Total Contact Hours = 36 Total Marks = 1000 Total Credits = 28

SEMESTER 1st		Contact Hrs.			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
BHUM0-104	Communicative English	2	1	0	40	60	100	3
BPHA1101	Pharmacognosy-I	2	1	-	40	60	100	3
BPHA1 102	Pharmaceutical Chemistry-I(Inorganic pharmaceutical Chemistry)	3	1	-	40	60	100	4
BPHA1 103	Pharmaceutical Analysis-I	3	1	-	40	60	100	4
BCAP0 195	Computer Science & Application	2	1	-	40	60	100	3
BPHA1 104	Introduction to Dosage Form	2	1	-	40	60	100	3
BPHA1 105	Pharmacognosy-I Lab.	-	-	4	60	40	100	2
BPHA1 106	Pharmaceutical Chemistry-I Lab. (Inorganic pharmaceutical Chemistry)	-	-	4	60	40	100	**2**
BPHA1 107	Pharmaceutical Analysis-I Lab.	-	-	4	60	40	100	**2**
BCAP0196	Computer Science & Applications Lab.	-	-	4	60	40	100	**2**
Total		**14**	**6**	**16**	**480**	**520**	**1000**	**28**

Total Contact Hours = 37/39 Total Marks = 1000/1100 Total Credits = 29/30

SEMESTER 2nd		Contact Hrs.			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
BPHA1-208	Human Anatomy and Physiology-I	3	1	-	40	60	100	4
BPHA1-209	Pharmaceutical Organic Chemistry - I	3	1	-	40	60	100	4
BPHA1-210	Biochemistry	3	1	-	40	60	100	4
BPHA1-211	Physical Pharmaceutics-I	3	1	-	40	60	100	4
***BPHA1-212/ *BPHA1-213**	Remedial Biology/Remedial Mathematics	2/3	-	-	40	60	100	2/3
BPHA1-214	Environmental Sciences	3	-	-	40	60	100	3
BPHA1-215	Human Anatomy and Physiology –I Lab	-	-	4	60	40	100	2
BPHA1-216	Pharmaceutical Organic Chemistry- I Lab	-	-	4	60	40	100	2
BPHA1-217	Biochemistry – Lab	-	-	4	60	40	100	2
BPHA1-218	Physical Pharmaceutics I - Lab	-	-	4	60	40	100	2
BPHA1-219	Remedial Biology - Lab	-	-	2	60	40	100	1
Total		**17/18**	**4**	**16/ 18**	**480/ 540**	**520/5 60**	**1000 / 1100**	**30**

* Non-medical students opt for Remedial Biology and Medical students opt for remedial mathematics

Total Contact Hrs. = 36 Total Marks = 900 Total Credits = 28

SEMESTER 3nd		Contact Hrs..			Marks			Credits
Course Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
BPHA1-320	Pharmaceutical Organic Chemistry-II	3	1	-	40	60	100	4
BPHA1-321	Pharmaceutical Microbiology	3	1	-	40	60	100	4
BPHA1-322	Pharmaceutical Engineering	3	1	-	40	60	100	4
BPHA1-323	Human Anatomy and Physiology-II	3	1	-	40	60	100	4
BPHA1-324	Pathophysiology	3	1	-	40	60	100	4
BPHA1-325	Pharmaceutical Organic Chemistry-II Lab.	-	-	4	60	40	100	2
BPHA1-326	Pharmaceutical Microbiology Lab.	-	-	4	60	40	100	2
BPHA1-327	Pharmaceutical Engineering Lab.	-	-	4	60	40	100	2
BPHA1-328	Human Anatomy and Physiology-II Lab.	-	-	4	60	40	100	2
Total		**15**	**5**	**16**	**440**	**460**	**900**	**28**

Total Contact Hours = 36 Total Marks = 900 Total Credits = 28

SEMESTER 4th		Contact Hrs..			Marks			Credits
Course Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
BPHA1-429	Pharmaceutical Organic Chemistry –III	3	1	-	40	60	100	4
BPHA1-430	Medicinal Chemistry – I	3	1	-	40	60	100	4
BPHA1-431	Pharmacology-I	3	1	-	40	60	100	4
BPHA1-432	Physical Pharmaceutics-II	3	1	-	40	60	100	4
BPHA1-433	Pharmacognosy and Phytochemistry- I	3	1	-	40	60	100	4
BPHA1-434	Medicinal Chemistry – I Lab.	-	-	4	60	40	100	2
BPHA1-435	Pharmacology-I Lab.	-	-	4	60	40	100	2
BPHA2-436	Physical Pharmaceutics- II Lab.	-	-	4	60	40	100	2
BPHA1-437	Pharmacognosy and Phytochemistry I Lab.	-	-	4	60	40	100	2
Total		**15**	**5**	**16**	**440**	**460**	**900**	**28**

NOTE: From 5th Semester onwards, Codes of subjects given in scheme will be followed.

Total Contact Hours =32 Total Marks = 800 Total Credits = 26

SEMESTER 5th		Contact Hrs.			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
BPHA1-538	Medicinal Chemistry-II	3	1	-	40	60	100	4
BPHA1-539	Industrial Pharmacy-I	3	1	-	40	60	100	4
BPHA1-540	Pharmacology-II	3	1	-	40	60	100	4
BPHA1-541	Pharmacognosy and Phytochemistry II	3	1	-	40	60	100	4
BPHA1-542	Pharmaceutical Jurisprudence	3	1	-	40	60	100	4
BPHA1-543	Industrial Pharmacy-I Lab.	-	-	4	60	40	100	**2**
BPHA1-544	Pharmacology-II Lab.	-	-	4	60	40	100	**2**
BPHA1-545	Pharmacognosy and Phytochemistry-II Lab.	-	-	4	60	40	100	**2**
Total		**15**	**5**	**12**	**380**	**420**	**800**	**26**

Total Contact Hours = 36 Total Marks = 900 Total Credits = 30

SEMESTER 6th		Contact Hrs.			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
BPHA1-646	Medicinal Chemistry-III -Theory	3	1	-	40	60	100	4
BPHA1-647	Pharmacology-III -Theory	3	1	-	40	60	100	4
BPHA1-648	Herbal Drug Technology -Theory	3	1	-	40	60	100	4
BPHA1-649	Biopharmaceutical and Pharmacokinetics - Theory	3	1	-	40	60	100	4
BPHA1-650	Pharmaceutical Biotechnology- Theory	3	1	-	40	60	100	4
BPHA1-651	Quality Assurance Theory	3	1	-	40	60	100	4
BPHA1-652	Medicinal Chemistry-III -Practical	-	-	4	60	40	100	2
BPHA1-653	Pharmacology-III -Practical	-	-	4	60	40	100	2
BPHA1-654	Herbal Drug Technology-Practical	-	-	4	60	40	100	2
Total		**18**	**6**	**12**	**420**	**480**	**900**	**30**

Total Contact Hrs. = 32 **Total Marks = 600** **Total Credits = 24**

SEMESTER 7th		Contact Hrs..			Marks			Credits
Course Code	Subject Name	L	T	P	Int.	Ext.	Total	
BPHA1-755	Instrumental Methods of Analysis	3	1	-	40	60	100	4
BPHA1-756	Industrial Pharmacy-II	3	1	-	40	60	100	4
BPHA1-757	Pharmacy Practice	3	1	-	40	60	100	4
BPHA1-758	Novel Drug Delivery System	3	1	-	40	60	100	4
BPHA1-759	Instrumental Methods of Analysis-Lab.	-	-	4	40	60	100	2
BPHA1-760	Practice School*	-	-	12	100	-	100	6
Total		**12**	**4**	**16**	**300**	**300**	**600**	**24**

*non University Examination

Total Contact Hours = 28 **Total Marks = 900** **Total Credits = 22**

SEMESTER 8th		Contact Hrs..			Marks			Credits
Course Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
BPHA1-861	Biostatistics and Research Methodology	3	1	-	40	60	100	4
BPHA1-862	Social and Preventive Medicine	3	1	-	40	60	100	4
Departmental Electives (Choose any two)		3+3 = 6	1+1 = 2	-	40+40 = 80	60+60 = 120	100+ 100 =200	4+4=8
BPHA1-863	Pharm Marketing Management							
BPHA1-864	Pharmaceutical Regulatory Sciences							
BPHA1-865	Pharmacovigilance							
BPHA1-866	Quality Control and Standardization of Herbals							
BPHA1-867	Computer aided Drug Design							
BPHA1-868	Cell and Molecular Biology							
BPHA1-869	Cosmetic Sciences							
BPHA1-870	Experimental Pharmacology							
BPHA1-871	Advanced instrumentation Techniques							
BPHA1-872	Dietary Supplements and Nutraceuticals							
BPHA1-873	Project Work*	-	-	12	100	-	100	6
Total		**12**	**4**	**12**	**260**	**240**	**500**	**22**

* The subject experts shall conduct examinations

Overall

Semester	Marks	Credits
1st	1000	28
2nd	1000/1100	30
3rd	900	28
4th	900	28
5th	800	26
6th	900	30
7th	600	24
8th	500	22
Total	**6600/6700**	**216**

COMMUNICATIVE ENGLISH

Subject Code: BHUM0-104 **L T P C** **Duration: 35 Hrs.**
2 1 0 3

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

Course Objectives:

Upon completion of the course the student shall be able to

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

UNIT-I (3 Hrs.)

Communication Skills: Introduction, Definition, the Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT-II (5 Hrs.)

Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

Communication Styles: Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT-III (5 Hrs.)

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

Effective Written Communication: Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication

Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT-IV (22 Hrs.)

Interview Skills: Purpose of an interview, Do's and Don'ts of an interview

Giving Presentations: Dealing with Fears, planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

Group Discussion: Introduction, Communication skills in group discussion, Do's and Don'ts of group discussion

(Tutorials)

The following learning modules may be conducted using Wordsworth® English language lab software.

Basic communication covering the following topics
Meeting People
Asking Questions
Making Friends
What did you do?
Do's and Don'ts
Pronunciations covering the following topics
Pronunciation (Consonant Sounds)
Pronunciation and Nouns
Pronunciation (Vowel Sounds)
Advanced Learning:
Listening Comprehension / Direct and Indirect Speech
1. Figures of Speech
2. Effective Communication
3. Writing Skills
4. Effective Writing
5. Interview Handling Skills
6. E-Mail etiquette
7. Presentation Skills

Recommended Books:

1. Andreja. J. Ruther Ford, 'Basic Communication Skills for Technology', 2nd Edn., Pearson Education, **2011.**
2. Sanjay Kumar, Pushpalata, 'Communication Skills', 1stEdn., Oxford Press, **2011.**
3. Stephen P. Robbins, 'Organizational Behaviour', 1st Edn., Pearson, **2013**.
4. Gill Hasson, 'Brilliant-Communication Skills', 1st Edn., Pearson Life, **2011**.
5. Gopala Swamy Ramesh, 'The Ace of Soft Skills: Attitude, Communication and Etiquette for Success', 5th Edn., Pearson, **2013**.
6. Deborah Dalley, Lois Burton, Margaret, 'Developing your Influencing Skills', Green Hall, 1st Edn., Universe of Learning LTD, **2010.**
7. Konar Nira, 'Communication Skills for Professionals', 2nd Edn., PHI, **2011.**
8. Barun K. Mitra, 'Personality Development and Soft Skills', 1st Edn., Oxford Press, **2011**.
9. 'Soft Skill for Everyone', Butter Field, 1st Edn., Cengage Learning India Pvt. Ltd., **2011**.
10. S.J. Francis Peters, 'Soft Skills and Professional Communication', 1st Edn., Mc Graw Hill Education, **2011.**
11. John Adair, 'Effective Communication', 4th Edn., Pan Mac Millan, **2009**.
12. Aubrey Daniels, 'Bringing out the Best in People', 2nd Edn., McGraw Hill, **1999**.

PHARMACOGNOSY-I

Subject Code: BPHA1-101 **L T P C** **Duration: 35 Hrs.**
2 1 0 3

UNIT-I (9 Hrs.)

Definition, History, Scope and Development of Pharmacognosy; Sources of drugs: Biological, marine, mineral and plant tissue culture.
Plant Cell, Histology and Morphology: Structure of plant cell and its non-living inclusions, different types of plant tissues and their functions. Morphology and histology of root, stem, bark, wood, leaf, flower, fruit and seed. Modifications of root and stem.

UNIT-II (7 Hrs.)

Classification of Drugs: Alphabetical, morphological, taxonomical, chemical and pharmacological; Plant taxonomy: Study of the following families with special reference to

medicinally important plants-Apocynacae, Solanaceae and Rubiacea.
Plant taxonomy: Study of the following families Umbelliferae, Leguminosae, Liliaceae, Labiatae, Cruciferae and Papaveraceae with special reference to medicinally important plants.

UNIT-III (10 Hrs.)

Cultivation, Collection, Processing and Storage of Crude Drugs: Factors influencing cultivation of medicinal plants. Polyploidy, mutation and hybridization with reference to medicinal plants.

Quality Control of Crude Drugs: Adulteration of Crude Drugs. Brief introduction to evaluation of crude drugs by organoleptic, microscopic, physical, chemical and biological methods.

UNIT-IV (9 Hrs.)

Introduction to crude drug monograph and its importance in registration of herbal products.
Introduction to Chromatographic Techniques: Column, Paper, Thin Layer (TLC).
Introduction to Phytoconstituents of drugs: Definition, classification, properties and identification tests of carbohydrates, alkaloids, glycosides, terpenoids, steroids and flavonoids.

Recommended Books:

1. G.E. Trease and W.C. Evans,' Pharmacognosy', Elsevier, a Division of Reed Elsevier India Pvt. Ltd., New Delhi.
2. C.K. Kokate, A.P. Purohit and S.B. Gokhale, 'Pharmacognosy', Nirali Prakashan, Pune.
3. S.S. Handa and V.K. Kapoor, 'Textbook of Pharmacognosy', Vallabh Prashan, New Delhi.
4. T.E. Wallis,,'Textbook of Pharmacognosy', 5th Edn., CBS Publishers and Distributors, New Delhi.
5. V.C. Tyler, L.R. Brady and J.E. Robers,'Pharmacognosy', Lea & Febiger, Philadelphia.
6. V.E. Tyler, Jr. and A.E. Schwarting, 'Experimental Pharmacognosy', Burgess Pub. Co, Hinneapois, Minnesotta.
7. K.R. Brain and T.D. Turner, 'The Practical Evaluation of Phytopharmaceuticals', Wright-Scientechnica, Bristol.

PHARMACEUTICAL CHEMISTRY-I (INORGANIC PHARMACEUTICAL CHEMISTRY)

Subject Code: BPHA1-102 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

UNIT-I (21 Hrs.)

Impurities in Pharmaceutical Substances & their control sources and types of impurities, their limits, limit test for chlorides, sulphates, iron, lead, arsenic & heavy metals.

Pharmaceutical Aids & Necessities (Antioxidants: Theory, the selection of Antioxidants, Official antioxidants (Hypophosphorus Acid, Sodium bisulphite, Sodium thiosulphate, Sodium nitrite**)**

Major Intra & Extracellular Electrolytes: Major Physiological ions (Chloride, Phosphate, Bicarbonate, Sodium, Potassium, Calcium, Magnesium); Electrolytes used in replacement therapy(Sodium chloride), Potassium replacement (potassium chloride), Calcium replacement (Calcium chloride, Calcium gluconate) Parenteral magnesium administration (Magnesium sulphate), Physiological acid base balance, Electrolytes used in acid base therapy (Sodium acetate, Potassium acetate, Sodium bicarbonate, Sodium citrate, Potassium citrate, Sodium lactate, Ammonium chloride), Electrolyte combination therapy.};

Essential and Trace Elements: {Iron, Copper, Zinc, Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine. Official Iodine Products (Iodine, Potassium iodide, Sodium iodide.

UNIT-II (7 Hrs.)

Gastrointestinal Agents {Acidifying agents, **Antacids:** (Sodium bicarbonate, Aluminium hydroxide, Aluminium phosphate, Dihydroxy Aluminium, Sodium carbonate, Calcium carbonate, Tribasic Calcium phosphate, Magnesium carbonate, Magnesium hydroxide, Magnesium oxide, Magnesium phosphate, Magnesium trisilicate) Combination antacid preparations.; **Protectives and Adsorbents:** Introduction. Bismuth containing products, Bismuth subnitrate, Bismuth subcarbonate, Kaolin, Activated charcoal.**}**; **{Saline Cathartics:** Introduction, Sodium phosphate, Potassium sodium tartrate, Magnesium hydroxide, Magnesium citrate, Magnesium sulphate, Potassium phosphate, Potassium bitartrate, Calomel.**}**

UNIT-III (5 Hrs.)

Protective: Definition, Protective products, Talc, Insoluble Zinc compounds (Zinc oxide, Calamine, Zinc stearate), Titanium dioxide, Aluminium as a protective agent, Silicone polymer;

Antimicrobials and Astringents: Antimicrobial terminology, mechanism of action, control of antimicrobial/ astringent action;

Oxidative Antimicrobial Agents: Hydrogen peroxide, Zinc peroxide, Sodium carbonate, Potassium permanganate, Iodine preparation and compounds**.**

UNIT-IV (12 Hrs.)

Protein Precipitant Antimicrobial Agents: Silver nitrate, Mild Silver Protein Mercury compounds (Yellow Mercuric oxide, Mercuric chloride), Sulphur and Sulphur compounds (Sublimed sulphur and Precipitated sulphur) Boric acid and Sodium borate, Antimony potassium tartrate, Official compounds of Aluminium and Zinc;

Dental Products: Anticaries agents: Fluorides, official products (Sodium fluoride, Stannous fluoride), Phosphates,

Dentifrices: Dentifrices containing Fluorides, Official products (Pumice). Dentifrices containing desensitizing agents, Official products (Zinc chloride and Zinc-Eugenol cement).

Co-ordination Compounds and Complexation: Theoretical considerations and official products (Calcium disodium edentate, Disodium edetate, Dimercaprol & Penicillamine**}**;

Miscellaneous Inorganic Pharmaceutical Agents: Inhalants, respiratory stimulants, expectorants and emetics, antidotes, tableting aids and suspending agents.

Recommended Books:

1. J.H. Block, E. Roche, T.O. Soine and C.O. Wilson, 'Inorganic Medicinal and Pharmaceutical Chemistry', Lea & Febiger, Philadelphia, P.A.
2. L.M. Artherden, Bentley and Drivers, 'Textbook of Pharmaceutical Chemistry', S& Ed., Oxford University Press, Delhi.
3. 'Pharmacopoeia of India', Govt. of India, Ministry of Health.
4. Block, Roche, Soine & Wilson,'Inorganic Medicinal & Pharmaceutical Chemistry'. 1st Edn., Varghese Publishing House, Mumbai, **1986**.
5. Chatwal, 'Pharmaceutical Chemistry Inorganic', 3rd Edn., Himalaya Publishing House, Mumbai, **2007**.
6. Singh & Kapoor, Practical Pharmaceutical Chemistry, 4th Edn., Vallabh Prakashan, Delhi, **1998**.

PHARMACEUTICAL ANALYSIS-I

Subject Code: BPHA1-103 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

UNIT-I (9 Hrs.)

Quantitative Analysis and Data Handling

Introduction to concept of Quality Control and Assurance in Pharmaceutical Industry and role of Statistics in pharmaceutical analysis. Significance of quantitative analysis in quality control, different techniques of analysis, preliminaries and definitions, significant figures. Rules for retaining significant figures, Types of errors (Determinate and Indeterminate). Minimization of errors, Propagation of errors in addition and subtraction, multiplication and division, exponents, logarithms, precision and accuracy, selection of sample.

Acid Base Titrations

Acid base concept, role of the solvent, Relative strengths of acids and bases; Law of mass action; common ion effect, ionic product of water, pH, Hydrolysis of salts, Handerson – Hasselbach equation; Buffer and buffer capacity: Acid base indicators, Theory of indicators, Choice of indicators; Neutralization curves (Strong acid and strong base, strong acid weak base, weak acid strong base and weak acid weak base).

UNIT-II (13 Hrs.)

Acid Base Titrations:

Polyprotic system, dissociation calculations for polyprotic acids, fractions and equilibrium concentrations of dissociating species at a given pH, salts of polyprotic acids, (Amphoteric salts and unprotonated salts), Buffer calculations for polyprotic acids, titrations of polyprotic acid, amino acid system and its titrations. Applications in assay of H_3BO_3, HCl, NaOH and Na_2CO_3.

Oxidation-Reduction Titrations:

Concepts of oxidation and reduction, redox reactions, equivalent weights of oxidizing and reducing agents, electrochemical cells, reduction potential, standard reduction potential, Nernst equation, cell representations, measurement of electrode potential and its application in determining the equilibrium constant of a reaction.

UNIT-III (12 Hrs.)

Oxidation-Reduction Titrations:

Concept of formal potential, oxidation reduction curves, redox indicators, potassium pemanganate titrations, iodimetry and iodometry, ceric sulphate titrations, potassium iodate titrations, sodium 2, 6- dichlorophenol - indophenol titrations, pharmaceutical applications.

Precipitation Titrations:

Precipitation reactions, solubility product, effects of common ion, acids, temperature and solvent upon the solubility of a precipitate, conditional solubility product, fractional precipitation.

UNIT-IV (11 Hrs.)

Precipitation Titrations:

Argentometric titrations, ammonium or potassium thiocyanate titrations, mercuric nitrate titrations, indicators, Gay-Lussac method, Mohr's method, Volhard's method, Fajan's method, Pharmaceutical applications.

Gravimetric Analysis:

Precipitation techniques, the colloidal state, gravimetric factor, super saturation, co-precipitation and its types, Post precipitation, digestion, washing of the precipitate, filtration, filter papers and crucibles, ignition, thermogravimetric curves of copper sulphate, specific examples like barium as barium sulphate, aluminium as aluminium oxide, calcium as calcium oxalate and magnesium as magnesium pyrophosphate, organic precipitants.

Recommended Books:

1. Becket & Stenlake, 'Practical Pharmaceutical Chemistry', Vol. 1, 2, 4th Edn., CBS Publishers, New Delhi, **2005**.
2. Jeffery, Bassett & Mendham, 'Vogel's Text Book of Quantitative Chemical Analysis', 5th Edn., Addison Wesley Longman Ltd., England, **1996.**
3. K. Danzer, 'Analytical Chemistry', Springer, **2007.**
4. R.M. Verma, 'Analytical Chemistry', 3rd Edn., CBS Publishers, New Delhi, **2007.**
5. Alexeyev, 'Qualitative Analysis'. 2nd Edn., CBS Publishers, New Delhi, **2005.**
6. L.M. Atherden, 'Bentley and Driver's Textbook of Pharmaceutical Chemistry', Oxford University Press, Delhi.

COMPUTER SCIENCE & APPLICATIONS

Subject Code: BCAP0-195 **L T P C** **Duration: 35 Hrs.**
2 1 0 3

Scope of the Subject: Subject deals with computer fundamentals and operating system. Computer applications are expected to offer various pharmaceutical services as drug information services, drug design and pharmacokinetic analysis.

Objectives of the Subject: Upon completion of the subject student shall be able

1. To understand the basic MS-Word, MS- Excel and MS- Power point
2. To know computer programming, data analysis, calculation and graphing using formulae and function.

UNIT-I (9 Hrs.)

Computer Fundamentals Introduction to Computers:
Characteristics of computers, Historical perspectives of computers, Computer generations, types of computers and uses, Software, Hardware, Basic architecture and functions of CPU and its parts, Important I/O devices like Keyboard, Mouse, Printers, Video Monitors;

Number System: Decimal, Binary, Basic Binary arithmetic (Conversion to and from decimal numbers, Binary addition and subtraction;

Memory Storage: Memory Cells, Semiconductor and Magnetic core memory, ROM (its types), RAM, Cache and Virtual memory, Secondary storage devices and their organization (Hard disk, Floppy disk, CD, DVD).

Operating Systems: Definitions, Need, Organization, Functions, Types of Operating Systems, DOS, Windows, Handling Drives, Directories and files, Commands (Internal & External), Icons, Clipboard, Folders, Major differences between DOS & Windows.

UNIT-II (9 Hrs.)

Communication Networks:
Hardware and software components, seven layers of OSI architecture, Network Topologies (Ring, Star, Fully Connected and Bus), LAN and WAN, Bounded and unbounded communication media, Internet, World Wide Web and I.T., Browsers, Important terminology regarding Internet applications, Electronic Mail, Potential uses and abuses of Internet.

Computer Programming:
Programming languages, Classifications, Low level and high level languages, merits and demerits of languages, object oriented languages, Syntax and semantics, Basic steps involved in software development, Flow charts, Compilers and Interpreters.

UNIT-III (10 Hrs.)

Simple Programming Using:
C Data types, Constants, Variables, Arithmetic and relational expressions, Symbolic constants, Input and output assignment statements, If-else, Switch statements, Loops (While, do-while and for), Transfer statements, Problem solving using "C" taking simple algorithms.

Computer Applications Word Processing:
Techniques, File manipulation, Formatting, Printing setups Table handling, Mail merge, etc. using MS-Word;
Spreadsheet Package: Worksheets, formatting sheets, Calculations and graphing using formulae and functions, Import and export of data using MS-Excel.

UNIT- IV (7Hrs.)

Computer Applications Graphics:
Objectives and types of graphics, Presentation packages, Slides designing, Diagrams and graphs, Import & Export data using MS-Power Point**;**
Data Security against Viruses: Definition of computer viruses, Detection, prevention and cure against viruses using anti-virus software packages.
Pharmaceutical Applications:
Basics of computer use in various pharmaceutical and clinical applications like drug information services, hospital and community pharmacy, drug design, pharmacokinetics and data analysis.
Recommended Books:
1. Rajaraman, 'Fundamentals of Computers', Prentice Hall of India.
2. N.K. Tiwari, 'Computer Fundamental with Pharmacy Applications', 1st Edn., Pharm. Med Press, **2008.**
3. Stultz, 'Learn MS-Office 2000', BPB Publications.
4. Ivens, 'Using Microsoft Windows', Prentice Hall of India, **1998.**
5. Stultz, 'Learn DOS in a day', BPB Publications.

INTRODUCTION TO DOSAGE FORM

Subject Code: BPHA1-104 **L T P C** **Duration: 35 Hrs.**
2 1 0 3

UNIT-I (2 Hrs.)

Pharmacy Profession:
History of Pharmacy, Pharmacy as a career, Pharmaceutical education in India and abroad, Pharmacopoeia of India and other Pharmacopoeias, Other official books.

UNIT-II (13 Hrs.)

Introduction to different dosage forms, their classification with examples (Official formulation), their relative application; Definitions, general formulation, manufacturing procedures and official products of solutions, aromatic waters, syrups, spirits, elixirs, glycerides, lotions, liniments, gargles, mouth washes, suspension, emulsion, douches, draught preparation.

UNIT-III (10 Hrs.)

Additive of dosage forms Introduction, classification and uses of following additives in formulation of different dosage forms: preservatives, antioxidants, surfactants, hydrocolloids, emulsify agent, suspending agent, Diluents, binders, lubricants, organoleptic additives.

UNIT-IV (10 Hrs.)

Crude Extracts: Infusion, decoction, tincture, and extracts, methods of preparation of dry, soft and liquid extracts of IP.
Allergenic Extracts: Types of allergens, preparation of extracts testing and standardization of extracts.
Important Terms of Pharmaceutics Definition and examples of expectorant, pharmaceutical aid, additives.
Recommended Books:
1. 'Remington's Pharmaceutical Sciences'.

2. 'Pharmacopoeia of India', Govt. of India, Ministry of Health.
3. Ansel, 'Introduction to Pharmaceutical Dosage Forms'.

PHARMACOGNOSY-I LAB.

Subject Code: BPHA1-105 **L T P C**
0 0 4 2

1. To study different features of a dicot stem (Sunflower)
2. To study different feature of a dicot root
3. To study various pharmacognostic characteristics of a monocot stem
4. To study various pharmacognostic characteristics of a monocot root (Maize)
5. To study various pharmacognostic characteristics of a monocot leaf
6. To study various pharmacognostic characteristics of a dicot leaf
7. To determine the veinislet and veinlet termination number.
8. To study diagnostic features of *Vinca rosea* (Apocynaceae)
9. To study diagnostic features of *Datura stramonium/metel* (Solanaceae)
10. To study diagnostic features of *Ocimum bassilicum* (Labiatae)
11. To study diagnostic features of *Brassica compestris* (Cruciferae)
12. To study diagnostic features of *Fennel* (Umbelliferae)
13. To study diagnostic features of *Cassia fistula* (Leguminosae)
14. To identify accacia gum by performing various tests
15. To identify tragacanth by performing various tests
16. To identify honey by performing various tests
17. To perform tests for identification of castor oil
18. To perform tests for identification of sesame oil
19. To determine the stomatal number and stomatal index of senna leaf
20. To determine the palisade ratio of Indian senna
21. To determine the average diameter of starch grains (Cinnamon powder)
22. To measure the average width of fiber in Cinnamon powder
23. Preparations of minimum of 50 herbarium sheets (one each for every student) of selected medicinal plants

Recommended Books:

1. G.E. Trease and W.C. Evans, 'Pharmacognosy', Elsevier, a Division of Reed Elsevier India Pvt. Ltd., New Delhi.
2. V.E. Tyler, Jr. and A.E. Schwarting, 'Experimental Pharmacognosy', Burgess Pub. Co, Hinneapois, Minnesotta.
3. K.R. Brain and T.D. Turner, 'The Practical Evaluation of Phytopharmaceuticals', Wright-Scientechnica, Bristol.
4. T.E. Wallis, 'Practical Pharmacognosy', 4th Edn, PharmaMed Press, Hyderabad, India, **2011.**
5. C.K. Kokate, 'Practical Pharmacognosy', 4th Edn,. Published by M.K Jain for Vallabh Prakashan, Delhi, India, **1994.**

PHARMACEUTICAL CHEMISTRY-I (INORGANIC PHARMACEUTICAL CHEMISTRY) LAB.

Subject Code: BPHA1-106 **L T P C**
0 0 4 2

1. To analyse the presence of acid radicals (anions) in the given mixture.
2. To analyse the presence of six radicals (three anions and three cations) in the given

mixture by semi-micro method.
3. To perform detection of group I and group II radicals.
4. To perform determination of melting point and boiling points.
5. To perform identification tests for Magnesium Sulphate
6. To perform identification tests for Calcium chloride.
7. To perform identification tests for barium sulphate.
8. To perform identification tests for Hydrochloric acid and qualitatively analyse the chloride ions.
9. To perform identification tests for ferrous sulphate.
10. To perform identification tests for hydrogen peroxide.
11. To perform identification tests for Boric acid**.**
12. To perform identification tests for Potassium permanganate and qualitatively analyse for potassium ions.
13. To perform identification tests for ammonium chloride and qualitatively analyse for ammonium as cation and chloride as anion.
14. To perform limit tests for chloride in Magnesium sulphate.
15. To perform limit tests for sulphate.
16. To perform limit tests for iron.
17. To perform limit tests for heavy metals.
18. To perform limit tests for Arsenic.

Recommended Books:

1. Nirmal Sharma, Yogeshwar Sharma, K.K. Thakur, Pratibha Nand, G.C. Sharma, 'Practical Inorganic Pharmaceutical Chemistry and Viva- voce', 1st Edn., Birla Publications Pvt. Ltd., **2007.**
2. Singh & Kapoor, 'Practical Pharmaceutical Chemistry', 4th Edn., Vallabh Prakashan, Delhi, **1998.**
3. G. Devala Rao, 'Practical Pharmaceutical Inorganic Chemistry', 3rd Edn., Birla Pub. (20101-2011).
4. Anees Ahmed Siddiqui, Mohammed Ali, 'Practical Pharmaceutical Chemistry', 1st Edn., CBS Publishers, **1997.**

PHARMACEUTICAL ANALYSIS-I LAB.

Subject Code: BPHA1-107 **L T P C**
0 0 4 2

1. To study the typical analytical balance, the requirements of a good balance, weights, care and use of balance, methods of weighing and errors in weighing.
2. To perform calibration of volumetric apparatus and weights including fractional weight using digital weighing balance of sensitivity 01 mg.
3. To carry out the standardization of 0.1 N HCl using standard solution of sodium carbonate.
4. To carry out the standardization of 0.1 N H_2SO_4 using standard solution of sodium carbonate.
5. To standardize the given of 0.1 N NaOH using standard solution of oxalic acid.
6. To perform the assay of given sample of sodium bicarbonate.
7. To perform the assay of given sample of boric acid.
8. To perform the assay of given sample borax using standard solution of HCl.
9. To standardise the given solution of 0.1N $KMnO_4$ using standard solution of oxalic acid.
10. To perform the assay of given sample of ferrous sulphate using standard solution of

$KMnO_4$.

11. To perform the assay of the given sample of copper sulphate.
12. To perform the assay of the given sample of sodium chloride.
13. To perform the assay of the given sample of KCl.
14. To prepare and standardize 0.1 N iodine solution.
15. To prepare and standardise 0.1 N sodium thiosulphate solution.
16. To estimate the amount of barium present in the given solution

Recommended Books:

1. Jeffery, Bassett & Mendham, 'Vogel Text Book of Quantitative Chemical Analysis', 5th Edn., Addison Wesley Longman ltd England, **1996.**
2. R.M. Verma, 'Analytical Chemistry', 3rd Edn., CBS Publishers, New Delhi. Becket & Stenlake, **2007.**
3. 'Practical Pharmaceutical Chemistry', Vol.1 & 2, 4th Edn., CBS publishers, New Delhi, **2005.**
4. Alexeyev, 'Quantative Analysis', 2nd Edn., CBS publishers, New Delhi, **2005.**
5. L.M. Atherden, 'Bentley and Driver's Textbook of Pharmaceutical Chemistry', Oxford University Press, Delhi.

COMPUTER SCIENCE & APPLICATIONS LAB.

Subject Code: BCAP0-196 **L T P C**
0 0 4 2

1. Give the various components, their functions and identification of various parts of a computer and peripherals. Perform installation of a computer and loading system software and application software.
2. Installation of DOS and simple exercises on TYPE, REN, DEL, CD, MD, COPY, TREE, BACKUP commands.
3. Exercises on entering text and data (Typing Practice) Features of Windows as an operating system.
4. File Management using Ms Word, Page set up using Ms Word Editing a document using Ms Word.
5. Formatting a document using Ms Word Tables and Borders using Ms Word Working with more than one window in MS Word.
6. Perform application of MS Excel.
7. Application of Menu commands, Work books and Creating a chart.
8. Customize MS-Excel.
9. Introduction to MS-Power Point and use of Wizards and Templates Preparing Presentations.
10. Prepare and submit a scientific power point presentation using various effects and application of power point.
11. Prepare a program in C language to find sum of any two numbers.
12. Prepare a program in C language to find gross salary.
13. Prepare a program in C language to find table (mathematical) of any number.
14. Prepare a program in C language to find greatest in 3 numbers.
15. Prepare a program in C language to show the use of conditional operator.
16. Program to find that entered year is leap year or not.
17. Prepare a program in C language to find whether given no is even or odd
18. Display the kind of output on screen (in the left of the screen)
    a. 1
    b. 22

c. 333
d. 4444

19. Write a C program to find the sum of first 100 natural numbers.
20. Prepare a program in C language to find the sum of first 100 odd or even numbers.
21. Write a C program to display first 25 Fibonacci number.
22. Write a C program to display first 100 prime numbers.
23. Write a C program to find factorial numbers and to print the accepted no and its reverse number.

HUMAN ANATOMY AND PHYSIOLOGY-I

Subject Code: BPHA1-208 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

Scope:

1. 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.

Course Objectives:

Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human 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 various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

UNIT-I (11 Hrs.)

Introduction to Human Body:

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

Cellular Level of Organization:

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

Tissue Level of Organization:

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

UNIT-II (11 Hrs.)

Integumentary System:

1. Structure and functions of skin

Skeletal System:

1. Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system
2. Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction.

Joints:

1. Structural and functional classification, types of joints movements and its articulation

UNIT-III (12 Hrs.)

Body Fuids and Blood:

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

Lymphatic System:

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

Peripheral Nervous System:

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

Special Senses:

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

UNIT-IV (11 Hrs.)

Cardiovascular System:

1. Heart – anatomy of heart, blood circulation, blood vessels,
2. Structure and functions of artery, vein and capillaries,
3. Elements of conduction system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle.
4. Regulation of blood pressure, pulse, electrocardiogram
5. Disorders of heart.

Recommended Books

1. K. Sembulingam and P. Sembulingam, 'Essentials of Medical Physiology', Jaypee Brothers Medical Publishers, New Delhi.
2. Kathleen J.W. Wilson, 'Anatomy and Physiology in Health and Illness', Churchill Livingstone, New York.
3. Best and Tailor, 'Physiological Basis of Medical Practice', Williams & Wilkins Co, Riverview, MI USA.
4. C. Arthur, Guyton and John. E. Hall, 'Text book of Medical Physiology', Miamisburg, OH U.S.A.
5. Tortora Grabowski, 'Principles of Anatomy and Physiology', Palmetto, GA, U.S.A.
6. Inderbir Singh, 'Textbook of Human Histology', Jaypee Brother's Medical Publishers, New Delhi.
7. C.L. Ghai, 'Textbook of Practical Physiology', Jaypee Brother's Medical Publishers, New Delhi.
8. K. Srinageswari and Rajeev Sharma, 'Practical Workbook of Human Physiology', Jaypee Brother's Medical Publishers, New Delhi.
9. Best and Tailor, 'Physiological Basis of Medical Practice', Williams & Wilkins Co, Riverview, MI USA.
10. Arthur C. Guyton and John. E. Hall, 'Text book of Medical Physiology', Miamisburg, OH, U.S.A.
11. C.C. Chatterrje, 'Human Physiology', Vol. 1, 2, Academic Publishers, Kolkata.

PHARMACEUTICAL ORGANIC CHEMISTRY-I

Subject Code: BPHA1-209 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

Scope:

1. 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.

Course 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

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained to emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I (10 Hrs.)

Classification, Nomenclature and Isomerism

1. Classification of Organic Compounds
2. Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds)
3. Structural isomerism in organic compounds

UNIT-II (12 Hrs.)

Alkanes*, Alkenes* and Conjugated dienes*

1. SP_3 hybridization in alkanes, Halogenation of alkanes, uses of paraffin. Stabilities of alkenes, SP_2 hybridization in alkenes
2. E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E1 verses E2 reactions, Factors affecting E1 and E2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.
3. Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III (12 Hrs.)

Alkyl halides*

1. SN1 and SN2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.
2. SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions
3. Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

Alcohols*-

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

UNIT-IV (11 Hrs.)

Carbonyl Compounds* (Aldehydes and Ketones)

1. Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin

condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanillin, Cinnamaldehyde.

Carboxylic acids*

1. Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester
2. 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
3. Aliphatic amines* - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine.

Recommended Books:

1. Morrison and Boyd, 'Organic Chemistry'.
2. I.L. Finar, 'Organic Chemistry', Volume-I.
3. B.S. Bahl & Arun Bahl, 'Textbook of Organic Chemistry'.
4. P.L. Soni, 'Organic Chemistry'.
5. Mann and Saunders, 'Practical Organic Chemistry'.
6. 'Vogel's Text Book of Practical Organic Chemistry'.
7. N.K. Vishnoi, 'Advanced Practical Organic Chemistry'.
8. Pavia, Lampman and Kriz, 'Introduction to Organic Laboratory Techniques'.

BIOCHEMISTRY

Subject Code: BPHA1-210 **L T P C** **3 1 0 4** **Duration: 45 Hrs.**

Scope:

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

Course Objectives:

Upon completion of course student shell able to

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

UNIT-I (11 Hrs.)

Biomolecules:

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

Bioenergetics:

1. Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.
2. Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT-II (11 Hrs.)

Carbohydrate Metabolism:

1. Glycolysis – Pathway, energetics and significance
2. Citric acid cycle- Pathway, energetics and significance

3. HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency,
4. Glycogen metabolism Pathways and glycogen storage diseases (GSD)
5. Gluconeogenesis- Pathway and its significance
6. Hormonal regulation of blood glucose level and Diabetes mellitus

Biological Oxidation:

1. Electron transport chain (ETC) and its mechanism.
2. Oxidative phosphorylation & its mechanism and substrate level phosphorylation
3. Inhibitors ETC and oxidative phosphorylation/Uncouplers.

UNIT-III (12 Hrs.)

Lipid Metabolism:

1. β-Oxidation of saturated fatty acid (Palmitic acid)
2. Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid)
3. Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D
4. Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

Amino Acid Metabolism:

1. General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders
2. Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)
3. Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline
4. Catabolism of heme; hyperbilirubinemia and jaundice

UNIT-IV (11 Hrs.)

Nucleic Acid Metabolism and Genetic Information Transfer:

1. Biosynthesis of purine and pyrimidine nucleotides
2. Catabolism of purine nucleotides and Hyperuricemia and Gout Disease Organization of mammalian genome
3. Structure of DNA and RNA and their functions DNA replication (semi conservative model) Transcription or RNA synthesis
4. Genetic code, Translation or Protein synthesis and inhibitors

Enzymes:

1. Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)
2. Enzyme inhibitors with examples
3. Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation
4. Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes – Structure and biochemical functions

Recommended Books:

1. Lehninger, ‘Principles of Biochemistry’.
2. Robert K. Murry, Daryl K. Granner and Victor W. Rodwell, ‘Biochemistry’, Harper Stryer, ‘Biochemistry’.
3. D. Satyanarayan and U. Chakrapani, ‘Biochemistry’.
4. Rama Rao, ‘Textbook of Biochemistry ‘.
5. R.C. Gupta and S. Bhargavan, ‘Practical Biochemistry’.
6. David T. Plummer, ‘Introduction of Practical Biochemistry’,3rd Edn.
7. Rajagopal and Ramakrishna, ‘Practical Biochemistry for Medical Students’.
8. Harold Varley, ‘Practical Biochemistry’.

PHYSICAL PHARMACEUTICS-I

Subject Code: BPHA1-211 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

Scope:

1. The course deals with the various physical and physicochemical properties, and the 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.

Course Objectives:

Upon the completion of the course student shall be able to

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

UNIT-I (11 Hrs.)

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

UNIT-II (11 Hrs.)

States of Matter and Properties of Matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols–inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical Properties of Drug Molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III (11 Hrs.)

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

UNIT-IV (12 Hrs.)

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.

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.

Recommended Books:

1. Alfred Martin, 'Physical Pharmacy'.
2. Eugene, Parott, 'Experimental Pharmaceutics'.
3. Cooper and Gunn, 'Tutorial Pharmacy'.
4. H.A. Liberman, C. Lachman, 'Pharmaceutical Dosage Forms, Tablets', Volume-1-3, Marcel Dekkar Inc.

5. H.A. Liberman, C. Lachman, 'Pharmaceutical Dosage Forms, Disperse Systems', volume 1, 2, 3. Marcel Dekkar Inc.
6. C. Ramasamyand R. Manavalan, 'Physical Pharmaceutics'.
7. C.V.S. Subramanyam, J. Thimma Settee, 'Laboratory Manual of Physical Pharmaceutics'.
8. C.V.S. Subramanyam, 'Physical Pharmaceutics'.
9. Gaurav Jain & Roop K. Khar, 'Text Book of Physical Pharmacy'.

REMEDIAL BIOLOGY

Subject Code: BPHA1-212 **L T P C** **Duration: 25 Hrs.**
2 0 0 2

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

Course Objectives:
Upon completion of the course, the student shall be able to
1. Know the classification and salient features of five kingdoms of life
2. Understand the basic components of anatomy & physiology of plant
3. Know understand the basic components of anatomy & physiology animal with special reference to human

UNIT-I (6 Hrs.)

Living World:
1. Definition and characters of living organisms
2. Diversity in the living world
3. Binomial nomenclature
4. Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering Plants:
1. Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
2. General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledons.

UNIT-II (7 Hrs.)

Body Fluids and Circulation:
1. Composition of blood, blood groups, coagulation of blood
2. Composition and functions of lymph
3. Human circulatory system
4. Structure of human heart and blood vessels
5. Cardiac cycle, cardiac output and ECG

Digestion and Absorption:
1. Human alimentary canal and digestive glands
2. Role of digestive enzymes
3. Digestion, absorption and assimilation of digested food

Breathing and Respiration:
1. Human respiratory system
2. Mechanism of breathing and its regulation
3. Exchange of gases, transport of gases and regulation of respiration
4. Respiratory volumes

UNIT-III (6 Hrs.)

Excretory Products and their Elimination:
1. Modes of excretion

2. Human excretory system- structure and function
3. Urine formation
4. Rennin angiotensin system

Neural Control and Coordination:

1. Definition and classification of nervous system
2. Structure of a neuron
3. Generation and conduction of nerve impulse
4. Structure of brain and spinal cord
5. Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical Coordination and Regulation:

1. Endocrine glands and their secretions
2. Functions of hormones secreted by endocrine glands

Human Reproduction:

1. Parts of female reproductive system
2. Parts of male reproductive system
3. Spermatogenesis and Oogenesis
4. Menstrual cycle

UNIT-IV (6 Hrs.)

Plants and Mineral Nutrition:

1. Essential mineral, macro and micronutrients
2. Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis:

1. Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

Plant Respiration:

1. Respiration, glycolysis, fermentation (anaerobic).

Plant Growth and Development:

1. Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators

Cell - The UNIT of Life:

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

Tissues:

1. Definition, types of tissues, location and functions.

Recommended Books:

1. S.B. Gokhale, ‘Text book of Biology’.
2. Thulajappa and Seetaram, ‘A Text Book of Biology’.
3. Naidu and Murthy, ‘A Text Book of Biology’.
4. A.C. Dutta, ‘Botany for Degree Students’.
5. M. Ekambaranatha Ayyer and T.N. Ananthakrishnan, ‘Outlines of Zoology’.
6. S.B. Gokhale and C.K. Kokate, ‘A Manual for Pharmaceutical Biology Practical’.

REMEDIAL MATHEMATICS

Subject Code: BPHA1-213 **L T P C** **Duration: 38 Hrs.**
3 0 0 3

Scope:

1. 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.

Course 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

UNIT – I (6 Hrs.)

Partial Fraction:

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

Logarithms:

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

Function:

1. Real Valued function, Classification of real valued functions,
   - **Limits and continuity** :

   Introduction , Limit of a function, Definition of limit of a function (□ - □□ definition) , lim ^{xn}□□^{an}□$_{na}$ n□1 , $\lim \frac{\sin \square}{\square_{\square}^{\square}}$ 1, x□ □□ a x □ a 0 □□

UNIT-II (6 Hrs.)

Matrices and Determinant:

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

UNIT-II (6 Hrs.)

Calculus:

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

UNIT–IV (7 Hrs.)

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

Differential Equations:

1. Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear
2. Differential equations, Exact equations, Application in solving Pharmacokinetic equations

Laplace Transform:

1. Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, Application in solving Chemical kinetics and Pharmacokinetics equations

Recommended Books:

1. Shanthinarayan, 'Differential Calculus'.
2. Panchaksharappa Gowda D.H., 'Pharmaceutical Mathematics with Application to Pharmacy'.
3. Shanthinarayan, 'Integral Calculus'.
4. B.S. Grewal, 'Higher Engineering Mathematics'.

ENVIRONMENTAL SCIENCES

Subject Code: BPHA1-214 **L T P C** **Duration: 38 Hrs.**
3 0 0 3

Scope:

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

Course 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 environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

UNIT-I (11 Hrs.)

1. The Multidisciplinary nature of environmental studies
2. Natural Resources
3. Renewable and non-renewable resources:
4. Natural resources and associated problems

UNIT-II (11 Hrs.)

1. 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-III (12 Hrs.)

1. Ecosystems
2. Concept of an ecosystem.
3. Structure and function of an ecosystem.
4. 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- IV (11 Hrs.)

1. Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books:

1. Y.K. Sing, 'Environmental Science', New Age International Pvt, Publishers, Bangalore.
2. K.C. Agarwal, 'Environmental Biology', Nidi Publ. Ltd. Bikaner, **2001.**
3. Bharucha Erach, 'The Biodiversity of India,' Mapin Publishing Pvt. Ltd.
4. R.C. Brunner, 'Hazardous Waste Incineration', McGraw Hill Inc.
5. R.S. Clark, 'Marine Pollution', Clanderson Press Oxford.
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 'Environmental Encyclopedia', Jaico Publ. House, Mumbai, 1196p, **2001**.
7. A.K. De, 'Environmental Chemistry', Wiley Eastern Ltd.
8. 'Down of Earth', Centre for Science and Environment.

HUMAN ANATOMY AND PHYSIOLOGY LAB.

Subject Code: BPHA1-215 **L T P C**
0 0 4 2

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:

1. K. Sembulingam and P. Sembulingam, 'Essentials of Medical Physiology' Jaypee Brothers Medical Publishers, New Delhi.
2. Kathleen J.W. Wilson, 'Anatomy and Physiology in Health and Illness', Churchill Livingstone, New York.
3. Best and Tailor, 'Physiological Basis of Medical Practice', Williams & Wilkins Co, Riverview, MI USA.
4. C. Arthur, Guyton and John. E. Hall, 'Text Book of Medical Physiology', Miamisburg, OH, U.S.A.
5. Tortora Grabowski, 'Principles of Anatomy and Physiology', Palmetto, GA, U.S.A.
6. Inderbir Singh, 'Textbook of Human Histology', Jaypee Brother's Medical Publishers, New Delhi.
7. C.L. Ghai, 'Textbook of Practical Physiology', Jaypee Brother's Medical Publishers, New Delhi.

8. K. Srinageswari and Rajeev Sharma, 'Practical Workbook of Human Physiology', Jaypee Brothers Medical Publishers, New Delhi.

PHARMACEUTICAL ORGANIC CHEMISTRY-I LAB.

Subject Code: BPHA1-216 **L T P C**
0 0 4 2

A. Systematic qualitative analysis of unknown organic compounds like
   a) Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and
   b) unsaturation, etc.
   c) Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
   d) Solubility test
   e) Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
   f) Melting point/Boiling point of organic compounds
   g) Identification of the unknown compound from the literature using melting point/ boiling point.
   h) Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
   i) Minimum 5 unknown organic compounds to be analyzed systematically.

B. Preparation of suitable solid derivatives from organic compounds
C. Construction of molecular models

Recommended Books:

1. Morrison and Boyd, 'Organic Chemistry'.
2. I.L. Finar, 'Organic Chemistry', Volume-I.
3. B.S. Bahl & Arun Bahl, 'Textbook of Organic Chemistry'.
4. P.L. Soni, 'Organic Chemistry'.
5. Mann and Saunders, 'Practical Organic Chemistry'.
6. 'Vogel's Text Book of Practical Organic Chemistry'.
7. N.K. Vishnoi, 'Advanced Practical Organic Chemistry'.
8. Pavia, Lampman and Kriz, 'Introduction to Organic Laboratory Techniques'.
9. Ahluwaliah, Chatwal, 'Reaction and Reaction Mechanism'.

BIOCHEMISTRY LAB.

Subject Code: BPHA1-217 **L T P C**
0 0 4 2

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

12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books:

1. Lehninger, 'Principles of Biochemistry'.
2. Robert K. Murry, Daryl K. Granner and Victor W. Rodwell, 'Biochemistry', Harper.
3. Stryer, 'Biochemistry'
4. D. Satyanarayan and U. Chakrapani, 'Biochemistry'.
5. Rama Rao, 'Textbook of Biochemistry '.
6. R.C. Gupta and S. Bhargavan, 'Practical Biochemistry'.
7. David T. Plummer, 'Introduction of Practical Biochemistry', 3rd Edn.
8. Rajagopal and Ramakrishna, 'Practical Biochemistry for Medical Students'.
9. Harold Varley, 'Practical Biochemistry'.

PHYSICAL PHARMACEUTICS-I LAB.

Subject Code: BPHA1-218 **L T P C**
0 0 4 2

1. Determination the solubility of drug at room temperature
2. Determination of pK_a 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 CCl_4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books:

1. Alfred Martin, 'Physical Pharmacy'.
2. Eugene, Parott, 'Experimental Pharmaceutics'.
3. Cooper and Gunn, 'Tutorial Pharmacy'.
4. H.A. Liberman, C. Lachman, 'Pharmaceutical Dosage Forms, Tablets', Volume-1 to 3, Marcel Dekkar Inc.
5. H.A. Liberman, C. Lachman, 'Pharmaceutical Dosage Forms, Disperse Systems', Volume 1, 2, 3, Marcel Dekkar Inc.
6. C. Ramasamy and R. Manavalan, 'Physical Pharmaceutics'.
7. C.V.S. Subramanyam, J. Thimma Settee, 'Laboratory Manual of Physical Pharmaceutics'.
8. C.V.S. Subramanyam, 'Physical Pharmaceutics'.
9. Gaurav Jain & Roop K. Khar, 'Text Book of Physical Pharmacy'.

REMEDIAL BIOLOGY LAB.

Subject Code: BPHA1-219 **L T P C**
0 0 2 1

1. Introduction to experiments in biology
   a. Study of Microscope
   b. Section cutting techniques

c. Mounting and staining
d. Permanent slide preparation

2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Recommended Books:

1. S.R. Kale and R.R. Kale, 'Practical Human Anatomy and Physiology'.
2. S.B. Gokhale, C.K. Kokate and S.P. Shriwastava, 'A Manual of Pharmaceutical Biology Practical'.
3. M.J.H. Shafi, 'Biology Practical Manual according to National Core Curriculum', Biology Forum of Karnataka.

PHARMACEUTICAL ORGANIC CHEMISTRY–II

Subject Code: BPHA1-320 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

MRSPTU

Scope:

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

Course 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. prepare organic compounds

Course Content:

1. General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained
2. To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I (10 Hrs.)

Benzene and its Derivatives:

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

UNIT-II (10 Hrs.)

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

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

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

UNIT-III (10 Hrs.)

Fats and Oils:

1. **Fatty Acids:** reactions.
2. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
3. **Analytical Constants:** Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT-IV (08 Hrs.)

Polynuclear Hydrocarbons:

1. Synthesis, reactions

2. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT-V (07 Hrs.)

Cycloalkanes*

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

Recommended Books:

1. Morrison and Boyd, 'Organic Chemistry'.
2. I.L. Finar, 'Organic Chemistry', Volume-I.
3. B.S. Bahl & Arun Bahl, 'Textbook of Organic Chemistry'.
4. P.L. Soni ,'Organic Chemistry'.
5. Mann and Saunders, 'Practical Organic Chemistry'.
6. 'Vogel's Text Book of Practical Organic Chemistry'.
7. N.K. Vishnoi, 'Advanced Practical Organic Chemistry'.
8. Pavia, Lampman and Kriz, 'Introduction to Organic Laboratory Techniques'.

PHARMACEUTICAL MICROBIOLOGY

Subject Code: BPHA1-321 **L T P C** **Duration: 45 Hrs.**

3 1 0 4

Scope:

Study of all categories of microorganisms especially for the production of alcohol antibiotics, vaccines, vitamins enzymes etc.

Course Objectives:

Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterilization in pharmaceutical processing 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.

Unit-I (10 Hrs.)

1. Introduction, history of microbiology, its branches, scope and its importance.
2. Introduction to Prokaryotes and Eukaryotes
3. Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).
4. Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

Unit-II (10 Hrs.)

1. Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC).
2. Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.
3. Evaluation of the efficiency of sterilization methods.
4. Evaluation of the efficiency of sterilization methods
5. Equipment employed in large scale sterilization.
6. Sterility indicators.

Unit-III (10 Hrs.)

1. Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.
2. Classification and mode of action of disinfectants
3. Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions
4. Evaluation of bactericidal & Bacteriostatic.
5. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit-IV (08 Hrs.)

1. Designing of aseptic area, laminar flow equipment; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.
2. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic.

Unit-V (07 Hrs.)

1. Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.
2. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.
3. Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.
4. Application of cell cultures in pharmaceutical industry and research.

Recommended Books:

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

7. Cooper and Gunn's, 'Tutorial Pharmacy', CBS Publisher and Distribution.
8. Peppler, 'Microbial Technology'.
9. I.P., B.P., U.S.P.
10. Ananthnarayan, 'Text Book of Microbiology', Orient-Longman, Chennai.
11. Edward, 'Fundamentals of Microbiology'.
12. N.K. Jain, 'Pharmaceutical Microbiology', Vallabh Prakashan, Delhi.
13. 'Bergeys Manual of Systematic Bacteriology', Williams and Wilkins-A Waverly Company.

PHARMACEUTICAL ENGINEERING

Subject Code: BPHA1-322 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

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

Course 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 of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

UNIT-I (10 Hrs.)

1. **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.
2. **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.
3. **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 Hrs.)

1. **Heat Transfer**: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.
2. **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.
3. **Distillation:** Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT-III (08 Hrs.)

1. **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
2. **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 Hrs.)

1. **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.
2. **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 Hrs.)

1. **Materials of Pharmaceutical Plant Construction, Corrosion and its Prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and their prevention. Ferrous and nonferrous metals, inorganic and organic non-metals, basic of material handling systems.

Recommended Books:

1. Walter L. Badger & Julius Banchero, 'Introduction to Chemical Engineering'.
2. 'Solid Phase Extraction, Principles, Techniques and Applications'.
3. Mcabe Smith, 'Unit Operation of Chemical Engineering'.
4. C.V.S. Subrahmanyam et al., 'Pharmaceutical Engineering Principles and Practices'.
5. Martin, 'Remington Practice of Pharmacy'.
6. Lachmann, 'Theory and Practice of Industrial Pharmacy'.
7. C.V.S. Subrahmanyam et al., 'Physical Pharmaceutics'.
8. S.J. Carter, 'Cooper and Gunn's Tutorial Pharmacy'.

HUMAN ANATOMY AND PHYSIOLOGY-II

Subject Code: BPHA1-323 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

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.

Course Objectives:

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

1. Explain the gross morphology, structure and functions of various organs of the human 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.

Unit-I (10 Hrs.)

1. **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 Hrs.)

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

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

Unit-III (10 Hrs.)

1 **Respiratory System:** Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration.
Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

2. **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 Hrs.)

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

Unit-V (09 Hrs.)

1. **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.
2. **Introduction to Genetics:** Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance.

Recommended Books:

1 K. Sembulingam and P. Sembulingam, 'Essentials of Medical Physiology', Jaypee Brothers Medical Publishers, New Delhi.
2 'Anatomy and Physiology in Health and Illness', Kathleen J.W. Wilson, Churchill Livingstone, New York.
3 'Physiological Basis of Medical Practice-Best and Tailor', Williams & Wilkins Co, Riverview, MI USA.
4 C. Arthur, 'Text Book of Medical Physiology', Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
5 Tortora Grabowski, 'Principles of Anatomy and Physiology', Palmetto, GA, U.S.A.
6 Inderbir Singh, 'Textbook of Human Histology', Jaypee Brothers Medical Publishers, New Delhi.

7 Textbook of Practical Physiology by C.L. Ghai, Jaypee Brothers Medical Publishers, New Delhi.
8 K. Srinageswari and Rajeev Sharma, 'Practical Workbook of Human Physiology', 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 C. Arthur, 'Text Book of Medical Physiology', Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3 C.C. Chatterrje, 'Human Physiology', Vol. 1, 2, Academic Publishers, Kolkata.

PATHOPHYSIOLOGY

Subject Code: BPHA1-324 **L T P C** **Duration: 45 Hrs.**
3 1 0 4

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.

Course Objectives:

Upon completion of the subject student shall be able to –

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

MRSPTU

Unit-I (10 Hrs.)

1. **Basic Principles of Cell Injury and Adaptation:** Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance.
2. **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 (10 Hrs.)

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

Unit-II (10 Hrs.)

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

4. **Gastrointestinal System:** Peptic Ulcer

Unit-IV (8 Hrs.)

1. Inflammatory Bowel Diseases, Jaundice, Hepatitis (A, B, C, D, E, F) alcoholic liver disease.
2. **Disease of Bones and Joints:** Rheumatoid arthritis, osteoporosis and gout.
3. **Principles of Cancer:** Classification, etiology and pathogenesis of cancer.
4. **Diseases of Bones and Joints:** Rheumatoid Arthritis, Osteoporosis, Gout.
5. **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit-V (7 Hrs.)

1. **Infectious Diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections
2. **Sexually Transmitted Diseases:** AIDS, Syphilis, Gonorrhea

Recommended Books:

1. Vinay Kumar, Abul K. Abas, Jon C. Aster, 'Robbins & Cotran Pathologic Basis of Disease', South Asia Edn., Elsevier, India, **2014**.
2. Harsh Mohan, 'Text Book of Pathology', 6th Edn., Jaypee Publications, India, **2010**.
3. B. Laurence, C. Bruce, K. Bjorn, 'Goodman Gilman's The Pharmacological Basis of Therapeutics', 12th Edn., McGraw-Hill, New York, **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 Edn., United States.
5. William and Wilkins, Baltimore, **1991** [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston, 'Davidson's Principles and Practice of Medicine', 21st Edn., ELBS/Churchill Livingstone, London, **2010**.
7. A. Guyton, John E. Hall, 'Textbook of Medical Physiology', 12th Edn., W.B. Saunders Company, **2010**.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey, 'Pharmacotherapy: A Pathophysiological Approach', 9th Edn., McGraw-Hill Medical, London, **2014**.
9. V. Kumar, R.S. Cotran and S.L. Robbins, 'Basic Pathology', 6th Edn., WB Saunders Company, Philadelphia, **1997**.
10. Roger Walker, Clive Edwards, 'Clinical Pharmacy and Therapeutics', 3rd Edn., Churchill Livingstone Publication, London, **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.

PHARMACEUTICAL ORGANIC CHEMISTRY-II LAB.

Subject Code: BPHA1-325 **L T P C**
0 0 4 2

I. Experiments involving Laboratory Techniques:

1. Recrystallization
2. Steam distillation

II. Determination of following Oil Values (including Standardization of Reagents):

1. Acid value
2. Saponification value
3. Iodine value

III. Preparation of Compounds:

1. Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
2. 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
3. Acetanilide by halogenation (Bromination) reaction.
4. 5-Nitro salicylic acid/Meta dinitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
5. Benzoic acid from Benzyl chloride by oxidation reaction.
6. Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
7. 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
8. Benzil from Benzoin by oxidation reaction.
9. Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
10. Cinnammic acid from Benzaldehyde by Perkin reaction
11. P-Iodo benzoic acid from P-amino benzoic acid

PHARMACEUTICAL MICROBIOLOGY LAB.

Subject Code: BPHA1-326 **L T P C**
0 0 4 2

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

PHARMACEUTICAL ENGINEERING LAB.

Subject Code: BPHA1-327 **L T P C**
0 0 4 2

1 Determination of radiation constant of brass, iron, unpainted and painted glass.
2 Steam distillation – To calculate the efficiency of steam distillation.
3 To determine the overall heat transfer coefficient by heat exchanger.
4 Construction of drying curves (for calcium carbonate and starch).
5 Determination of moisture content and loss on drying.
6 Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
7 Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.

8 Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
9 Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
10 Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
11 Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
12 To study the effect of time on the Rate of Crystallization.
13 To calculate the uniformity Index for given sample by using Double Cone Blender.

HUMAN ANATOMY AND PHYSIOLOGY LAB.

Subject Code: BPHA1-328 **L T P C**
0 0 4 2

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

PHARMACEUTICAL ORGANIC CHEMISTRY –III

Subject Code: BPHA1-429 **T L P C** **Duration: 45 Hrs.**
1 3 0 4

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

Course Objectives:
At the end of the course, the student shall be able to
1. Understand the methods of preparation and properties of organic compounds.
2. Explain the stereo chemical aspects of organic compounds and stereo chemical reactions.

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

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

UNIT-I (10 Hrs.)

Stereo Isomerism:

Optical Isomerism:

Optical activity, enantiomerism, diastereoisomerism, meso compounds, Elements of symmetry, chiral and achiral molecules, DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers, Reactions of chiral molecules, Racemic modification and resolution of racemic mixture, Asymmetric synthesis: partial and absolute.

UNIT-II (10 Hrs.)

Geometrical Isomerism:

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems), Methods of determination of configuration of geometrical isomers, Conformational isomerism in Ethane, n-Butane and Cyclohexane, Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity, Stereospecific and stereoselective reactions.

UNIT-III (10 Hrs.)

Heterocyclic Compounds:

Nomenclature and classification, Synthesis, reactions and medicinal uses of following compounds/derivatives, Pyrrole, Furan, and Thiophene, Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene.

UNIT-IV (8 Hrs.)

Synthesis, reactions and medicinal uses of following compounds/derivatives, Pyrazole, Imidazole, Oxazole and Thiazole, Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine, Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives.

UNIT-V (7 Hrs.)

Reactions of Synthetic Importance:

Metal hydride reduction (NaBH4 and LiAlH4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction, Oppenauer-oxidation and Dakin reaction, Beckmanns rearrangement and Schmidt rearrangement, Claisen-Schmidt condensation.

Recommended Books:

1. I.L. Finar, ‘Organic Chemistry’, Vol.-I & II.
2. Arun Bahl, B.S. Bahl ‘A Text Book of Organic Chemistry’.
3. Raj K. Bansal, ‘Heterocyclic Chemistry’.
4. Morrison and Boyd, ‘Organic Chemistry’.
5. T.L. Gilchrist, ‘Heterocyclic Chemistry’.

MEDICINAL CHEMISTRY – I

Subject Code: BPHA1-430 **T L P C** **Duration: 45 Hrs.**

1 3 0 4

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.

Course 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 (SAR) of different class of drugs
4. Write the chemical synthesis of some drugs

Course Content:

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

UNIT- I (10 Hrs.)

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

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

Drug Metabolism: Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II (10 Hrs.)

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic Agents:

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

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

Adrenergic Antagonists:

Alpha Adrenergic Blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

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

UNIT-III (10 Hrs.)

Cholinergic Neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic Agents: SAR of Parasympathomimetic agents

Direct Acting Agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):

Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase Reactivator: Pralidoxime chloride.

Cholinergic Blocking Agents: SAR of cholinolytic agents

Solanaceous Alkaloids and Analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

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

UNIT-IV (8 Hrs.)

Drugs Acting on Central Nervous System:

A. Sedatives and Hypnotics:

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

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics:

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

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

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

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

Barbiturates: Phenobarbitone, Methabarbital. **Hydantoins:** Phenytoin*, Mephenytoin, Ethotoin **Oxazolidine diones:** Trimethadione, Paramethadione **Succinimides:** Phensuximide, Methsuximide, Ethosuximide* **Urea and monoacylureas**: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

MRSPTU

UNIT–V (7 Hrs.)

Drugs Acting on Central Nervous System:

General Anaesthetics:

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

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

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic Analgesics

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

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

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

MEDICINAL CHEMISTRY – I LAB.

Subject Code: BPHA1-434 **T L P C** **Duration: 4 Hours/Week**
0 0 4 2

I. Preparation of Drugs/Intermediates

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

II. Assay of Drugs

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

III. Determination of Partition Coefficient for any two drugs

Recommended Books:

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. Smith and Williams, 'Introduction to Principles of Drug Design'.
5. 'Remington's Pharmaceutical Sciences'.
6. 'Martindale's extra Pharmacopoeia'.
7. I.L. Finar, 'Organic Chemistry', Vol. II.
8. Lednicer, 'The Organic Chemistry of Drug Synthesis', Vol. 1-5.
9. 'Indian Pharmacopoeia'.
10. A.I. Vogel, 'Text Book of Practical Organic Chemistry'.

PHARMACOLOGY-I

Subject Code – BPHA1-431 **T L P C** **Duration: 45 Hrs.**
1 3 0 4

s

Scope:

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

Course Objectives:

Upon completion of this course the student should be able to

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.

3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences.

UNIT-I (8 Hrs.)

General Pharmacology:

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

UNIT-II (12 Hrs.)

General Pharmacology:

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

UNIT-III (10 Hrs.)

Pharmacology of Drugs Acting on Peripheral Nervous System

1. Organization and function of ANS.
2. Neurohumoral transmission,co-transmission and classification of neurotransmitters.
3. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
4. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
5. Local anesthetic agents.
6. Drugs used in myasthenia gravis and glaucoma.

UNIT-IV (8 Hrs.)

Pharmacology of Drugs Acting on Central Nervous System

1. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
2. General anesthetics and pre-anesthetics**.**
3. Sedatives, hypnotics and centrally acting muscle relaxants.
4. Anti-epileptics
5. Alcohols and disulfiram

UNIT-V (7 Hrs.)

Pharmacology of Drugs acting on Central Nervous System:

1. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
2. Drugs used in Parkinsons disease and Alzheimer’s disease.
3. CNS stimulants and nootropics.
4. Opioid analgesics and antagonists
5. Drug addiction, drug abuse, tolerance and dependence.

PHARMACOLOGY-I LAB.

Subject Code: BPHA1-430 **T L P C** **Duration: 4Hrs./Week**
0 0 4 2

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

Note: *All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and video.*

Recommended Books:

1. H.P. Rang, M.M. Dale, J.M. Ritter, R.J. Flower, Rang and Dale's Pharmacology, Churchil Livingstone, Elsevier.
2. B.G. Katzung, S.B. Masters, A.J. Trevor, '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., K.A. Brian, L.C. Robbin, G.B. Joseph, A.K. Wayne, R.W. Bradley, 'Applied Therapeutics, The Clinical use of Drugs', The Point Lippincott Williams &Wilkins
5. M.J. Mycek, S.B. Gelnet and M.M. Perper, 'Lippincott's Illustrated Reviews- Pharmacology'.
6. K.D. Tripathi, 'Essentials of Medical Pharmacology', JAYPEE Brothers Medical Publishers (P) Ltd., New Delhi.
7. H.L. Sharma, K.K. Sharma, 'Principles of Pharmacology', Paras Medical Publisher.
8. Charles R. Craig & Robert, 'Modern Pharmacology with Clinical Applications'.
9. M.N. Ghosh, 'Fundamentals of Experimental Pharmacology', Hilton & Company, Kolkata.
10. S.K. Kulkarni, 'Handbook of Experimental Pharmacology', Vallabh Prakashan.

PHYSICAL PHARMACEUTICS-II

Subject Code: BPHA1-432 **T L P C** **Duration: 45 Hrs.**
1 3 0 4

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.

Course Objectives:

Upon the completion of the course student shall be able to

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

UNIT-I (7 Hrs.)

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 Hrs.)

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

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

UNIT-III (10 Hrs.)

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

UNIT-IV (10 Hrs.)

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 Hrs.)

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

PHYSICAL PHARMACEUTICS- II LAB.

Subject Code: BPHA1-436

T	L	P	C
0	0	4	2

1. Determination of particle size, particle size distribution using sieving method
2. Determination of particle size, particle size distribution using Microscopic method
3. Determination of bulk density, true density and porosity
4. Determine the angle of repose and influence of lubricant on angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent

7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books:

1. Alfred Martin, 'Physical Pharmacy', 6th Edn.
2. Eugene, Parott, 'Experimental Pharmaceutics'.
3. Cooper and Gunn, 'Tutorial Pharmacy'.
4. Stocklosam J. 'Pharmaceutical Calculations', Lea & Febiger, Philadelphia.
5. H.A. Liberman, C. Lachman, 'Pharmaceutical Dosage Forms', Tablets, Vol. 1-3, Marcel Dekkar Inc.
6. H.A. Liberman, C. Lachman, 'Pharmaceutical Dosage Forms. Disperse Systems', Vol. 1,2,3. Marcel Dekkar Inc.
7. C. Ramasamy and R. Manavalan, 'Physical Pharmaceutics'.

PHARMACOGNOSY AND PHYTOCHEMISTRY-I

Subject Code: BPHA1-433 **T L P C** **Duration: 45 Hrs.**
1 3 0 4

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.

Course 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

UNIT-I (10 Hrs.)

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, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II (10 Hrs.)

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 (7 Hrs.)

Plant Tissue Culture:

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

Applications of plant tissue culture in pharmacognosy.

Edible vaccines

UNIT-IV (10 Hrs.)

Pharmacognosy in various systems of medicine:

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

Introduction to secondary metabolites:

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

UNIT-V (8 Hrs.)

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

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary Metabolites:

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

Carbohydrates: Acacia, Agar, Tragacanth, Honey

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

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

Marine Drugs:

Novel medicinal agents from marine sources

PHARMACOGNOSY AND PHYTOCHEMISTRY-I LAB.

Subject Code: BPHA1-437

T	L	P	C
0	0	4	2

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 Edn., W.B. Sounders & Co., London, **2009**.

2. V.E. Tyler, L.R. Brady and J.E. Robbers, Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, **1988**.
3. T.E. Wallis, 'Text Book of Pharmacognosy'.
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. C.K. Kokate, Purohit, Gokhlae, 'Text Book of Pharmacognosy', 37th Edn., Nirali Prakashan, New Delhi, **2007**.
6. R.D. Choudhary, 'Herbal Drug Industry', 1st Edn, Eastern Publisher, New Delhi, **1996**.
7. 'Essentials of Pharmacognosy', S.H. Ansari, 2nd Edn., Birla Publications, New Delhi, **2007**.
8. C.K. Kokate, Purohit, Gokhlae, 'Practical Pharmacognosy'.
9. M.A. Iyengar, 'Anatomy of Crude Drugs'.

MRSPTU

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 superscripted (*)

UNIT- I **10 Hours**

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

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

H_2-antagonists: Cimetidine*, Famotidine, Ranitidin.

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

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan,

Chlorambucil, Busulfan, Thiotepa

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II **10 Hours**

Anti-anginal:

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

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

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

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

UNIT- III **10 Hours**

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

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

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

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

UNIT- IV **08 Hours**

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

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

UNIT – V **07 Hours**

Antidiabetic agents:

Insulin and its preparations

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

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

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

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

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

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Recommended Books (Latest Editions)

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.

BP 502 T. Industrial PharmacyI (Theory)

45 Hours

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

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

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

Course content:

3 hours/ week

UNIT-I **07 Hours**

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

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

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

BCS classification of drugs & its significant

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

UNIT-II **10 Hours**

Tablets:

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

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

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

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

UNIT-III **08 Hours**

Capsules:

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

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

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

UNIT-IV **10 Hours**

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and 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; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

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

BP 506 P. 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.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10hours**

1. Pharmacology of drugs acting on cardio vascular 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 **10hours**

1. Pharmacology of drugs acting on cardio vascular system

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

2. Pharmacology of drugs acting on urinary system

a. Diuretics
b. Anti-diuretics.

UNIT-III **10hours**

3. Autocoids and related drugs

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

UNIT-IV **08hours**

5. Pharmacology of drugs acting on endocrine system

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

UNIT-V **07hours**

5. Pharmacology of drugs acting on endocrine system

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

6. Bioassay

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

BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of 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 of drug using central and peripheral methods

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

Recommended Books (Latest Editions)

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

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

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

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

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

Course Content:

UNIT-I **7 Hours**

Metabolic pathways in higher plants and their determination

a) Brief study of basic metabolic pathways and formation of different secondary 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, biosources, therapeutic uses and commercial applications of following

secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,
Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta
Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis
Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,
Tannins: Catechu, Pterocarpus
Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony
Glycosides: Senna, Aloes, Bitter Almond
Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III **06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

a) Terpenoids: Menthol, Citral, Artemisin
b) Glycosides: Glycyrhetinic acid & Rutin
c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine
d) Resins: Podophyllotoxin, Curcumin

UNIT-IV **10 Hours**

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

UNIT V **8 Hours**

Basics of Phytochemistry

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

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, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

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 of pharmaceuticals.
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.

UNIT-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

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

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

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

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

UNIT-III **10 Hours**

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

Penalties

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

UNIT-IV **08 Hours**

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

UNIT-V **07 Hours**

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

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh

2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.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)

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

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

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

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 superscripted by (*)

UNIT – I **10 Hours**

Antibiotics

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

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

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II **10 Hours**

Antibiotics

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

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

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

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

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

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

UNIT – IV **08 Hours**

Antifungal agents:

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

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

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

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

Sulphonamides and Sulfones

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

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V **07 Hours**

Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

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

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

1 Sulphanilamide

2 7-Hydroxy, 4-methyl coumarin

3 Chlorobutanol

4 Triphenyl imidazole

5 Tolbutamide

6 Hexamine

II Assay of drugs

1 Isonicotinic acid hydrazide

2 Chloroquine

3 Metronidazole

4 Dapsone

5 Chlorpheniramine maleate

6 Benzyl penicillin

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

IV Drawing structures and reactions using chem draw®

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

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

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

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10hours**

1. Pharmacology of drugs acting on Respiratory system

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

2. Pharmacology of drugs acting on the Gastrointestinal Tract

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

UNIT-II **10hours**

3. Chemotherapy

a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

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

UNIT-III **10hours**

3. Chemotherapy

a. Antitubercular agents

b. Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08hours**

3. Chemotherapy

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

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

UNIT-V **07hours**

5. Principles of toxicology

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

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

c. General principles of treatment of poisoning

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

6. Chronopharmacology

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

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

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

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

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

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

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

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.

UNIT-II **7 Hours**

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.
Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

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

UNIT-III **10 Hours**

Herbal Cosmetics

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

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

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

UNIT- IV **10 Hours**

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

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

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

UNIT-V **07 Hours**

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

Schedule T – Good Manufacturing Practice of Indian systems of medicine
Components of GMP (Schedule – T) and its objectives
Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

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 and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy 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 of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Introduction to Biopharmaceutics

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

UNIT- II **10 Hours**

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

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

UNIT- III **10 Hours**

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

UNIT- IV **08 Hours**

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

UNIT- V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.
c. Michaelis-menton method of estimating parameters, Explanation with example 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 4th edition,Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

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

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

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 in Industries
4. Appreciate the use of microorganisms in fermentation technology

Unit I **10 Hours**

a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.

c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

d) Brief introduction to Protein Engineering.

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

f) Basic principles of genetic engineering.

Unit II **10 Hours**

a) Study of cloning vectors, restriction endonucleases and DNA ligase.

b) Recombinant DNA technology. Application of genetic engineering in medicine.

c) Application of r DNA technology and genetic engineering in the production of:

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

d) Brief introduction to PCR

Unit III **10 Hours**

Types of immunity- humoral immunity, cellular immunity

a) Structure of Immunoglobulins

b) Structure and Function of MHC

c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.

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

e) Storage conditions and stability of official vaccines

f) Hybridoma technology- Production, Purification and Applications

g) Blood products and Plasma Substituties.

Unit IV **08Hours**

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

b) Genetic organization of Eukaryotes and Prokaryotes

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

d) Introduction to Microbial biotransformation and applications.

e) Mutation: Types of mutation/mutants.

Unit V **07 Hours**

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

b) Large scale production fermenter design and its various controls.

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

d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.

Recommended Books (Latest edition):

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

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

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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

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

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

Course content:

UNIT – I **10 Hours**

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

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

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

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

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

UNIT – III **10 Hours**

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

materials.

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

UNIT – IV **08 Hours**

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

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

UNIT – V **07 Hours**

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

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

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

SEMESTER VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

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

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

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

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

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

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

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

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

UNIT –II **10 Hours**

IR spectroscopy

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

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

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III **10 Hours**

Introduction to chromatography

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

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

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

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT –IV **08 Hours**

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

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

UNIT –V **07 Hours**

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

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

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

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical 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

BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

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

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

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of 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 agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III **10 Hours**

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

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

UNIT-IV **08 Hours**

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

UNIT-V **07 Hours**

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

Recommended Books: (Latest Editions)

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

BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

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

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

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 clinical review
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.

Unit I: **10 Hours**

a) Hospital and it's organization

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

b) Hospital pharmacy and its organization

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

c) Adverse drug reaction

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

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

d) Community Pharmacy

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

Unit II: 10 Hours

a) Drug distribution system in a hospital

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

b) Hospital formulary

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

c) Therapeutic drug monitoring

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

d) Medication adherence

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

e) Patient medication history interview

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

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III: 10 Hours

a) Pharmacy and therapeutic committee

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

b) Drug information services

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

c) Patient counseling

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

d) Education and training program in the hospital

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

e) Prescribed medication order and communication skills

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

Unit IV 8 Hours

a) Budget preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

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

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

c) Over the counter (OTC) sales

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

Unit V 7 Hours

a) Drug store management and inventory control

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

b) Investigational use of drugs

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

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

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

Journals:

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

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

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

Objectives: Upon completion of the course student shall be able

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

Course content:

Unit-I **10 Hours**

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

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

Unit-II **10 Hours**

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

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

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

Unit-III **10 Hours**

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

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

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

Unit-IV **08 Hours**

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

Unit-V **07 Hours**

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

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

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John 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, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

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

SEMESTER VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel**.**

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

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

Course content:

Unit-I **10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

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

Unit-II **10 Hours**

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples

Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

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

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

Unit-III **10 Hours**

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

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

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV **8 Hours**

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V **7Hours**

Design and Analysis of experiments:

Factorial Design: Definition, 2^2, 2^3design. Advantage of factorial design

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

Recommended Books (Latest edition):

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

BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

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

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

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

Course content:

Unit I: 10 Hours

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

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

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

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

Unit II: 10 Hours

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

Unit III: 10 Hours

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

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV: **08 Hours**

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

Unit V: **07 Hours**

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

Recommended Books (Latest edition)*:*

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

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope:

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

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

Unit I **10 Hours**

Marketing:

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

Pharmaceutical market:

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

Unit II **10 Hours**

Product decision:

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

Unit III **10 Hours**

Promotion:

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

Unit IV **10 Hours**

Pharmaceutical marketing channels:

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

Professional sales representative (PSR):

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

Unit V **10 Hours**

Pricing:

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

Emerging concepts in marketing:

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

Recommended Books: (Latest Editions)

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

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

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

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

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

Course content:

Unit I **10Hours**

New Drug Discovery and development

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

Unit II **10Hours**

Regulatory Approval Process

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

Regulatory authorities and agencies

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

Unit III **10Hours**

Registration of Indian drug product in overseas market

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

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

Unit IV **08Hours**

Clinical trials

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

Unit V **07Hours**

Regulatory Concepts

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

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug 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 and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By 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

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

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

Objectives:

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

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

Course Content

Unit I **10 Hours**

Introduction to Pharmacovigilance

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

Introduction to adverse drug reactions

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

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II **10 hours**

Drug and disease classification

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

Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

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

Unit III **10 Hours**

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

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

Communication in pharmacovigilance

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

Unit IV **8 Hours**

Safety data generation

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

ICH Guidelines for Pharmacovigilance

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

Unit V **7 hours**

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

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

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, 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 PK Manna

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

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

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

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

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 international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

Unit II **10 hours**

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

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

WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08 hours**

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

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions

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

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

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

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

UNIT-II **10 Hours**

Quantitative Structure Activity Relationship (QSAR)

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

UNIT-III **10 Hours**

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

UNIT-IV **08 Hours**

Informatics & Methods in drug design

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

UNIT-V **07 Hours**

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

Recommended Books (Latest Editions)

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

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

Scope:

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

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

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

Course content:

Unit I **10Hours**

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

Unit II **10 Hours**

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

Unit III **10 Hours**

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

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

Unit IV **08 Hours**

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

Unit V **07 Hours**

a) Cell Signals: Introduction
b) Receptors for Cell Signals
c) Signaling Pathways: Overview
d) Misregulation of Signaling Pathways
e) Protein-Kinases: Functioning

Recommended Books (latest edition):

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

BP809ET. COSMETIC SCIENCE(Theory)

45Hours

UNIT I **10Hours**

Classification of cosmetic and cosmeceutical products

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

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

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums**.**

UNIT II **10 Hours**

Principles of formulation and building blocks of skin care products:

Face wash,

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

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.

UNIT III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste**.**

UNIT IV **08 Hours**.

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

Soaps,and syndet bars. Evolution and skin benfits.

UNIT V **07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

References

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

BP810 ET. EXPERIMENTAL PHARMACOLOGY

45 Hours

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

Objectives

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

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

Unit –I	**08 Hours**
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	**10 Hours**
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. 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 **Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	
Unit –IV **Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data	**05 Hours**

Recommended Books (latest edition):

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 J Richard

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II **10 Hours**

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

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, structural elucidation and applications.

UNIT-III **10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV **08 Hours**

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

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

UNIT-V **07 Hours**

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

Recommended Books (Latest Editions)

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

BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

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

Scope :

This subject covers foundational topic that are important for understanding the need and requirements of 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 maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

UNIT I **07 hours**

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

UNIT II **15 hours**

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

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

UNIT III **07 hours**

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

b) Dietary fibres and complex carbohydrates as functional food ingredients..

UNIT IV **10 hours**

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

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

c) Functional foods for chronic disease prevention

UNIT V **06 hours**

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

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

c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

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