1.3.1 :

Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability in transacting the Curriculum.

Loknete shree dadapatil pharate College of Pharmacy, mandavgan pharata offers B. Pharm, and M. Pharm. LSDP is permanently affiliated to Savitribai Phule Pune University (SPPU) for B. Pharm and M.Pharm program and follows the curriculum prescribed by it. Institute has taken the initiative by recognizing the significance of cross cutting issues to cultivate and sustain the value of ethics in students of Pharmacy, to increase awareness about gender equality amongst students, to instil the sense of social responsibility and best character in the students, to increase the awareness about sustainability of environment. The achievements of these cross cutting issues are integrated through curricular, co-curricular and extracurricular activities are as given below.

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Sr.no.	Cross cutting issue	Program wise/course wise emphasized the integration of cross cutting issue	
		Curriculum Courses	Co-curricular and Extracurricular activities
1	Professional ethics	View document	View document
2	Gender		View document
3	Human values		View document
4	Environment and Sustainability		View document

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CURRICULUM COURSES (SUMMARY)

The Institution integrates cross-cutting issues relevant to gender, environment and sustainability, human values, health determinants, Right to Health and emerging demographic issues and Professional Ethics into the Curriculum as prescribed by the University / respective regulative councils.

Sr. No	Course code	Name of the course	Professional Ethics	Gender	Human Values	Enviorment and sustainability	Documents
1	BP101T	Human Anatomy and Physiology I– Theory	✓				View document
2	BP102T	Pharmaceutical Analysis I – Theory	✓				
3	BP103T	Pharmaceutics I – Theory	✓		✓		
4	BP104T	Pharmaceutical Inorganic Chemistry – Theory	✓				
5	BP105T	Communication skills – Theory *	✓				
6	BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	✓				
7	BP107P	Human Anatomy and Physiology – Practical	✓				
8	BP108P	Pharmaceutical Analysis I – Practical	✓				
9	BP109P	Pharmaceutics I – Practical					

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10	BP110P	Pharmaceutical Inorganic Chemistry – Practical	✓				
11	BP111P	Communication skills – Practical*			✓		
12	BP112RBP	Remedial Biology – Practical*	✓	✓			
13	BP201T	Human Anatomy and Physiology II – Theory	✓	✓			View document
14	BP204T	Pathophysiology – Theory	✓	✓			
15	BP205T	Computer Applications in Pharmacy – Theory *	✓				
16	BP206T	Environmental sciences – Theory *				✓	
17	BP207P	Human Anatomy and Physiology II – Practical	✓	✓			
18	BP208P	Pharmaceutical Organic Chemistry I– Practical	✓				
19	BP209P	Biochemistry – Practical	✓				
20	BP210P	Computer Applications in Pharmacy – Practical*	✓				
21	BP301T	Pharmaceutical Organic Chemistry II – Theory	✓				View document
22	BP303T	Pharmaceutical Microbiology – Theory					
23	BP304T	Pharmaceutical Engineering – Theory				✓	
24	BP305P	Pharmaceutical Organic Chemistry II – Practical	✓				
25	BP307P	Pharmaceutical Microbiology – Practical				✓	
26	BP402T	Medicinal		✓			View document

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		Chemistry I – Theory					
27	BP404T	Pharmacology I – Theory	✓			✓	
28	BP405T	Pharmacognosy and Phytochemistry I– Theory	✓			✓	
29	BP406P	Medicinal Chemistry I – Practical	✓				
30	BP502T	Industrial PharmacyI– Theory	✓				View document
31	BP503T	Pharmacology II – Theory	✓	✓		✓	
32	BP504T	Pharmacognosy and Phytochemistry II– Theory					
33	BP505T	Pharmaceutical Jurisprudence – Theory	✓			✓	
34	BP602T	Pharmacology III – Theory					View document
35	BP603T	Herbal Drug Technology – Theory	✓			✓	
36	BP604T	Biopharmaceutics and Pharmacokinetics – Theory	✓				
37	BP605T	Pharmaceutical Biotechnology – Theory				✓	
38	BP606T	Quality Assurance – Theory	✓			✓	
39	BP607P	Medicinal chemistry III – Practical					
40	BP608P	Pharmacology III – Practical	✓			✓	
41	BP609P	Herbal Drug Technology – Practical	✓				
42	BP701T	Instrumental Methods of Analysis – Theory	✓				View document
43	BP702T	Industrial PharmacyII – Theory	✓				

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44	BP703T	Pharmacy Practice – Theory	✓		✓		
45	BP704T	Novel Drug Delivery System – Theory					
46	BP705P	Instrumental Methods of Analysis – Practical	✓				
47	BP802T	Social and Preventive Pharmacy	✓		✓		View document
48	BP803ET	Pharma Marketing Management	✓				
49	BP804ET	Pharmaceutical Regulatory Science	✓		✓		
50	BP805ET	Pharmacovigilance	✓		✓		
51	BP806ET	Quality Control and Standardizati on ofHerbals	✓				
52	BP809ET	Cosmetic Science	✓				
53	BP810ET	Experimental Pharmacology	✓				
54	BP812ET	Dietary Supplements and Nutraceuticals	✓	✓	✓		
55	MPH103 T	Modern Pharmaceutics	✓				View document
56	MPH104 T	Regulatory Affair	✓				
57	MPH105 P	Pharmaceutics Practical I	✓				
58	MPC10 5P	Pharmaceutical Chemistry Practical I	✓				
59	MPC20 1T	Advanced Analysis	✓				
60	MPC20 5P	Pharmaceutical Chemistry Practical II	✓				
61	MPL 101T	Modern Pharmaceutical Analytical Techniques	✓				
62	MPL 103T	Pharmacological and Toxicological Screening	✓				

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		Methods–I					
63	MPL 105P	Pharmacology Practical I	✓				
64	MPL 202T	Pharmacological and Toxicological ScreeningMethods–II	✓		✓		

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Semester I

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

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)

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

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

Reference Books (Latest Editions)

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

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BP102T.

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 Permanganometry
(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)

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

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

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

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

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities andpharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:

UNIT – I **10 Hours**

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

UNIT – II **10 Hours**

- **Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

- **Powders:** Definition, classification, advantages and disadvantages,Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms, Solubility enhancement techniques

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UNIT – III **08 Hours**

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
- **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type ofEmulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV **08 Hours**

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

UNIV – V **07 Hours**

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

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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) Terpin Hydrate Linctus IP'66
b) Iodine Throat Paint (Mandles Paint)

4. Solutions
a) Strong solution of ammonium acetate
b) Cresol with soap solution
c) Lugol's solution

5. Suspensions
a) Calamine lotion
b) Magnesium Hydroxide mixture
c) Aluminimum Hydroxide gel

6. Emulsions
a) Turpentine Liniment
b) Liquid paraffin emulsion

7. Powders and Granules
a) ORS powder (WHO)
b) Effervescent granules
c)Dusting powder
d)Divded powders

8. Suppositories
a) Glycero gelatin suppository
b) Coca butter suppository
c) Zinc Oxide suppository

8. Semisolids
a) Sulphur ointment
b) Non staining-iodine ointment with methyl salicylate
c) Carbopal gel

9. Gargles and Mouthwashes
a) Iodine gargle
b) Chlorhexidine mouthwash

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Recommended Books: (Latest Editions)

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

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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 SulphatesLimit test for Iron

Limit test for Heavy metals

Limit test for Lead

Limit test for ArsenicII

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 IodideIV **Preparation of inorganic pharmaceuticals**

Boric acid

Potash alum

Ferrous sulphate

Recommended Books (Latest Editions)

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

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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, RootLeaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

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

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BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

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

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

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

Course Content:

UNIT – I **06 Hours**

- **Partial fraction**

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

- **Logarithms**

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

- **Function***:*

Real Valued function, Classification of real valued functions,

- **Limits and continuity** :

Introduction , Limit of a function, Definition of limit of a function (□ - □ definition) , lim $\frac{x^n \square a}{n}$ □$na^{n\square 1}$, li m $\frac{\sin}{\square}$ □1,

$x\square a$ $x \square a$ □□0 □

UNIT –II **06 Hours**

- **Matrices and Determinant:**

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

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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 , Derivativeof 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 Laplacetransform, Laplace Transforms of elementary functions, InverseLaplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

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

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Semester II

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

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

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

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

Course Content:

Unit I **10 hours**

- **Nervous system**

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

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

Unit II **06 hours**

- **Digestive system**

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

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

- **Energetics**

  Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

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

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

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

- **Urinary system**

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

Unit IV **10 hours**

- **Endocrine system**

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

Unit V **09 hours**

- **Reproductive system**

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

- **Introduction to genetics**

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

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BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

1. To 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 reproductivesystems 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 analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

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

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

Reference Books:

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

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BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

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

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

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

Course Content:

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

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

UNIT-I **07 Hours**

- **Classification, nomenclature and isomerism**

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds(up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

UNIT-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, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

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

UNIT-III **10 Hours**

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- **Alkyl halides***

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

  SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions

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

- **Alcohols*-** Qualitative tests, Structure and uses of Ethyl alcohol, 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, Vanilin, Cinnamaldehyde.

UNIT-V **08 Hours**

- **Carboxylic acids***

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

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

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

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BP 209 P. 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.

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Recommended Books (Latest Editions)

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

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BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

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

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

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

Course content:

Unit I **10Hours**

- **Basic principles of Cell injury and Adaptation:**
  Introduction, definitions, Homeostasis, Components and Types of Feedback systems,Causes of cellular injury,Pathogenesis (Cell membrane damage, Mitochondrial damage,Ribosome damage, Nuclear damage),Morphology of cell injury – Adaptive changes(Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia),Cell swelling, Intra cellularaccumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance
- **Basic mechanism involved in the process of inflammation and repair:**
  Introduction, Clinical signs of inflammation, Different types of Inflammation,Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's,Mediators of inflammation,Basic principles of wound healing in the skin,Pathophysiology of Atherosclerosis

Unit II **10Hours**

- **Cardiovascular System:**
  Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)
- **Respiratory system:**Asthma, Chronic obstructive airways diseases.
- **Renal system:**Acute and chronic renal failure

Unit II **10Hours**

- **Haematological Diseases:**
  Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia
- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- **Gastrointestinal system:** Peptic Ulcer

Unit IV **8 Hours**

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

- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V **7 Hours**

- **Infectious diseases:**Meningitis,Typhoid, Leprosy, TuberculosisUrinary tract infections
- **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

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

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9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

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

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BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

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

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

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

Course content:

UNIT – I **06 hours**

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

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

UNIT –II **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

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UNIT – IV **06 hours**

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

UNIT-V **06 hours**

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

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BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather informationabout a particular disease.
2. Create a HTML web page to show personal information.
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 requiredfields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record inthe 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):

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

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BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

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

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

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

Course content:

Unit-I **10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

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

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Recommended Books (Latest edition):

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

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..CHAPTER - II: SYLLABUS

Semester III

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Semester III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory) **45 Hours**

Scope

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

Objectives

Upon completion of the course the student shall be able to

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

Write the reaction, name the reaction and orientation of reactions

Account for reactivity/stability of compoundsPrepare small organic compounds

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Practical) **4** **Hours/Week**	
I. Experiments involving laboratory techniques Recrystallisatio n Steam distillation	**1 turn**
II. Experiments involving Separation of Binary mixtures	**2 turns**
III. Determination of saponification value of oil samples (Any two)	**1 turn**
IV. Synthesis of following compounds Benzanilide /phenyl benzoate /acetanilide from aniline/ phenol/ aniline bybenzoylation/acylation reaction 2, 4, 6-Tribromoaniline/para-bromo acetanilide from aniline p-bromo Acetanilide by halogenation (Bromination) reaction. 5-Nitrosalicylic /meta-dinitrobenzene from salicylic acid/ nitrobenzene by nitration reaction Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysisreaction. 1-Phenylazo-2-naphthol from aniline by diazotization and coupling reactions/ *p*-Iodobenzoic acid from P-aminobenzoic acid by replacement reaction. Benzil from benzoin by oxidation reaction Dibenzal acetone from benzaldehyde by Claisen-Schmidt reaction	**11 turns**

Recommended Books

1. Morrison, R. T. & Boyd, R. D., Textbook of Organic Chemistry, VI (ed.) EEBS, London.

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1996

2. Pine, S. H, Organic Chemistry, V, Tata McGraw Hill, New Delhi, 2003
3. Finar, I. L., Organic Chemistry Vol. I, V (ed.), ELBS, Pearson Education, New Delhi, 2003
4. Joule and Mills, Heterocyclic Chemistry, IV (ed.), Blackwel Publishing House, Oxford,UK,
5. 2004
6. Li, J. J., Name Reactions, III (ed.), Springer, Berlin, 2006
7. Stereochemistry of Organic Compound Principles and Applications by Nasipuri, Revised Edition, New Age International Publishers.
8. Stereochemistry Conformation and Mechanism by P.S. Kalsi, 7/Ed 2008, New Age International Publishers, New Delhi.
9. Furniss, B. S., Hannaford, A. J. Smith, P. W. G., and Tatchel, A. R., "Vogel's Textbookof Practical Organic Chemistry", V (ed.), Pearson, London, **1994**
10. Finar, I. L., Organic Chemistry Vol. I, V (ed.), ELBS, Pearson Education, New Delhi, **2003**
11. Mann, F. G. and Saunders, B. C., Practical Organic Chemistry, IV(ed.), Pearson, UK, **2009**
12. Advanced General Organic Chemistry-A Modern Approach by Sachin Kumar Ghosh,3/Ed. 2009, New Central Book Agency (P) Ltd.

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BP302T. PHYSICAL PHARMACEUTICS-I (Theory) 45Hours

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

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

1. Investigate and apply various theories, laws and equations related to different states ofmatter
2. Distinguish the principles of complexation/ protein binding & to use them for calculations of drug release and stability constant**.**
3. **Demonstrate use of physicochemical properties of drugs in the formulationdevelopment and evaluation of dosage forms.**

Course Content:

UNIT-I **12 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, Solubility of Solids in liquids (Binary solutions, ideal solutions with respect to their colligative properties) Raoult's law, real solutions. Partially miscible liquids(Phase equilibria, Phase rule, One , two and three component systems, ternary phase diagram, Critical solution temperature and applications). Distribution law, its limitations and applications

UNIT-II **10Hours**

States of Matter and properties of matter:State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, Liquefaction of gases,aerosols– inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid crystalline, amorphous(Methods of crystal analysis: X-Ray Diffraction, Bragg's equation.) & polymorphism (Definition, Different shapes of polymorphs, Example and its Pharmaceutical applications, Brief introduction of Detection techniques).

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

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UNIT-III **08 Hours**

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions, surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solidinterface.

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.

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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 byCST 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 complexby solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complexby pH titration method.
12. Determination of Refractive index of given sample.
13. Determination of thermodynamic parameters using solubility

studies.**Recommended Books:**

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3,MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1,2, 3. Marcel Dekkar Inc.

7. Physical Pharmaceutics by Ramasamy C and ManavalanR**.**

8. LaboratoryManual of Physical Pharmaceutics, C.V.S. Subramanyam, J.Thimma settee

9. Physical Pharmaceutics by C.V.S. Subramanyam

10. Text book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

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BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory) 45Hours

Scope:

•Study of microorganisms and its effect on pharmaceutical products

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

1. Understand methods of identification, cultivation and preservation of variousmicroorganisms
2. To understand the importance and implementation of sterlization in pharmaceuticalprocessing and industry
3. Learn sterility testing of pharmaceutical products**.**
4. Carried out microbiological standardization of Pharmaceuticals**.**
5. Understand the cell culture technology and its applications in pharmaceutical industries.**Course content:**

Unit I **10 Hours**

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

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

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

Definition and examples of Probiotics and Prebiotics

Unit II **10 Hours**

Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC). Definition of D value & Z value and its significance.

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.

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Equipments employed in large scale sterilization.

Sterility indicators.

Unit III **10 Hours**

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

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BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hours/week

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow or 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 (Any two samples).
9. Bacteriological analysis of water
10. Biochemical test of any one microorganism**.**

Recommended Books

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

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

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

11. Edward: Fundamentals of Microbiology**.**

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

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

14. "Nutrition Probiotics and prebiotics" by Pamela Mason; The Pharmaceutical Journal Vol266 No 7132 p118-121**.**

15. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.

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BP 304 T. PHARMACEUTICAL ENGINEERING (Theory) 45 Hours

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

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

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

Course content:

UNIT-I **10 Hours**

•**Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer**.**

•**Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill**.**

•**Size Separation:** Objectives, applications & mechanism of size separation**,** official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT-II **10 Hours**

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

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•**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, fractionaldistillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT- III **08 Hours**

•**Drying:** Objectives, applications & mechanism of drying process, measurements & applicationsof 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 Seidtz filter.

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

UNIT- V **07 Hours**

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

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BP308 P - PHARMACEUTICAL ENGINEERING (PRACTICAL)

4 Hours/week

I. Determination of radiation constant of any one of – brass/ iron/unpainted and painted glass.

II. Steam distillation- To calculate the efficiency of steam distillation.

III. To determine the overall heat transfer coefficient by heat exchanger.

IV. Construction of drying curves (for calcium carbonate and starch)

V. Determination of moisture content and loss on drying.

VI. Determination of humidity of air - i) From wet and dry bulb temperatures -use of Dew point method

VII. Description of Construction, working and application of any two Pharmaceutical Machinery such as Rotary tablet Machine, capsule filling machine, tablet coating machine, autoclave, oven and dehumidifier.

VIII. Size analysis by sieving -To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.

IX. Size reduction: To verify the laws of size reduction using ball mill and and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.

X. Demonstration of any two equipments such as colloid mill, planetary mixer, fluidized bed dryer, Spray dryer Laminar Air Flow, Ball Mill and such other major equipments.

XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity).

XII. To study the effect of time on the Rate of Crystallization.

XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

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Semester – IV

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Semester – IV

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope

The subject imparts knowledge on stereo chemical aspects of organic compounds and organic reactions, important name reactions, chemistry of important heterocyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives

Upon completion of the course the student shall be able to

Understand the methods of preparation and properties of organic compounds.

Explain the stereochemical aspects of organic compounds and stereo chemical reactions.

3. Know the medicinal uses and other applications of organic compounds

COURSE CONTENT

UNIT-I

Stereo isomerism **07 Hours**

Reactions of Chiral molecules

Racemic modification and resolution of racemic mixture.

Introduction to Asymmetric synthesis with suitable examples

UNIT-II

Geometrical isomerism **06 Hours**

Conformational isomerism in *n*-Butane and cyclohexane.

Stereoisomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

UNIT-III

Heterocyclic compounds

Nomenclature and classification of heterocyclic compounds in to classes: Oxygen containing five & six membered rings, Nitrogen containing five & six membered rings, sulphur containing five & six member rings; Oxygen & nitrogen containing five & six membered rings, oxygen & sulphur containing five & six membered rings, and sulphur and nitrogen five & six membered rings; benzo-fused heterocyclic compounds as ole, benzthiazole, benzopyran **08Hours**

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Chemistry (reactivity, stability, acidity and basicity), Synthesis (any one), reactions and medicinal uses of following compounds Pyrrole, Furan, and Thiophene and their derivatives (any one from each class)

UNIT-IV

Chemistry(reactivity, stability, acidity and basicity), Synthesis (any one), reactions and medicinal uses of following compounds and their derivatives (any one from each class) **12 Hours**

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole

Synthesis (any one) and medicinal uses of following compounds Pyrimidine, Purine,Azepines and their derivatives (any one from each class)

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UNIT-V

Name Reactions of synthetic importance

Pinacol-Pinacolone, Hofmann, Baeyer-Villiger oxidation, Benzilic acid rearrangement reaction, Beckmann's rearrangement and Schmidt rearrangement, Claisen-Schmidt condensation, Clemmensen reduction, Wolff rearrangement, Oppenauer-oxidation and Dakin reaction, and Birch reduction.

12 Hours

Recommended Books

1. Morrison, R. T. & Boyd, R. D., Textbook of Organic Chemistry, VI (ed.) ELBS, London, 1996
2. Advanced General Organic Chemistry-A Modern Approach by Sachin Kumar Ghosh, 3/Ed.2009, New Central Book Agency (P) Ltd.
3. Pine, S. H, Organic Chemistry, V, Tata McGraw Hill, New Delhi, 2003
4. Finar, I. L., Organic Chemistry Vol. I, V (ed.), ELBS, Pearson Education, New Delhi, 2003
5. Joule and Mills, Heterocyclic Chemistry, IV (ed.), Blackwell Publishing House, Oxford, UK,2004
6. Li, J. J., Name Reactions, III (ed.), Springer, Berlin, 2006
7. Stereochemistry of Organic Compound Principles and Applications by Nasipuri, Revised Edition,New Age International Publishers.
8. Stereochemistry Conformation and Mechanism by P.S. Kalsi, 7/Ed 2008, New Age InternationalPublishers, New Delhi.
9. Stereochemistry of Organic Compound Principles and Applications by Nasipuri, Revised Edition,New Age International Publishers.

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BP402T. MEDICINAL CHEMISTRY – I (Theory) 45 hours

Scope

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

Objectives

Upon completion of the course the student shall be able to

Understand the chemistry of drugs with respect to their pharmacological activity.
Understand the drug metabolic pathways, adverse effect and therapeutic value of Drugs.
Know the Structural Activity Relationship (SAR) of different class of drugs.
Write the chemical synthesis of some drugs.

COURSE CONTENT

Note: Study of the development of the following classes of drugs, classification, mechanismof action, Structure activity relationship, uses of drugs mentioned in the course.

The synthesis of drugs mentioned in bracket [] only needs to be covered.

UNIT-I **hours**

Introduction to Medicinal Chemistry

a) History and development of medicinal chemistry

b) Physicochemical properties in relation to biological action Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation,Bioisosterism, Optical and Geometrical isomerism.

c) 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

a) Adrenergic Neurotransmitters: Biosynthesis and catabolism of catecholamine. Adrenergic receptors (Alpha & Beta) and their distribution.

b) Sympathomimetic agents: SAR of Sympathomimetic agents Direct acting: Nor-epinephrine, Epinephrine, Dopamine, Phenylephrine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol, Oxymetazoline andXylometazoline

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

c) Adrenergic Antagonists:

- **Alpha adrenergic blockers:** Tolazoline, Phentolamine, Phenoxybenzamine,Prazosin.
- **Beta adrenergic blockers:** SAR of beta blockers, Propranolol, Atenolol,Labetolol, Carvedilol.

[Phenylephrine, Salbutamol, Tolazoline, Propranolol]

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UNIT-III **10 hours**

a) Cholinergic neurotransmitters: Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

b) Parasympathomimetic agents: SAR of Parasympathomimetic agentsDirect acting agents: Acetylcholine**,** Carbachol, Bethanechol, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine, Edrophonium chloride, Donepezil, Tacrine hydrochloride, Parathion, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents :Solanaceous alkaloids and analogues: Atropine sulphate, Scopolamine hydrobromide, Ipratropiumbromide

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Dicyclomine, Glycopyrrolate, Propantheline bromide

[Neostigmine, Dicyclomine hydrochloride]

UNIT-IV **10 hours**

Drugs acting on Central Nervous System

a) Sedatives and Hypnotics:

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

Barbiturtes: SAR of barbiturates, Barbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital **Miscelleneous:**Amides & imides Alcohol & their carbamate derivatives Aldehyde & their derivatives

b) Antipsychotics Phenothiazeines: SAR of Phenothiazines - Chlorpromazine hydrochloride, Triflupromazine, Thioridazine hydrochloride, Trifluoperazine hydrochloride

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

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Benzamides: Sulpiride.

c) Anticonvulsants: SAR of Anticonvulsants**,** mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Mephobarbital**Hydantoins:** Phenytoin, Mephenytoin **Oxazolidine diones:** Trimethadione

Succinimides: Phensuximide, Methsuximide

Urea and monoacylureas: Phenacemide, Carbamazepine

Benzodiazepines: Clonazepam

Miscellaneous: Levetiracetam, Valproic acid , Gabapentin ,Felbamate

d) General anesthetics:

Inhalation

anesthetics: Halothane, Enflurane
Ultra short acting barbitutrates: Methohexital sodium, Thiopental sodium.
Dissociative anesthetics: Ketamine hydrochloride

[Diazepam, Barbital, Chlorpromazine hydrochloride,Phenytoin, Carbamazepine, Halothane, Ketamine hydrochloride]

UNIT-V **07 Hours**

Centrally Acting analgesics

a) Narcotic and non-narcotic analgesics Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Diphenoxylate hydrochloride,Loperamide hydrochloride, Fentanyl citrate, Methadone hydrochloride, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

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

b) Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid, Indomethacin, Sulindac, Diclofenac,Ketorolac, Ibuprofen, Piroxicam, Acetaminophen, Phenylbutazone.

[Fentanyl citrate, Methadone hydrochloride, Mefenamic acid, Ibuprofe

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BP406P. MEDICINAL CHEMISTRY – I (Practical) **4Hrs/week**

Synthesis of following medicinally important compounds / drug intermediates withRecrystallization of compound and monitoring reactions with TLC

Preparation of drugs/ intermediates (any six) **10 turns**

1,3-pyrazole
1,3-oxazole
Benzimidazole
Benztriazole
2,3- diphenyl quinoxaline
Benzocaine
Phenytoin
Phenothiazine
Barbiturate

Purification of above synthesized compounds by Column chromatography **(any one)** **01 turns**

Determination of Partition coefficient and Ionisation constants **(any two compounds).** **04 turns**

Recommended Books (Latest Editions)

1. John Marlowe Beale, Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry. 11th E/d,
2. Thomas L. Lemke, David A. Williams, Victoria F. Roche, Foye's Principles of MedicinalChemistry.
3. Burger's Medicinal Chemistry, Vol I to IV, 6th E/d, M. E. Wolff. John Wiley & Sons, New York. 1997.
4. Smith and Williams, Introduction to principles of drug design, CRC Press; 4 edition.
5. John E. Hoover, Remington's Pharmaceutical Sciences, Mack Publishing Company; 13thedition (1965).
6. Sean C. Sweetman, Martindale's extra pharmacopoeia, Pharmaceutical Society of GreatBritain.
7. Organic Chemistry by I.L. Finar, Vol. II, Longmans Green & Co., 3rd E/d.
8. Daniel Lednicer, Lester A. Mitscher, The Organic Chemistry of Drug Synthesis, JohnWiley & Sons, Inc, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel

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BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory) 45 Hours

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

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

1. Relate various physicochemical properties of drug and excipient molecules in designing the dosage forms

2. Distinguish the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations

3. Demonstrate the behavior and mechanism of drugs and excipients in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I **07 Hours**

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

UNIT-II **10 Hours**

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

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 theoriesof emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

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UNIT-IV **08 Hours**

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

UNIT-V **10 Hours**

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order(complex reaction:reversible, parallel and side reactions), 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 datingof pharmaceutical dosage forms.Photolytic degradation and its prevention

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BP 407P. PHYSICAL PHARMACEUTICS- II (Practical) 4 Hours/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
12. Determination of Cloud point and Krafft point of given surfactant.
13. Determination of effect of salts on stability of hydrophobic sols

Recommended Books:

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

BP 404 T. PHARMACOLOGY-I (Theory) 45Hours

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

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

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

Unit-I **General Pharmacology:** **Hrs**

Introduction to Pharmacology

Definition, Historical landmarks and scope of pharmacology, Nature and source of drugs, Essential drugs concept and Routes of drug administration.

Pharmacokinetics

Membrane transport, Absorption, Distribution, Metabolism and Excretion of drugs. Enzyme induction, Enzyme inhibition, Introduction tokinetics of elimination.

Unit-II **General Pharmacology** **Hrs**

Pharmacodynamics:

Principles and mechanisms of drug action.

Receptortheories and classification of receptors, regulation of receptors. Drugreceptors interactions, Signal transduction mechanisms, G-protein–coupledreceptors, Ion channel receptors, Transmembrane enzyme linked receptors,JAK-STAT binding receptors and receptors that regulate transcriptionfactors,Spare receptors.

Dose response relationship, Therapeutic index,Agonists, Antagonists (competitive and non-competitive),Combined effects of drugs.

Factors modifying drug action.

Adverse drug reactions:

Addiction, Tolerance, Dependence, Tachyphylaxis, Idiosyncrasy, Allergy (explain with suitable examples).

Drug interactions:

Pharmacokinetic and pharmacodynamic drug interactions.

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	Drug discovery and clinical evaluation of new drugs: Introduction to drug discovery, Preclinical evaluation and Clinical trialsIntroduction to Pharmacovigilance	
Unit III	**Pharmacology of drugs acting on Peripheral Nervous System** Introduction to Autonomic Nervous System, Parasympathomimetics, Parasympatholytics, Sympathomimetics and Sympatholytics. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).Local anaesthetic agents. Drugs used in myasthenia gravis and glaucoma	**08 Hrs**
Unit-IV	**Pharmacology of drugs acting on central nervous system** Neurohumoral transmission in the C.N.S.- Special emphasis tobe given on importance of various neurotransmitterslike with GABA, Glutamate, Glycine, Serotonin, Dopamine. General anaesthetics and pre-anaesthetics Sedatives, Hypnotics and Centrally acting muscle relaxantsAnti-epileptics Alcohol and Disulfiram	**09 Hrs**
Unit-V	**Pharmacology of drugs acting on Central Nervous System** Psychopharmacological agents:Antipsychotics, Antidepressants, Anti-anxiety agents, anti-manics and Hallucinogens Drugs used in Parkinson's disease and Alzheimer's diseaseCNS stimulants and Nootropics Opioid analgesics and antagonists (including addiction, abuse, toleranceand dependence)	**08 Hrs**

REFERENCES:

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

10. Barar, F.S.K., Essentials of Pharmacotherapeutics; S. Chand and Company, New Delhi.
11. A textbook of Pathophysiology, Bodhankar, SL and Vyawahare, NS, NiraliPrakashan,Pune.
12. Das, M. M. and Dutta S. K. : R. Ghosh,s Modern Concepts on pharmacology andTherapeutics, (HILTON and Co. Calcutta)
13. Satoskar , R.S. and Bhandarkar S.D. Pharmacology and Pharmacotherapeutics(PopularPrakashan, Bombay).
14. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, Little Brown and Co, Boston.
15. JamesCrossland. Lewis,s Pharmacology Basis of Therapeutics, Pergamon Press, NewYork.
16. Harrison's Principle and Practice of Medicine, 18th Edition, Churchill, Livingston, .London.
17. Roger and Walker. Clinical Pharmacy and Therapeutics, Churchill, Livingston, London.
18. Dipiro Joseph L. A pathphysiological Approach, Elsevier.
19. Davidson's Principle of Internal Medicine, McGraw-Hill companies.
20. Guyton AC. Textbook of medical Physiology. W. B. Sanders CO., Philadelphia, USA.
21. Chatterjee, C.C., Human Physiology. Medical Allied Agency, Kolkata.
22. Ganong, W.F., Review of Medical Physiology. Prentice-Hall International, London.

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BP 408 P.PHARMACOLOGY-I (Practical) **4 Hours/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 sleepingtime 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 byMES 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 softwares and videos

REFERENCES:

1. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton &Company,Kolkata.
2. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.
3. Burn JH. Practical Pharmacology Blackwell Scientific, Oxford London.
4. Jaju BP. Pharmacology: A Practice Exercise Book, Jaypee Brothers, New Delhi.
5. Sheth UK, Dadkar NK and Kamat UG. selected topics in experimentalpharmacology,(Kothari Book Depot, Mumbai)
6. Perry W.L.M. Pharmacological Experiments on Isolated Preparation, E&SLivingstone,London.
7. Goyal R. K., Practicals in Pharmacology, B. S. Shah Prakashan, Ahemadabad.

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory) - 45 Hours

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

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

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

COURSE CONTENT

UNIT-I 10 **Hours**

Introduction to Pharmacognosy:

(a) Definition, history, scope and development of Pharmacognosy

(b) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts,gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

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

Quality control of Drugs of Natural Origin:

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

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, 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

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UNIT-IV

Plant description, morphology and anatomy: **10 Hours**

Leaves, Roots, Barks, Wood, Flowers, Fruits, Seeds, subterranean organs

Introduction to secondary metabolites:

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

08 Hours

UNIT-V

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): General methods of extraction of lipids.

Castor oil, Chaulmoogra oil, Shark liver oil and Cod liver oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources a) Cardiovascular agents and b) Anti cancer agents

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BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical): 4Hrs/week

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

Recommended Books:

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

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T.Y.B.PHARM

SEMESTER – V

BP501T. MEDICINAL CHEMISTRY – II (Theory) 45 Hours

Scope:

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

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

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

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs mentioned in bracket []only to be covered.

UNIT- I **10 Hours**

Antihistaminic agents and autacoids

a) **Antihistaminic agents:** Histamine, receptors and their distribution in the human body

b) **H1-antagonists:** Diphenhydramine hydrochloride, Dimenhydrinate, Doxylamine ssuccinate, Clemastine fumarate, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride, Phenindamine tartarate, Promethazine hydrochloride, Trimeprazine tartrate, Fexofenadine, Astemizole, Loratadine, Cetirizine,

Cromolyn sodium

c) **H_2-antagonists:** Cimetidine, Famotidine, Ranitidine

d) **Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

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e) **Autacoids:** Prostaglandins, Prostanoids, Leucotriene antagonists

[Diphenhydramine hydrochloride, Cetirizine, Promethazine hydrochloride,Ranitidine]

UNIT – II **10 Hours**

Drugs acting on Cardiovascular system

a) **Anti-anginals**:

Vasodilators: Amyl nitrite, Nitroglycerin, Pentaerythritol tetranitrate, Isosorbide dinitrite, Dipyridamole.

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

b) **Diuretics:**

Carbonic anhydrase inhibitors: Acetazolamide, Methazolamide, Dichlorphenamide.**Thiazides:** Chlorthiazide, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide **Loop diuretics:** Furosemide, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

c) **Anti-hypertensive Agents**:

α blockers- Prazosin, Terazosin

β blockers- Propanolol, Timolol, Atenolol

ACE inhibitors- Captopril, Lisinopril, Enalapril, Quinapril hydrochloride

Angiotensin II receptor antagonists- Losartan, Telmisartan, Valsartan

Misc.class- Methyldopate hydrochloride, Clonidine hydrochloride, Guanethidinemonosulphate, Reserpine, Hydralazine hydrochloride.

[Isosorbide dinitrite, Nifedipine, Chlorthiazide, Furosemide, Lisinopril, Atenolol]

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UNIT-III **10 Hours**

Drugs acting on cardiovascular system (Continued)

a) Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride,

Disopyramide phosphate, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

b) Anti-hyperlipidemic agents

HMG Co-A reductase inhibitors: Lovastatin, Simvastatin, Atorvastatin

Misc. class-Ezetimibe, Clofibrate

c) Coagulant & Anticoagulants: Menadione, Warfarin, Clopidogrel

d) Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan

[Amiodarone, Atorvastatin]

UNIT-IV **08 Hours**

Drugs acting on Endocrine system

a) Chemistry, Nomenclature, Stereochemistry and metabolism of steroids

b) Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione,Diethyl stilbestrol.

c) Drugs for erectile dysfunction: Sildenafil, Tadalafil.

d) Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

e) Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone,Dexamethasone

f) Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil,Methimazole.

UNIT – V **07 Hours**

Antidiabetic agents and Local anaesthetics

a) Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Meglitinides: Repaglinide, Nateglinide.

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Glucosidase inhibitors: Acrabose, Voglibose.

DPP IV inhibitors -Sitagliptin, Teneligliptin

SGLT2 inhibitors – Empagliflozin,

Canagliflozin

b) **Local Anesthetics:** SAR of Local anesthetics

Benzoic Acid derivatives; Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine, Procaine, Butacaine, Propoxycaine,Tetracaine.

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

Miscellaneous: Phenacaine

[Tolbutamide, Benzocaine]

Recommended Books (Latest Editions)

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

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BP 502 T. Industrial Pharmacy I (Theory) **45 Hours**

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

1. illustrate various pharmaceutical dosage forms and their manufacturing techniques.
2. describe various factors to be considered in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content: **3 hours/ week**

UNIT-I **03 Hours**

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

UNIT-II **14 Hours**

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, preformulation and Formulation of tablets, granulation methods, compression and processing problems, Equipments and tablet tooling.

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

c. Quality control tests: In process and finished product tests

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

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UNIT-III **08 Hours**

Capsules:

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

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

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

UNIT-IV **10 Hours**

Parenteral Products:

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

b. Production procedure, production facilities and controls, aseptic processing

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

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. 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; preformulation, formulation and manufacture of aerosols; Evaluation of aerosols; Quality controland stability studies.

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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.

Recommended Books: (Latest Editions)

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

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

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

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

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

6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman

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

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

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

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BP503.T. PHARMACOLOGY-II (Theory) **45 Hours**

Scope:

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

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

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

Course Content:

UNIT-I **10hr**

Pharmacology of drugs acting on cardiovascular system

a. Introduction to hemodynamic and electrophysiology of heart.

b. Drugs used in congestive heart failure

c. Anti-hypertensive drugs.

d. Anti-anginal drugs.

e. Anti-arrhythmic drugs.

f. Anti-hyperlipidemic drugs.

UNIT-II

Pharmacology of drugs acting on cardiovascular system **10hr**

a. Drug used in the therapy of shock.

b. Hematinics, coagulants and anticoagulants.

c. Fibrinolytics and anti-platelet drugs

d. Plasma volume expanders

Pharmacology of drugs acting on urinary system

a. Diuretics

b. Anti-diuretics.

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UNIT-III

Autocoids and related drugs **10hr**

a. Introduction to autacoids and classification

b. Histamine, 5-HT and their antagonists.

c. Prostaglandins, Thromboxanes and Leucotrienes

d. Angiotensin, Bradykinin and Substance P.

e. Non-steroidal anti-inflammatory agents

f. Anti-gout drugs

g. Antirheumatic drugs

UNIT-IV

Pharmacology of drugs acting on endocrine system **08hr**

a. Basic concepts in endocrine pharmacology.

b. Anterior Pituitary hormones- analogues and their inhibitors.

c. Thyroid hormones- analogues and their inhibitors.

d. Hormones regulating plasma calcium level- Parathormone, Calcitonin andVitamin-D.

d. Insulin, Oral Hypoglycemic agents and glucagon.

e. ACTH and corticosteroids.

UNIT-V

Pharmacology of drugs acting on endocrine system **07hr**

a. Androgens and Anabolic steroids.

b. Estrogens, progesterone and oral contraceptives.

c. Drugs acting on the uterus.

Bioassay

a. Principles, applications and types of bioassay.

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

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Recommended Books (Latest Editions)

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

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BP504 T PHARMACOGNOSY AND PHYTOCHEMISTRY-II (Theory) 45 Hours

Scope:

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

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

1. To know the modern extraction techniques, characterization and identification of the herbaldrugs and phytoconstituents
2. To understand the production of of Phytoconstituents /herbal formulation.
3. To understand the metabolic pathways in formation of secondary metabolites and applicationof biogenetic studies.
4. To carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I 7 Hours

Metabolic pathways in higher plants and their determination

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

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

UNIT-II 14 Hours

General introduction, composition, chemistry & chemical classes, bio sources, **methods of extraction**, 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

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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

a) Terpenoids: Menthol, Citral, Artemisin

b) Glycosides: Glycyrhetinic acid & Rutin

c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine

d) Resins: Podophyllotoxin, Curcumin

UNIT-IV **06 Hours**

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

UNIT V **12 Hours**

Basics of Phytochemistry

Methods of extraction (Soxhlet, Maceration, Percolation , Supercritical fluid extraction, Microwave assisted extraction, Ultrasound assisted extraction , Solid Phase Extraction) Application of latest techniques like Spectroscopy, Chromatography and electrophoresis in theisolation, purification and identification of crude drugs

Non-chromatographic separation techniques: Fractional distillation, fractional liberation, sublimation, chemical derivatization, fractional crystallization, centrifugation, Froth floatation technique.

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BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory) 45 Hours

Scope:

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

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

1. The Pharmaceutical legislations and their implications in the development and marketing ofpharmaceuticals.

2. Various Indian pharmaceutical Acts and Laws

3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

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

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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 andfunctions, Registration of Pharmacists, Offences and 122 Penalties

Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV **08 Hours**

Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

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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

ActRight to Information Act

Introduction to Intellectual Property Rights

(IPR)Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-byM.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory) 124

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BP 506 P. Industrial PharmacyI (Practical) **4 Hours/week**

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

Recommended Books: (Latest Editions)

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

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BP 507 P. PHARMACOLOGY-II (Practical) **4Hrs/Week**

Sr. No	Experiment
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.	Dose calculation in pharmacological experiments
10.	Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11.	Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12.	Determination of PD_2 value using guinea pig ileum.
13.	Effect of spasmogens and spasmolytics using rabbit jejunum.
14.	Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15.	Analgesic activity using hotplate method
16.	Antiallergic activity by mast cell stabilization assay
17.	Clinical Case study

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

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Recommended Books (Latest Editions)

1. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
2. Kulkarni SK. Handbook of experimental pharmacology. Valla

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3. Goyal RK. Practicals in Pharmacology, BS Shaha Prakashan.
4. Kasture SB. A handbook of experiments in pre-clinical pharmacology, Career Publications.
5. Bikas Medhi, Ajay Prakash. Practical Manual of Experimental and Clinical Pharmacology. Jaypee Publications.

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BP 508 P. 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 phytoconstitutents by TLC

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

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co.,London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers &Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition,Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, NewDelhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, NewDelhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New

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7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi,2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.

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11. Remington‟s Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

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SEMESTER – VI

T.Y.B.PHARM

BP601T. MEDICINAL CHEMISTRY – III (Theory) 45 Hours

Scope :

This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject also discusses the concept of quantitative structure activity relationship (QSAR) in drug design. The subject also emphasizes on thechemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives:

Upon completion of the course student shall be able to

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

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

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

4 Know the importance of SAR of drugs.

Course Content:

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 mentioned in bracket []only to be covered

UNIT - I 10 Hours

Antibiotics

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

a) β-Lactam antibiotics: Penicillins, Cepholosporins, β-Lactamase inhibitors, Monobactams

b) Aminoglycosides: Streptomycin, Neomycin, Kanamycin

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c) **Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline,Doxycycline

UNIT – II **07 Hours**

a) **Antibiotics**

Macrolide: Erythromycin, Clarithromycin, Azithromycin.**Polypeptide antibiotics-**Vancomycin, Bacitracin **Miscellaneous:** Chloramphenicol, Clindamycin, Linzolide

b) **Antimalarials:** Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine, Amodiaquine, Primaquine phosphate, Pamaquine, Quinacrine hydrochloride, Mefloquine.**Biguanides and dihydrotriazines:** Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone, Halofantrine, Lumefantrine.

[Chloramphenicol, Chloroquine]

UNIT – III **08 Hours**

Antimycobacterial and Antiviral agents

a) **Anti-tubercular Agents**

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

Anti tubercular antibiotics: Rifampicin, Rifabutin, CycloserineStreptomycine, Capreomycin sulphate.

b) **Antileprosy agents:** Clofazimine, Dapsone, Rifamycin

c) **Antiviral agents**:

DNA virus inhibitors-Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoridine, Acyclovir, Gancyclovir.

RNA virus inhibitors

Anti-HIV agents- Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine , Ribavirin, Saquinavir, Indinavir, Ritonavir.

[Isoniazid, Ethambutol, Acyclovir]

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UNIT – IV **10 Hours**

a) **Antifungal agents**

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

Synthetic Antifungal agents: Clotrimazole, Oxiconazole,Tioconozole, Miconazole, Ketoconazole, Itraconazole, Fluconazole, Tolnaftate.

b) **Anti-protozoal Agents:** Metronidazole, Tinidazole, Ornidazole, Diloxanide, Iodoquinol,Atovaquone, Eflornithine.

c) **Anthelmintics:** Diethylcarbamazine citrate, Thiabendazole, Mebendazole, Albendazole,Niclosamide, Oxamniquine, Praziquantel, Ivermectin.

d) **Synthetic anti-infective agents :**

Sulphonamides: Historical development, chemistry and drug resistance Sulfacetamide, Sulphapyridine, Sulfamethoxazole, Sulphadiazine, Sulfasalazine.**Folate reductase inhibitors:** Trimethoprim

Quinolones: Nalidixic Acid, Norfloxacin, Ciprofloxacin, Ofloxacin, Lomefloxacin,Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin, Methanamine.

[Fluconazole, Metronidazole, Mebendazole, Sulfamethoxazole, Trimethoprim , Ciprofloxacin]

UNIT – V **07 Hours**

Anti-neoplastic agents:

Alkylating agents: Meclorethamine, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin **Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate **Kinase inhibitors:** Gefitinib, Imatinib, Erlotinib

Monoclonal antibodies-Bedvacizumab, Cetuximab**Miscellaneous:** Cisplatin, Mitotane.

[Chlorambucil, Mercaptopurine, Methotrexate)

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UNIT – VI **03 Hours**

Introduction to Drug Design

Various approaches used in drug design.

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

Recommended Books (Latest Editions)

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

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BP602 T. PHARMACOLOGY-III (Theory) **45 Hours**

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

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

1. Understand the mechanism of drug action and its relevance in the treatment of differentinfectious diseases
2. Comprehend the principles of toxicology and treatment of various poisonings and appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hr**

Pharmacology of drugs acting on Respiratory system

a. Anti -asthmatic drugs
b. Drugs used in the management of COPD
c. Expectorants and antitussives
d. Nasal decongestants
e. Respiratory stimulants

Pharmacology of drugs acting on the Gastrointestinal Tract

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

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UNIT-II

Chemotherapy **10hr**

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

UNIT-III

Chemotherapy **10hr**

a. Antitubercular agents
b. Antileprotic agents
c. Antifungal agents
d. Antiviral drugs
a. Anthelmintics
e. Antimalarial drugs
f. Antiamoebic agents

UNIT-IV

Chemotherapy **08hr**

a. Urinary tract infections and sexually transmitted diseases.
b. Chemotherapy of malignancy.

Immunopharmacology

a. Immunostimulants
b. Immunosuppressant

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

UNIT-V

Principles of toxicology **07hr**

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

Chronopharmacology

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

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale‟s Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill
3. Goodman and Gilman‟s, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., WayneA.K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point LippincottWilliams &Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott‟s Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers MedicalPublishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

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BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

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

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

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

Course content:

UNIT-I **11 Hours**

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal 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

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

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

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.

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UNIT-II **7 Hours**

Nutraceuticals

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

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

Study of Omega-3-polyunsaturated fatty acids, Dietary fibers, Carotenoids, proanthocyanidins, and Resveratrol

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

Market overview, ,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:

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

Herbal formulations :

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

UNIT- IV **12 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:

a) Definition of the terms: Patent, IPR, Farmers right, Breeder‟s right, Bioprospecting andBiopiracy

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b) 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.

Other issues related to export of natural products (such as CITES Certificate, DGFT Notification, Negative list of herbs, TRAFFIC)

UNIT-V **05Hours**

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 medicinaland aromatic plants in India.

S**chedule T – GoodManufacturing 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.

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BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory) 45 Hours

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical dosage form development.

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

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and theirsignificance.
- Use plasma drug concentration-time data to calculate the pharmacokinetic parameters todescribe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- Understand the concepts of bioavailability and bioequivalence of drug products and theirsignificance.
- Understand the concept of dissolution and application of in vitro in vivo correlation indrug product development.

Course Content:

UNIT-I 10 Hours

Introduction to Biopharmaceutics

Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes;

Distribution: Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding, 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, factors affecting drug metabolism, renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Biopharmaceutical classification system, theories of dissolution, dissolution test apparatus, dissolution models, *in-vitro-in-vivo* correlations

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UNIT- III **10 Hours**

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, bioequivalence studies and study designs, Review of regulatory requirements for conducting bioequivalence study, bio-waivers, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- IV **10 Hours**

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model (a) Intravenous Injection (Bolus) (b) Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E, $t_{1/2}$, Vd, AUC, Ka, CL_T and CL_R- definitions methods of eliminations, understanding of their significance and application. Introduction to multi- compartment model.

UNIT- V **05 Hours**

Nonlinear Pharmacokinetics: Introduction, Factors causing Non-linearity, Michaelis-menten equation, Determination of V_{max} and K_m. Significance of nonlinear pharmacokinetics, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4thedition, Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and SunilB.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker, Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADISHealth Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Rowland M, Tozer T, Ed 4,WolterKluwers – Lippincott,Williams and Wilkins.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.

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10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revisedand expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
11. Remington‟s Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvnia.

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY(Theory) 45 Hours

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine andfermentation technologymakes the subjectinteresting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cureof diseases, new and cheaper pharmaceuticaldrugs.
- Biotechnology has already produced transgenic crops and animals and thefuture promiseslot more.
- It is basically a research-basedsubject.

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

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

Unit I 10 Hours

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

Enzyme Biotechnology- Methods of enzyme immobilization and applications.

Biosensors- Working and applications of biosensors in Pharmaceutica

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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 DNAligase. Recombinant

DNA technology. Application of genetic engineering inmedicine.Application of r

DNA technology and genetic engineering in the productionof:

i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.

Brief introduction toPCR139

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 vaccines, toxoids, viral vaccine, antitoxins,serum-immune blood derivatives and other products relative to immunity.

Storage conditions and stability of official vaccines

Hybridoma technology- Production, Purification and Applications

Unit IV **08Hours**

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

Microbial genetics including transformation, transduction, conjugation, plasmids andtransposons.

Introduction to Microbial biotransformation andapplications.

Mutation: Types of mutation/mutants.

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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

variouscontrols. Study of the production of - penicillins, Vitamin B12,

Glutamicacid,

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

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles andApplications ofRecombinant DNA: ASM Press WashingtonD.C.
2. RA Goldshyet. al., :KubyImmunology.
3. J.W. Goding: MonoclonalAntibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology byRoyal SocietyofChemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland,Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) BlackwellScientificPublication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentationtechnology, 2ndedition, Aditya books Ltd., NewDelhi.

BP 606T PHARMACEUTICAL QUALITY ASSURANCE (Theory) 45 Hours

Scope:

This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It deals with the important aspects likeGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives:

Upon completion of the course student shall be able to:

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1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to pharmaceutical industries
4. Understand the responsibilities of QA & QC departments

COURSE CONTENT

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP, Introduction to Regulatory agencies like CDSCO, USFDA, WHO, PIC/S.

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

ICH Guidelines: Brief overview of QSEM, ICH stability testing guidelines **Quality by design (QbD)**: Definition, Overview, Elements of QbD program**ISO 9000 & ISO14000**: Overview, Benefits and Elements

NABL accreditation : Principles and procedures

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personalrecords.

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 of Packaging material: Quality control test for containers, rubber closuresand secondary packing materials.

Good Laboratory Practices &Role of CPCSEA

UNIT – IV **08 Hours**

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

Document maintenance in pharmaceutical industry in brief: Batch Formula Record, Master

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Formula Record, SOP, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, type of validation.

General principles of Analytical method Validation. Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines andRelatedmaterials Vol IWHO Publications.
4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP‟s – P P Sharma.
6. ISO 9000 and Total QualityManagement – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of AnalysisandQuality specification for Pharmaceutical Substances, Excipients and Dosageforms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines142
10. Pharmaceutical Quality Assurance – Sohan Chitlange, Sanjeevani Deshkar, Rupali Kaleand Bhupesh Patil.

BP607P. MEDICINAL CHEMISTRY-III (Practical) **4 Hours / week**

I Preparation of drugs and intermediates (Any six) **10 turns**

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

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9. Caprolactum

II Preparation of medicinally important compounds or intermediates by Microwavesynthesis (any two) **02 turns**

III Drawing structures and reactions using Chem draw® **01 turn**

IV Determination of physicochemical properties such as logP, clogP, MR, Molecularweight **01 turn**

V Hydrogen bond donors and acceptors for class of drugs using drug design software Drug likeliness screening (Lipinskies RO5) **01 turn**

Recommended Books (Latest Editions)

1. Martindale‟s extra pharmacopoeia.
2. Organic Chemistry by I. L. Finar Vol II
3. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
4. Indian Pharmacopoeia.
5. Text book of practical organic chemistry-A.I.Vogel.
6. Medicinal Chemistry By Ashutosh Kar
7. Practical Pharmaceutical Chemistry: Part II Fourth Edition, A. H. Beckett, J. B.Stenlake.

BP 608 P. PHARMACOLOGY-III (Practical) **4Hrs/Week**

Sr. No	Experiment
1.	Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
2.	Study of effect of drugs on gastrointestinal motility
3.	Effect of agonist and antagonists on guinea pig ileum
4.	Estimation of serum biochemical parameters by using semi- autoanalyser
5.	Effect of saline purgative on frog intestine

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7. Test for pyrogens (rabbit method)
8. Determination of acute oral toxicity (LD50) of a drug from a given data
9. Determination of acute skin irritation / corrosion of a test substance
10. Determination of acute eye irritation / corrosion of a test substance
11. Calculation of pharmacokinetic parameters from a given data
12. Biostatistics methods in experimental pharmacology(student‟s t test, ANOVA)
13. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon

    Signed Rank test)
14. Bioassay of serotonin using rat fundus strip by three point bioassay.
15. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
16. Study of mydriatic and miotic effects on rabbit eye.

*Experiments are demonstrated by simulated experiments/videos

Recommended Books (Latest Editions)

1. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company,Kolkata.
2. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.
3. Goyal RK. Practicals in Pharmacology, BS Shaha Prakashan.
4. Kasture SB. A handbook of experiments in pre-clinical pharmacology, CareerPublications.
5. Bikas Medhi, Ajay Prakash. Practical Manual of Experimental and Clinical Pharmacology. Jaypee Publications.

BP 609 P. 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 andtablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias

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7. Determination of Aldehyde content

8. Determination of Phenol content

9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.

2. Textbook of Pharmacognosy by Tyler, Brady & Robber.

3. Pharmacognosy by Kokate, Purohit and Gokhale

4. Essential of Pharmacognosy by Dr.S.H.Ansari

5. Pharmacognosy & Phytochemistry by V.D.Rangari

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

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

8. B.A.Baviskar, S.L.Deore, Dr.S.S.Khadbadi : Experimental Phytopharmacognosy, Nirali Publication

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FINAL YEAR B. PHARM

SEMESTER – VII

BP701T INSTRUMENTAL METHODS OF ANALYSIS (Theory) 45 Hours

Scope:

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

Objectives:

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

1. Upon completion of the course the student shall be able to
2. Illustrate the interaction of matter with electromagnetic radiations and justify itsapplications in drug analysis
3. Classify the chromatographic separation methods and choose appropriate technique for analysis of drugs.
4. Design methods for performing quantitative & qualitative analysis of drugs usingvarious analytical instruments.

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

Introduction to 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 componentAnalysis

Fluorimetry

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

UNIT –II **10 Hours**

FTIR 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, FTIR instrument, sample handling attachments –DRS and ATR and applications

Flame Photometry

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Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy

Principle, interferences, instrumentation and Applications

Nepheloturbidimetry

Introduction

UNIT –III **10 Hours**

Introduction to chromatography -

Adsorption and partition column chromatography:

Methodology, advantages, disadvantages and applications.

Paper chromatography:

Introduction, methodology, development techniques, advantages, disadvantages andapplications

Thin layer chromatography:

Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

HPTLC:

Introduction, Instrumentation and applications

UNIT –IV **08 Hours**

Theory of Chromatography

Plate theory, Rate theory, System suitability parameters

Gas chromatography

Introduction, theory, instrumentation, 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 exchangeprocess, factors affecting ion exchange, methodology and applications

Gel chromatography-

Introduction, theory, instrumentation and applicationsAffinity chromatography-

Introduction

Recommended Books (Latest Editions):

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

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BP702T INDUSTRIAL PHARMACY -II (Theory) **45 Hours**

Scope:
This course is designed to impart fundamental knowledge on pharmaceuticalproductdevelopment and translation from laboratory to market.

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

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

Course Content:

UNIT-I **10 Hours**

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

UNIT-II **10 Hours**

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

UNIT-III **10 Hours**

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

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

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Product Development, Data Presentation for FDASubmissions, Management of Clinical
Studies.

UNIT-IV **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.

UNIT-V **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

Recommended Books: (Latest Editions)

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

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BP703T PHARMACY PRACTICE (Theory) 45 Hours

Scope:

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

Objectives:

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

1. Know various drug distribution methods in a hospital
2. Appreciate the pharmacy stores management and inventory control
3. Monitor drug therapy of patient through medication chart review and clinicalreview.
4. Obtain medication history interview and counsel the patients
5. Identify drug related problems
6. Detect and assess adverse drug reactions
7. Interpret selected laboratory results (as monitoring parameters in therapeutics)of specific disease states
8. Know pharmaceutical care services
9. Do patient counseling in community pharmacy;
10. Appreciate the concept of rational drug therapy.

Course Content:

UNIT-I **10 Hours**

Hospital and it's organization

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

Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout andstaff 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.

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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 proprietaryproducts, maintenance of records of retail and wholesale drug store.

10 Hours

UNIT-II

Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.**Hospital formulary**

Definition, contents of hospital formulary, Differentiation of hospital formulary and Druglist, 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, andmonitoring 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.

10 Hours

UNIT-III

Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in includingdrugs 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 counseling

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

Education and training program in the hospital

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

Prescribed medication order and communication skills

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

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UNIT-IV **08 Hours**

Budget preparation and implementation Budget preparation and implementationClinical 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 countermedications.

UNIT-V **07 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, hematology, and urinalysis

Recommended Books (Latest Edition):

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

Journals:

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

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BP704T NOVEL DRUG DELIVERY SYSTEM (Theory) 45 Hours

Scope:

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

Objectives:

Upon completion of the course student shall be able

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

Course Content:

UNIT-I **10 Hours**

Controlled drug delivery systems:

Introduction, terminology/definitions and rationale, advantages, disadvantages, selectionof drug candidates. Approaches to design controlled release formulations based ondiffusion, 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.

Gastroretentive drug delivery systems:

Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high densitysystems, inflatable and gastroadhesive

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systems and their applications

Nasopulmonary drug delivery system:

Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (drypowder 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, ocularformulations and ocuserts

Intrauterine Drug Delivery Systems:

Introduction, advantages and disadvantages, development of intra uterine devices (IUDs)and applications

Recommended Books: (Latest Editions)

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

Journals

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

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BP705P INSTRUMENTAL METHODS OF ANALYSIS (Practical) **04 Hours/ Week**

1. Weights and measures and pharmacopoeia in analysis
2. Determination of absorption maxima and effect of solvent on absorption maxima oforganic compounds
3. Assay of Drug product as per IP (Assay of Paracetamol tablet by UV-Spectrophotometry)
4. Assay of Drug product by Calibration curve method
5. Assay of any drug/drug product by colorimetry.
6. Simultaneous estimation of multicomponent formulation by UV spectroscopy (SE/Qanalysis)
7. Estimation of drug by fluorimetry
8. Study of quenching of fluorescence
9. Determination of sodium and potassium by flame photometry
10. Separation of amino acids by paper chromatography
11. Separation of sugars by thin layer chromatography
12. Separation of plant pigments by column chromatography
13. Demonstration of HPLC instrument
14. Demonstration of FTIR instrument
15. Interpretation of spectra of organic compounds by IR spectroscopy as perpharmacopoeia

Recommended Books (Latest Editions)

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

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BP706PS PRACTICE SCHOOL*

150 Hours

In the VII semester, every candidate shall undergo practice school for a period of 150hours evenly distributed throughout the semester. The student shall opt any one of thedomains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along withthe exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject
experts at college level and grade point shall be awarded.

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SEMESTER – VIII

BP802T SOCIAL AND PREVENTIVE PHARMACY (Theory) 45 Hours

Scope:

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

Objectives:

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

1. Acquire high consciousness/realization of current issues related to health andpharmaceutical problems within the country and worldwide.
2. Develop a critical way of thinking based on current healthcare development.
3. Evaluate alternative ways of solving problems related to health and pharmaceuticalissues.

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 diseasesand social problems of the sick.

Sociology and health

Socio cultural factors related to health and disease, Impact of urbanization on health anddisease, 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, Nationalprogramme for prevention and control of deafness, Universal immunization programme,

National programme for control of blindness, Pulse polio programme.

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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 ofWHO in Indian national program

UNIT-V **07 Hours**

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

Recommended Books (Latest edition):

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

Recommended Journals:

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

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BP803ET PHARMACEUTICAL MARKETING (Theory) 45 Hours

Scope:

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

Objective:

The course aims to provide an understanding of marketing concepts and techniques andtheir applications in the pharmaceutical industry.

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 consumerbuying behaviour; 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; patients' choice of physician and retail pharmacist. Analyzing the Market; Roleof market research.

UNIT-II **10 Hours**

Product decision:

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

UNIT-III **10 Hours**

Promotion:

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

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UNIT-IV **08 Hours**

Pharmaceutical marketing channels:

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

Professional sales representative (PSR):

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

UNIT-V **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)

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

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BP804ET PHARMACEUTICAL REGULATORY SCIENCE (Theory) 45 Hours

Scope:

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

Objectives:

Upon completion of the subject student shall be able to;

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

Course content:

UNIT-I **10 Hours**

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinicalactivities, 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 anapproved 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 MasterFiles (DMF), Common Technical Document (CTD), electronic Common Technical

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

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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):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry andRobert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Healthcare publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard AGuarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel andIsader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory ComplianceBy Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I.Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

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BP805ET PHARMACOVIGILANCE (Theory) 45 Hours

Scope:

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

Objectives:

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

1. Understand importance of drug safety monitoring.
2. Explain History, development, National and international scenario of pharmacovigilance & comprehend dictionaries, coding and terminologies usedin pharmacovigilance
3. Understand detection and assessment of new adverse drug reactions, Adverse drug reaction reporting systems and communication in pharmacovigilance, Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilanceplanning. CIOMS requirements for ADR reporting
4. Comprehend methods of safety data during pre-clinical, clinical and postapproval phases of drugs' life cycle.
5. Write case narratives of adverse events and their quality.

Course Content:

UNIT-I **10 Hours**

Introduction to Pharmacovigilance

History and development of Pharmacovigilance, Importance of safety monitoring of Medicine, WHO international drug monitoring programme, Pharmacovigilance Programof 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

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UNIT-II **10 Hours**

Drug and disease classification

Anatomical, therapeutic and chemical classification of drugs, International classificationof diseases, Daily defined doses, International Nonproprietary 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 programme.

UNIT-III **10 Hours**

Vaccine safety surveillance

Vaccine Pharmacovigilance, Vaccination failure, Adverse events following immunization

Pharmacovigilance methods

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

Communication in pharmacovigilance

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

UNIT-IV **08 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 **07 Hours**

Pharmacogenomics of adverse drug reaction

Genetics related ADR with example focusing PK parameters.

CIOMS

CIOMS Working Groups, CIOMS Form

CDSCO (India) and PharmacovigilanceD&C Act and Schedule Y

Differences in Indian and global pharmacovigilance requirements

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Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and BartlettPublishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle,Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones&Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel,Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G.Parthasarathi, Karin NyfortHansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PKManna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

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BP806ET **QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)** **45 Hours**

Scope:

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

Objectives:

Upon completion of the subject student shall be able to;

1. Know WHO guidelines for quality control of herbal drugs
2. Know Quality assurance in herbal drug industry
3. Know the regulatory approval process and their registration in Indian and internationalmarkets
4. Appreciate EU and ICH guidelines for quality control of herbal drugs

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 intraditional system of medicine

WHO guidelines on current Good Manufacturing Practices (cGMP) for HerbalMedicines, 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 techniquesin standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

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UNIT-V **07 Hours**

Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilancesystems.
Comparison of various Herbal Pharmacopoeias.
Role of chemical and biological markers in standardization of herbal products

Recommended Books (Latest edition):

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

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BP807ET COMPUTER AIDED DRUG DESIGN (Theory) 45 Hours

Scope:

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

Objectives:

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

1. Understand the design and discovery of lead molecules
2. Classify the role of drug design tools for drug discovery process
3. Understand and analyse concepts of QSAR and docking
4. Analyse and apply various strategies to develop new drug like molecules.
5. Use various molecular modeling software to design new drug molecule

Course Content

UNIT-I **14 Hours**

Introduction to Drug Discovery and Development -

Stages of drug discovery and development,

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

Introduction to Ligand based and Structure Based DD

Analog Based Drug Design - Bioisosterism, Bioisosteric replacement

Case studies -

Ligand based (Design of inhibitors of tubulin polymerization eg. Colchicine), Structure based (Design of HMG-CoA reductase inhibitors. eg. Statins) and Analog based DD (Design of H2 histamine antagonist eg. Cimetidine)

UNIT- II **10 Hours**

Introduction to Computational toolsMolecular Modeling -

Introduction to molecular mechanics and quantum mechanics.

Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Molecular docking -

Rigid docking, flexible docking, manual docking, Docking based screening.

UNIT- III **14 Hours**

Quantitative Structure Activity Relationship (QSAR) and Pharmacophoremodeling

Introduction -

SAR versus QSAR, History and development of QSAR, Types of physicochemical

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parameters

2D QSAR -

Experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch's analysis, Free Wilson analysis

3D-QSAR approaches -

COMFA and COMSIA.

Pharmacophore modeling

Drug likeness screening, Concept of Pharmacophore mapping and Pharmacophore basedscreening

UNIT- IV **07 Hours**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemo informatics**Databases -**

Chemical database, Natural compound database, Drug like compound database , Drugbank

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak PressBaltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, NewYork.
3. Delgado JN, Remers WA eds "Wilson &Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, NewYork.
4. Foye WO "Principles of Medicinal chemistry 'Lea &Febiger.
5. Korolkovas A, BurckhalterJH. "Essentials of Medicinal Chemistry" WileyInterscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" JohnWiley & Sons, NewYork.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design"WrightBoston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" AcademicPress New York.
10. D. J. Triggle, John Bodenhan Taylor, Peter Kennewell,ComprehensiveMedicinal Chemistry, Volume I-VIII : Germany: Elsevier Science

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BP808ET CELL AND MOLECULAR BIOLOGY (Theory) 45 Hours

Scope:

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

Objectives:

Upon completion of the subject student shall be able to:

1. Summarize cell and molecular biology history, cellular functioning andComposition & describe the chemical foundations of cell biology.
2. Describe cellular membrane structure and function properties and functions ofDNA, Cell Cycle.
3. Describe basic molecular genetics mechanisms.
4. Understand the cell signaling pathways with their regulations and role in diseaseprocess.

Course contents

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 on Protein Synthesis

UNIT-IV **08 Hours**

Science of Genetics, Transgenics and Genomic Analysis, Cell Cycle analysis, Mitosis and Meiosis, Cellular Activities and Checkpoints Clinical phase, Post approvalphase (PMS)

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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):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, BlackwellScientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers &Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.Rose: Industrial Microbiology.
5. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
6. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.Peppler: Microbial Technology.
7. Edward: Fundamentals of Microbiology.
8. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
9. Bergeys manual of systematic bacteriology, Williams and Wilkins- AWaverly Company
10. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and
11. Applications of Recombinant DNA: ASM Press Washington D.C.RA Goldshy et. al., : Kuby Immunology.

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BP809ET COSMETIC SCIENCE (Theory) **45 Hours**

Scope:

This course is designed to impart fundamental knowledge of cosmetic and cosmeceuticalproducts & their formulation studies.

Objectives:

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

1. Understand the concepts of cosmetics; anatomy of skin v/s hair, general excipientsused in cosmetics.
2. Explain the concept of cosmeceuticals, history, difference between cosmetics &cosmeceuticals& cosmeceuticals agents
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course contents

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 asquasi and OTC drugs

Cosmetic excipients:

Surfactants, rheology modifiers, humectants, emollients, preservatives. Classificationand 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 anddisadvantages. Application of these products in formulation of cosmeceuticals.

Antiperspants & 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-phylene diamine based hair dye.

Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash

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UNIT-III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmericHair care: Henna and amla. Oral care: Neem and clove **Analytical cosmetics:**

BIS specification and analytical methods for shampoo, skin cream and toothpaste**.**

UNIT-IV **08 Hours**

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

UNIT-IV **07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understandingof 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 andbody odor.

Antiperspirants and Deodorants- Actives and mechanism of action

References

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

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BP810ET EXPERIMENTAL PHARMACOLOGY (Theory) 45 Hours

Scope:

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

Objectives

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

1. Understand the applications of various commonly used laboratory animals.
2. Demonstrate the various screening methods used in preclinical research.
3. Comprehend and demonstrate the importance of biostatistics and research methodology.
4. Design and execute a research hypothesis independently.

Course contents

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

a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.
b. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative 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 anaethetics

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UNIT-IV **08 Hours**

Preclinical screening models:
for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants
Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics

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):

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

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BP811ET ADVANCED INSTRUMENTATION TECHNIQUES (Theory) 45 Hours

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

1. Express the principle of the advanced instruments used and justify its applications indrug analysis
2. Understand the principles of analytical techniques and its application in analysis ofdrugs
3. Explain the importance and methods for the calibration of various analyticalinstruments
4. Formulate and justify techniques for the analysis of drugs using various analyticalinstruments.

Course contents

UNIT-I **14 Hours**

Nuclear Magnetic Resonance spectroscopy

Principles of ^{1}H-NMR, chemical shift, factors affecting chemical shift, coupling constant,Spin - spin coupling, relaxation, instrumentation and applications

^{13}C-NMR- Introduction to ^{13}C-NMR spectroscopy

Mass Spectrometry

Principles, , Ionization techniques –Electron impact, chemical ionization, MALDI, FAB,Analyzers-Time of flight and Quadrupole, instrumentation, Fragmentation, applications **Simple structural elucidation problems**

UNIT-II **07 Hours**

Thermal Methods of Analysis

Principles, instrumentation and applications ofThermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

UNIT-III **10 Hours**

Electrophoresis

Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel,

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capillary electrophoresis, applications

X-Ray Diffraction Methods

Origin of X-rays, basic aspects of crystals, Xray Crystallography, rotating crystaltechnique, single crystal diffraction,powder diffraction, and applications.

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter,HPLC.

UNIT-IV **06 Hours**

Radioimmuno assay

Principle, different methods, Importance, various components, Limitation andApplications of Radioimmuno assay

Extraction techniques

General principle and procedure involved in the solid phase extraction and liquid-liquidextraction.

UNIT-V **08 Hours**

Hyphenated techniques

Introduction to hyphenated techniques and types of techniquesDetails of LC-MS, GC-MS, HPTLC-MS, MS/MS.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic spectroscopy by William Kemp
7. Quantitative Analysis of Drugs by D. C. Garrett
8. Spectrophotometric identification of Organic Compounds by Silverstein
9. Introduction to Spectroscopy by Donald Pavia
10. Spectroscopy of Organic compounds by P.S.Kalsi
11. Introduction to Spectroscopy by Donald Pavia
12. Spectroscopy of Organic compounds by P.S.Kalsi

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BP812ET **DIETARY SUPPLEMENTS AND NUTRACEUTICALS (Theory)** **45 Hours**

Scope:
This subject covers foundational topic that are important for understanding the need andrequirements of dietary supplements among different groups in the population.

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

1. Understand the need of supplements by the different group of people to maintainhealthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Recognize the components in dietary supplements and the application.
4. Acquaint with the regulatory and commercial aspects of dietary supplements including health claims.

Course content:

UNIT-I **07 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, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT-II **15 Hours**

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

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

Sulfides: Diallyl sulfides, Allyl trisulfide.

Polyphenolics: Reservetrol

Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones

Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum**Phyto estrogens :** Isoflavones, daidzein, Geebustin, lignans **Tocopherols**

Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats,

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Wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT-III **07 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 **10 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 nonenzymatic antioxidant defense, 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-IV **06 Hours**

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

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

Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

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

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MASTER OF PHARMACY

MODERN PHARMACEUTICS

(MPH 103T)

Scope

Course designed to impart advanced knowledge and skills required to learnvarious aspects and concepts at pharmaceutical industries

Objectives

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY		60 HRS
1.	a. Preformation Concepts – Drug Excipient interactions – different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental - physiological and formulation consideration, Manufacturing and evaluation.	10 Hrs
	b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	10 Hrs
2	Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
3	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10 Hrs

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4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10 Hrs
5	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors - f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T–test , ANOVA test.	10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1–3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1–2; By LeonLachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1–2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1–5; By H.S. Bean & A.H.Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics - by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total qualitycontrol, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers ofIndia.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson,Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I - III.

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REGULATORY AFFAIRS(MPH 104T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug developmentprocess
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies indifferent countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY 60 Hrs

1. a. Documentation in Pharmaceutical industry: Masterformula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch– Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in–vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in - vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 12 Hrs

   b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for genericdrugs ways and means of US registration for foreign drugs

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2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA– new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargeland IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185,Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard AGuarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley& Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga–basics

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PHARMACEUTICS PRACTICALS - I
(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS– hydro dynamically balancedDDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarityfactors.

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MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)
(MPH 201T)

Scope

This course is designed to impart knowledge on the area of advances in noveldrug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development ofNTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY 60 Hrs

1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3	Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
5	Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex–vivo & in–vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery – concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 200

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ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope

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

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY 60 Hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability–Solubility–Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. 12 Hrs

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2	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate–limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product.	12 Hrs
3	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model– IV bolus, IV infusion, extra–vascular. Multi compartment model:two compartment – model in brief, non–linear pharmacokinetics: cause of non–linearity, Michaelis - Menten equation, estimation of k_{max} and v_{max}. Drug interactions: introduction, the effect of protein– binding interactions,the effect of tissue–binding interactions,cytochrome p450–based drug interactions,drug interactions linked to transporters.	12 Hrs
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In–vitro, in–situ and In–vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5	Application of Pharmacokinetics: Modified–Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

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REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development– Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

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COMPUTER AIDED DRUG DEVELOPMENT(MPH 203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY 60 Hrs

1. a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling — 12 Hrs

   b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD – examples of application.

2 Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P–gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB–Choline Transporter. — 12 Hrs

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3	Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers inPharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computingin Pharmaceutical Research, Computers in Market analysis	12 Hrs
4	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	12 Hrs
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development,Sean Ekins, 2006, John Wiley & Sons.
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COSMETICS AND COSMECEUTICALS
(MPH 204T)

Scope

This course is designed to impart knowledge and skills necessary forthefundamental need for cosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals withdesired Safety, stability, and efficacy.

THEORY	60 Hrs
1. Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics - Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12 Hrs
2 Cosmetics - Biological aspects : Structure of skin relating toproblems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Commonproblems associated with oral cavity. Cleansing and care needsfor face, eye lids, lips, hands, feet, nail, scalp, neck, body andunder–arm.	12 Hrs
3 Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants - Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.	12 Hrs

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	Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	
4	Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun–protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	12 Hrs
5	Herbal Cosmetics : Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics byprivate bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	12 Hrs

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2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics – Formulation, Manufacture and quality control, PP.Sharma,4thedition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

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PHARMACEUTICS PRACTICALS - II
(MPH 205P)

1. To study the effect of temperature change , non solvent addition,incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Soliddispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly proteinbound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality–by–Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

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PHARMACEUTICALCHEMISTRY(MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES(MPC 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY		60 Hrs
1.	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV–Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV–Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin–Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT–NMR and 13CNMR. Applications of NMR spectroscopy.	10 Hrs

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3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography	10 Hrs
5	a.Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b)X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X–ray diffraction.	10 Hrs
6	a. Potentiometry: Principle, working, Ion selective Electrodesand Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power–compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation	10 Hrs

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and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage anddisadvantages, pharmaceutical applications.

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1. Spectrometric Identification of Organic compounds – Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
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4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
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ADVANCED ORGANIC CHEMISTRY - I(MPC 102T)

Scope

The subject is designed to provide in–depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of reterosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for smalltarget molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY 60 Hrs

1. Basic Aspects of Organic Chemistry: 12 Hrs
   1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
   2. Types of reaction mechanisms and methods of determining them,
   3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

   Addition reactions

   a) Nucleophilic uni– and bimolecular reactions (SN1 and SN2)
   b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
   c) Rearrangement reaction

2 Study of mechanism and synthetic applications following of 12 Hrs

named Reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner–Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer–Haack Reaction, Sharpless asymmetric epoxidation, Baeyer–Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

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3	**Synthetic Reagents & Applications:** Aluminiumisopropoxide, N–bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol–1–yloxy) tris (dimethylamino) phosphonium hexafluoro–phosphate (BOP). **Protecting groups** a. Role of protection in organic synthesis b. Protection for the hydroxyl group, including 1,2–and1,3–diols:ethers, esters, carbonates, cyclic acetals & ketals c. Protection for the Carbonyl Group: Acetals and Ketals d. Protection for the Carboxyl Group: amides and hydrazides,esters e. Protection for the Amino Group and Amino acids: carbamatesand amides	12 Hrs
4	**Heterocyclic Chemistry:** Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus–Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis. Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine,Theophylline , Mercaptopurine and Thioguanine.	12 Hrs
5	**Synthon approach and retrosynthesis applications** i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA) ii. C-X disconnections; C-C disconnections - alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds iii. Strategies for synthesis of three, four, five and six-membered ring.	12 Hrs

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5. A guide to mechanisms in Organic Chemistry, Peter Skyes (OrientLongman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford& IBH Publishers.
7. Combinational Chemistry - Synthesis and applications - Stephen RWilson & Anthony W Czarnik, Wiley - Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis – The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, NelsonThorns.
11. Organic Synthesis – Special Techniques. VK Ahluwalia and R Agarwal,Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar,Narosa Publishers.

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ADVANCED MEDICINAL CHEMISTRY(MPC 103T)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules forbiological targets
- Peptidomimetics

THEORY 60 Hrs

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. 12 Hrs

   Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2 Prodrug Design and Analog design: 12 Hrs

   a) Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

   b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

   c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs,

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alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3 a) Medicinal chemistry aspects of the following class of drugs — 12 Hrs

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

a) Anti–hypertensive drugs, Psychoactive drugs, Anticonvulsantdrugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre–requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4 Rational Design of Enzyme Inhibitors — 12 Hrs

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non–covalently and covalently binding enzyme inhibitors.

5 Peptidomimetics — 12 Hrs

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

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2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry - Corwin and Hansch.
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7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers,Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
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12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarnaand Andrea Trabocchi, First edition, Wiley publishers.

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CHEMISTRY OF NATURAL PRODUCTS
(MPC 104T)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

At completion of this course it is expected that students will be able to understand–

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drugdiscovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of naturalorigin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY 60 Hrs

1. Study of Natural products as leads for new pharmaceuticalsfor the following class of drugs — 12 Hrs
   a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
   b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
   c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
   d) Neuromuscular Blocking Drugs: Curare alkaloids
   e) Anti–malarial drugs and Analogues
   f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β – Lactam antibiotics (Cephalosporins and Carbapenem) — 12 Hrs
2. a) Alkaloids

   General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

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b) Flavonoids

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit - D).

3	a) Terpenoids Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene). b) Vitamins Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.	12 Hrs
4	a). Recombinant DNA technology and drug discovery rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy - Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction - Phyllanthus niruri; Antitumor - Curcuma longa Linn.	12 Hrs
5	Structural Characterization of natural compounds Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit–D, Quercetin and Digitalis glycosides.	12 Hrs

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PHARMACEUTICAL CHEMISTRY PRACTICAL - I(MPC 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen–schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co–chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

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ADVANCED SPECTRAL ANALYSIS
(MPC 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniquesfor identification, characterization and quantification of drugs. Instruments dealt are LC–MS, GC–MS, ATR–IR, DSC etc.

Objectives

At completion of this course it is expected that students will be able to understand–

- Interpretation of the NMR, Mass and IR spectra of various organiccompounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY 60Hrs

1. UV and IR spectroscopy: 12 Hrs

Wood ward - Fieser rule for 1,3– butadienes, cyclic dienes and a, β–carbonyl compounds and interpretation compounds of enones. ATR–IR, IR Interpretation of organic compounds.

2 NMR spectroscopy: 12 Hrs

1–D and 2–D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

3 Mass Spectroscopy 12 Hrs

Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

4 Chromatography: 12 Hrs

Principle, Instrumentation and Applications of the following :

a) GC–MS b) GC–AAS c) LC–MS d) LC–FTIR e) LC–NMR f) CE–MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I–EC (Ion– Exclusion Chromatography) k) Flash chromatography

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5 a). Thermal methods of analysis — 12 Hrs

Introduction, principle, instrumentation and application of DSC,DTA and TGA.

b). Raman Spectroscopy

Introduction, Principle, Instrumentation and Applications.

c). Radio immuno assay

Biological standardization , bioassay, ELISA, Radioimmunoassay of digitalis and insulin.

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2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC – P DSethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
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ADVANCED ORGANIC CHEMISTRY - II(MPC 202T)

Scope

The subject is designed to provide in–depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY 60 Hrs

1. Green Chemistry: 12 Hrs
   a. Introduction, principles of green chemistry
   b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
   c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid–liquid and liquid–solid reactions, synthetic applications
   d. Continuous flow reactors: Working principle, advantages and synthetic applications.
2. Chemistry of peptides 12 Hrs
   a. Coupling reactions in peptide synthesis
   b. Principles of solid phase peptide synthesis, t–BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site–specific chemical modifications of peptides
   c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
   d. Side reactions in peptide synthesis: Deletion peptides, side

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reactions initiated by proton abstraction, protonation, over–activation and side reactions of individual amino acids.

3	**Photochemical Reactions** Basic principles of photochemical reactions. Photo–oxidation, photo–addition and photo–fragmentation. **Pericyclic reactions** Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples	12 Hrs
4	**Catalysis:** a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages b. Heterogeneous catalysis - preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs d. Transition–metal and Organo–catalysis in organic synthesis: Metal–catalyzed reactions e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. f. Phase transfer catalysis - theory and applications	12 Hrs
5	**Stereochemistry & Asymmetric Synthesis** a. Basic concepts in stereochemistry - optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis–trans isomerism, E and Z notation. b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.	12 Hrs

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4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis–the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis– Special techniques VK Ahluwalia and R Aggarwal,Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar,Narosa Publishers.

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COMPUTER AIDED DRUG DESIGN
(MPC 203T)

Scope

The subject is designed to impart knowledge on the current state of the arttechniques involved in computer assisted drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Theory 60 Hrs

1. Introduction to Computer Aided Drug Design (CADD) — 12 Hrs

History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics

History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi–substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2 Quantitative Structure Activity Relationships: Applications — 12 Hrs

Hansch analysis, Free Wilson analysis and relationship betweenthem, Advantages and disadvantages; Deriving 2D–QSAR equations.

3D–QSAR approaches and contour map analysis.

Statistical methods used in QSAR analysis and importance ofstatistical parameters.

3 Molecular Modeling and Docking — 12 Hrs

a) Molecular and Quantum Mechanics in drug design

b) Energy Minimization Methods: comparison between global

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minimum conformation and bioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra–precision docking. Agents acting on enzymes such as DHFR, HMG–CoA reductase and HIV protease, choline esterase (AchE & BchE)

4 Molecular Properties and Drug Design — 12 Hrs

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

c) Homology modeling and generation of 3D–structure of protein.

5 Pharmacophore Mapping and Virtual Screening — 12 Hrs

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques
Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

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1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press,Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, ElsevierPublishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor &Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.

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7. An Introduction to Medicinal Chemistry -Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and PharmaceuticalChemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry - Corwin and Hansch, PergamonPublishers.
10. Computational and structural approaches to drug design edited by RobertM Stroud and Janet. F Moore

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PHARMACEUTICAL PROCESS CHEMISTRY(MPC 204T)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost–effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization ofa synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

At completion of this course it is expected that students will be able to understand

- The strategies of scale up process of apis and intermediates
- The various unit operations and various reactions in process chemistry

THEORY 60 Hrs

1. Process chemistry 12 Hrs

Introduction, Synthetic strategy

Stages of scale up process: Bench, pilot and large scale process.In–process control and validation of large scale process.

Case studies of some scale up process of APIs.

Impurities in API, types and their sources including genotoxicimpurities

2 Unit operations 12 Hrs

a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b) Filtration: Theory of filtration, pressure and vacuumfiltration, centrifugal filtration,
c) Distillation: azeotropic and steam distillation
d) Evaporation: Types of evaporators, factors affecting evaporation.
e) Crystallization: Crystallization from aqueous, non– aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

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3	**Unit Processes - I** a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration, b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process. c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas, ozonolysis.	12 Hrs
4	**Unit Processes - II** a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) Fermentation: Aerobic and anaerobic fermentation. Production of i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 iii. Statins: Lovastatin, Simvastatin c) Reaction progress kinetic analysis i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost–effective routes, reagent selection, families of reagents useful for scale–up.	12 Hrs
5	**Industrial Safety** a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) b) Fire hazards, types of fire & fire extinguishers c) Occupational Health & Safety Assessment Series 1800 (OHSAS–1800) and ISO–14001(Environmental Management System), Effluents and its management	12 Hrs

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2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1–8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: HG Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale–Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East–West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II,Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

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PHARMACEUTICAL CHEMISTRY PRACTICALS – II(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward - Fieser rule
5. Interpretation of organic compounds by FT–IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT–IR, NMR, CNMR and Massspectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4–chlorobenzhydrylpiperazine. (an intermediate for cetirizineHCl).
12. Preparation of 4–iodotolene from p–toluidine.
13. $NaBH_4$ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance(Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis usingsoftwares Pharmacophore modeling
19. 2D–QSAR based experiments
20. 3D–QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

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PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES(MPL 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY		60 Hrs
1.	UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV–Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV–Visible spectroscopy, Difference/ Derivative spectroscopy. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin–Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT–NMR and 13CNMR. Applications of NMR spectroscopy.	10 Hrs

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3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: j) Thin Layer chromatography k) High Performance Thin Layer Chromatography l) Ion exchange chromatography m) Column chromatography n) Gas chromatography o) High Performance Liquid chromatography p) Ultra High Performance Liquid chromatography q) Affinity chromatography r) Gel Chromatography	10 Hrs
5	Electrophoresis: Principle, Instrumentation, Working conditions,factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X–ray diffraction.	10 Hrs
6	Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle,thermal transitions and Instrumentation (Heat flux and power–compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (samplepreparation, experimental conditions, calibration, heating andcooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	10 Hrs

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2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis – Modern Methods - Part B – J W Munson, Vol11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.

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ADVANCED PHARMACOLOGY - I
(MPL 102T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

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

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses ofdrugs used in treatment of diseases

THEORY 60 Hrs

1. General Pharmacology 12 Hrs

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non–linear compartment models. Significance of Protein binding.

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drugreceptors interaction and elicited effects.

2 Neurotransmission 12 Hrs

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters– Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters– histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Co–transmission

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Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

3	Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non–narcotic analgesics.	12 Hrs
4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti– arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti–platelet drugs	12 Hrs
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin,Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12 Hrs

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1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer–Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach
9. Green Pathophysiology for Pharmacists.

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11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastavapublished by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications - Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

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PHARMACOLOGICAL AND TOXICOLOGICAL SCREENINGMETHODS - I
(MPL 103T)

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Objectives

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY 60 Hrs

1. Laboratory Animals 12 Hrs

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applicationsAnaesthesia and euthanasia of experimental animals.
Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.

Bioassay–Principle, scope and limitations and methods

2 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

General principles of preclinical screening. CNS Pharmacology:behavioral and muscle co ordination, CNS stimulants and

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depressants, anxiolytics, anti–psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti–asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti – emetic, anti– diarrheal and laxatives.	12 Hrs
4	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti–diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.	12 Hrs
5	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Iimmunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical tohumans	12 Hrs

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2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition,Kluwer Academic Publishers, London, UK.
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15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

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CELLULAR AND MOLECULAR PHARMACOLOGY(MPL 104T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives:

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

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

THEORY 60 Hrs

1. Cell biology 12 Hrs

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death- events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

2 Cell signaling 12 Hrs

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G–protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5–trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclicAMP signaling pathway, mitogen–activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

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3	Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology–Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy– Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12 Hrs
4	Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacologyPolymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	12 Hrs
5	a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	12 Hrs

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J.Licinio and M –L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickensonet.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I(MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimentalanimals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti–inflammatory, local anesthetic, mydriatic andmiotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, a amylase, a glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by differentroutes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugsin biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugsin biological fluids using different analytical techniques (HPLC)

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REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds – Robert M Silverstein,
6. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler,Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

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ADVANCED PHARMACOLOGY - II
(MPL 201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

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

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses ofdrugs used in treatment of diseases

THEORY 60 Hrs

1. **Endocrine Pharmacology** — 12 Hrs

Molecular and cellular mechanism of action of hormones such asgrowth hormone,

prolactin, thyroid, insulin and sex hormones

Anti–thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

2 **Chemotherapy** — 12 Hrs

Cellular and molecular mechanism of actions and resistance ofantimicrobial agents

such as ß–lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti–TB drugs.

3 **Chemotherapy** — 12 Hrs

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer Immunopharmacology

Cellular and biochemical mediators of inflammation and immuneresponse. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

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4	**GIT Pharmacology** Antiulcer drugs, Prokinetics, antiemetics, anti–diarrheals and drugs for constipation and irritable bowel syndrome. **Chronopharmacology** Biological and circadian rhythms, applications of chronotherapy invarious diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12 Hrs
5	**Free radicals Pharmacology** Generation of free radicals, role of free radicals in etiopathology ofvarious diseases such as diabetes, neurodegenerative diseases and cancer.Protective activity of certain important antioxidant **Recent Advances in Treatment:** Alzheimer's disease, Parkinson's disease, Cancer, Diabetesmellitus	12 Hrs

REFERENCES

1. The Pharmacological basis of therapeutics– Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy byDavid E Golan et al.
3. Basic and Clinical Pharmacology by B.G –Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T.Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel andAndrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and DrugMetabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastavapublished by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer–Lippincott Williams & Wilkins Publishers

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II
(MPL 202T)

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements fortoxicity studies.
- Demonstrate the practical skills required to conduct the preclinicaltoxicity studies.

	THEORY	60 Hrs
1.	Basic definition and types of toxicology (general, mechanistic,regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH,EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12 Hrs
2	Acute, sub–acute and chronic– oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization– importance and methods in regulatory toxicology studies	12 Hrs
3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12 Hrs
4	IND enabling studies (IND studies)– Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.	12 Hrs

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	Safety pharmacology studies– origin, concepts and importance ofsafety pharmacology. Tier1– CVS, CNS and respiratory safety pharmacology, HERGassay. Tier2– GI, renal and other studies	
5	Toxicokinetics– Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12 Hrs

REFERENCES

1. Hand book on GLP, Quality practices for regulated non–clinical research and development (http://www.who.int/tdr/publications/documents/glp– handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

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PRINCIPLES OF DRUG DISCOVERY
(MPL 203T)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics andbioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design indrug discovery

THEORY 60 Hrs

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation–Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation. — 12 Hrs

2 Lead Identification– combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X–ray crystallography in protein structure prediction — 12 Hrs

3 Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches — 12 Hrs

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	Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,	
4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	12 Hrs
5	QSAR Statistical methods - regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D–QSAR approaches like COMFA and COMSIA Prodrug design–Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12 Hrs

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley–VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley–VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

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CLINICAL RESEARCH AND PHARMACOVIGILANCE(MPL 204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre–clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close–out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY 60 Hrs

1. Regulatory Perspectives of Clinical Trials: 12 Hrs

Origin and Principles of International ConferenceonHarmonization – Good Clinical Practice (ICH–GCP) guidelines Ethical Committee: Institutional Review Board, EthicalGuidelines for Biomedical Research and Human Participant–Schedule Y, ICMR
Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

2 Clinical Trials: Types and Design 12 Hrs

Experimental Study– RCT and Non RCT,

Observation Study: Cohort, Case Control, Cross sectional

Clinical Trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

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3	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring– Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	12 Hrs
4	Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	12 Hrs
5	Methods, ADR reporting and tools used inPharmacovigilance International classification of diseases, International Non– proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	12 Hrs
6	Pharmacoepidemiology, pharmacoeconomics, safetypharmacology	12 Hrs

REFERENCES

1. Central Drugs Standard Control Organization– Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

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3. Ethical Guidelines for Biomedical Research on Human Subjects 2000.Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and SylvanGreen, March 2005,John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs.Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.

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PHARMACOLOGICAL PRACTICAL - II(MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonistusing suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay byusing suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassayby using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassayby using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple pointbioassay by using suitable tissue preparation.
7. Estimation of PA_2 values of various antagonists using suitable isolatedtissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies– Serum biochemical, haematological, urineanalysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone–marrow chromosomal aberrationtest.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology–by M.N.Ghosh
2. Hand book of Experimental Pharmacology–S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta–ur–Rahman, Iqbalchoudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel andAndrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and DrugMetabolism for Industrial Scientists.

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Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blindingtechniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non–parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non–maleficence, double effect, conflicts between autonomy and beneficence/non–maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and

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Co-curricular and Extracurricular activities

Institution integrates crosscutting issues relevant to Professional Ethics

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Institution integrates crosscutting issues relevant to Professional Ethics

SR. NO	ACTIVITY RELETED TO PROFESSIONAL ETHICS
1	WORLD AIDS DAY
2	WORLD DIABETES DAY
3	WORLD HEPATITIS DAY
4	HEALTH CHECKUP CAMP
5	NSS CAMP ACTIVITY
6	BLOOD DONATION CAMP
7	WORLD PHARMACIST DAY
8	COAD OF CONDUCT
9	TREE PLANTATION PROGRAM
10	SWATCH BHARAT ABHIYAN
11	WORLD CANCER DAY

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WORLD AIDS DAY

World AIDS Day, was celebrated on 1 December every year, is an international day. December 1 marks the 34th anniversary of World AIDS Day. The objective of the event was to create awareness about AIDS. “Know Your Status “is the theme for this year.

In a dignified way World AIDS Day has been celebrated at LSDP College of Pharmacy organized by the NSS unit of the College. The programmed started at 03:50 pm. with the inaugural speech of Dr. Dhambor B.R ,who stated the importance of this celebration and observation of this day. Chief Guest Dr. H.V.Kamble , Principal LSDP College of Pharmacy addressed the students and gave a very relevant speech on AIDS, HIV and causes of them, symptoms and ways to cure them. His speech included various ways how a youth can protect the society through awareness and prevention. The positive sign was the students’ including the NSS Volunteers concentration and eagerness towards the problems caused by AIDS. To stay safe from this deadly disease. All faculties were present on this event and participate in Rally.

CELEBRATION OF WORLD AIDS DAY

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WORLD DIABETES DAY

World Diabetes Day was celebrated on 14th November 2022. The theme for World Diabetes Day 2022- 2023 is "The Family and Diabetes". The objective of the event was to raise awareness of the impact that diabetes has on the family and support network of those affected. Also promote the role of the family in the management, care, prevention and education of diabetes. Ms. Holkar D.H and Ms. Kshirsagar S.B was Organize the health checkup for the B. Pharm students. Doctor given the information about diabetes and its prevention. He said that the regular healthy diet help to prevent diabetis. Dr. H.V.Kamble, Principal, interacted with the students highlighted the importance of celebrating days like Diabetes Day to create awareness about healthcare issues in the society.

CELEBRATION OF WORLD DIABETES DAY

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WORLD HEPATITIS DAY

World Hepatitis Day was celebrated on 28thof July 2022. The objective of the event was to create awareness about prevention and treatment of hepatitis. It is the world level awareness program launched as a global public health campaign by the World Health Organization to make the world a hepatitis free world. Ms. A.A. Najan was showed videos for the causes and treatment of Hepatitis disease. What type of precaution should be taken for this disease was included in video Dr. H.V.Kamble, Principal, interacted with the students highlighted the importance of celebrating days like Hepatatis Day to create awareness about healthcare issues in the society. The students visited, Vasantarao pharate patil arts and commers college, and interacted with the BA, Bcom students and presented detailed information about prevention and treatment of hepatitis. The students also visited Mandavgan pharata village and created awareness about causes, prevention and treatment of hepatitis amongst villagers.

CELEBRATION OF WORLD HEPATITIS DAY

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WORLD PHARMACIST DAY

World Pharmacist Day was celebrated on 25th September 2022. "Pharmacists: Your Medicine Experts" is the theme for this year. The objective of the event was to create awareness about safe medicine. International Pharmaceutical Federation (FIP) encourages pharmacists to use this day to organize activities that promote and advocate for the role of the pharmacist in improving health in every corner of the world. The theme of World Pharmacists Day emphasizes that pharmacists are a trusted source of knowledge and advice, not only for patients but for other healthcare professionals. For every patient who walks into a pharmacy, pharmacists ensure that the right medicine is provided at the right dose and in the most suitable formulation. Students were visited Pharmacist in Mandavgan pharata area for Pharmacy Survey about "Awareness Campaign on Safe Use of Medicines". They Request to Pharmacist not to sale Medicines without prescription. They also gave the information about banned drugs and its formulations. Pharmacist Rally for all B. Pharm students from college to Wagheshwar temple, Mandavgan pharata, Pune at 9.30 am to 10.30 am was arranged on that day. Students create awareness about the pharmacist day; they gave the information that not to take medicines and antibiotics without prescription. This event was inaugurated by our campus director Shri. Sangram Rajedhavade and Principal Dr. H.V.Kamble. This event was organized by Prof. A. A. Mukharji and Prof. A. K. Andhale.

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CELEBRATION OF WORLD PHARMACIST DAY

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WORLD CANCER DAY

World Cancer Day was celebrated on 4th of February 2023 in Loknete Shri Dadapatil Pharate College of Pharmacy A/p-Mandavgan Pharata, Tal-Shirur, Dist-Pune. World Cancer Day is the one singular initiative under which the entire world can unite together in the fight against the global cancer epidemic. The theme for 2023 is "I am and I will". The objective of the event was Support cancer patients and survivors with the physical and emotional impacts of cancer even after treatment ends. Other objective is to prevent the cancer and give awareness to society about cancer. Prof. V. B. Khatal was showed videos for the causes and treatment of cancer disease. Principal Dr. H.V.Kamble, interacted with the students highlighted the importance of celebrating days like cancer Day to create awareness about healthcare issues in the society. He discussed the following points about how to prevent the cancer from society

- Call on government leaders to commit adequate resources to reduce cancer deaths and provide a better quality of life for patients and survivors.
- Educate themselves and others about the link between certain lifestyle behaviors – including smoking, poor diet, and lack of physical activity – and cancer risk.
- Dispel rumors and myths that lead to stigma and discrimination against people with cancer in some communities.
- Encourage schools and workplaces to implement nutrition, physical activity, and no smoking policies that help people adopt healthy habits for life.

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CELEBRATION OF WORLD CANCER DAY

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TREE PLANTATION PROGRAMM

Tree Plantation Program was conducted on Saturday, 11/08/2022, by the students of LSDP College of Pharmacy , Mandavgan pharata, Pune. This program was organized on behalf of the National Service Scheme Department of the College in the village of Inamgaon . The program was completed in the presence of Dr. Dhambor B.R and Principal Dr. H.V.Kamble. A total of 180 seedlings were planted under this program. These trees consisted mainly of various types of trees such as wad, pimple, cinnamon, limb, gourd, beard, etc. College teacher Prof. Mr. Lokhande A.B, Mr. A. T. Shinde, Prof. Rasave V.R, Prof. Vikram Jadhav, Prof. A.S. Gaikwad, Prof. M. K. Ghug and students were present. A total of 200 students participated in this program. At this time students also pledged to plant trees along with plantation and also planted trees. All students pledged to take care of these trees and assured to water the plants regularly. Artificial ponds were also prepared for storage of natural water. Dr. Dhambor B.R expressed the need for continuous engagement of students and employees to improve the forest structure and maintain environment. The forest department officer expressed that the growing number of vehicles in the city and rising urbanization required tree plantation and maintaining the environment. This program was given to the community by a message of tree plantation and its maintenance. The Student Council has actively participated in organizing this plantation program.

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CELEBRATION OF TREE PLANTATION PROGRAMM

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NSS CAMP ACTIVITY

Venue: At post Pimpalsuti , Taluka Shirur, Dist. Pune. Date: 28/12/2022 to 03/01/ 2023

❖ The activities carried during this camp are as follows:

- Health Check-up camp- All the villagers were counseled with regard to keeping the blood sugar levels in control and effective and safe used of medicines. All the patients suffering from blood pressure/diabetes were counseled to continue taking medicines on regular basis and not to stop medication on their own. Blood sugar levels and Blood Pressure of the villagers was checked and informed to them. The patients were advised to consult pharmacist/doctor for counseling as and when required. Total 180 villagers participated in the camp.
- Election Awareness -Election awareness along with green nest a election awareness campaign is organized . This event consists dance, drama and a human rally promoting the importance of voting.
- Helmet awareness - Helmet awareness by NSS Valunteers explains about “Head injury management and prevention-Importance of helmet”.
- Free medicines were distributed to villagers in presence of doctors.
- Swatch Bharat Abhiyan: Swachchh Bharat Abhiyan was carried out every day soon after the Prabhat-Pheri. Different areas of the village were taken day by day and were cleaned by the volunteers. This created a buzz in the village and suddenly NSS Team started getting more attention than ever before from people across the village.
- Digital India Campaign was carried out throughout the village. The importance of digital transactions and its role in curbing corruption was conveyed to the villagers.
- Socio-economic survey socio-economic survey was carried out by the volunteers throughout the village. Google forms were used to facilitate the activity.

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- Street play on importance of education & women empowerment A Street play was practiced and performed by the student volunteers of the NSS Team on the third day of the camp. The theme of the play was: “Importance of Education” and “Women Empowerment”. The volunteers were enthusiastic to perform in the play. It was a life cherishing moment for all of them. Girl volunteers also helped the boys volunteers prepare the skit as well as in their dress up and make up.
- Awareness Programme on Life Insurance, Government Schemes, Scholarships for girls, Banking and visuals on Water Conservatioand Tree Plantation an awareness programmes had been conducted on the govt schemes specially for women, govt scholarships and exams All the villagers were made aware about these activities through the videos on laptop and speaker. Apart from that, Models to explain banking were made by the volunteers to explain them each and every facility of the banks.
- The NSS Camp concluded in presence of Village Gram Panchayat functionaries, Principal & faculty of college, Principal, Non-teaching staff and students of the school, and NSS student volunteers of college on 02 January 2023.

- The gram panchayat members appreciated the activities conducted during NSS Camp and issued Appreciation Letter to the college for the efforts taken by students.

NSS CAMP ACTIVITY

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SWATCH BHARAT ABHIYAN

Venue: A/P-Inamgaon, Tal- Shirur, Dist-Pune Date: 31/12/2022 to 02/01/2023 Time of the Event:08.00 A.M. TO 10.00 AM a) Introduction:Swachh Bharat Abhiyan (SBA) or Swachh Bharat Mission (SBM) is a nation-wide campaign in India for the period 2014 to 2019 that aims to clean up the streets, roads and infrastructure of India's cities, towns, and rural areas.

The objectives of Swachh Bharat include:

a) Eliminating open defecation through the construction of household-owned and community-owned toilets and establishing an accountable mechanism of monitoring toilet use.

b) Theme:"Clean India Mission"

c) Significance:The mission will also contribute to India reaching Sustainable Development Goal 6 (SDG 6), established by the UN in 2015.

d) Conduction:The NSS Unit of institute has organized the Swatch bharat mission atA/P-Inamgaon, Tal-Shirur, Dist-Pune in association with local Gram Panchayat.

They also interacted with the students and helped to create awareness on cleanliness, new alternatives for electricity use, water harvesting and management of waste. This day whole and solely was dedicated for the cleaning purpose. The team work was noticeable students drove a cleanliness programme around the school area, village roads removed dust heaps. roads were cleaned with the help of brooms. The drainage flows were cleared for this they made the large wells, the larger garbage damp were burned out.

e) Guest Details: Campus Director Shri. Sangram Rajedhavade and Principal Dr.H.V.Satpute were present for the camp.

f) Students & Faculty response & participation: In totality 22 NSS students & 02 Faculty were participated.

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SWATCH BHARAT ABHIYAN

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REPORT OF BLOOD DONATION CAMP

Venue: LSDP College campus . Date: 20th OCT 2022, Tuesday Time of the Event:10.00 A.M. TO 5.00 PM

a. Introduction: So on the occasion of Occasion of Birthday of our Hon. Shri. Rajiv pharate patil Wagheshwar Campus organized blood donation camp in LSDP With Pharate patil Multisuper Speciality Auyrvedic Hospital. Donated blood is used for a wide range of circumstances that can potentially affect anyone, which is also a main reason people donate. Patients undergoing treatment for injuries suffered during an accident often rely on donated blood to save their lives.

b. Theme: Occasion of Birthday of our Hon. Shri. Rajiv Pharate Patil . (Founder President of Wagheshwar gramvikas pratisthan group.

c. Significance: It serves to raise awareness of the need for blood.

d. Conduction: Campus Director Shri. Sangram Rajedhavde inaugurated the program. At this time the Mrs. Mrunal Pharate (Founder Secretory of Wagheshwar gramvikas pratisthan group) and

e. Dr. Shelke nitin were also present. A total of 98 students donated blood from this camp. After donating blood, tea and snacks were also provided to the students.

f. Guest Details: Campus Director Shri. Sangram Rajedhavde were present for the camp.

g. Students & Faculty response & participation: In totality, 98 students donated blood.

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BLOOD DONATION CAMP

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REPORT OF HEALTH CHECKUP CAMP

Venue: A/P-Pimpalsuti, Tal- Shirur, Dist-Pune Date: 29/12/2022 Time of the Event:09.00 A.M. TO 5.00 PM

a) Introduction: These camps also ensure provision of timely referral services to the patients for further or specialized care. The aim of the NSS special camp is to educate the people and empower them. Free medical camps are set up with a sacred aim to bring awareness amongst the deprived population of the country who have no access to basic healthcare services or knowledge about the diseases they are suffering from. So on the occasion of National Service Scheme.

b) Theme: Health is a state of complete physical, mental and social well-being.

c) Significance: Comprehensive Care' for the Health & Well-being of all.

d) Conduction: The NSS Unit of institute has organized the health check-up camp at A/P- Pimpalsuti,Tal- Shirur ,Dist-Pune and High School in association with local Govt. Hospital & Gram Panchayat. The peoples of the village were subjected to routine health check-up and medicines were distributed among the people in the health check-up camp. A total of 275-300 patients got the benefits of the free camp. The free health checkup include blood pressure, hemoglobin, blood group thyroid level, calcium level sugar level in the body and weight which was totally free and the villager has taken the maximum benefit of the health camp. The patients above 40 years were screened for Diabetes, Hypertension and cardiovascular diseases using ECG. They were given treatment on spot with the help of specialists from General Medicine.

e) Guest Details: Campus Director Shri. Sangram Rajebhavde and Principal Dr.H.V.Kamble were present for the camp.

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f) Students & Faculty response & participation: In totality, 25 NSS students & 02 Faculty were participated.

g) Outcome: Getting the right type of health check-up is important and while considering it, certain factors like age, lifestyle, family history, and risks should be taken into account. Regular health examinations and tests help detect problems before they start. Opting for a right health check-up, screenings, and treatments means one is taking steps to help one live longer and healthier life.

HEALTH CHECKUP CAMP

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THE CODE OF CONDUCT FOR TEACHERS

The role of the Teaching Council is to regulate the teaching profession and the professional conduct of teachers, to establish and promote professional standards, to support the continuing professional development of teachers and to promote teaching as a profession.

1. Introduction: The teaching profession has a distinguished record of service in Ireland. This *Code of Professional Conduct for Teachers* restates and makes clear the values and standards that have long been experienced by pupils/students through their participation in education.
2. Purpose of the Code:

It serves as a guiding compass as teachers seek to steer an ethical and respectful course through their career in teaching and to uphold the honor and dignity of the teaching profession. It is universally felt that the status of teaching profession requires to be raised to ensure its dignity and integrity. Accordingly, it is considered necessary that there should be a code of ethics which may be evolved by the teaching community itself for its guidance. There are five major areas of professional activities which encompass the work of a teacher. For each of these areas certain principles have been identified to serve as guidelines for teacher's conduct. These are preceded by a Preamble which provides a rationale for the principles identified

PART–I

Teacher in Relation to Students

The teachers shall,

1. Always be punctual in attending to duties in the College.

2. Always teach the curriculum after making thorough preparation for the lessons to be taught.

3. Treat all students with love and affection and be just and impartial to all irrespective of caste, creed, sex, status, religion, language and place of birth.

4. Guide the students in their physical, social, intellectual, emotional, moral and spiritual development.

5. Take notice of the individual needs and differences among students in their socio-cultural background and adapt his/her teaching accordingly.

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6. Refrain from accepting remuneration for coaching or tutoring his/her own students except for remedial teaching under an approved scheme.

7. Refrain from divulging confidential information about students except to those who are legitimately entitled to it.

8. Refrain from inciting students against other students, teaches or administration;

9. Set a standard of dress, speech and behavior worthy of example to the students.

10. Respect basic human dignity of children while maintain discipline in the College.

PART–II

Teacher in Relation to Parents/ Guardians

The teacher shall,

1. Seek to establish cordial relations with parents/ guardians.

2. Provide information regularly to parents regarding the attainments and shortfalls of the wards.

3. Refrain from doing anything which may undermine student's confidence in their Parents or guardians.

PART–III

Teacher in Relation to Society and the Nation

The teacher shall

1. Strive to develop the educational College as a community and human resource development center providing knowledge and information and developing skills and attitudes needed for such development.
2. Strive to understand the social problems and take part in such activities as would be conductive to meet the challenges passed by the problems.
3. Retrain from taking part in activities having potential to spread feeling of hatred or enmity among different communities, religious or linguistic groups.
4. work actively to strengthen national integration and spirit to togetherness and oneness
5. respect Indian culture and develop positive attitudes towards it among students
6. respect and be loyal to the school, community, state and nation

PART–IV

Teacher in Relation to Profession, colleagues and other Professional Organizations

A. Teacher in relation to Colleagues and Profession

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The teacher shall

1. Treat other members of the profession in the same manner as he/ she himself/herself wishes to be treated.
2. Refrain from lodging unsubstantiated allegations against colleagues or higher authorities
3. Participate in programmes of professional growth like in-service education and training, seminars, symposia workshops, conferences, self-study etc.
4. Avoid making insulting statements about colleagues especially in the presence of pupils, other teachers, official or parents.
5. Cooperate with the head of the College and colleagues in and outside the College in both curricular and co-curricular activities.
6. Accept as a professional the individual responsibility of reporting to the concerned authorities in an appropriate manner all matters that are considered to be prejudicial to the interests of the students and the development of the College.

B. Teacher in Relation to Professional Organizations

The teacher shall

1. Take membership of professional organizations treating it as a professional responsibility.
2. Participate as a matter of right in the formulation of policies and programmes of professional organizations and contribute to their strength, unity and solidarity.
3. Always function within the framework of the Constitution of the organization concerned.

PART–V

Teacher in Relation to Management/ Administration

The teacher shall,

1. Recognize the management as the prime source of his sustainable development
2. Develop mutual respect and trust through his professional activities and outputs Observance of the Code.

A true professional organization regulates admission of its members, exerts control over them and fights against all odds to promote their welfare. It thus represents unified voice of its members. The professional organizations of teaches should take upon themselves the moral

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responsibilities to safeguard all clauses of this code by ensuring their observance by the teachers. They should accept the

responsibility to evolve a suitable mechanism for its enforcement.

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INSTITUTIONAL CODE OF CONDUCT FOR STUDENTS

1. INTRODUCTION:

This Handbook indicates the standard procedures and practices of the JSPM's Charak College of Pharmacy and Research, Wagholi, Pune for all students enrolling with the College for pursuing varied courses. All students must know that it is mandatory upon them to take by this Code of Ethics and Conduct and the rights, responsibilities including the restrictions flowing from it.

That the College attempt by means of enforcing this Code is to forge and administer a student discipline process that is equal, meticulous, successful and efficient; and providing a system which promotes student growth through individual and collective responsibility. All Students are requested to be well aware with this Code, which can be also reviewed on the official website of the College.

2. JURISDICTION:

2.1. The College shall have the authority over the conduct of the students associated /enrolled with the College and to take knowledge of all acts of misconduct including incidents of ragging or otherwise which are taking place on the College campus or in connection with the College related activities and functions.

2.2. College may also exercise jurisdiction over conduct which occurs off-campus violating the ideal student conduct and discipline as laid down in this Policy and other regulations, as if the conduct has occurred on campus which shall include

A. Any violations of the Sexual Harassment Policy of the College against other students of the College.

B. Physical assault, threats of violence, or conduct that threatens the health or safety of any person including other students of the College.

C. Control or use of weapons, explosives, or destructive devices off-campus.

D. Sale or distribution of prohibited drugs, alcohol, Narcotic Drugs etc.

E. Conduct which has a negative impact or constitutes a bother to members of the surrounding off-campus community.

The College, while determining whether or not to exercise such off-campus jurisdiction in

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situations computed here in above, the College shall consider the seriousness of the unproven

Offense, the risk of harm involved, whether the victim(s) are members of the campus community and/or whether the off campus conducts is part of a series of actions, which occurred both on, and off-campus.

3. ETHICS AND CONDUCT

3.1 This Code shall apply to all kinds of conduct of students that occurs on the College premises including in University sponsored activities, functions hosted by other recognized student organizations and any off -campus conduct that has or may have serious consequences or adverse impact on the College Interests or reputation.

3.2 At the time of admission, **each student must sign a statement accepting this Code** and by giving an undertaking that

a) He/she shall be regular and must complete his/her studies in the College.

b) In the event, a student is forced to discontinue studies for any genuine reason; such a student may be relieved from the College with written consent of the Principal.

c) As a result of such relieving, the student shall be required to clear pending hostel / mess dues and if a student had joined the College on a scholarship, the said grant shall be revoked.

3.3 College believes in promoting a safe and efficient climate by enforcing behavioral standards. All students must uphold academic integrity, respect all persons and their rights and property and safety of others; etc.

3.4 All students must put off from spoiling in any and all forms of misconduct including contribution in any activity off-campus which can affect the College interests and reputation substantially. The various forms of misconduct include:

3.5 Any act of discrimination (physical or verbal conduct) based on an individual's gender, caste, religion or religious beliefs, color, region, language, disability, or sexual orientation, marital or family status, physical or mental disability, gender identity etc.

3.6 Intentionally damaging or destroying College property or property of other students and/or faculty members.

3.7 Any disruptive activity in a class room or in an event sponsored by the College.

3.8 Unable to produce the identity card, issued by the College, or refusing to produce it on

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demand by campus security guards.

3.9 Participating in activities including:

- **I.** Organizing meetings and processions without permission from the College.
- **II.** Accepting membership of religious or terrorist groups banned by the College and Government of India.
- **III.** Unauthorized possession, carrying or use of any weapon, ammunition, explosives, or potential weapons, fireworks, contrary to law or policy.
- **IV.** Unauthorized possession or use of harmful chemicals and banned drugs.
- **V.** Smoking on the campus of the College.
- **VI.** Possessing, Consuming, distributing, selling of alcohol in the College and/or throwing empty bottles on the campus of the College.
- **VII.** Parking a vehicle in a no parking zone or in area earmarked for parking other type of vehicles
- **VIII.** Rash driving on the campus that may cause any inconvenience to others.
- **IX.** Theft or unauthorized access to others resources.
- **X.** Engaging in disorderly, vulgar, or indecent conduct, including, but not limited to, creating unreasonable noise; pushing and shoving; inciting or participating in a riot or group disruption at the College.

3.10 Students are expected not to interact, on behalf of the College, with Media Representatives or invite media persons on to the campus without the permission of the College authorities.

3.11 Students are not permitted to either audio or video record lectures in class rooms or actions of other students, faculty, or staff without prior permission.

3.12 Students are not permitted to provide audio and video clippings of any activity on the campus to media without prior permission.

3.13 Students are expected to use the social media carefully and responsibly. They cannot post derogatory comments about other individuals from the College on the social media or spoiling in any such related activities having serious consequences on the reputation of the College.

3.14 Theft or abuse of the College computers and other electronic resources such as Instruments (HPLC, UV-Vis Spectrophotometer, other analytical instruments,

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machinery, electronic communications facilities, systems, and services which includes unauthorized entry, use, tamper, etc. of College property or facilities, private residences of staff/professors etc. offices, classrooms, computers networks, and other restricted facilities and Interference with the work of others is punishable.

3.15 Damage to, or destruction of, any property of the College, or any property of others on the College premises.

3.16 Making a video/audio recording, taking photographs, or streaming audio/video of any person in a location where the person has a reasonable expectation of privacy, without that person's knowledge and express consent.

3.17 Coddling in any form of Harassment which is defined as a conduct that is severe and objectively, a conduct that is motivated on the basis of a person's race, color, national or ethnic origin, citizenship, sex, religion, age, sexual orientation, gender, gender identity, marital status, ancestry, physical or mental disability, and medical condition.

4. If there is a case against a student for a possible break of code of conduct, then a committee will be formed to recommend a suitable disciplinary action who shall inquire into the suspected violation and accordingly suggest the action to be taken against the said student. . The committee may meet with the student to ascertain the misconduct and suggest one or more of the following disciplinary actions based on the nature of misconduct.

4.1 WARNING -Indicating that the action of the said negligent student was in violation of the Code and any further acts of misconduct shall result in severe disciplinary action.

4.2 RESTRICTIONS - Restricting access to various facilities on the College for a specified period of time.

4.3 COMMUNITY SERVICE - For a specified period of time to be extended if need be. However, any future misconduct along with failure to comply with any conditions imposed may lead to severe disciplinary action, including suspension or expulsion.

4.4 EXPULSION - Expulsion of a student from the College permanently. Indicating prohibition from entering the College premises or participating in any student related activities or campus residences etc.

4.5 MONETARY PENALTY - May also include suspension or penalty of

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scholarship/fellowship for a specific time period.

4.6 SUSPENSION- A student may be suspended for a specified period of time which will entail prohibition on participating in student related activities, classes, programs etc. Additionally, the student will be forbidden to use various College facilities unless permission is obtained from the Competent Authority. Suspension may also follow by possible dismissal, along with the additional penalties like Ineligibility to re-apply for admission to the College for a period of three years, and withholding the grade card or certificate for the courses studied or work carried out.

5 APPEAL: If the delinquent student is aggrieved by the imposition of any of the aforementioned penalties, he/she may appeal to the Director. The Director may decide on one of the following:

5.1 Accept the recommendation of the committee and impose the punishment as suggested by the Committee or modify and impose any of the punishments a as stipulated in this Code which is Commensurate with the gravity of the proved misconduct.

5.2 Refer the case back to the committee for reconsideration. In any case the Director's decision is final and binding in all the cases where there is a possible misconduct by a student.

6. Academic Integrity: As a premier College for advanced scientific and technological research and Education, the College values academic integrity and is committed to fostering an intellectual and ethical environment based on the principles of academic integrity. Academic Integrity encompasses honesty and responsibility and awareness relating to ethical standards for the conduct of research and scholarship. The College believes that in all academic work, the ideas and contributions of others must be appropriately acknowledged. Academic integrity is essential for the success of the College and its research missions, and hence, violations of academic integrity constitute a serious offence.

6.1 Scope and Purpose:

A. This Policy on academic integrity, which forms an integral part of the Code, applies to all students at the College and are required to adhere to the said policy. The purpose of the Policy is twofold:

- To clarify the principles of academic integrity, and
- To provide examples of unfair conduct and violations of academic integrity.

B. Failure to uphold these principles of academic integrity threatens both the reputation of the College and the value of the degrees awarded to its students.

C. Every member of the College therefore bears a responsibility for ensuring that the highest standards of academic integrity are upheld.

D. The principles of academic integrity require that a student,

- Properly acknowledges and cites use of the ideas, results, material or words of others.
- Properly acknowledges all contributors to a given piece of work.
- Makes sure that all work submitted as his or her own in a course or other academic activity is produced without the aid of impermissible materials or impermissible collaboration.
- Obtains all data or results by ethical means and reports them accurately without suppressing any results inconsistent with his or her interpretation or conclusions.
- Treats all other students in an ethical manner, respecting their integrity and right to pursue their educational goals without interference. This requires that a student neither facilitates academic dishonesty by others nor obstructs their academic progress.

6.2. Violations of this policy include, but are not limited to:

(i) Plagiarism means the use of material, ideas, figures, code or data as one's own, without appropriately acknowledging the original source. This may involve submission of material, verbatim or paraphrased, that is authored by another person or published earlier by oneself.

Examples of plagiarism include:

- Reproducing, in whole or part, text/sentences from a report, book, thesis, publication or the internet.
- Reproducing one's own previously published data, illustrations, figures, images, or someone else's data, etc.
- Taking material from class-notes or incorporating material from the internet graphs, drawings, photographs, diagrams, tables, spreadsheets, computer

programs, or other non-textual material from other sources into one's class reports, presentations, manuscripts, research papers or thesis without proper attribution.

- Self-plagiarism which constitutes copying verbatim from one's own earlier published work in a journal or conference proceedings without appropriate citations.
- Submitting a purchased or downloaded term paper or other materials to satisfy a course requirement.
- Paraphrasing or changing an author's words or style without citation.

(ii) Cheating: Cheating includes, but is not limited to:

- Copying during examinations, and copying of homework assignments, term papers, theses or manuscripts.
- Allowing or facilitating copying, or writing a report or taking examination for someone else.
- Using unauthorized material, copying, collaborating when not authorized, and purchasing or borrowing papers or material from various sources.
- Fabricating (making up) or falsifying (manipulating) data and reporting them in thesis and publications.
- Creating sources, or citations that do not exist.
- Altering previously evaluated and re-submitting the work for re-evaluation.
- Signing another student's name on an assignment, report, research paper, thesis or attendance sheet

(iii) Conflict of Interest: A clash of personal or private interests with professional activities can lead to a potential conflict of interest, in diverse activities such as teaching, research, publication, working on committees, research funding and consultancy. It is necessary to protect actual professional independence, objectivity and commitment, and also to avoid an appearance of any impropriety arising from clashes of interest. Conflict of interest is not restricted to personal financial gain; it extends to a large gamut of professional academic activities including peer reviewing, serving on various committees, which may, for example, oversee funding or give recognition, as well as influencing public policy. To promote transparency and enhance credibility, potential conflicts of interests must be disclosed in

writing to appropriate authorities, so that a considered decision can be made on a case-by-case basis. Some additional information is available also in the section below dealing with resources.

4.3 Guidelines for academic conduct are provided below to guard against negligence as well as deliberate dishonesty:

- Use proper methodology for experiments and computational work. Accurately describe and compile data.
- Carefully record and save primary and secondary data such as original pictures, instrument data readouts, laboratory notebooks, and computer folders. There should be minimal digital manipulation of images/photos; the original version should be saved for later scrutiny, if required, and the changes made should be clearly described.
- Ensure robust reproducibility and statistical analysis of experiments and simulations. It is important to be truthful about the data and not to omit some data points to make an impressive figure (commonly known as "cherry picking").
- Laboratory notes must be well maintained in bound notebooks with printed page numbers to enable checking later during publications or patenting. Date should be indicated on each page.
- Write clearly in your own words. It is necessary to resist the temptation to "copy and paste" from the Internet or other sources for class assignments, manuscripts and thesis.
- Give due credit to previous reports, methods, computer programs, etc. with appropriate citations. Material taken from your own published work should also be cited; as mentioned above, it will be considered self-plagiarism otherwise.

7. ANTI-RAGGING

The College has a coherent and an effective anti-ragging policy in place which is based on the 'UGC Regulation on Curbing the Menace of Ragging in Higher Educational Institutions, 2009 [hereinafter referred to as the 'UGC Regulations']'. The UGC Regulations have been framed in view of the directions issued by the Hon'ble Supreme Court of India to prevent and prohibit ragging in all Indian Educational Institutions and Colleges. The said UGC Regulations shall apply the necessary changes having been made to the College and the students are requested kindly

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to

- Any conduct by any student or students whether by words spoken or written or by an act which has the effect of teasing, treating or handling with rudeness any student.
- Indulging in rowdy or undisciplined activities by any student or students which causes or is likely to cause annoyance, hardship, physical or psychological harm or to raise fear or apprehension thereof in any other student.
- Asking any student to do any act which such student will not in the ordinary course do and which has the effect of causing or generating a sense of shame, or torment or embarrassment so as to adversely affect the physique or psyche of such a student.
- Any act by a senior student that prevents, disrupts or disturbs the regular academic activity of any student.
- Exploiting the services of a student for completing the academic tasks assigned to an individual or a group of student.
- Any act of financial extortion or forceful expenditure burden put on a student by other student.
- Any act of physical abuse including all variants of it: sexual abuse, stripping, forcing obscene and lewd acts, and gestures, causing bodily harm or any other danger to health or person.
- Any act or abuse by spoken words, emails, post, and public insults which would also include arising perverted pleasure, indirect or aggressive thrill from actively or passively participating in the embarrassment to any other student.

i) Any act that affects the mental health and self-confidence of any other student with or without an intent to derive a sadistic pleasure or showing off power, authority or superiority by a student over any other student.

7.2 ANTI-RAGGING COMMITTEE:

The Anti-Ragging Committee, as constituted by the Principal and headed by students affairs advisors shall examine all complaints of anti-ragging and come out with recommendation based on the nature of the incident. The committee shall be headed by students affairs advisors, and can have as its members, the Deans, Student Counselors, Faculty Advisors, Chairperson of the

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concerned Department.

7.3 ANTI-RAGGING SQUAD

To render assistance to students, an Anti-Ragging Squad, which is a smaller body, has also been constituted consisting of various members of the campus community. The said Squad shall keep a vigil on ragging incidents taking place in the community and undertake patrolling functions. Students may note that the Squad is active and alert at all times and are empowered to inspect places of potential ragging, and also make surprise raids in hostels and other hotspots in the College. The Squad can also investigate incidents of ragging and make recommendations to the Anti-Ragging Committee and shall work under the guidance of the Anti-Ragging Committee.

7.4 A student found guilty by the committee will attract one or more of the following punishments,

as imposed by the Anti-Ragging Committee:

a) Suspension from attending classes and academic privileges.

b) Withholding/ withdrawing scholarship/ fellowship and other benefits.

c) Debarring from appearing in any test/ examination or other evaluation process.

d) Withholding results.

e) Debarring from undertaking any collaborative work or attending national or international conferences/symposia/meeting to present his/her research work.

f) Suspension/ expulsion from the hostels and mess.

g) Cancellation of admission.

h) Expulsion from the institution and consequent debarring from admission to any other institution for a specified period.

i) In cases where the persons committing or abetting the act of ragging are not identified, the College shall resort to collective punishment.

j) If need be, in view of the intensity of the act of ragging committed, a First Information Report (FIR) shall be filed by the College with the local police authorities. The Anti-Ragging Committee of the College shall take appropriate decision, including imposition of punishment, depending on the facts and circumstances of each incident of ragging and nature and gravity of the incident of ragging.

7.5 An Appeal against the any of the orders of punishment enumerated hereinabove shall lie to:

i) In case of an order of an institution, affiliated to or constituent pavrt of the College, to the

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or of the College.

8. SEXUAL HARASSMENT

The College's Policy on prevention and prohibition of sexual harassment at workplace, 2016 shall apply to make necessary changes to the students of the College which can be accessed and reviewed by the students at http://www.iisc.ernet.in/misc/harashment.htm.

Students should note that sexual misconduct or harassment encompasses a range of conduct, including but not limited to sexual assault, unwanted touching or persistent unwelcome comments, e-mails, or pictures of an insulting or degrading sexual nature, which may constitute harassment, which shall depend of the circumstances of each case.

9. STUDENT GRIEVANCE PROCEDURES

Any student of the College aggrieved by any acts of sexual harassment, misconduct or ragging as defined and summarized hereinabove can approach the Student Grievance Redressal cell at the College. Further, any student who is aware of any violations must report the same to the Cell. The Cell shall consist of members as appointed by the Principal. Said grievance must be in writing and should be made within 60 days from the day of the alleged violation. The Cell shall take perception of the grievance and inform the Committee formed to enforce this Code or the Internal Complaints Committee, in cases of any sexual harassment complaints.

10. STUDENT PARTICIPATION IN GOVERNANCE

The Code, policies and the varied procedures laid down herein intends that the standard of student involvement in governance in both administrative and academic areas is essential and it is fundamental that Students must be, at all occasions, be encouraged to put forth their views and advice, for an informed decision making. Student Participation is encouraged and must be strengthened through the involvement of students in all levels. Therefore, all students who are a part of the College and who are going to be enrolled in the College are advised to uphold the policy and inform the College of any violations and assist individually and collectively to improve the quality and effectiveness of this Code and appended policies.

REFERNCES

–http://deanofstudents.ucsc.edu/student-conduct/student-handbook/pdf/120.0-policy-student-participation-governance.pdf

additional principles for medical research combined with medical care

Institution integrates crosscutting issues relevant to Gender

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1	INTERNATIONAL WOMEN'S DAY
2	CONSTITUTION DAY
3	RASHTRIYA EKTA DIWAS

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INTERNATIONAL WOMEN DAY

1. The Theme for international women's day is "Balance for Better". This day was celebrated for Achieving a gender-equal world requires social innovations that work for both women and men and leave no one behind.
2. The International Women's day was celebrated on Friday, 08/03/2023 in auditorium all at 03.30 pm.
3. On occasion of international woman's day, Prof.Surekha Deshmukh was invited for delivered a lecture on topic on Woman Issue- Human Rights and Legal Perspective. There is the discussion about; Achievement and skill pointed out by woman nowadays make us consider that women and men are not differing much. It is seen by leadership and roles of women in various areas.
4. She told about, Achievement and skill pointed out by woman nowadays make us consider that women and men are not differing much. When time goes by, point of view toward women, from which women deserved to keep the house only and stayed at home all the time while men had to work outside to the current development when emancipation arises, makes women get equal rights to men. It is seen by leadership and roles of women in various areas.
5. International woman's day concluded with National Anthem.

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CELEBRATION OF WOMEN'S DAY

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PLEDGE FOR RASHTRIYA EKTA DIWAS

Name of Activity	Date	Time	Venue	No. of Students Present/Participated
PLEDGE FOR RASHTRIYA EKTA DIWAS	01/11/2022	03pm-3:30pm	LSDP campus	100

Shri Wagheshwar Gramvikas Pratishthan's loknete shri dadapatil pharate college of pharmacy Mandavgan Pharata Pune has organized Rashtriya Ekta Diwas on 01st November 2022. Under this programme Principal Dr. H.V.Kamble had given the information to the students regarding creating awareness about unity of nation as Indian around the world is an important indicator to understand power of unity of nation. On this occasion college has organized pledge taking activity in which students and Teachers had taken the pledge of Rashtriya Ekta Diwas. All the teaching and Non-teaching staffs attended this programme. Total 100 students Participated in this programme. This activity demonstrated that, Yet, despite many successes in Sardar Vallabhbhai Patel, numerous issues still exist in all areas of life, ranging from the cultural, political to the economic.

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CELEBRATION OF CONSTITUTION DAY (2022-23)

Name of Activity	Date	Time	Venue	No. of Students Present/Participated
Celebration of Constitution Day	26/11/2022	3:30pm	Lsdp Campus	100

Shri Wagheshwar Gramvikas Pratishthan's loknete shri dadapatil pharate college of pharmacy, celebrated a “Constitution Day”, on 26/11/2021 at 3.30 pm in college campus. The event was started by taking pledge by the students and staff. As many as 100 students and 10 staff took pledge during the ceremony. The Principal sir Dr. H.V.Kamble and all Teaching and Non-teaching staff was present for this event. Principal Sir guided to the students about importance of constitution of India, and also gives information about importance of voter registration of students. The All the students participated in event actively & enthusiastically and gathered lot of knowledge about Indian Constitution. Their thinking skills were groomed through this event. All the students, Teaching and Non-teaching staff took the following pledge.

Pledge

“I, as a citizen of India, affirm my faith in the universal principle of civilized society, namely that every dispute between citizens, or groups, institutions or organizations of citizens, should be settled by peaceful means; and, in view of the growing danger to the integrity and unity of the country, I hereby pledge myself never to resort to physical violence in the case of any dispute, whether in my neighborhood or in any other part of India.”

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Institution integrates crosscutting issues relevant to Human Values

SR. NO	ACTIVITIES RELETED TO HUMAN VALUE
1	BLOOD DONATION
2	HEALTH CHEKUP
3	CONSTITUTION DAY
4	CELEBRATION BIRTH ANNIVERSARY OF MAHATMA GANDHI
5	CELEBRATION BIRTH ANNIVERSARY OF Dr. A. P. J. ABDUL KALAM
6	INTERNATIONAL YOGA DAY
7	CELEBRATION OF INDEPENDENCE DAY

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CELEBRATION OF INDEPENDENCE DAY

Pharate patil Groups of Institutes mandavgan pharata, Pune, celebrated a “Independence”, on 15/08/2022 at 8.30 am in LSDP Campus. Every year, Pharate patil Groups of Institutes organizes Prize distribution ceremony , Hon. Founder Secretary addresses the employees and students and Prize distribution ceremony for the academic rankers, Researcher‟s and Achievers.

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CELEBRATION BIRTH ANNIVERSARY OF MAHATMA GANDHI

Name of Activity	Date	Time	Venue	No. of Students Present/Participated
Anniversary of mahatma gandhi	2nd October 2022	3:20pm	Lsdp Campus	50

Shri Wagheshwar Gramvikas Pratishthan's loknete shri dadapatil pharate college of pharmacy, celebrated as Birth Anniversary of Mahatma Gandhi on 2 nd October 2022. Under this programme Principal Dr. H.V.Kamble had given the information to the students regarding freedom fighters of Nation. Also he highlighted the contribution of Mahatma Gandhi in the independence of India. All the students and staff were present in lsdp campus.

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CELEBRATION BIRTH ANNIVERSARY OF Dr. A. P. J. ABDUL KALAM

Name of Activity	Date	Time	Venue	No. of Students Present/Participated
Celebration Birth Anniversary of Dr. A. P. J. Abdul Kalam	15/10/2022	03pm3:30pm	Auditorium	98

Shri Wagheshwar Gramvikas Pratishthan's loknete shri dadapatil pharate college of pharmacy Mandavgan Pharata Pune has celebrated as birth anniversary of Dr. A. P. J. Abdul Kalam on 15/10/2022. Under this programme Principal Dr. H.V.Kamble had given the information to the students regarding Dr. A. P. J. Abdul Kalam. he highlighted that He was an aerospace scientist who served as the 11th President of India from 2002 to 2007. He spent the next four decades as a scientist and science administrator, mainly at the Defence Research and Development Organisation (DRDO) and Indian Space Research Organisation (ISRO) and was intimately involved in India's civilian space programme and military missile development efforts. He thus came to be known as the Missile Man of India for his work on the development of ballistic missile and launch vehicle technology. He also played a pivotal organisational, technical, and political role in India's Pokhran-II nuclear tests in 1998, the first since the original nuclear test by India in 1974. All the students participated in event actively & enthusiastically and gathered lot of knowledge about Dr. A. P. J. Abdul Kalam.

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REPORT OF BLOOD DONATION CAMP

Venue: LSDP College campus . Date: 20th OCT 2022, Tuesday Time of the Event:10.00 A.M. TO 5.00 PM

a. Introduction: So on the occasion of Occasion of Birthday of our Hon. Shri. Rajiv pharate patil Wagheshwar Campus organized blood donation camp in LSDP With Pharate patil Multisuper Speciality Auyrvedic Hospital. Donated blood is used for a wide range of circumstances that can potentially affect anyone, which is also a main reason people donate. Patients undergoing treatment for injuries suffered during an accident often rely on donated blood to save their lives.

b. Theme: Occasion of Birthday of our Hon. Shri. Rajiv Pharate Patil . (Founder President of Wagheshwar gramvikas pratisthan group.

c. Significance: It serves to raise awareness of the need for blood.

d. Conduction: Campus Director Shri. Sangram Rajedhavde inaugurated the program. At this time the Mrs. Mrunal Pharate (Founder Secretory of Wagheshwar gramvikas pratisthan group) and

e. Dr. Shelke nitin were also present. A total of 98 students donated blood from this camp. After donating blood, tea and snacks were also provided to the students.

f. Guest Details: Campus Director Shri. Sangram Rajedhavde were present for the camp.

g. Students & Faculty response & participation: In totality, 98 students donated blood.

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BLOOD DONATION CAMP

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REPORT OF INTERNATIONAL YOGA DAY

1. Yoga is an invaluable gift of India's ancient tradition. It embodies unity of mind and body; thought and action; restraint and fulfillment; harmony between man and nature; a holistic approach to health and well-being. It is not about exercise but to discover the sense of oneness with yourself, the world and the nature. By changing our lifestyle and creating consciousness, it can help in well-being.
2. The International Yoga day was celebrated on Friday, 21/06/2022 in auditorium all at 09.00 am.
3. All teaching, non-teaching staff and 60 students attended the session on Yogasana.
4. International Yoga day started with Yoga Prayer and yoga common protocol was followed in session.
5. Ms. S.S. Darandale demonstrated different Yogasana positions and described the benefits of each of the aasan covered in the session.
6. Dr. H.V.Kamble, Principal, highlighted the importance of incorporating Yogasana practice in day to day life instead of celebrating it just once in a year. He emphasized on prevention of disease as there is no permanent cure to diseases like diabetes, hypertension etc. He also informed the students that it is their prime responsibility as Pharmacist to spread awareness in society about practicing yoga for a healthy life.
7. International Yoga day celebration concluded with National Anthem.

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REPORT OF HEALTH CHECKUP CAMP

Venue: A/P-Pimpalsuti, Tal- Shirur, Dist-Pune Date: 28/01/2023 Time of the Event:09.00 A.M. TO 5.00 PM

a. Introduction: These camps also ensure provision of timely referral services to the patients for further or specialized care. The aim of the NSS special camp is to educate the people and empower them. Free medical camps are set up with a sacred aim to bring awareness amongst the deprived population of the country who have no access to basic healthcare services or knowledge about the diseases they are suffering from. So on the occasion of National Service Scheme.

b. Theme: Health is a state of complete physical, mental and social well-being.

c. Significance: Comprehensive Care' for the Health & Well-being of all.

d. Conduction: The NSS Unit of institute has organized the health check-up camp at A/P-Pimpalsuti,Tal- Shirur ,Dist-Pune and High School in association with local Govt. Hospital & Gram Panchayat. The peoples of the village were subjected to routine health check-up and medicines were distributed among the people in the health check-up camp. A total of 275-300 patients got the benefits of the free camp. The free health checkup include blood pressure, hemoglobin, blood group thyroid level, calcium level sugar level in the body and weight which was totally free and the villager has taken the maximum benefit of the health camp. The patients above 40 years were screened for Diabetes, Hypertension and cardiovascular diseases using ECG. They were given treatment on spot with the help of specialists from General Medicine.

e. Guest Details: Campus Director Shri. Sangram Rajedhavde and Principal Dr.H.V.Kamble were present for the camp.

f. Students & Faculty response & participation: In totality, 25 NSS students & 02 Faculty were participated.

g. Outcome: Getting the right type of health check-up is important and while considering it, certain factors like age, lifestyle, family history, and risks should be taken into account. Regular health examinations and tests help detect problems before they start. Opting for a right health check-

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up, screenings, and treatments means one is taking steps to help one live longer and healthier life.

HEALTH CHECKUP CAMP

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CELEBRATION OF CONSTITUTION DAY (2022-23)

Name of Activity	Date	Time	Venue	No. of Students Present/Participated
Celebration of Constitution Day	26/11/2022	3:30pm	Lsdp Campus	100

Shri Wagheshwar Gramvikas Pratishthan's loknete shri dadapatil pharate college of pharmacy, celebrated a "Constitution Day", on 26/11/2022 at 3.30 pm in college campus. The event was started by taking pledge by the students and staff. As many as 100 students and 10 staff took pledge during the ceremony. The Principal sir Dr. H.V.Kamble and all Teaching and Non-teaching staff was present for this event. Principal Sir guided to the students about importance of constitution of India, and also gives information about importance of voter registration of students. The All the students participated in event actively & enthusiastically and gathered lot of knowledge about Indian Constitution. Their thinking skills were groomed through this event. All the students, Teaching and Non-teaching staff took the following pledge.

Pledge

"I, as a citizen of India, affirm my faith in the universal principle of civilized society, namely that every dispute between citizens, or groups, institutions, or organizations of citizens, should be settled by peaceful means; and, in view of the growing danger to the integrity and unity of the country, I hereby pledge myself never to resort to physical violence in the case of any dispute, whether in my neighborhood or in any other part of India."

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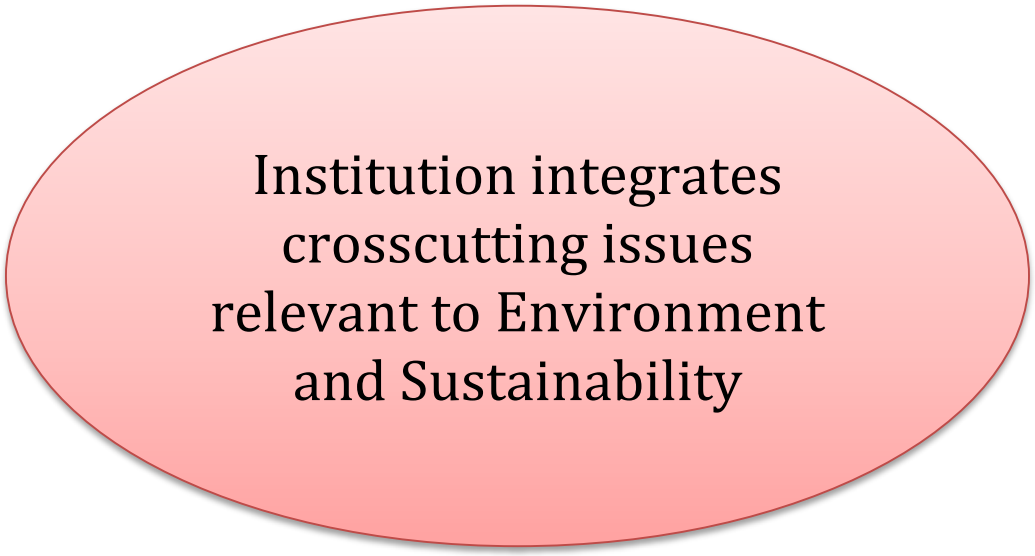
Institution integrates crosscutting issues relevant to Environment and Sustainability



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1	ENVIRONMENT SCIENCE FIELD TRIP VISIT
2	SWATCH BHARAT ABHIYAN
3	NSS CAMP ACTIVITY

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REPORT OF ENVIRONMENT SCIENCE FIELD TRIP VISIT

To undertake the Environmental Studies Field Work which is a part of the new EVS Syllabus in Savitribai Phule Pune University (S. Y. B. Pharm), a visit was organized by the LSDP mandavgan College Campus to inamgaon village & inamgaon river side, Pune on 30/10/2022, Saturday. Inamgaon village & inamgaon river side is a small settlement that lies to the North of Mandavgan, off ashtvinyak highway. A total number of 109 students were taken for the Environment field work. This group consisted of Second Year B.Pharm students from our college. General. This group was placed under the charge of 03 teachers from the respective departments. EAST is an organization set up under the Bombay Societies Act, 1950 . We believe that today's communities need to change their lifestyles if they wish that their future generations survive. We believe that this transformation, which has to be sustainable, can occur by appropriate and adequate environmental action. This action is brought about, to being with, environmental education. EAST delivers environmental education at school and college level and has started this from their home city of Pune. The students and the teachers were accommodated in 2 buses. The journey to inamgaon from the College premises at about 8:15 am and reached the destination at 9:00 am, i.e. in one-hours. The route taken to inamgaon was the following – LSDP mandavgan – Check Post – mandavgan to inamgaon route and the Inamgaon village . The students of the LSDPCOP mandavgan were taken to Inamgaon and Inamgaon river area for field work.

The focus of the field work was on various environmental issues in the region and sensitizing the students to such issues. The students were very enthusiastic about the field work and later presented detailed field work reports which were during the viva voice exams. All the arrangement and guidance were provided by the EAST Representative Mr. Pritam bhore.

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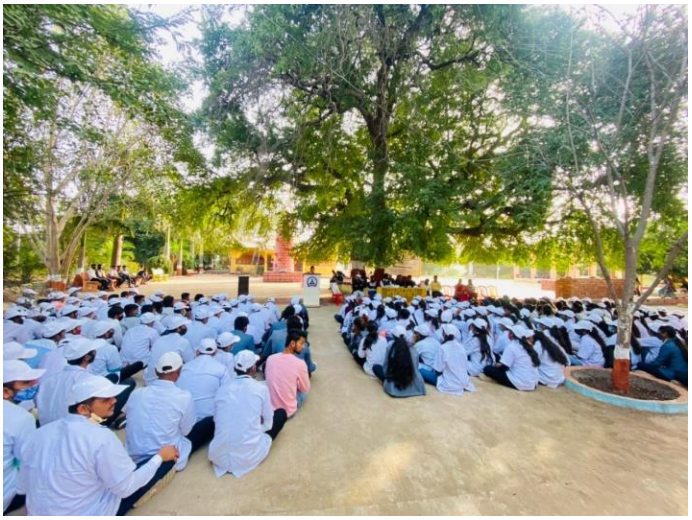

ENVIRONMENT SCIENCE FIELD TRIP VISIT

The students were provided with field observation sheet which they have to fill by their own observation on the field. The detailed observation sheet will be submitted along with the project for examination purpose. Various themes covered during the field work like Forest ecosystem, aquatic ecosystems, food chains, food webs, community conservation methods, Devrais, threatened species conservation, Urbanization and development, Agriculture etc. Fish farming or culture involves raising fish commercially in tanks or enclosures such as fish ponds, usually for food.

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SWATCH BHARAT ABHIYAN

Venue: A/P-Inamgaon, Tal- Shirur, Dist-Pune Date: 31/12/2022 to 01/01/2023 Time of the Event:08.00 A.M. TO 10.00 AM

a) Introduction:Swachh Bharat Abhiyan (SBA) or Swachh Bharat Mission (SBM) is a nation-wide campaign in India for the period 2014 to 2019 that aims to clean up the streets, roads and infrastructure of India's cities, towns, and rural areas.

The objectives of Swachh Bharat include:

a) Eliminating open defecation through the construction of household-owned and community-owned toilets and establishing an accountable mechanism of monitoring toilet use.

b) Theme:"Clean India Mission"

c) Significance:The mission will also contribute to India reaching Sustainable Development Goal 6 (SDG 6), established by the UN in 2015.

d) Conduction:The NSS Unit of institute has organized the Swatch bharat mission atA/P-Inamgaon, Tal-Shirur, Dist-Pune in association with local Gram Panchayat.

They also interacted with the students and helped to create awareness on cleanliness, new alternatives for electricity use, water harvesting and management of waste. This day whole and solely was dedicated for the cleaning purpose. The team work was noticeable students drove a cleanliness programme around the school area, village roads removed dust heaps. roads were cleaned with the help of brooms. The drainage flows were cleared for this they made the large wells, the larger garbage damp were burned out.

e) Guest Details: Campus Director Shri. Sangram Rajedhayade and Principal Dr.H.V.Satpute were present for the camp.

f) Students & Faculty response & participation: In totality, 22 NSS students & 02 Faculty were participated.

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SWGP'S LOKNETE SHRI DADAPATIL PHARATE
COLLEGE OF PHARMACY
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SWATCH BHARAT ABHIYAN

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SWGP'S LOKNETE SHRI DADAPATIL PHARATE
COLLEGE OF PHARMACY
Mandavgan Pharata, Tal. Shirur, Dist. Pune 412211

NSS CAMP ACTIVITY

Venue: At post Pimpalsuti , Taluka Shirur, Dist. Pune. Date: 28/12/2022 to 03/01/ 2023

❖ The activities carried during this camp are as follows:

- Health Check-up camp- All the villagers were counseled with regard to keeping the blood sugar levels in control and effective and safe used of medicines. All the patients suffering from blood pressure/diabetes were counseled to continue taking medicines on regular basis and not to stop medication on their own. Blood sugar levels and Blood Pressure of the villagers was checked and informed to them. The patients were advised to consult pharmacist/doctor for counseling as and when required. Total 180 villagers participated in the camp.
- Election Awareness -Election awareness along with green nest a election awareness campaign is organized . This event consists dance, drama and a human rally promoting the importance of voting.
- Helmet awareness - Helmet awareness by NSS Valunteers explains about “Head injury management and prevention-Importance of helmet”.
- Free medicines were distributed to villagers in presence of doctors.
- Swatch Bharat Abhiyan: Swachchh Bharat Abhiyan was carried out every day soon after the Prabhat-Pheri. Different areas of the village were taken day by day and were cleaned by the volunteers. This created a buzz in the village and suddenly NSS Team started getting more attention than ever before from people across the village.
- Digital India Campaign was carried out throughout the village. The importance of digital transactions and its role in curbing corruption was conveyed to the villagers.
- Socio-economic survey socio-economic survey was carried out by the volunteers throughout the village. Google forms were used to facilitate the activity.

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- Street play on importance of education & women empowerment A Street play was practiced and performed by the student volunteers of the NSS Team on the third day of the camp. The theme of the play was: “Importance of Education” and “Women Empowerment”. The volunteers were enthusiastic to perform in the play. It was a life cherishing moment for all of them. Girl volunteers also helped the boys volunteers prepare the skit as well as in their dress up and make up.
- Awareness Programme on Life Insurance, Government Schemes, Scholarships for girls, Banking and visuals on Water Conservatioand Tree Plantation an awareness programmes had been conducted on the govt schemes specially for women, govt scholarships and exams All the villagers were made aware about these activities through the videos on laptop and speaker. Apart from that, Models to explain banking were made by the volunteers to explain them each and every facility of the banks.
- The NSS Camp concluded in presence of Village Gram Panchayat functionaries, Principal & faculty of college, Principal, Non-teaching staff and students of the school, and NSS student volunteers of college on 02 January 2023.

- The gram panchayat members appreciated the activities conducted during NSS Camp and issued Appreciation Letter to the college for the efforts taken by students.

NSS CAMP ACTIVITY

SWGP'S LOKNETE SHRI DADAPATIL PHARATE COLLEGE OF PHARMACY MANDAVGAN PHARATA, PUNE 412211

PRINCIPAL
SWGP'S LOKNETE SHRI DADAPATIL PHARATE
COLLEGE OF PHARMACY
Mandavgan Pharata, Tal. Shirur, Dist. Pune 412211