATP, Creatinine Phosphate and BMR.

Unit-III

10 hours

Respiratory system

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

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

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

Unit-IV

10 hours

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

Unit-V

09 hours

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

Introduction to genetics: Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance.

BP207P. HUMAN ANATOMY AND PHYSIOLOGY-II (Practical)

4 Hours/week

1. To study the integumentary and special senses using specimen, models, etc.
2. To study the nervous system using specimen, models, etc.
3. To study the endocrine system using specimen, models, etc.
4. To demonstrate the general neurological examination.
5. To demonstrate the function of olfactory nerve.
6. To examine the different types of taste.
7. To demonstrate the visual acuity.
8. To demonstrate the reflex activity.
9. Recording of body temperature.
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index.
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyzer.
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

- Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York.
- Best and Taylor's Physiological Basis of Medical Practice by Best, Charles Herbert, Taylor, Norman Burke, John Bernard, 12th edition; William and Wilkins, Baltimore.
- Textbook of Medical Physiology by Arthur C, Guyton and John. E. Hall. Miamisburg, Ohio, U.S.A.
- Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
- Pharmacotherapy- A Pathophysiological Approach by Dipiro J.L., Elsevier, Amsterdam.
- Human Anatomy, Regional & Applied Part I, II & III by Chaurasia B.D, CBS Publishers & Distributors, New Delhi.
- Anatomy and Physiology in Health and Illness by Ross and Wilson, Churchill Livingstone, London.
- Essentials of Anatomy and Physiology by Seeley R.R., Stephens T.D. and Tate, P., McGraw-Hill, New York.
- Human Physiology, Volume 1 and 2 by Dr. C.C. Chatterjee, Academic Publishers Kolkata.

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY-I (Theory)

45 Hours

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 isomerism in organic compounds.

Unit II

10 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, Saytzeff's orientation and evidences. E_1 versus 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 III

10 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 ethyl chloride, chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

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

Unit-IV**10 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, Vanillin, 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

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

Recommended Books (Latest Editions)

- Organic Chemistry by Morrison R.T., Boyd R.N. and Bhattacharjee, S.K., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- Organic Chemistry by I.L. Finar, Volume-I, Pearson Education Ltd, New Delhi.
- Organic Chemistry by Bruice P.Y. and Prasad, K.J.R., Dorling Kindersley (India) Pvt. Ltd, New Delhi.
- A Guidebook to Mechanism in Organic Chemistry by Peter Sykes, Longman Group Ltd., Noida.
- Strategic Applications of Named Reactions in Organic Chemistry by Laszlo Kurti and Barbara Czako, Elsevier Academic Press.
- Reaction and Reaction Mechanism by Ahluwalia/Chatwal, Narosa Publishing House, New Delhi.
- Organic Chemistry by Jain M.K., Sohan Lal Nagin Chand & Co, New Delhi.
- Elementary Practical Organic Chemistry by Vogel A.I., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- Practical Organic Chemistry by Mann F.G, and Saunders, B.C., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- Advanced Practical Organic Chemistry by N.K. Vishnoi, Vikas Publishing House Pvt. Ltd., Noida.
- Introduction to Organic Laboratory Techniques by Pavia, Lampman and Kriz, Cengage Learning, Delhi.

BP203T. BIOCHEMISTRY (Theory)

45 Hours

Course Content:

Unit-I

08 Hours

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

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

Energy rich compounds; classification; biological significances of ATP and cyclic AMP.

Unit-II

10 Hours

Carbohydrate metabolism:

Glycolysis- Pathway, energetics and significance.

Gluconeogenesis- Pathway and its 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).

Hormonal regulation of blood glucose level and Diabetes mellitus.

Biological oxidation:

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation.

Inhibitors ETC and oxidative phosphorylation/Uncouplers.

Unit-III

10 Hours

Lipid metabolism: β -Oxidation of saturated 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 and decarboxylation, Urea cycle and its disorders. Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, Alkaptonuria, Tyrosinemia).

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

Catabolism of heme; hyperbilirubinemia and jaundice.

Unit-IV**10 Hours****Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides.

Catabolism of purine nucleotides and Hyperuricemia and Gout disease.

Organization of mammalian genome.

Structure of DNA and RNA and their functions DNA replication (semi conservative model)

Transcription or RNA synthesis.

Genetic code, Translation or Protein synthesis and inhibitors.

07 Hours**Enzymes**

Introduction, properties, nomenclature and IUBMB classification of enzymes.

Enzyme kinetics (Michaelis-Menten plot, Line-Weaver Burke plot) Enzyme inhibitors with examples.

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

Coenzymes: Structure and biochemical functions.

Therapeutic and diagnostic applications of enzymes and isoenzymes.

BP209P. BIOCHEMISTRY (Practical)

4 Hours / Week

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

Recommended Books (Latest Editions)

- Harper's Illustrated Biochemistry by Murray R.K. and Granner D.K., Lange Medical Publication.
- Lehninger Principles of Biochemistry by Nelson D.L. and Cox M.M., Macmillan Worth Publishers.
- Fundamentals of Biochemistry by Voet D., Voet J.G., Pratt C.W., John Wiley and Sons Inc.
- Lippincott's Illustrative Reviews: Biochemistry by Champe P.C., Harvey R.A., Ferrier D.R., Lippincott Williams and Wilkins.
- Principles and Techniques of Biochemistry and Molecular Biology- by Wilson K. and Walker J., Cambridge University Press.
- Bioorganic Chemistry: A Chemical Approach to Enzyme Action by Dugas H., Springer (India) Private Limited, New Delhi.
- Molecular Cell Biology by Lodish H., Berk A., Matsudaira P., Kaiser C.A., Krieger M. and Scott M.P., W. H. Freeman and Company, New York.
- Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition), McGraw Hill, New Delhi.
- Outline of Biochemistry by Conn E.E. and Stumph P.K., John Wiley & Sons, New York.

- Biochemistry by Stryer L. and Berg J.M., W.H. Freeman and Company, New York.
- Textbook of Biochemistry by Harrow B. and Mazur A., W.B. Saunders Co., Philadelphia.
- Practical Biochemistry by Harold Varley. CBS Publishers and Distributors. New Delhi.
- Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
- Laboratory Manual in Biochemistry by Jayaraman J., Wiley Eastern Limited.
- Practical Manual to Biochemistry by Singh S.P., CBS Publisher, New Delhi.
- Modern Experimental Biochemistry by Boyer R.F., Dorling Kindersley (India) Pvt. Ltd.
- Comprehensive Viva and Practical Biochemistry by Deb A.C., New Centre Book Agency (P.) Ltd. London.
- Pharmaceutical Biochemistry by Vyas S.P. and Kohli D.V., CBS Publishers & Distributors, New Delhi.

BP204T. PATHOPHYSIOLOGY (THEORY)

45Hours

Course content:

Unit-I

10 Hours

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-III

10Hours

Hematological Diseases:

Iron deficiency, megaloblastic anemia (Vitamin B12 and folic acid), sickle cell anemia, thalassemia, 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.

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.

Unit-V**7 Hours****Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis, Urinary tract infections.**Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhea.**Recommended Books (Latest Editions)**

- Robbins & Cotran Pathologic Basis of Disease by Vinay Kumar, Abul K. Abas, Jon C. Aster; South Asia edition; India; Elsevier.
- Text book of Pathology by Harsh Mohan; 6th edition; India; Jaypee Publications.
- Goodman Gilman's The Pharmacological Basis of Therapeutics by Laurence B, Bruce C., Bjorn K. 12th edition; McGraw-Hill, New York.
- Best and Taylor's Physiological Basis of Medical Practice by Best, Charles Herbert, Taylor, Norman Burke, John Bernard, 12th edition; United States; William and Wilkins, Baltimore.
- Davidson's Principles and Practice of Medicine by Nicki R. College, Brian R. Walker, Stuart H. Ralston, 21st edition; London; ELBS/Churchill Livingstone.
- Textbook of Medical Physiology by Guyton A, John. E Hall; 12th edition; WB Saunders Company.
- Pharmacotherapy by Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey, A Pathophysiological Approach; 9th edition; London; McGraw Hill Medical.
- Basic Pathology by V. Kumar, R. S. Cotran and S. L. Robbins, 6th edition; Philadelphia; WB Saunders Company.
- Clinical Pharmacy and Therapeutics by Roger Walker, Clive Edwards, 3rd edition; London; Churchill Livingstone Publication.

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

BP205T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hours (2 Hours/Week)

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, 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

06 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

06 hours

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine 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 data analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS).

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

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

Recommended books (Latest edition):

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

BP206T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Course content:

Unit-I

10hours

The multidisciplinary nature of environmental studies.

Natural Resources.

Renewable and non-renewable resources: Natural resources and associated problems

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

Unit-II

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):

- Environmental Science by Singh, Y.K., New Age International Pvt. Publishers, Bangalore.
- Environmental Biology by Agarwal, K.C., 2001, Nidi Publ. Ltd. Bikaner.
- The Biodiversity of India by Bharucha Erach, Mapin Publishing Pvt. Ltd., Ahmedabad, India.
- Hazardous Waste Incineration by Brunner R.C., 1989, McGraw Hill Inc.
- Marine Pollution by Clark R.S., Clanderson Press Oxford.
- Environmental Encyclopedia, by Cunningham, W.P. Cooper, T.H., Gorhani, E. & Hepworth, M.T., Jaico Pub. House, Mumbai.
- Environmental Chemistry by De A.K., Wiley Eastern Ltd.
- Down of Earth, Centre for Science and Environment, Editor Sunita Narain.

SEMESTER III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Course Content:

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

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

Unit-I

10 Hours

Benzene and its derivatives

- A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule.
- B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedel Crafts alkylation-reactivity, limitations, Friedel Crafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction.
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine T.

Unit-II

10 Hours

Phenols* - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols.

Aromatic Amines* - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts.

Aromatic Acids* – Acidity, effect of substituents on acidity and important reactions of benzoic acid.

Unit-III

10 Hours

Fats and Oils

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

Cycloalkanes*

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

1. Experiments involving laboratory techniques:
 - Recrystallization.
 - Steam distillation.
2. Determination of following oil values (including standardization of reagents):
 - Acid value.
 - Saponification value.
 - Iodine value.
3. **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-nitrosalicylic acid/meta di-nitrobenzene 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-naphthol from Aniline by diazotization and coupling reactions.
 - Benzil from benzoin by oxidation reaction.
 - Dibenzal acetone from benzaldehyde by Claisen-Schmidt reaction.
 - Cinnamic acid from benzaldehyde by Perkin reaction.
 - *p*-Iodo benzoic acid from *p*-amino benzoic acid.

Recommended Books (Latest Editions)

- Organic Chemistry by Morrison R.T., Boyd R.N. and Bhattacharjee, S.K. Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- Organic Chemistry by Jonathan Clayden, Nick G. S. Warren. Oxford University Press, Oxford.
- Organic Chemistry by G. Marc Loudon, Oxford University Press, Oxford.
- Organic Chemistry by Francis A. Carey and Robert M. Giuliano, Tata McGraw Hill Publishing Company Ltd., New Delhi.
- Strategic Applications of Named Reactions in Organic Chemistry by Laszlo Kurti and Barbara Czako, Elsevier Academic Press.
- Organic Chemistry by I.L. Finar, Volume-I, Pearson Education Ltd, New Delhi.
- Elementary Practical Organic Chemistry by Vogel A.I., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.

- Practical Organic Chemistry by Mann F.G, and Saunders B.C., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- Introduction to Organic Laboratory Techniques by Pavia, Lampman and Kriz, Cengage Learning, Delhi.
- Reaction and Reaction Mechanism by Ahluwalia/Chatwal, Narosa Publishing House, New Delhi.
- A Guidebook to Mechanism in Organic Chemistry by Sykes P., Longman Group Ltd, London.
- Organic Chemistry by Jain M.K., Sohan Lal Nagin Chand & Co, New Delhi.
- Textbook of Organic Chemistry by P.L. Soni, Sultan Chand & sons, New Delhi.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

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

Unit-II

10 Hours

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapor 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

10 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, solubilization, detergency, adsorption at solid interface.

Unit-IV

08Hours

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

1. Determination the solubility of drug at room temperature.
2. Determination of pKa value by Half Neutralization/Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water.
4. Determination of Partition co- efficient of Iodine in CCl₄ and water.
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method.
6. Determination of surface tension of given liquids by drop count and drop weight method.
7. Determination of HLB number of a surfactant by saponification method.
8. Determination of Freundlich and Langmuir constants using activated char coal.
9. Determination of critical micellar concentration of surfactants.
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method.
11. 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, Lippincott Williams and Wilkins, USA.
- Tutorial Pharmacy by Cooper and Gunn, CBS, New Delhi.
- Pharmaceutical Calculations by Stocklosam J., Lea & Febiger, Philadelphia.
- Pharmaceutical Dosage forms: Disperse systems by Lieberman H.A, Lachman C, Volume 3, Marcel Dekker Inc.
- Physical Pharmaceutics by Ramasamy C. and Manavalan R., PharmaMed Press, Hyderabad.
- Laboratory Manual of Physical Pharmaceutics by C.V.S. Subramanyam. J., Thimma Settee.
- Experimental Pharmaceutics by Eugene, Parott, Burgess Pub. Co., UK.
- Physical Pharmaceutics by C.V.S. Subramanyam. CBS Publication
- Textbook of Physical Pharmacy by Gaurav Jain & Roop K. Khar, Reed Elsevier India Pvt. Ltd., New Delhi.
- Physical Pharmaceutics by Shotton E & Ridgeway K, Oxford University Press, London.
- Essentials of Physical Pharmacy by D.V. Derle, BSP Book Pvt. Ltd., Hyderabad.
- Pharmaceutics: The Design and Manufacture of Medicines by Aulton M.E, Churchill Livingstone.

BP303T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45 Hours

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 contrast 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 gaseous, radiation 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 Viruses.

Classification and mode of action of disinfectants.

Factors influencing disinfection, antiseptics and their evaluation.

For bacteriostatic and bactericidal actions.

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other 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.

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.

BP307P. PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

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

Recommended Books (Latest edition)

- Pharmaceutical Microbiology by W.B. Hugo and A.D. Russel: Blackwell Scientific Publications, Oxford London.
- Industrial Microbiology by Prescott and Dunn., 4th edition, CBS Publishers & Distributors, Delhi.
- Microbiology by Pelczar and Chan Kreig, Tata McGraw Hill, New Delhi.
- Lippincott's Illustrated Reviews-Microbiology by Harvey, Champe and Fisher, Lippincott Williams and Wilkins, New Delhi.
- Principles and Practices of Contamination Control and Cleanrooms by C.K. Moorthy, Pharma Book Syndicate, Hyderabad.
- Pharmaceutical Microbiology by Malcolm Harris, Balliere Tindall and Cox., The Williams & Wilkins Co., NY.
- Fundamental Food Microbiology by Bibek Ray and Arun Bhunia, CRC Press, NY.
- Industrial Microbiology by Rose, Butterworths, USA.
- Fundamentals of Microbiology by Frobisher M., Hinsdill et al., 9th ed., Japan.
- Cooper and Gunn's Tutorial Pharmacy, CBS Publisher and Distribution.
- Microbial Technology by Peppler, Academic Press.
- I.P., B.P., U.S.P. - latest editions.
- Ananthnarayan and Paniker's Textbook of Microbiology, edited by C.K.J. Paniker, Orient-Longman, Hyderabad.
- Fundamentals of Microbiology by Edward, Benjamin Cummings, USA.

- Pharmaceutical Microbiology by N.K. Jain, Vallabh Prakashan, Delhi.
- Bergey's Manual of Systematic Bacteriology, Williams and Wilkins, Philadelphia.
- Disinfection and Sterilization- Theory and Practice, General and Industrial Chemistry Series by Sykes G., E & F.N. Spon Ltd., London.
- General Microbiology by Stanier R.Y., Ingraham, J.L., Wheelis M.L., Painter P.R., Macmillan Press Limited, London.
- Microbiology: An Introduction by Tortora, G.J., Funke, B.R. and Case, C.L., Pearson India Education Services Pvt. Ltd., Noida.
- Pharmaceutical Dosage Forms: Parenteral Medications by Sandeep Nema, John D. Ludwig, Informa Healthcare.

BP304T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

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, Venturi meter, Pitot tube and Rotameter.

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.

Unit-II

10 Hours

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

Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.

Distillation: Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation.

Unit-III

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.

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-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 Seitz filter.

Centrifugation: Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

Unit-V**07 Hours**

Materials of pharmaceutical plant construction, corrosion and its prevention:

Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and their prevention. Ferrous and non-ferrous metals, inorganic and organic non-metals, basic of material handling systems.

BP308P. PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

1. Determination of radiation constant of brass, iron, unpainted and painted glass.
2. Steam distillation – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient by heat exchanger.
4. Construction of drying curves (for calcium carbonate and starch).
5. Determination of moisture content and loss on drying.
6. Determination of humidity of air – From wet and dry bulb temperatures- use of Dew point method.
7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
8. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
9. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond coefficients, power requirement and critical speed of Ball Mill.
10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
11. Factors affecting rate of filtration and evaporation (Surface area, Concentration and Thickness/viscosity).
12. To study the effect of time on the rate of crystallization.
13. To calculate the uniformity Index for given sample by using Double Cone Blender.

Recommended Books: (Latest Editions):

- Introduction to Chemical Engineering by Walter L. Badger & Julius Banchero, Tata McGraw Hills, New Delhi.
- Solid Phase Extraction, Principles, Techniques and Applications by Nigel J.K. Simpson- Latest edition.
- Pharmaceutical Engineering by K. Sambamurthy, New Age International (P) Ltd., New Delhi.
- Unit Operation of Chemical Engineering by McCabe Smith, McGraw Hills, New Delhi.
- Pharmaceutical Engineering Principles and Practices by C.V.S Subrahmanyam et al., Vallabh Prakashan, Delhi.
- Remington Practice of Pharmacy by Martin, Latest edition.
- Lachman/Lieberman's Theory and Practice of Industrial Pharmacy by Roop K. Khar, S.P. Vyas, F.J. Ahmad and G.K. Jain, CBS Publishers & Distributors Pvt. Ltd., New Delhi.

- Cooper and Gunn's Tutorial Pharmacy edited by S.J. Carter, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Unit Operations by G.G. Brown, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Perry's Chemical Engineers' Handbook by R.H. Perry and D.W. Green, McGraw-Hill, USA.
- Aulton's Pharmaceutics: The Design and Manufacture of Medicines; 3rd edition, Churchill Livingstone, UK.
- Bentley's Textbook of Pharmaceutics edited by E.A. Rawlins, Reed Elsevier India Pvt. Ltd., New Delhi.
- Pharmaceutical Process Engineering by Anthony J. Hickey and David Ganderton, Vol-112, Drugs and Pharmaceutical Sciences, Marcel Dekker, Inc., USA.

KVE301. UNIVERSAL HUMAN VALUES AND PROFESSIONAL ETHICS

30 Hours

Course Content:

UNIT-I

Course Introduction - Need, Basic Guidelines, Content and Process for Value Education
Understanding the need, basic guidelines, content and process for Value Education, Self-Exploration–what is it? - its content and process; ‘Natural Acceptance’ and Experiential Validation- as the mechanism for self-exploration, Continuous Happiness and Prosperity- A look at basic Human Aspirations, Right understanding, Relationship and Physical Facilities the basic requirements for fulfilment of aspirations of every human being with their correct priority, Understanding Happiness and Prosperity correctly- A critical appraisal of the current scenario, Method to fulfil the above human aspirations: understanding and living in harmony at various levels.

UNIT-II

Understanding Harmony in the Human Being - Harmony in Myself Understanding human being as a co-existence of the sentient ‘I’ and the material ‘Body’, Understanding the needs of Self (‘I’) and ‘Body’ - Sukh and Suvidha, Understanding the Body as an instrument of ‘I’ (I being the doer, seer and enjoyer), Understanding the characteristics and activities of ‘I’ and harmony in ‘I’, Understanding the harmony of I with the Body: Sanyam and Swasthya; correct appraisal of Physical needs, meaning of Prosperity in detail, Programs to ensure Sanyam and Swasthya.

UNIT-III

Understanding Harmony in the Family and Society- Harmony in Human-Human Relationship
Understanding harmony in the Family- the basic unit of human interaction, Understanding values in human-human relationship; meaning of Nyaya and program for its fulfillment to ensure Ubhay-tripti; Trust (Vishwas) and Respect (Samman) as the foundational values of relationship, Understanding the meaning of Vishwas; Difference between intention and competence, Understanding the meaning of Samman, Difference between respect and differentiation; the other salient values in relationship, Understanding the harmony in the society (society being an extension of family): Samadhan, Samridhi, Abhay, Sah-astitva as comprehensive Human Goals, Visualizing a universal harmonious order in society Undivided Society (Akhand Samaj), Universal Order (Sarvabhaum Vyawastha)- from family to world family.

UNIT-IV

Understanding Harmony in the Nature and Existence - Whole existence as Co-existence
Understanding the harmony in the Nature, Interconnectedness and mutual fulfilment among the four orders of nature- recyclability and self-regulation in nature, Understanding Existence as Co-existence (Sah-Astitva) of mutually interacting units in all-pervasive space, Holistic perception of harmony at all levels of existence.

UNIT-V

Implications of the above Holistic Understanding of Harmony on Professional Ethics Natural acceptance of human values, Definitiveness of Ethical Human Conduct, Basis for Humanistic Education, Humanistic Constitution and Humanistic Universal Order, Competence in Professional Ethics: a) Ability to utilize the professional competence for augmenting universal human order, b) Ability to identify the scope and characteristics of people-friendly and eco-friendly production systems, technologies and management models, Case studies of typical holistic technologies, management models and production systems, Strategy for transition from the present state to Universal Human Order: a) At the level of individual: as socially and ecologically responsible engineers, technologists and managers, b) At the level of society: as mutually enriching institutions and organizations.

Recommended books:

- A Foundation Course in Human Values and Professional Ethics by R.R. Gaur, R Sangal, G P. Bagaria, 2009.
- Energy & Equity by Ivan Illich, 1974, the Trinity Press, Worcester, and Harper Collins, USA.
- Small Is Beautiful: A Study of Economics As If People Mattered by E.F. Schumacher, 1973, Blond & Briggs, Britain.
- How the Other Half Dies by Susan George, 1976, Penguin Press. Reprinted 1986, 1991.
- Limits to Growth – Club of Rome's report by Donella H. Meadows, Dennis L. Meadows, Jorgen Randers, William W. Behrens III, 1972, Universe Books.
- Jeevan Vidya Ek Parichay by A. Nagraj, 1998, Divya Path Sansthan, Amarkantak.
- Science and Humanism by P.L. Dhar, RR Gaur, 1990, Commonwealth Publishers.
- Human Values by A.N. Tripathy, 2003, New Age International Publishers.
- How to Practice Natural Farming by Subhas Palekar, 2000, Pracheen (Vaidik) Krishi Tantra Shodh, Amravati.
- Fundamentals of Ethics for Scientists & Engineers by E G Seebauer & Robert L. Berry, 2000, Oxford University Press.
- Engineering Ethics (including Human Values) by M Govindrajran, S Natrajan & V.S. Senthil Kumar, Eastern Economy Edition, Prentice Hall of India Ltd.
- Foundations of Ethics and Management by B.P. Banerjee, Excel Books.

SEMESTER IV

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Course Content:

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

Unit-I

10 Hours

Stereo isomerism:

Optical isomerism– Optical activity, enantiomerism, diastereomerism, 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, E-Z, 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 and reactivity of Pyrrole, Furan and Thiophene.

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.

Beckmann rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation.

Recommended Books (Latest Editions)

- Organic Chemistry by Morrison R.T. and Boyd R.N., Bhattacharjee S.K., 7th Edition, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education).
- Organic Chemistry by Finar I.L., 6th Edition, Vol.-I, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education).
- An Introduction to the Chemistry of Heterocyclic Compounds by Acheson R.M., 3rd Edition, Wiley (India) Pvt. Ltd.
- Organic Chemistry by Bruice P.Y., 3rd Edition, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education).
- Organic Chemistry by Francis A. Carey and Robert M. Giuliano, Tata McGraw Hill Publishing Company Ltd., New Delhi.
- Strategic Applications of Named Reactions in Organic Chemistry by Laszlo Kurti and Barbara Czako, Elsevier Academic Press.
- Heterocyclic Chemistry by Gilchrist T.L., Pearson Education (Singapore) Ltd.
- Heterocyclic Chemistry by Bansal R.K., New Age International Publishers.
- A Textbook of Organic Chemistry by Jain M.K. and Sharma S.C., Shoban Lal and Co. Educational Publishers.
- The Chemistry of Organic Medicinal Products by Jenkins G.L., Hartung W.H., Hamlin K.E. and Data J.B., 4th Edition, PharmaMed Press, Hyderabad.

BP402T. MEDICINAL CHEMISTRY – I (Theory)

45 Hours

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*, Metipranolol, 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, Isoflurophate, Echothiophate iodide, Parathion, 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*, Glycopyrrrolate, 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

Barbiturates: SAR of barbiturates, Barbitol*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital.

Miscellaneous: Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

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

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

Fluoro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpiride.

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

Barbiturates: Phenobarbitone, Metharbital.

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 barbiturates: 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, Anileridine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartrate.

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

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

BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/week

I. Preparation of drugs/ intermediates

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benzotriazole
- 5 2,3- diphenyl quinoxaline
- 6 Benzocaine
- 7 Phenytoin
- 8 Phenothiazine
- 9 Barbiturate

II. Assay of drugs

- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

- Wilson and Gisvold's Organic Medicinal and Pharmaceutical Chemistry by Block J.H. and Beale J.M., Lippincott Williams and Wilkins.
- Foye's Principles of Medicinal Chemistry by Lemke T.L., Williams D.A., Roche V.F. and Zito S.W., Lippincott Williams and Wilkins.
- Burger's Medicinal Chemistry and Drug Discovery by Abraham D.J., Vol I to IV. John Wiley and Sons Inc., New York.
- Synthesis of Essential Drugs by Vardanyan R.S. and Hruby V.J., Elsevier.
- Medicinal and Pharmaceutical Chemistry by Singh H. and Kapoor V.K., Vallabh Prakashan, Delhi.
- An Introduction to Medicinal Chemistry by Patrick Graham L., Oxford University Press.
- Medicinal Chemistry: A Biochemical Approach by Nogrady T., Oxford University Press, New York.
- The Organic Chemistry of Drug Design and Drug Action by Silverman R.B., Elsevier.
- Essentials of Medicinal Chemistry by Korolkovas A., John Wiley and Sons Inc., New York.

- Textbook of Drug Design and Discovery by Larsen P.K., Liljefors T. and Madsen U., Taylor and Francis Inc.
- Practical Organic Chemistry by Mann F.G. and Saunders B.C., Orient Longman Limited.
- Vogel's Textbook of Practical Organic Chemistry by Furniss B.S., Hannaford A.J., Smith P.W.G. and Tatchell A. R., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.).
- The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
- Pharmacopoeia of India, the Controller of Publications, Delhi.
- The Chemistry of Organic Medicinal Products by Jenkins G.L., Hartung W.H., Hamlin K.E. and Data J.B., PharmaMed Press Hyderabad.

BP403T. PHYSICAL PHARMACEUTICS-II (Theory)

45 Hours

Course Content:

Unit-I

07 Hours

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

Unit-II

10 Hour

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

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

Unit-III

10 Hours

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

Unit-IV

10 Hours

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

Unit-V

8 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.

BP407P. PHYSICAL PHARMACEUTICS- II (Practical)**3 Hrs/week**

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

Recommended Books: (Latest Editions)

- Physical Pharmacy by Alfred Martin, Lippincott Williams and Wilkins, USA.
- Experimental Pharmaceutics by Eugene, Parott, Burgess Pub. Co., UK.
- Pharmaceutical dosage forms: Disperse systems by Liberman H.A., Lachman C., Volume 1-3. Marcel Dekker Inc.
- Bentley's Textbook of Pharmaceutics edited by E.A. Rawlins, Reed Elsevier India Pvt. Ltd., New Delhi.
- Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems by Loyd V. Allen, Jr., N.G. Popovich and H. C. Ansel, Lippincott Williams & Wilkins, USA.
- Lachman/Lieberman's Theory and practice of industrial pharmacy by Roop K. Khar, S.P. Vyas, F.J. Ahmad and G.K. Jain, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Cooper and Gunn's Tutorial Pharmacy edited by S.J. Carter, CBS Publishers & Distributors Pvt. Ltd., New Delhi.

BP404T. PHARMACOLOGY-I (Theory)

45 Hours

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 noncompetitive), 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

Pharmacology of drugs acting on peripheral nervous system

Organization and function of ANS.

Neurohumoral transmission, co-transmission and classification of neurotransmitters.

Parasympathomimetic, Parasympatholytic, Sympathomimetics, sympatholytic.

Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

Local anesthetic agents.

Drugs used in myasthenia gravis and glaucoma.

Unit-IV

08 Hours

Pharmacology of drugs acting on central nervous system

Neurohumoral transmission in the CNS 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

Pharmacology of drugs acting on central nervous system

Psychopharmacological agents: antipsychotics, antidepressants, anti-anxiety agents, antimanics and hallucinogens.
Drugs used in Parkinson's disease and Alzheimer's disease.
CNS stimulants and nootropics.
Opioid analgesics and antagonists.
Drug addiction, drug abuse, tolerance and dependence.

BP408P. PHARMACOLOGY-I (Practical)

4Hours/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus.
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using Rota-rod apparatus.
11. Effect of drugs on locomotor activity using Actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods.

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

Recommended Books (Latest Editions)

- Rang and Dale's Pharmacology by Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Churchill Livingstone Elsevier.
- Basic and Clinical Pharmacology by Katzung B. G., Masters S. B., Trevor A. J., Tata McGraw-Hill.
- The Pharmacological Basis of Therapeutics by Goodman and Gilman's, McGraw Hill, USA.
- Applied Therapeutics: The Clinical use of Drugs by Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., the Point Lippincott Williams & Wilkins.
- Lippincott's Illustrated Reviews- Pharmacology by Mycek M.J., Gelnet S.B. and Perper M.M.
- Essentials of Medical Pharmacology by K.D. Tripathi, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi.
- Principles of Pharmacology by Sharma H. L., Sharma K. K., Paras medical publisher
- Modern Pharmacology with Clinical Applications, by Charles R. Craig & Robert.
- Fundamentals of Experimental Pharmacology by Ghosh M.N., Hilton & Company, Kolkata.
- Handbook of Experimental Pharmacology by Kulkarni S.K., Vallabh Prakashan.

BP405T. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours

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 mucilage, 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, leaf constant, 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.

BP408P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

1. Analysis of crude drugs by chemical tests:
 - (i) Tragacanth.
 - (ii) i) Acacia.
 - (iii) Gelatin.
 - (iv) Starch.
 - (v) Honey.
 - (vi) Castor oil.
 - (vii) Agar.
2. Determination of stomatal number and index.
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer.
5. Determination of Fiber length and width.
6. Determination of number of starch grains by Lycopodium spore method.
7. Determination of Ash value.
8. Determination of Extractive values of crude drugs.
9. Determination of moisture content of crude drugs.
10. Determination of swelling index and foaming.

Recommended Books: (Latest Editions)

- Trease and Evans Pharmacognosy by W.C. Evans, 16th edition, W.B. Saunders & Co., London.
- Pharmacognosy by Tyler V.E., Brady L.R. and Robbers J.E., 9th Ed., Lea and Febiger, Philadelphia.
- Textbook of Pharmacognosy by Wallis T.E., CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Pharmacognosy and Phytochemistry by Mohammad Ali, CBS Publishers & Distribution, New Delhi.
- Textbook of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
- Herbal Drug Industry by R.D. Choudhary (1996), 1st Ed., Eastern Publisher, New Delhi.
- Essentials of Pharmacognosy, Dr. S.H. Ansari, 2nd Ed., Birla publications, New Delhi.
- Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhale, Vallabh Prakashan, Delhi.
- Pharmacognosy of Powdered Crude Drugs by M.A. Iyengar, PharmaMed Press, Hyderabad.

SEMESTER V

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 human body.

H1-antagonist: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Triphelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartrate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine Cromolyn sodium.

H2-antagonists: Cimetidine*, Famotidine, Ranitidine.

Gastric proton-pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole.

Anti-neoplastic agents:

Alkylating agents: Meclorothamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiopeta.

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine.

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin.

Plant products: Etoposide, Vinblastine sulphate, Vincristine sulphate.

Miscellaneous: Cisplatin, Mitotane.

Unit-II

10 Hours

Anti-anginal: Vasodilators: Amyl Nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrate*, Dipyridamole.

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

Diuretics: Carbonic Anhydrase Inhibitors: Acetazolamide*, Methazolamide, Dichlorophenamide.

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, Lorcaïnide Hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholestyramine and Colestipol.

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, Andralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl Stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrel

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.

Sulfonylureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone, Meglitinides, Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, 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, Dipreron, Dibucaine.

Recommended Books (Latest Editions)

- Wilson and Gisvold's Organic Medicinal and Pharmaceutical Chemistry by Block J.H. and Beale J.M., Lippincott Williams and Wilkins, NY.
- Foye's Principles of Medicinal Chemistry by Lemke T.L., Williams D.A., Roche V.F. and Zito S.W., Lippincott Williams and Wilkins.
- Burger's Medicinal Chemistry and Drug Discovery by Abraham D.J., Volume I to IV, John Wiley and Sons Inc., New York.
- Synthesis of Essential Drugs by Vardanyan R.S. and Hruby V.J., Elsevier.
- Introduction to Medicinal Chemistry by Alex Gringauz, Wiley VCH.
- An Introduction to Medicinal Chemistry by Patrick Graham L., Oxford University Press.
- Medicinal Chemistry: A Biochemical Approach by Nogrady T., Oxford University Press, New York.
- The Organic Chemistry of Drug Design and Drug Action by Silverman R.B., Elsevier.
- Introduction to Principles of Drug Design by Smith and Williams, CRC Press, US.
- Medicinal and Pharmaceutical Chemistry by Singh H. and Kapoor V.K., Vallabh Prakashan, Delhi.
- Textbook of Drug Design and Discovery by Larsen P.K., Liljefors T. and Madsen U., Taylor and Francis Inc.
- Martindale's Extra Pharmacopoeia.
- Organic Chemistry by I.L. Finar, Vol. II, Dorling Kindersley (India) Pvt. Ltd., Delhi.
- The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
- The Pharmacopoeia of India, the Controller of Publications, Delhi.
- Elementary Practical Organic Chemistry by Vogel A.I., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.

BP502T. INDUSTRIAL PHARMACY I (Theory)

45 Hours

Course content:

Unit-I

07 Hours

Pre-formulation Studies: Introduction to pre-formulation, goals and objectives, study of physicochemical characteristics of drug substances.

Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism.

Chemical Properties: Hydrolysis, oxidation, reduction, racemization, polymerization. BCS classification of drugs & its significance.

Application of pre-formulation 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. Equipment's 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 syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in Pharmacopoeia.

Unit-III

08 Hours

Capsules:

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

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

Pellets: Introduction, formulation requirements, palletization process, and equipment for manufacture of pellets.

Unit-IV**10 Hours****Parenteral Products:**

Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity.

Production procedure, production facilities and controls, aseptic processing.

Formulation of injections, sterile powders, large volume parenteral and lyophilized products.

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

Quality control tests of parenteral products.

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

Unit-V**10 Hours**

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

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

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

BP506P. INDUSTRIAL PHARMACY I (Practical)

4 Hours/week

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

Recommended Books: (Latest Editions)

- Modern Pharmaceutics by Gilbert S. Banker; Christopher T. Rhodes, 4th edition; (Volume-121), Marcel Dekker, Inc., NY.
- Pharmaceutical Dosage Forms by Lieberman H.A., Lachman C., Parenteral Medications, Volume 1-3, Marcel Dekker Inc., USA.
- Pharmaceutical Dosage Forms by Lieberman H.A., Lachman C., Tablets, Volume 1-3, Marcel Dekker Inc., USA.
- Pharmaceutical Dosage Forms by Lieberman H.A., Lachman C., Disperse System, Volume 1-3, Marcel Dekker Inc., USA.
- The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS) by Remington.
- Lachman/Lieberman's Theory and Practice of Industrial Pharmacy by Roop K. Khar, S.P. Vyas, F.J. Ahmad and G.K. Jain, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- 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, 5th edition, 2005.
- Drug stability- Principles and Practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series.
- Bentley and Driver's Textbook of Pharmaceutical Chemistry, Oxford University Press, New Delhi.
- J. Swarbrick, J.C. Boylar, 2nd ed., Encyclopedia of Practical Technology, Vol. 1-3, 2004. (Updated supplement).

BP503T. PHARMACOLOGY-II (Theory)**45 Hours****Course Content:****Unit-I****10 Hours****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**10 Hours****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**10 Hours****Autacoids and related drugs**

Introduction to autacoids and classification of Histamine, 5-HT and their antagonists.

Prostaglandins, Thromboxanes and Leukotrienes.

Angiotensin, Bradykinin and Substance P.

Non-steroidal anti-inflammatory agents.

Antigout drugs, Anti rheumatic drugs.

Unit-IV**08 Hours****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**07 Hours****Pharmacology of drugs acting on endocrine system**

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

Bioassay

Principles and applications of bioassay. Types of bioassay.

Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT.

BP507P. PHARMACOLOGY-II (Practical)

4Hours/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog *rectus abdominis* muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog *rectus abdominis* muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three-point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four-point bioassay.
11. Determination of PA₂ value of prazosin using rat anococcygeus muscle (by Schild plot method).
12. Determination of PD₂ value using guinea pig ileum.
13. Effect of spasmogens and spasmolytic using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

Recommended Books (Latest Editions)

- Rang and Dale's Pharmacology by Rang H. P., Dale M. M., Ritter J. M., Flower R. J. Churchill Livingstone Elsevier.
- Basic and Clinical Pharmacology by Katzung B. G., Masters S. B., Trevor A. J., Tata McGraw-Hill.
- The Pharmacological Basis of Therapeutics by Goodman and Gilman's, McGraw Hill, USA.
- Applied Therapeutics: The Clinical use of Drugs by Marry Anne K. K., Lloyd Yee Y., Brian K.A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., Lippincott Williams & Wilkins.
- Lippincott's Illustrated Reviews - Pharmacology by Mycek M.J, Gelnet S.B and Perper M.M.
- Essentials of Medical Pharmacology by K.D. Tripathi, Jaypee Brothers Medical Publishers, New Delhi.
- Principles of Pharmacology by Sharma H. L., Sharma K. K., Paras medical publisher.
- Modern Pharmacology with Clinical Applications by Charles R. Craig & Robert, Lippincott Williams & Wilkins, USA.
- Fundamentals of Experimental Pharmacology by Ghosh M.N., Hilton & Company.
- Handbook of Experimental Pharmacology by Kulkarni S.K., Vallabh Prakashan.

BP504T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

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

14 Hours

General introduction, composition, chemistry & chemical classes, bio -sources, 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

06 Hours

Isolation, Identification and Analysis of Phytoconstituents.

Terpenoids: Menthol, Citral, Artemisin.

Glycosides: Glycyrrhetic acid & Rutin.

Alkaloids: Atropine, Quinine, Reserpine, Caffeine

Resins: Podophyllotoxin, Curcumin.

Unit-IV

10 Hours

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

Unit-V

8 Hours

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, Chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

BP508P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

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

Recommended Books: (Latest Editions)

- Trease and Evans Pharmacognosy by W.C. Evans, 16th edition, W.B. Saunders & Co., London.
- Pharmacognosy and Phytochemistry by Mohammad Ali, CBS Publishers and Distribution.
- Textbook of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
- Herbal Drug Industry by R.D. Choudhary, 1st Ed, Eastern Publisher, New Delhi.
- Essentials of Pharmacognosy by Dr. S.H. Ansari, 2nd Ed, Birla publications, New Delhi.
- Herbal Cosmetics by H. Panda, Asia Pacific Business Press, Inc., New Delhi.
- Textbook of Industrial Pharmacognosy by A.N. Kalia, CBS Publishers, New Delhi.
- Plant Cell Biotechnology by R. Endress, Springer-Verlag, Berlin, 1994.
- Pharmacognosy & Pharmacobiotechnology by James Bobbers, Marilyn KS, VE Tylor.
- The Formulation and Preparation of Cosmetic, Fragrances and Flavors by Louis Appell, Micelle Press.
- The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS) by Remington.
- Textbook of Biotechnology by Vyas and Dixit, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Biosynthesis of Natural Products by Manitto P., Ellis Horwood Limited.

BP505T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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; 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, CPCSE guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.

National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM).

Unit-V

07 Hours

Pharmaceutical Legislations - A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee.

Code of Pharmaceutical ethics - Definition, 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)

- Forensic Pharmacy by B. Suresh, Birla Publication Pvt. Ltd., Delhi.
- Textbook of Forensic Pharmacy by B.M. Mittal, Vallabh Prakashan, Delhi.
- Handbook of Drug Law by M.L. Mehra, the University Book Agency, Lucknow.
- A Textbook of Forensic Pharmacy by N.K. Jain, Vallabh Prakashan, Delhi.
- Drugs and Cosmetics Act/Rules, Govt. of India publications.
- Medicinal and Toilet Preparations Act 1955, Govt. of India Publications.
- Narcotic Drugs and Psychotropic Substances Act, Govt. of India Publications.
- Drugs and Magic Remedies Act, Govt. of India Publication.
- Bare Acts of the Laws.
- Intellectual Property Rights in Pharmaceutical Industry: Theory and Practice by B. Subba Rao and P.V. Appaji, PharmaMed Press, Hyderabad.

BP509P. HOSPITAL TRAINING-I

Training of students at a hospital establishment for a minimum duration of 45 days. The hospital training shall include: First aid (wound dressing, artificial respiration etc.), different routes of injection, study of patient observation charts, prescriptions and dispensing, simple diagnostic reports, etc.

May be performed at the end of the 4th semester.

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Course Content:

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, Cephalosporin, β -Lactamase inhibitors, Monobactams.

Aminoglycosides: Streptomycin, Neomycin, Kanamycin.

Tetracycline: 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.

Antimalarial: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

Unit-III

10 Hours

Anti-tubercular Agents:

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

Ant-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine, Streptomycin, 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*, Ganciclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

Unit-IV

08 Hours

Antifungal agents:

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

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

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

Anthelmintic: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin.

Sulphonamides and Sulfones: Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, 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, Hammett's electronic parameter, Taft's 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:

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

II Assay of drugs:

- 1 Isonicotinic acid hydrazide.
- 2 Chloroquine.
- 3 Metronidazole.
- 4 Dapsone.
- 5 Chlorpheniramine maleate.
- 6 Benzyl penicillin.

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique.

IV Drawing structures and reactions using chem draw ®.

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinski's RO5).

Recommended Books (Latest Editions)

- Wilson and Gisvold's Organic Medicinal and Pharmaceutical Chemistry by Block J.H. and Beale J.M., Lippincott Williams and Wilkins.
- Foye's Principles of Medicinal Chemistry by Lemke T.L., Williams D.A., Roche V.F. and Zito S.W., Lippincott Williams and Wilkins.
- Burger's Medicinal Chemistry and Drug Discovery by Abraham D.J., Vol I to IV. John Wiley and Sons Inc., New York.
- Synthesis of Essential Drugs by Vardanyan R.S. and Hruby V.J., Elsevier.
- Medicinal Chemistry: A Biochemical Approach by Nogrady T., Oxford University Press, New York.
- Textbook of Drug Design and Discovery edited by K. Stromgaard, P.V. Larsen and U. Madsen, CRC Press, NY.
- An Introduction to Medicinal Chemistry by Patrick Graham, L., Oxford University Press.
- The Organic Chemistry of Drug Design and Drug Action by Silverman R.B., Elsevier.
- Introduction to Principles of Drug Design by Smith and Williams.
- New Approaches to Drug Development edited by P. Jolles, Library of Congress

~~Cataloging in Publication Data, Germany.~~

- Textbook of Drug Design and Discovery by Larsen P.K., Liljefors T. and Madsen U., Taylor and Francis Inc.
- Martindale's Extra Pharmacopoeia.
- The Organic Chemistry of Drug Design and Drug Action by Richard B. Silverman, Academic Press, USA.
- Elementary Practical Organic Chemistry by Vogel A.I., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- Practical Organic Chemistry by Mann F.G, and Saunders, B.C., Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.
- The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
- The Pharmacopoeia of India, the Controller of Publications, Delhi.

BP602T. PHARMACOLOGY-III (Theory)

45 Hours

Course Content

Unit-I

10 hours

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

10 hours

Chemotherapy: General principles of chemotherapy.

Sulfonamides and Cotrimoxazole.

Antibiotics- Penicillins, cephalosporin, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides.

Unit-III

10 hours

Chemotherapy:

Antitubercular agents.

Antileprotic agents.

Antifungal agents.

Antiviral drugs.

Anthelmintics.

Antimalarial drugs.

Antiamoebic agents.

Unit-IV**08 hours****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**07 hours****Principles of toxicology:**

Definition and basic knowledge of acute, sub-acute 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, and organophosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology:

Definition of rhythm and cycles.

Biological clock and their significance leading to chronotherapy.

BP608P. PHARMACOLOGY-III (Practical)

4Hrs/Week

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

**Experiments are demonstrated by simulated experiments/videos.*

Recommended Books (Latest Editions)

- Rang and Dale's Pharmacology by Rang H.P., Dale M.M., Ritter J.M., Flower R.J., Churchill Livingstone Elsevier.
- Basic and Clinical Pharmacology by Katzung B.G., Masters S.B., Trevor A.J., Tata McGraw-Hill.
- The Pharmacological Basis of Therapeutics by Goodman and Gilman's, McGraw Hill, USA.
- Applied Therapeutics: The Clinical Use of Drugs by Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., The Point Lippincott Williams & Wilkins.
- Lippincott's Illustrated Reviews- Pharmacology by Mycek M.J., Gelnet S.B. and Perper M.M.
- Essentials of Medical Pharmacology by K.D. Tripathi, Jaypee Brothers Medical Publishers (P) Ltd, New Delhi.
- Principles of Pharmacology, Sharma H.L., Sharma K.K., Paras Medical Publisher.
- Modern Pharmacology with Clinical Applications by Charles R. Craig & Robert.
- Fundamentals of Experimental Pharmacology by Ghosh M.N., Hilton & Company, Kolkata,
- Handbook of Experimental Pharmacology by Kulkarni S.K., Vallabh Prakashan,
- Concepts in Chronopharmacology by N. Udupa and P.D. Gupta.

BP603T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Course content:

Unit-I

10 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.

Indian Systems of Medicine: 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-II

8 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: Alfa-alfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina.

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

Unit-III

10 Hours

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

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

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

Unit-IV**10 Hours**

Evaluation of Drugs WHO & ICH guidelines for the assessment 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-V**07 Hours**

General Introduction to Herbal Industry: Herbal drugs industry: Present scope and future prospects. A brief account of plant-based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine:

Components of GMP (Schedule –T) and its objectives.

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

P609P. HERBAL DRUG TECHNOLOGY (Practical)

4 Hours/ week

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

Recommended Books: (Latest Editions)

- Trease and Evans Pharmacognosy by W. C. Evans, 16th edition, W.B. Saunders & Co., London.
- Textbook of Industrial Pharmacognosy by A.N. Kalia, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Textbook of Pharmacognosy by Tyler, Brady & Robber, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Handbook of Cosmetic Science & Technology by M. Paye, A.D. Barel, H. Maibach, Informa Healthcare, NY.
- Cosmetics Formulation, Manufacture and QA by P.P. Sharma, 4th edition, Vandana Publication Pvt. Ltd.
- Poucher's Perfumes, Cosmetics and Soaps edited by Hilda Bulter, Springer (India) Pvt. Ltd., New Delhi.
- Textbook of Pharmacognosy by C.K. Kokate, Purohit, Gokhale, Nirali Prakashan, New Delhi.
- Essential of Pharmacognosy by Dr. S.H. Ansari, Birla Publications Pvt. Ltd., Delhi.
- Pharmacopeial Standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).
- Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals by Mukherjee, P.W. Business Horizons Publishers, New Delhi.

BP604T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

Introduction to Biopharmaceutics:

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from non per-oral extra-vascular routes.

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

Unit-II

10 Hours

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

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

Unit-III

10 Hours

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. Intravenous Injection (Bolus), Intravenous infusion and Extra vascular administrations. Pharmacokinetics parameters – K_E , $t_{1/2}$, V_d , AUC, K_a , Cl_t and CL_R - definitions, methods of eliminations, understanding of their significance and application.

Unit-IV

08 Hours

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

Unit-V

07 Hours

Nonlinear Pharmacokinetics: Introduction, Factors causing Non-linearity. Michaelis-Menten method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

- Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew, B.C.Y.U. 4th edition Prentice-Hall International edition. USA.
- Biopharmaceutics and Pharmacokinetics-A Treatise by D.M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi.
- Handbook of Clinical Pharmacokinetics by Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- Biopharmaceutics by Swarbrick, Lea and Febiger, USA.
- Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, PharmaMed Press, Hyderabad.
- Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Sarfaraz Niazi, PharmaMed Press, Hyderabad.
- Basic Pharmacokinetics by Mohsen A. Hedaya, CRC Press, NY.
- Biopharmaceutics and Pharmacokinetics by V. Ventashewarlu, PharmaMed Press, Hyderabad.
- Clinical Pharmacokinetics, Concepts and Applications by Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
- Dissolution, Bioavailability and Bioequivalence by Abdou H.M, Mack, Publishing Company, Pennsylvania, 1989.
- Biopharmaceutics and Clinical Pharmacokinetics: An Introduction by Robert F. Notari, 4th edition, Marcel Dekker Inc., New York.

BP605T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Course content:

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 production of:
i) Interferon
ii) Vaccines- hepatitis- B
iii) Hormones-Insulin.
Brief introduction to PCR.

Unit-III

10 Hours

Types of immunity- humoral immunity, cellular immunity.
Structure of Immunoglobulins.
Structure and Function of MHC.
Hypersensitivity reactions, Immune stimulation and Immune suppressions.
General method of the preparation of bacterial infections, 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, Blood products and Plasma Substitutes.

Unit-IV

08 Hours

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: Types of mutation/mutants.

Unit-V**07 Hours**

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.

Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

Recommended Books (Latest edition):

- Molecular Biotechnology: Principles and Applications of Recombinant DNA by B.R. Glick and J.J. Pasternak, ASM Press Washington D.C.
- Kuby Immunology by R.A. Goldsby *et. al.*, W.H. Freeman and Company, NY.
- Biotechnology by U. Satyanarayan, Books and allied Pvt. Ltd., Kolkata.
- Industrial Microbiology by L.E. Casida Jr., New Age International Pub., New Delhi.
- Crueger's Biotechnology- A textbook of Industrial Microbiology by Crueger and Aneja, Medtech, New Delhi.
- Monoclonal Antibodies by J.W. Goding, Academic Press.
- Molecular Biology and Biotechnology by J.M. Walker and E.B. Gingold, Royal Society of Chemistry.
- Immobilized Enzymes by Zaborsky, CRC Press, Ohio.
- Molecular Biotechnology by S.B. Primrose, Blackwell Scientific Publication.
- Principles of Fermentation Technology by Stanbury F.P., Whitakar A., and Hall J.S., 2nd ed., Aditya books Ltd., New Delhi.
- Pharmaceutical Biotechnology: Concepts and Applications by G. Walsh, Wiley and Sons Pvt. Ltd., USA.
- Pharmaceutical Biotechnology: Biochemistry and Biotechnology by G. Walsh, Wiley and Sons Pvt. Ltd., USA.

BP606T. PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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 procedures.

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

Unit-III

10 Hours

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

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

Unit-IV

08 Hours

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling 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 Guidelines and Related Materials, Volume-I, WHO Publications.
- A Guide to Total Quality Management by Kushik Maitra and Sedhan K. Ghosh.
- How to Practice GMPs by P.P. Sharma, Vandana Publications Pvt. Ltd., Delhi.
- How to Practice GLP by P.P. Sharma, Vandana Publications Pvt. Ltd., Delhi.
- ISO 9000 and Total Quality Management by Sadhank G. Ghosh, Oxford Publishing House, UK.
- The International Pharmacopoeia – Volume I, II, III, IV- General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excipients and Dosage forms.
- Good Laboratory Practices by Marcel Dekker Series.
- ICH guidelines, ISO 9000 and 14000 guidelines.
- Quality Control of Packaging Materials in the Pharmaceutical Industry by Kenneth and Harburn, Marcel Dekker, Inc., NY.
- cGMP (Current Good Manufacturing Practices) for Pharmaceuticals, Manohar A. Potdar, PharmaMed Press, Hyderabad.
- Lachman/Lieberman's Theory and Practice of Industrial Pharmacy by Roop K. Khar, S.P. Vyas, F.J. Ahmad and G.K. Jain, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- N.K. Jain, Pharmaceutical Product Development, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Production and Operation Management by S.N. Chary, 3rd edition, Tata McGraw-Hill Education
- Concepts of Quality Management in Pharmaceutical Industry by Manohar A. Potdar, PharmaMed press, Hyderabad.
- Quality Assurance and Quality Management in Pharmaceutical Industry by Y. Anjaneyulu; R. Marayya, PharmaMed press.
- Pharmaceutical Quality Assurance and Quality management by Bhusari K.P; Shivhare U.D; Goupale D.C., PharmaMed press, Hyderabad.
- Modern Pharmaceutics by Gilbert S. Banker; Christopher T. Rhodes, 4th edition; (vol-121), Marcel Dekker, Inc., NY.
- Pharmaceutical Facilities: Design by Manohar. A. Potdar, Layout and Validation, 2nd edition; PharmaMed press, Hyderabad.
- Pharmaceutical Packaging Technology by V.K. Jain, D.C. Goupale, S. Nayak, PharmaMed press, Hyderabad.
- Quality Control & Total Quality Management by P.L. Jain, Tata McGraw Hill, New Delhi.

BP610P. REPORT ON INDUSTRIAL TRAINING

Training of students at an industrial establishment or an approved research laboratory. The industrial training shall include: in case of industry- different sections and subsections of the industry, an idea about the functioning of the industry, product range of the industry and various approvals of the industry; in case of research laboratory- different departments of the laboratory, an idea about the interdisciplinary coordination, contribution of the laboratory to the society and various approvals of the laboratory. A proper report of the same shall be submitted by the students, which shall be subsequently evaluated to assess the impact of the visit.

May be performed at the end of the 5th semester.

Semester VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

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.

Nephelo-turbidimetry- 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, R_f 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 / NDDS (Practical)

4 Hours/Week

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.
2. Estimation of sulphanilamide by colorimetry.
3. Simultaneous estimation of ibuprofen and Paracetamol by UV spectroscopy.
4. Estimation of quinine sulphate by fluorimetry.
5. Study of quenching of fluorescence.
6. Determination of sodium by flame photometry.
7. Determination of potassium by flame photometry.
8. Determination of chlorides and sulphates by nephelometry-turbidimetry.
9. Separation of sugars by thin layer chromatography.
10. Separation of plant pigments by column chromatography.
11. Demonstration experiment on HPLC.
12. Demonstration experiment on Gas Chromatography.
13. To perform in-vitro dissolution profile of CR/SR marketed formulation.
14. To prepare sustained release matrix tablets and evaluate by UV spectroscopy.
15. Formulation of nanoparticles and evaluate by HPLC.
16. Formulation and evaluation of liposomes.
17. To prepare buccal dosage form and evaluate by UV spectroscopy.
18. To prepare Paracetamol transdermal patch and evaluate by UV spectroscopy.

Recommended Books (Latest Editions)

- Instrumental Methods of Chemical Analysis by B.K. Sharma, Krishna Prakashan Media (P) Ltd., Meerut, India.
- Organic Spectroscopy by Y.R Sharma, S. Chand & Company Ltd., New Delhi.
- Pharmaceutical Chemistry Instrumental Technique by Leslie G. Chatten, CBS Publisher and Distributor Pvt. Ltd., New Delhi.
- Textbook of Pharmaceutical Analysis by Kenneth A. Connors, John Wiley & Sons, Inc., New York.
- Vogel's Textbook of Quantitative Chemical Analysis by A.I. Vogel, Addison Wesley Logman, Singapore.
- Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Organic Spectroscopy by William Kemp, Palgrave, NY.
- Quantitative Analysis of Drugs by D.C. Garrett, Chapman & Hall Ltd., London.
- Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Spectrophotometric Identification of Organic Compounds by Silverstein, John Wiley & Sons, Inc., New York.
- Controlled and Novel Drug Delivery by N.K. Jain, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- Novel Drug Delivery Systems by Y W. Chien, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York.

BP702T. INDUSTRIAL PHARMACY II (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

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

Unit-II

10 Hours

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

Unit-III

10 Hours

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

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

Unit-IV

08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, 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, 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](http://en.wikipedia.org/wiki/Regulatory_Affairs).
- International Regulatory Affairs Updates, 2005, available at <http://www.iraup.com/about.php>.
- Textbook of FDA Regulatory Affairs. A Guide for Prescription Drugs, Medical Devices, and Biologics' by Douglas J Pisano and David S. Mantus.
- Regulatory Affairs brought by Learning Plus, Inc., available at <http://www.cgmp.com/ra.htm>.
- Intellectual Property Rights in Pharmaceutical Industry Theory and Practice by Bayya Subba Rao and Appaji.
- How to Practice GLP by P.P. Sharma, Vandana Publications Pvt. Ltd., Delhi.
- Validation of Active Pharmaceuticals Ingredients by Ira R. Bony & Daniel Harpaz., CRC Press.
- Drugs and Pharmaceutical Sciences by Richard A. Guarina, 4th edition, Vol 139.

BP703T. PHARMACY PRACTICE (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

Hospital and its 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.

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 labeling. 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.

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.

Drug information services

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

Patient counselling

Definition of patient counselling; steps involved in patient counselling, 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

Budget preparation and implementation: Budget preparation and implementation. **Clinical Pharmacy:** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring- medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

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

Organization 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, haematology and urine analysis.

Recommended Books (Latest Edition):

- A Textbook of Hospital Pharmacy by Merchant S.H. and Dr. J.S. Quadry, 4th ed. Ahmadabad: B.S. Shah Prakashan.
- A Textbook of Clinical Pharmacy Practice- Essential Concepts and Skills by Parthasarathi G., Karin Nyfort-Hansen, Milap C. Nahata, 1st ed. Chennai: Orient Longman Private Limited.
- Hospital Pharmacy by William E. Hassan, 5th ed. Philadelphia: Lea & Febiger; 1986.
- Hospital Pharmacy by Tipnis Bajaj, 1st ed. Maharashtra: Career Publications.
- Basic Skills in Interpreting Laboratory Data by Scott L.T., 4th ed. American Society of Health System Pharmacists Inc.
- Health Education and Community Pharmacy by Parmar N.S. 18th ed. India: CBS Publishers & Distributors.

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)

BP704T. NOVEL DRUG DELIVERY SYSTEMS (NDDS) (Theory)

45 Hours

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 implants and osmotic pump.

Unit-III

10 Hours

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

Gastro-retentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS– Floating, high density systems, inflatable and gastro-adhesive systems and their applications.

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

Unit-IV

08 Hours

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

Unit-V

07 Hours

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome– 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)

- Novel Drug Delivery Systems by Y W. Chien, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- Controlled Drug Delivery Systems by Robinson, J. R., Lee V. H. L, Marcel Dekker, Inc., New York, 1992.
- Encyclopaedia of Controlled Drug Delivery by Edith Mathiowitz, Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim.
- Controlled and Novel Drug Delivery by N.K. Jain, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- Controlled Drug Delivery-Concepts and Advances by S.P. Vyas and R.K. Khar, Vallabh Prakashan, New Delhi, First edition 2002.
- Modern Pharmaceutics by Gilbert S. Banker; Christopher T. Rhodes, 4th edition; (vol-121), Marcel Dekker, Inc., NY.
- Handbook of Pharmaceutical Controlled Release Technology by Donald L. Wise, Marcel & Dekker Inc., NY.
- Dermatological and Transdermal Formulations by Kenneth A. Walters, Merrell & Dekker Inc., NY.
- Drug Delivery System by Vasant V. Ranaday, Manfred A. Hollinger, CRC Press, NY.
- Design of Controlled Release Drug Delivery System by Xialing Li, Bhaskara R. Jasti, Mc-Graw Hill.

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)

BP706PS. PRACTICE SCHOOL

150 Hours

Course content:

Every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains. Every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages).

Domains (anyone to be opted):

- ❖ Phytomedicine
- ❖ Formulation development
- ❖ Quality control and quality assurance
- ❖ Drug design and process chemistry
- ❖ Pharmaceutical software
- ❖ Artificial intelligence
- ❖ 3D printing
- ❖ Nutraceuticals
- ❖ Cosmeceuticals
- ❖ Alternative medicine

Recommended Books (Latest Editions)

- Trease and Evans Pharmacognosy by W. C. Evans, 16th edition, W.B. Saunders & Co., London.
- Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals by Mukherjee, P. W., Business Horizons Publishers, New Delhi, India, 2002.
- Current Concepts in Drug Design by T. Durai and Ananda Kumar, BSP Books.
- An Introduction to Medicinal Chemistry by Patrick Graham, L., Oxford University Press.
- Introduction to the Principles of Drug Design by Smith H.J., Williams H, Wright Boston.
- Industrial Microbiology by Prescott and Dunn, 4th edition, CBS Publishers & Distributors, Delhi.
- Molecular Biotechnology: Principles and Applications of Recombinant DNA by B.R. Glick and J.J. Pasternak: ASM Press Washington, D.C.
- Harry's Cosmetology by Wilkinson, Moore, Seventh Edition.
- Poucher's Perfumes, Cosmetic and Soaps by Poucher W.A., Butler, H., Springer India Pvt. Ltd, New Delhi.

BP707P. HOSPITAL TRAINING-II

Training of students at a hospital establishment for a minimum duration of 45 days. The hospital training shall include: First aid (wound dressing, artificial respiration etc.), different routes of injection, study of patient observation charts, prescriptions and dispensing, simple diagnostic reports etc.

May be performed at the end of the 6th semester.

SEMESTER VIII

BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

45 Hours

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 regression models

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB[®], Design of experiment, R- Online Statistical Software's to Industrial and Clinical trial approach.

Unit-V**7 Hours****Design and Analysis of experiments:****Factorial Design:** Definition, 2^2 , 2^3 design. Advantages of factorial design.**Response Surface methodology:** Central composite design, Historical design, Optimization Techniques.**Recommended Books (Latest edition):**

- Pharmaceutical Statistics- Practical and Clinical Applications by Sanford Bolton, Marcel Dekker Inc. New York.
- Fundamental of Statistics by S.C. Gupta, Himalaya Publishing House.
- Design and Analysis of Experiments by R. Pannerselvam, PHI Learning Private Limited.
- Design and Analysis of Experiments by Douglas and C. Montgomery, Wiley Students Edition.

BP802T. SOCIAL AND PREVENTIVE PHARMACY (Theory)

45 Hours

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, G.N. Prabhakara, 2nd Edition, Jaypee Publications.
- Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, Jaypee Publications.
- Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, Jaypee Publications.
- Essentials of Community Medicine A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, Jaypee Publications.
- Park Textbook of Preventive and Social Medicine, K. Park, 21st Edition, Banarasidas Bhanot Publishers.
- Community Pharmacy Practice by Ramesh Adepu, BSP publishers, Hyderabad.
- Sociology for Pharmacist by Kevin Taylor, Sarah Nettleton and Geoffery Harding.

Recommended Journals:

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

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Course content:

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 behaviour and industrial buying behaviour.

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; patient's choice of physician and retail pharmacist. Analysing the Market; Role of market research.

Unit-II

10 Hours

Product decision:

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

Unit-III

10 Hours

Promotion:

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

Unit-IV

08 Hours

Pharmaceutical marketing channels:

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

Professional sales representative (PSR):

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

Unit-V

07 Hours

Pricing:

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

Emerging concepts in marketing:

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

Recommended Books: (Latest Editions)

- Marketing Management by Philip Kotler and Kevin Lane Keller, Prentice Hall of India, New Delhi.
- Marketing Strategy- Planning and Implementation by Walker, Boyd and Larreche, Tata McGraw Hill Publishing Company Ltd., New Delhi.
- Organization and Management by R. D. Agarwal, Tata McGraw Hill Publishing Company Ltd., New Delhi.
- Marketing by Dhruv Grewal and Michael Levy, Tata McGraw Hill Publishing Company Ltd., New Delhi.
- Marketing Management by Arun Kumar and N. Meenakshi, Vikas Publishing, India.
- Marketing Management by Rajan Saxena, Tata McGraw Hill Publishing Company Ltd., New Delhi.
- Principles of Pharmaceutical Marketing edited by Mickey Smith, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Textbook of Forensic Pharmacy by B.M. Mittal, Vallabh Prakashan, Delhi.
- A textbook of Forensic Pharmacy by N.K. Jain, Vallabh Prakashan, Delhi.
- Marketing Management: Global Perspective, Indian Context by Ramaswamy, U.S & Nanakamari, S. Macmillan India, New Delhi.
- Service Marketing by Shanker, Ravi, Excel Books, New Delhi.
- Pharmaceutical Marketing in India (GIFT – Excel series) by Subba Rao Changanti Excel Publications.
- Salesmanship and Publicity by R.S. Daver, S.R. Davar and N.R. Davar, Vikas Publishing, India.
- Pharmaceutical Industrial Management by Vidya Sagar, PharmaMed Press, Hyderabad.
- Sales management: Decision, Strategies and Cases by R.S. Richard, C.W. Edward, G.A. Norman, Prentice-Hall of India Pvt. Ltd., New Delhi.
- Drugs and Cosmetics Act 1940 by Vijay Malik, EBC Publishing House Pvt. Ltd. Lucknow.

BP804ET. PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Course content:

Unit-I

10 Hours

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

10 Hours

Regulatory Approval Process

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

Regulatory authorities and agencies

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

Unit-III

10 Hours

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

08 Hours

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

07 Hours

Regulatory Concepts

Basic terminology, 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 (Drugs and the Pharmaceutical Sciences) 2nd edition by Ira R. Berry and Robert P. Martin, 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 by Sandy Weinberg, John Wiley & Sons. Inc., USA.
- 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 by 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 by Rick Ng., 2nd Edition, Wiley-Blackwell.
- Intellectual Property Rights in Pharmaceutical Industry: Theory and Practice by B. Subba Rao and P.V. Appaji, PharmaMed Press, Hyderabad.
- Validation of Active Pharmaceuticals Ingredients by Ira R. Bony & Daniel Harpaz, CRC Press, US.

BP805ET. PHARMACOVIGILANCE (Theory)

45 hours

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 Standardized MedDRA queries, WHO drug dictionary, EudraVigilance medicinal product dictionary.

Information resources in pharmacovigilance

Basic drug information resources, Specialized resources for ADRs.

Establishing pharmacovigilance programme

Establishing in a hospital, Establishment & operation of drug safety department in industry, Contract Research Organizations (CROs), Establishing a national program.

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**

Safety data generation: Pre clinical phase, Clinical phase, Post approval phase (PMS).

ICH Guidelines for Pharmacovigilance: Organization and objectives of ICH, Expedited reporting, Individual case 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: Genetics related ADR with example focusing PK parameters.

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 by S K Gupta, Jaypee Brothers, Medical Publishers.
- Quintessence of Pharmacovigilance by Tapan Kumar Chatterjee, PharmaMed Press.
- Practical Drug Safety from A to Z by Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
- Mann's Pharmacovigilance by Elizabeth B. Andrews, Nicholas, Wiley Publishers.
- Stephens' Detection of New Adverse Drug Reactions by John Talbot, Patrick Walle, Wiley Publishers.
- An Introduction to Pharmacovigilance by Patrick Waller, Wiley Publishers.
- Cobert's Manual of Drug Safety and Pharmacovigilance by Barton Cobert, Jones & Bartlett Publishers.
- Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
- A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills by G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata, Orient Longman Pvt Ltd.
- National Formulary of India.
- Textbook of Medicine by Yashpal Munjal.
- Textbook of Pharmacovigilance: Concept and Practice by G.P. Mohanta and P.K. Manna.
- <http://www.who.unc.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

BP806ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS
(Theory)

45 Hours

Course Content

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-III

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)

- Trease and Evans Pharmacognosy by W. C. Evans, 16th edition, W.B. Saunders & Co., London.
- Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals by Mukherjee, P.W. Business Horizons Publishers, New Delhi, India, 2002.
- Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.

- Textbook of Pharmacognosy and Phytochemistry, V.D. Rangari, Vol. I, Carrier Pub., 2006.
- Herbal Drug Technology by S.S. Aggarwal, Universities Press, 2012.
- EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products.
- Application of Quality Control Principles to Herbal Drugs by Shinde M.V., Dhalwal K., Potdar K., Mahadik K., International Journal of Phytomedicine 1(2009); p. 4-8.
- 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 Ed. 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.

BP807ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Course Content:

UNIT-I

10 Hours

Introduction to Drug Discovery and Development: Stages of drug discovery and development.

Lead discovery and Analogue 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.

Analogue 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, Hammett's substituent constant and Taft's 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)

- Drug Action at the Molecular Level by Robert G.C.K., University Park Press, Baltimore.
- Quantitative Drug Design by Martin Y.C., Dekker, New York.
- Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry by Delgado J.N., Remers W.A., Lippincott, New York.
- Principles of Medicinal chemistry by Foye WO, Lea & Febiger. Wolters Kluwer Pvt. Ltd.
- Essentials of Medicinal Chemistry by Koro I kovas A., Burckhalter J.H., Wiley Interscience.
- The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry by Wolf M.E., John Wiley & Sons, New York.
- Current Concepts in Drug Design by T. Durai and Ananda Kumar, BSP Books, Hyderabad.
- An Introduction to Medicinal Chemistry by Patrick Graham, L., Oxford University Press.
- Introduction to the Principles of Drug Design by Smith H.J., Williams H., Wright Boston.
- Computer Aided Drug Design by P.J. Thomas and Propst C.L. Marcel Dekker Inc.NY. Essentials of Drug Design by Kothekar V, Dhruv Publications Delhi.
- Structure-Based Drug Discovery by J. Harren, and L Andrew, Springer (India) Pvt. Ltd., Delhi.
- Molecular Modelling and Design by Vinter J.V. and G. Mark, CRC Press, NY.
- The Organic Chemistry of Drug Design and Drug Action by Silverman R.B., Academic Press, New York

BP808ET. CELL AND MOLECULAR BIOLOGY (Theory)

45 Hours

Course content:

Unit-I

10 Hours

Cell and Molecular Biology: Definitions theory and basics and Applications. Cell and Molecular Biology: History and Summation.
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 Information. 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):

- Pharmaceutical Microbiology by W.B. Hugo and A.D. Russel, Blackwell Scientific publications, Oxford London.
- Industrial Microbiology by Prescott and Dunn., 4th edition, CBS Publishers & Distributors, Delhi.
- Molecular Biotechnology: Principles and Applications of Recombinant DNA: by B.R. Glick and J.J. Pasternak, ASM Press Washington D.C.
- Microbiology by Pelczar, Chan Kreig, Tata McGraw Hill, New Delhi.
- Pharmaceutical Microbiology by Malcolm Harris, Balliere Tindall and Cox.
- Industrial Microbiology by Rose, Butterworths, USA.
- Fundamentals of Microbiology by Frobisher, Hinsdill et al, 9th ed. Japan.
- Cooper and Gunn's Tutorial Pharmacy by Carter S.J., CBS Publications, New Delhi.
- Microbial Technology by Peppler, Academic Press.
- Fundamentals of Microbiology by Edward, Benjamin Cummings, USA.
- Pharmaceutical Microbiology by N.K. Jain, Vallabh Prakashan, Delhi.
- Bergey's Manual of Systematic Bacteriology by Williams and Wilkins, A Waverly company.
- Kuby Immunology by R.A. Goldsby *et. al.*, W.H. Freeman and Company, NY.

BP809ET. COSMETIC SCIENCE (Theory)

45 Hours

Unit-I

10 Hours

Classification of cosmetic and cosmeceutical products.

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

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

Unit-II

10 Hours

Principles of formulation and building blocks of skin care products:

Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Antiperspirants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products: Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils.

Chemistry and formulation of para phenylenediamine 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

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Colour, Hair tensile strength, Hair combing properties.

Soaps and syndet bars. Evolution and skin benefits.

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 odour. Antiperspirants and Deodorants- Actives and mechanism of action.

Recommended Books (latest edition):

- Harry's Cosmetology by Wilkinson, Moore, Seventh Edition.
- Poucher's Perfumes, Cosmetics and Soaps edited by Hilda Bulter, Springer (India) Pvt. Ltd., New Delhi.
- Cosmetics Formulation, Manufacture and Quality Control by P.P. Sharma, 4th edition, Vandana Publication Pvt. Ltd., Delhi.
- Cosmetology by Sanju Nanda & Roop K. Khar, Publishers. Birla Publications Pvt Ltd.
- Cosmeceuticals by Madhusudan Rao, PharmaMed Press, Hyderabad.
- Cosmetics: Science and Technology by Balsam M.S., Sagarin, E., Wiley Interscience, New York.
- Handbook of Cosmetic Science and Technology by Pave M., Basel, A.O., Maibach H.I., Informa Healthcare, New York.
- Cosmeceuticals by Rao Y.N., Shayeda, PharmaMed Press, Hyderabad.
- Herbal Cosmetics by H. Panda, Asia Pacific Business Press, Inc., New Delhi.
- Drugs and Cosmetics Act/Rules, Govt. of India Publications.
- Drugs and Cosmetics Act 1940 by Vijay Malik, EBC Publishing House Pvt. Ltd. Lucknow.

BP810ET. PHARMACOLOGICAL SCREENING METHODS (Theory)

45 Hours

Course content:

Unit-I

10 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

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, anti-asthmatics.

Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, Alzheimer's disease.

Unit-III

10 Hours

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.

Unit-IV

08 Hours

Preclinical screening models: for CVS activity – anti-hypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, anti-diabetic, anticancer and anti-asthmatics.

Unit-V

07 Hours

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.

Recommended Books (latest edition):

- Fundamentals of Experimental Pharmacology by M.N. Ghosh., Hilton and Company, Kolkata.
- Handbook of Experimental Pharmacology by S.K. Kulkarni, Vandana Prakashan Delhi.
- CPCSEA Guidelines for Laboratory Animal Facility.
- Drug Discovery and Evaluation by Vogel H.G., Springer Berlin, Germany.
- Screening Methods in Pharmacology by Turner, Elsevier a Division of Reed India Pvt. Ltd. Noida.
- Introduction to Biostatistics and Research Methods by P.S.S. Sundar Rao and J. Richard.

BP811ET. ADVANCED INSTRUMENTATION TECHNIQUES (Theory)

45 Hours

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 Thermogravimetric Analysis (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 immunoassay.

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, Krishna Prakashan Media (P) Ltd., Meerut, India.
- Organic Spectroscopy by Y.R. Sharma, S. Chand & Company Ltd., New Delhi.
- Pharmaceutical Chemistry Instrumental Technique by Leslie G. Chatten, CBS Publisher and Distributer Pvt. Ltd., New Delhi.
- Textbook of Pharmaceutical Analysis by Kenneth A. Connors, John Wiley & Sons, Inc., New York.
- Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Vogel's Textbook of Quantitative Chemical Analysis by A.I. Vogel, Addison Wesley Logman, Singapore.
- Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi, CBS Publishers & Distributers Pvt. Ltd., New Delhi.
- Quantitative Analysis of Drugs by D.C. Garrett, Chapman & Hall Ltd., London.
- Spectrophotometric Identification of Organic Compounds by Silverstein, John Wiley & Sons, Inc., New York.
- Organic Spectroscopy by William Kemp, Palgrave, NY.

BP812ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.

Public health nutrition, maternal and child nutrition. Nutrition and ageing, nutrition education in community.

Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soybean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds.

Unit-II

10 Hours

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

Carotenoids: α and β -Carotene, Lycopene, Xanthophylls, leutin.

Sulfides: Diallyl sulfides, Allyl trisulfide.

Polyphenolics: Resveratrol.

Flavonoids: Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones.

Prebiotics/Probiotics: Fructo-oligosaccharides, Lacto bacillum.

Phyto estrogens: Isoflavones, daidzein, Geeststin, lignans.

Tocopherols.

Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

Unit-III

10 Hours

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

Dietary fibres and complex carbohydrates as functional food ingredients.

Unit-IV

08 Hours

Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free- radicals theory of ageing.

Antioxidants: Endogenous antioxidants– enzymatic and non-enzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione, Vitamin C, Vitamin E, α -Lipoic acid, melatonin. Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

Functional foods for chronic disease prevention.

Unit-V**07 Hours**

Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

Regulatory Aspects: FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Pharmacopeial Specifications for dietary supplements and nutraceuticals.

Recommended Books (Latest editions)

- Role of Dietary Fibers and Nutraceuticals in Preventing Diseases by K.T. Agusti and P. Faizal: BS Publication.
- Advanced Nutritional Therapies by Cooper. K.A., Thomas Nelson, Inc., USA.
- The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
- Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Ed., Avery Publishing Group, NY (1997).
- Functional Foods by G. Gibson and C. Williams Editors 2000, Woodhead Publ. Co. London.
- Functional Foods by Goldberg, I., 1994. Chapman and Hall, New York.
- Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods by M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
- Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition).
- Modern Nutrition in Health and Disease by Shils, M.E., Olson, J.A., Shike, M. 1994, Eighth edition. Lea and Febiger.
- Food Science by Potter N. Norman and J.H. Hotchkiss, CBS Publishers & Distributors Pvt. Ltd., New Delhi.
- Essentials of Food Process Engineering by Chandra Gopala Rao, BS Publications, Hyderabad.
- Food Chemistry and Nutrition - A Comprehensive Treatise by S. Sumathi, BS Publications, Hyderabad.

BP813ET. PHARMACEUTICAL PRODUCT DEVELOPMENT (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

Introduction to pharmaceutical product development, objectives, and 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 for 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, Charles Bon; Marcel Dekker Inc., USA.
- Encyclopaedia of Pharmaceutical Technology, edited by James Swarbrick, Third Edition, Informa Healthcare publishers.
- Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, by A. Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker Inc., USA.
- Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, by H.A. Liberman, Martin, M.R and Gilbert S. Banker, Marcel Dekker Inc., USA.
- Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, by Kenneth E. Avis and H.A. Liebermann, Marcel Dekker Inc., USA.
- The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop K Khar, 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, Lippincott Williams & Wilkins, USA.
- 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.
- Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems by Loyd V. Allen, Jr., N.G. Popovich and H. C. Ansel, Lippincott Williams & Wilkins, USA.
- Aulton's Pharmaceutics – The Design and Manufacture of Medicines by Michael E. Aulton, 3rd Ed., Churchill Livingstone, UK.
- The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS) by Remington.
- Advanced Review Articles related to the topics.

BP803ET to BP814ET (Elective Subjects)

The student has the choice to choose both the elective subjects from the already prescribed list of elective subjects by the PCI **or** choose one elective subject from the existing prescribed list of elective subjects of B. Pharm. programme by the PCI and the other (second subject) elective from list of skill pack/modules available with the LSSSDC from time to time.

BP815PW. PROJECT WORK (On Elective)

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subjects opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

BP816P. REPORT ON INDUSTRIAL TOUR

Visit of students to an industrial establishment or an approved research laboratory. The industrial visit shall include: in case of industry- visit to different sections and subsections of the industry, an idea about the functioning of the industry, product range of the industry and various approvals of the industry; in case of research laboratory-visit to different departments of the laboratory, an idea about the interdisciplinary coordination, contribution of the laboratory to the society and various approvals of the laboratory. A proper report of the same shall be submitted by the students, which shall be subsequently evaluated to assess the impact of the visit.

May be performed at the end of the 7th semester.