

Study & Evaluation Scheme

of

Bachelor of Pharmacy

B.Pharm. (Lateral Entry)

[Applicable w.e.f. Academic Session 2017-18 till revised]



TEERTHANKER MAHAVEER UNIVERSITY

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TEERTHANKER MAHAVEER UNIVERSITY

(Established under Govt. of U. P. Act No. 30, 2008)
Delhi Road, Bagarpur, Moradabad (U.P)

Study & Evaluation Scheme of Bachelor of Pharmacy SUMMARY

Programme	: B. Pharm. (Lateral Entry)
Duration	: Three years (Six Semester)
Medium	: English
Minimum Required Attendance	: 80 percent in individual courses considering theory and practical separately
Maximum credits	: 175/ 224*
Minimum credits` required for getting degree	: 171/220*

* In view of the PCI guidelines 49 Credits will be granted to the student(s) of Lateral entry
Assessment Theory:

Internal	External	Total
25	75	100

Internal evaluation Theory:

Class Test-I	Class Test-II	Class Test-III	Continue evaluation (10 Marks)			Total
			Attendance	Academic activities	Student – Teacher interaction	
Average of best two out of three						
15 Marks	15 Marks	15 Marks	4 Marks	3 Marks	3 Marks	25 Marks

Assessment Practical:

Internal	External	Total
30	70	100

Internal evaluation Practical:

Class Test-I	Class Test-II	Class Test-III	Continue evaluation (10 Marks)			Total
			Attendance	Academic activities	Student – Teacher interaction	
Average of best two out of three						
20 Marks	20 Marks	20 Marks	4 Marks	3 Marks	3 Marks	30 Marks

Duration of Examination:

Theory		Practical	
External	Internal	External	Internal
3 hrs.	1.5 hrs.	4 hrs.	4 hrs.

To qualify the course a student is required to secure a minimum of 50% marks in aggregate in the end semester examination and teachers continuous evaluation (i.e. both internal and external) for getting a grade. A candidate who secures less than 50% of marks in any theory or practical course shall be deemed to have failed course. In

case a student fails to secure minimum 50% marks in any theory or practical course, he/she shall re-appear for the end semester examination of that course. However his/ her marks of the internal assessment shall be carried over and he/ she shall be entitled for grade obtained by him or her on passing.

There will be three Class Tests in a semester and an average of the marks obtained in best two tests will be computed for the final result.

The class tests would comprise of six questions. Students shall have to answer four questions out of which one question will be compulsory. The distribution of marks will be assigned to each question.

Question Paper Structure:

- 1. The question paper shall consist of six questions. Out of which first question shall be of MCQ/ objective nature and will be compulsory, two long and three short answer (not exceeding 50 words) types. Question No. 1 shall contain 8 parts representing all units of the syllabus and students shall have to answer any five (objective) and/ or ten (MCQ) questions.*
- 2. Out of the rest five questions, student shall be required to attempt any three questions. There will be minimum one question from each unit of the syllabus. The weightage of Question No. 2 to 6 shall be 10 marks (for Long answer) and 5 marks (for short answer) types.*

Study & Evaluation Scheme
Programme: B.Pharm. (Lateral Entry)

Semester III

S. N.	Course Code	Subject	Periods			Credits	Evaluation Scheme		
			L	T	P		Internal	External	Total
1	BPHT301	Pharmaceutical Organic Chemistry II	4	2		5	25	75	100
2	BPHT302	Physical Pharmaceutics I	4	2		5	25	75	100
3	BPHT303	Pharmaceutical Microbiology	4	2		5	25	75	100
4	BPHT304	Pharmaceutical Engineering	4	2		5	25	75	100
5	BPHT305/ BPHT105	Communication skills	2	-		2	25	75	100
6	BPHP351	Pharmaceutical Organic Chemistry II		-	4	2	30	70	100
7	BPHP352	Physical Pharmaceutics I		-	4	2	30	70	100
8	BPHP353	Pharmaceutical Microbiology		-	4	2	30	70	100
9	BPHP354	Pharmaceutical Engineering		-	4	2	30	70	100
10	BPHP355/ BPHP155	Communication skills			2	1	30	70	100
Total			18	8	18	31	275	725	1000

Semester IV

S. N.	Course Code	Subject	Periods			Credits	Evaluation Scheme		
			L	T	P		Internal	External	Total
1	BPHT401	Pharmaceutical Organic Chemistry III	4	2		5	25	75	100
2	BPHT402	Medicinal Chemistry I	4	1		4.5	25	75	100
3	BPHT403	Physical Pharmaceutics II	3	1		3.5	25	75	100
4	BPHT404	Pharmacology I	3	1		3.5	25	75	100
5	BPHT405	Pharmacognosy and Phytochemistry I	3	1		3.5	25	75	100
	BPHT205/ BPHT405	Computer Applications in Pharmacy	3	-		3	25	75	100
6	BPHP451	Medicinal Chemistry I		-	4	2	30	70	100
7	BPHP452	Physical Pharmaceutics II			4	2	30	70	100
8	BPHP453	Pharmacology I		-	4	2	30	70	100
9	BPHP454	Pharmacognosy and Phytochemistry I		-	4	2	30	70	100
10	BPHP254/ BPHP454	Computer Applications in Pharmacy			2	1	30	70	100
Total			20	6	18	32	200	800	900

DIPLOMA BASED CREDIT

S. No	Code	Particular					Credits			
1	BPHL001	Diploma lateral Entry based credit	-		-	-	49	-	-	-
Total							49			

Semester V

S. N.	Course Code	Subject	Periods			Credits	Evaluation Scheme		
			L	T	P		Internal	External	Total
1	BPHT501	Medicinal Chemistry II	4	2		5	25	75	100
2	BPHT502	Industrial Pharmacy I	4	1		4.5	25	75	100
3	BPHT503	Pharmacology II	4	1		4.5	25	75	100
4	BPHT504	Pharmacognosy and Phytochemistry II	4	1		4.5	25	75	100
5	BPHT505	Pharmaceutical Jurisprudence	3	1		3.5	25	75	100
6	BPHP551	Industrial Pharmacy I		-	4	2	30	70	100
7	BPHP552	Pharmacology II		-	4	2	30	70	100
8	BPHP553	Pharmacognosy and Phytochemistry II		-	4	2	30	70	100
		Total	19	6	12	28	215	585	800

Semester VI

S. N.	Course Code	Subject	Periods			Credits	Evaluation Scheme		
			L	T	P		Internal	External	Total
1	BPHT601	Medicinal Chemistry	4	1		4.5	25	75	100
2	BPHT602	Pharmacology III	4	1		4.5	25	75	100
3	BPHT603	Herbal Drug Technology	3	2		4	25	75	100
4	BPHT604	Biopharmaceutics and Pharmacokinetics	3	2		4	25	75	100
5	BPHT605	Pharmaceutical Biotechnology	2	1		2.5	25	75	100
6	BPHT606	Quality Assurance	2	1		2.5	25	75	100
7	BPHP651	Medicinal chemistry III			4	2	30	70	100
8	BPHP652	Pharmacology III			4	2	30	70	100
9	BPHP653	Herbal Drug Technology			4	2	30	70	100
		Total	18	8	12	28	240	660	900

Semester VII

S. N.	Course Code	Subject	Periods			Credits	Evaluation Scheme		
			L	T	P		Internal	External	Total
1	BPHT701	Instrumental Methods of Analysis	4	2		5	25	75	100
2	BPHT702	Industrial Pharmacy II	4	2		5	25	75	100
3	BPHT703	Pharmacy Practice	4	2		5	25	75	100
4	BPHT704	Novel Drug Delivery System	4	2		5	25	75	100
5	BPHP751	Instrumental Methods of Analysis		-	4	2	30	70	100
6	BPHP752	Practice School*		-	12	6	50	150	200
		Total	16	8	16	28	180	520	700

Semester VIII

S. N.	Course Code	Subject	Periods			Credits	Evaluation Scheme		
			L	T	P		Internal	External	Total
1	BPHT801	Biostatistics and Research Methodology	4	2		5	25	75	100
2	BPHT802	Social and Preventive Pharmacy	4	2		5	25	75	100
3*	BPHT803	Pharma Marketing Management	4 + 4 = 8	2 + 2 = 4		10	50	150	200
	BPHT804	Pharmaceutical Regulatory Science							
	BPHT805	Pharmacovigilance							
	BPHT806	Quality Control and Standardization of Herbals							
	BPHT807	Computer Aided Drug Design							
	BPHT808	Cell and Molecular Biology							
	BPHT809	Cosmetic Science							
	BPHT810	Pharmacological Screening Methods							
	BPHT811	Advanced Instrumentation Techniques							
	BPHT812	Dietary Supplements and Nutraceuticals							
4	BPHP851	Project Work	-	-	16	8	-	400	400
		Total	16	8	16	28	100	700	800

* Two courses to be opted as electives out of ten

Note:

L – Lecture
1L = 1Hr

T- Tutorial
1T= 1 Hr

P- Practical
1P= 1 Hr

C-Credits
1C = 1Hr of Theory Paper
= 2 Hrs of Practical/Tutorial

B. Pharm. – Semester III
PHARMACEUTICAL ORGANIC CHEMISTRY –II

Course Code: BPHT301

L-4, T-2, P-0, C-5

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

- write the structure, name and the type of isomerism of the organic compound
- write the reaction, name the reaction and orientation of reactions
- account for reactivity/stability of compounds, prepare organic compounds

Course Contents

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

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

UNIT I

10 Hours

Benzene and its derivatives

Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedel crafts alkylation- reactivity, limitations, Friedelcrafts acylation.

Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II

10 Hours

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

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

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

UNIT III

10 Hours

Fats and Oils

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

UNIT IV

08 Hours

Polynuclear hydrocarbons:

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

UNIT V

07 Hours

Cyclo alkanes*

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

Recommended Books (Latest Editions)

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

B. Pharm. – Semester III
PHYSICAL PHARMACEUTICS-I

Course Code: BPHT302

L-4, T-2, P-0, C-5

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

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

Course Contents

UNIT-I

10 Hours

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions)

Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II

10Hours

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

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

UNIT-III

08 Hours

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

UNIT-IV

08Hours

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

UNIT-V

07 Hours

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

Recommended Books: (Latest Editions)

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

B. Pharm. – Semester III
PHARMACEUTICAL MICROBIOLOGY

Course Code: BPHT303

L-4, T-2, P-0, C-5

Objective:

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

- Understand methods of identification, cultivation and preservation of various microorganisms
- To understand the importance and implementation of sterilization in pharmaceutical processing and industry
- Learn sterility testing of pharmaceutical products.
- Carried out microbiological standardization of Pharmaceuticals.
- Understand the cell culture technology and its applications in pharmaceutical industries.

Course Contents

Unit I

10 Hours

Introduction, history of microbiology, its branches, scope and its importance.

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

Unit II

10 Hours

Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC). Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators.

Unit III

10 Hours

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

Classification and mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions Evaluation of bactericidal & Bacteriostatic. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV

08 Hours

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

Principles and methods of different microbiological assay.

Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic.

Unit V

07Hours

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

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

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

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

B. Pharm. – Semester III
PHARMACEUTICAL ENGINEERING

Course Code: BPHT304

L-4, T-2, P-0, C-5

Objective:

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

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

Course Contents

UNIT-I

10 Hours

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

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

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

UNIT-II

10 Hours

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

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

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

UNIT- III

08 Hours

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

Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction,

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

UNIT-IV

08 Hours

Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.

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

UNIT- V

07 Hours

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

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchemo, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn’s Tutorial pharmacy, S.J. Carter, Latest edition.

B. Pharm. – Semester III COMMUNICATION SKILLS

Course Code: BPHT305/105BPHT

L-2, T-0, P-0, C-2

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

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

Course Contents

UNIT – I

07 Hours

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

UNIT – II

07 Hours

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

UNIT – III

07 Hours

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV

05 Hours

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

UNIT – V

04 Hours

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

Recommended Books

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

* Latest editions of all the suggested books are recommended.

B. Pharm. – Semester III
PHARMACEUTICAL ORGANIC CHEMISTRY -II

Course Code: BPHP351

L-0, T-0, P-4, C-2

4 Hours/week

Experiments involving laboratory techniques

Recrystallization

Steam distillation

Determination of following oil values (including standardization of reagents)

Acid value

Saponification value

Iodine value

Preparation of compounds

Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.

2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/

Acetanilide by halogenation (Bromination) reaction.

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

Benzoic acid from Benzyl chloride by oxidation reaction.

Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.

1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.

Benzil from Benzoin by oxidation reaction.

Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction

Cinnamic acid from Benzaldehyde by Perkin reaction

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

Recommended Books (Latest Editions)

9. Organic Chemistry by Morrison and Boyd
10. Organic Chemistry by I.L. Finar , Volume-I
11. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
12. Organic Chemistry by P.L.Soni
13. Practical Organic Chemistry by Mann and Saunders.
14. Vogel's text book of Practical Organic Chemistry
15. Advanced Practical organic chemistry by N.K.Vishnoi.
16. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz

B. Pharm. – Semester III
PHYSICAL PHARMACEUTICS – I

Course Code: BPHP352

L-0, T-0, P-4, C-2

4 Hrs/week

Determination the solubility of drug at room temperature

Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.

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

Determination of Partition co- efficient of Iodine in CCl₄ and water

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

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

Determination of HLB number of a surfactant by saponification method

Determination of Freundlich and Langmuir constants using activated char coal

Determination of critical micellar concentration of surfactants

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

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

Recommended Books: (Latest Editions)

11. Physical Pharmacy by Alfred Martin
12. Experimental Pharmaceutics by Eugene, Parott.
13. Tutorial Pharmacy by Cooper and Gunn.
14. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
15. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
16. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
17. Physical Pharmaceutics by Ramasamy C and ManavalanR.
18. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
19. Physical Pharmaceutics by C.V.S. Subramanyam
20. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

B. Pharm. – Semester III
PHARMACEUTICAL MICROBIOLOGY

Course Code: BPHP353

L-0, T-0, P-4, C-2

4 Hours/week

Introduction and study of different equipment's and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.

Sterilization of glassware, preparation and sterilization of media.

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

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

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

Microbiological assay of antibiotics by cup plate method and other methods

Motility determination by Hanging drop method.

Sterility testing of pharmaceuticals.

Bacteriological analysis of water

Biochemical test.

Recommended Books (Latest edition)

14. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
15. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
16. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
17. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
18. Rose: Industrial Microbiology.
19. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
20. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
21. Pepler: Microbial Technology.
22. I.P., B.P., U.S.P.- latest editions.
23. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
24. Edward: Fundamentals of Microbiology.
25. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
26. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

B. Pharm. – Semester III
PHARMACEUTICAL ENGINEERING

Course Code: BPHP354

L-0, T-0, P-4, C-2

4 Hours/week

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

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchemo, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

B. Pharm. – Semester III COMMUNICATION SKILLS

Course Code: BPHP355/BPHP155

L-0, T-0, P-2, C-1

2 Hours / week

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

Basic communication covering the following topics

Meeting People, Asking Questions, Making Friends

What did you do?, Do's and Don't's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds), Pronunciation and Nouns, Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech, Figures of Speech, Effective Communication

Writing Skills, Effective Writing, Interview Handling Skills, E-Mail etiquette, Presentation Skills

Recommended Books: (Latest Edition)

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

B. Pharm. – Semester IV
PHARMACEUTICAL ORGANIC CHEMISTRY –III

Course Code: BPHT401

L-4, T-2, P-0, C-5

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

- understand the methods of preparation and properties of organic compounds
- explain the stereo chemical aspects of organic compounds and stereo chemical reactions
- know the medicinal uses and other applications of organic compounds

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

Course Contents

UNIT-I

10 Hours

Stereo isomerism

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

UNIT-II

10 Hours

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

UNIT-III

10 Hours

Heterocyclic compounds:

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

UNIT-IV

8 Hours

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

UNIT-V

07 Hours

Reactions of synthetic importance

Metal hydride reduction (NaBH_4 and LiAlH_4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement. Claisen-Schmidt condensation

Recommended Books (Latest Editions)

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

B. Pharm. – Semester IV
MEDICINAL CHEMISTRY – I

Course Code: BPHT402

L-4, T-1, P-0, C-4.5

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

- understand the chemistry of drugs with respect to their pharmacological activity
- understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- know the Structural Activity Relationship (SAR) of different class of drugs
- write the chemical synthesis of some drugs

Course Content:

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

UNIT- I

10 Hours

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

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

Drug metabolism

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

UNIT- II

10 Hours

Drugs acting on Autonomic Nervous System

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

Sympathomimetic agents: SAR of Sympathomimetic agents

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

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

Adrenergic Antagonists:

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

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

UNIT-III

10 Hours

Cholinergic neurotransmitters: Biosynthesis and catabolism of acetylcholine. Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Para-symphathomimetic agents: SAR of Parasympathomimetic agents

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

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

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

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

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

UNIT- IV

08 Hours

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

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

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

Miscellaneous: Amides & imides: Glutethimide. Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

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

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

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

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

Barbiturates: Phenobarbitone, Methabarbitol.

Hydantoins: Phenytoin*, Mephenytoin, Ethotoin

Oxazolindione diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide, Ethosuximide*

Urea and monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT – V

07 Hours

Drugs acting on Central Nervous System

General anesthetics:

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

Ultra-short acting barbiturates: Methohexital sodium*, Thiopental sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

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

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

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

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.

B. Pharm. – Semester IV
PHYSICAL PHARMACEUTICS-II

Course Code: BPHT403

L-3, T-1, P-0, C-3.5

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

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

Course Content:

UNIT-I

07 Hours

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

UNIT-II

10 Hours

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

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

UNIT-III

10 Hours

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

UNIT-IV

10Hours

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

UNIT-V

10 Hours

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents

against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

Recommended Books: (Latest Editions)

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

B. Pharm. – Semester IV PHARMACOLOGY-I

Course Code: BPHT404

L-3, T-1, P-0, C-3.5

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

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

Course Content:

UNIT-I

08 hours

General Pharmacology

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

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

UNIT-II

12 Hours

1. General Pharmacology

Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein-coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. Adverse drug reactions.

Drug interactions (pharmacokinetic and pharmacodynamic) Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III

10 Hours

2. Pharmacology of drugs acting on peripheral nervous system

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

UNIT-IV

08 Hours

3. Pharmacology of drugs acting on central nervous system

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

UNIT-V

07 Hours

4. Pharmacology of drugs acting on central nervous system

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

Recommended Books (Latest Editions)

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

B. Pharm. – Semester IV
PHARMACOGNOSY AND PHYTOCHEMISTRY I

Course Code: BPHT405

L-3, T-1, P-0, C-3.5

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

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

Course Content:

UNIT-I

10 Hours

Introduction to Pharmacognosy: Definition, history, scope and development of Pharmacognosy Sources of Drugs – Plants, Animals, Marine & Tissue culture Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

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

Quality control of Drugs of Natural Origin: Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties. Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II

10 Hours

Cultivation, Collection, Processing and storage of drugs of natural origin: Cultivation and Collection of drugs of natural origin Factors influencing cultivation of medicinal plants. Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III

07 Hours

Plant tissue culture: Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy. Edible vaccines

UNIT IV

10 Hours

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

Introduction to secondary metabolites: Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V

08 Hours

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs
Plant Products: Fibers - Cotton, Jute, Hemp Hallucinogens, Teratogens, Natural allergens

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

Carbohydrates: Acacia, Agar, Tragacanth, Honey

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

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

Drugs: Novel medicinal agents from marine sources

Recommended Books: (Latest Editions)

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

B. Pharm. – Semester IV
COMPUTER APPLICATIONS IN PHARMACY

Course Code: BPHT205/BPHT405

L-3, T-0, P-0, C-3

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

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

Course Contents

UNIT – I

06 hours

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

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

UNIT –II

06 hours

Web technologies: Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III

06 hours

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring, Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

UNIT – IV

06 hours

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

UNIT-V

06 hours

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

Recommended Books

1. Computer Application in Pharmacy – William E. Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Inter science, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)

4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

B. Pharm. – Semester IV
MEDICINAL CHEMISTRY – I

Course Code: BPHP451

L-0, T-0, P-4, C-2

4 Hours/Week

I. Preparation of drugs/ intermediates

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

II. Assay of drugs

Chlorpromazine, Phenobarbitone, Atropine, Ibuprofen, Aspirin, Furosemide

III. Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

11. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
12. Foye's Principles of Medicinal Chemistry.
13. Burger's Medicinal Chemistry, Vol I to IV.
14. Introduction to principles of drug design- Smith and Williams.
15. Remington's Pharmaceutical Sciences.
16. Martindale's extra pharmacopoeia.
17. Organic Chemistry by I.L. Finar, Vol. II.
18. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
19. Indian Pharmacopoeia.
20. Text book of practical organic chemistry- A.I.Vogel.

B. Pharm. – Semester IV
PHYSICAL PHARMACEUTICS- II

Course Code: BPHP452

L-0, T-0, P-4, C-2

3 Hrs/week

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

Recommended Books: (Latest Editions)

8. Physical Pharmacy by Alfred Martin, Sixth edition
9. Experimental pharmaceuticals by Eugene, Parott.
10. Tutorial pharmacy by Cooper and Gunn.
11. Stock losam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
12. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
13. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
14. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

B. Pharm. – Semester IV PHARMACOLOGY-I

Course Code: BPHP453

L-0, T-0, P-4, C-2

4Hrs/Week

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

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

Recommended Books (Latest Editions)

11. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
12. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
13. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
14. 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
15. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
16. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
17. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
18. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
19. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
20. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

B. Pharm. – Semester IV
PHARMACOGNOSY AND PHYTOCHEMISTRY I

Course Code: BPHP454

L-0, T-0, P-4, C-2

4 Hours/Week

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

Determination of stomatal number and index

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

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

Determination of Fiber length and width

Determination of number of starch grains by Lycopodium spore method

Determination of Ash value

Determination of Extractive values of crude drugs

Determination of moisture content of crude drugs

Determination of swelling index and foaming

Recommended Books: (Latest Editions)

10. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
11. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
12. Text Book of Pharmacognosy by T.E. Wallis
13. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
14. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
15. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
16. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
17. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
18. Anatomy of Crude Drugs by M.A. Iyengar.

B. Pharm. – Semester IV
COMPUTER APPLICATION IN PHARMACY

Course Code: BPHP254/BPHP454

L-0, T-0, P-2, C-1

4 Hours/week

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

Create a HTML web page to show personal information.

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

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

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

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

Generating report and printing the report from patient database

Creating invoice table using – MS Access

Drug information storage and retrieval using MS Access

Creating and working with queries in MS Access

Exporting Tables, Queries, Forms and Reports to web pages

Exporting Tables, Queries, Forms and Reports to XML pages

Recommended Books

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

B. Pharm. – Semester V
MEDICINAL CHEMISTRY – II

Course Code: BPHT501

L-4, T-2, P-0, C-5

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

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

Course Content:

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

UNIT- I

10 Hours

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

H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline 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

H₂-antagonists: Cimetidine*, Famotidine, Ranitidin.

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

Anti-neoplastic agents:

Alkylating agents: Meclorothamine*, 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, Cholestamine and Cholestipol

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

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

UNIT- IV

08 Hours

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progesterones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, 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: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

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

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

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

Miscellaneous: Phenacaine, Dipiperdon, Dibucaine.*

Recommended Books (Latest Editions)

Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.

Foye's Principles of Medicinal Chemistry.

Burger's Medicinal Chemistry, Vol I to IV.

Introduction to principles of drug design- Smith and Williams.

Remington's Pharmaceutical Sciences.

Martindale's extra pharmacopoeia.

Organic Chemistry by I.L. Finar, Vol. II.

The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.

Indian Pharmacopoeia.

Text book of practical organic chemistry- A.I.Vogel.

B. Pharm. – Semester V
INDUSTRIAL PHARMACY I

Course Code: BPHT502

L-4, T-1, P-0, C-4.5

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

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

Course content:

3 hours/ week

UNIT-I 07 Hours

Pre-formulation 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:

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

Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. Quality control tests: In process and finished product tests

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

UNIT-III 08 Hours

Capsules:

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

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

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

UNIT-IV

10 Hours

Parenteral Products:

Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity Production procedure, production facilities and controls, aseptic processing, Formulation of injections, sterile powders, large volume parenterals and lyophilized products. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

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

UNIT-V

10 Hours

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

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

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

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, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

B. Pharm. – Semester V PHARMACOLOGY-II

Course Code: BPHT503

L-4, T-1, P-0, C-4.5

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

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

Course Content:

UNIT-I

10hours

Pharmacology of drugs acting on cardio vascular system

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

UNIT-II

10hours

Pharmacology of drugs acting on cardio vascular system

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

Pharmacology of drugs acting on urinary system

Diuretics, Anti-diuretics.

UNIT-III 10hours

Autocoids and related drugs

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

UNIT-IV

08 hours

Pharmacology of drugs acting on endocrine system

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

UNIT-V

07 hours

Pharmacology of drugs acting on endocrine system

Androgens and Anabolic steroids.

Estrogens, progesterone and oral contraceptives.

Drugs acting on the uterus.

Bioassay

- a. Principles and applications of bioassay.

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

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill 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.
- Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

B. Pharm. – Semester V
PHARMACOGNOSY AND PHYTOCHEMISTRY II

Course Code: BPHT504

L-4, T-1, P-0, C-4.5

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

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

Course Content:

UNIT-I

7 Hours

Metabolic pathways in higher plants and their determination

Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway. Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II

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: Glycyrrhetic 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.

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & 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), 1st Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, 2nd 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.

B. Pharm. – Semester V
PHARMACEUTICAL JURISPRUDENCE

Course Code: BPHT505

L-3, T-1, P-0, C-3.5

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

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- Various Indian pharmaceutical Acts and Laws
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules
Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

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

UNIT-II

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

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

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

UNIT-III

10 Hours

Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; 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 Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

Forensic Pharmacy by B. Suresh

Text book of Forensic Pharmacy by B.M. Mithal

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

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

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

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

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

Drugs and Magic Remedies act by Govt. of India publication

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

B. Pharm. – Semester V
INDUSTRIAL PHARMACY I

Course Code: BPHP551

L-0, T-0, P-4, C-2

4 Hours/week

Preformulation studies on paracetamol/asparin/or any other drug
Preparation and evaluation of Paracetamol tablets
Preparation and evaluation of Aspirin tablets
Coating of tablets- film coating of tables/granules
Preparation and evaluation of Tetracycline capsules
Preparation of Calcium Gluconate injection
Preparation of Ascorbic Acid injection
Quality control test of (as per IP) marketed tablets and capsules
Preparation of Eye drops/ and Eye ointments
Preparation of Creams (cold / vanishing cream)
Evaluation of Glass containers (as per IP)

Recommended Books: (Latest Editions)

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

B. Pharm. – Semester V
PHARMACOLOGY-II

Course Code: BPHP552

L-0, T-0, P-4, C-2

4Hrs/Week

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

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

Recommended Books (Latest Editions)

10. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
11. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
12. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
13. 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.
14. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology.
15. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
16. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
17. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
18. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
19. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

B. Pharm. – Semester V
PHARMACOGNOSY AND PHYTOCHEMISTRY II

Course Code: BPHP553

L-0, T-0, P-4, C-2

4 Hours/Week

Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander, Exercise involving isolation & detection of active principles

Caffeine - from tea dust.

Diosgenin from Dioscorea

Atropine from Belladonna

Sennosides from Senna

Separation of sugars by Paper chromatography

TLC of herbal extract

Distillation of volatile oils and detection of phytoconstituents by TLC

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

Recommended Books: (Latest Editions)

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

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

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

Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.

Essentials of Pharmacognosy, Dr.SH.Ansari, 2nd edition, Birla publications, New Delhi, 2007

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

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

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

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

The formulation and preparation of cosmetic, fragrances and flavours.

Remington's Pharmaceutical sciences.

Text Book of Biotechnology by Vyas and Dixit.

Text Book of Biotechnology by R.C. Dubey.

B. Pharm. – Semester VI
MEDICINAL CHEMISTRY – III

Course Code: BPHT601

L-4, T-1, P-0, C-4.5

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

- Understand the importance of drug design and different techniques of drug design.
- Understand the chemistry of drugs with respect to their biological activity.
- Know the metabolism, adverse effects and therapeutic value of drugs.
- Know the importance of SAR of drugs.

Course Content:

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

UNIT – I **10**

Hours

Antibiotics

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

β-Lactam antibiotics: Penicillin, Cephalosporins, 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, Artesunate, Artemether, Atovoquone.

UNIT – III **10**

Hours

Anti-tubercular Agents

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

Anti-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate.

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, 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 Tioconazole, 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, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

07

Hours

Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

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

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.

**B. Pharm. – Semester VI
PHARMACOLOGY-III**

Course Code: BPHT602

L-4, T-1, P-0, C-4.5

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

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

Course Content:

UNIT-I

10hours

Pharmacology of drugs acting on Respiratory system

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

Pharmacology of drugs acting on the Gastrointestinal Tract

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

UNIT-II

10hours

Chemotherapy

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

UNIT-III

10hours

Chemotherapy

Antitubercular agents, Antileprotic agents, Antifungal agents, Antiviral drugs, Anthelmintics, Antimalarial drugs, Antiamoebic agents

UNIT-IV

08hours

Chemotherapy

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

Immunopharmacology

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

UNIT-V

07hours

Principles of toxicology

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

Chronopharmacology

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

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill 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.Udapa and P.D. Gupta, Concepts in Chronopharmacology.

B. Pharm. – Semester VI
HERBAL DRUG TECHNOLOGY

Course Code: BPHT603

L-3, T-2, P-0, C-4

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

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

Course content:

UNIT-I

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

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

UNIT-II

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:

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

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

UNIT-V**07 Hours****General Introduction to Herbal Industry**

Herbal drugs industry: Present scope and future prospects.

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

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

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

B. Pharm. – Semester VI
BIOPHARMACEUTICS AND PHARMACOKINETICS

Course Code: BPHT604

L-3, T-2, P-0, C-4

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

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- 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 through GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II

10 Hours

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

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

UNIT- III

10 Hours

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, one compartment open model.

(a). Intravenous Injection (Bolus)

(b). Intravenous infusion and

(c) Extra vascular administrations. Pharmacokinetics parameters - K_E , $t_{1/2}$, V_d , AUC , K_a , Cl_t and CL_R - definitions methods of eliminations, understanding of their significance and application

UNIT- IV

08 Hours

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

UNIT- V

07 Hours

Nonlinear Pharmacokinetics:

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

Recommended Books: (Latest Editions)

Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.

Biopharmaceutics and Pharmacokinetics; By Robert F Notari

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

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

Pharmacokinetics: By Milo Gibaldi Donald, R. Merck Dekker Inc.

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

Biopharmaceutics; By Swarbrick

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

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

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

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

B. Pharm. – Semester VI
PHARMACEUTICAL BIOTECHNOLOGY

Course Code: BPHT605

L-2, T-1, P-0, C-2.5

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

- Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
- Genetic engineering applications in relation to production of pharmaceuticals
- Importance of Monoclonal antibodies in Industries
- Appreciate the use of microorganisms in fermentation technology

Unit I

10 Hours

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

Unit II

10 Hours

Study of cloning vectors, restriction endonucleases and DNA ligase. Recombinant DNA technology. Application of genetic engineering in medicine. Application of r DNA technology and genetic engineering in the production of:

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

Brief introduction to PCR

Unit III

10 Hours

Types of immunity- humoral immunity, cellular immunity Structure of Immunoglobulins Structure and Function of MHC Hypersensitivity reactions, Immune stimulation and Immune suppressions. General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. Storage conditions and stability of official vaccines Hybridoma technology- Production, Purification and Applications Blood products and Plasma Substitutes.

Unit IV

08Hours

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

Unit V

07 Hours

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

Recommended Books (Latest edition):

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

B. Pharm. – Semester VI
PHARMACEUTICAL QUALITY ASSURANCE

Course Code: BPHT606

L-2, T-1, P-0, C-2.5

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 Dekker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

B. Pharm. – Semester VI
MEDICINAL CHEMISTRY- III

Course Code: BPHP651

L-0, T-0, P-4, C-2

4 Hours / week

I Preparation of drugs and intermediates

Sulphanilamide, 7-Hydroxy, 4-methyl coumarin, Chlorobutanol, Triphenyl imidazole, Tolbutamide, Hexamine

II Assay of drugs

Isonicotinic acid hydrazide, Chloroquine, Metronidazole, Dapsone, Chlorpheniramine maleate, Benzyl penicillin

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

IV Drawing structures and reactions using chem draw®

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

Recommended Books (Latest Editions)

11. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
12. Foye's Principles of Medicinal Chemistry.
13. Burger's Medicinal Chemistry, Vol I to IV.
14. Introduction to principles of drug design- Smith and Williams.
15. Remington's Pharmaceutical Sciences.
16. Martindale's extra pharmacopoeia.
17. Organic Chemistry by I.L. Finar, Vol. II.
18. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
19. Indian Pharmacopoeia.
20. Text book of practical organic chemistry- A.I.Vogel.

B. Pharm. – Semester VI PHARMACOLOGY-III

Course Code: BPHP652

L-0, T-0, P-4, C-2

4Hrs/Week

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

Recommended Books (Latest Editions)

11. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
12. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
13. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
14. 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
15. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
16. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
17. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
18. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
19. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
20. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

B. Pharm. – Semester VI
HERBAL DRUG TECHNOLOGY

Course Code: BPHP653

L-0, T-0, P-4, C-2

4Hrs/Week

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

Recommended Books: (Latest Editions)

12. Textbook of Pharmacognosy by Trease & Evans.
13. Textbook of Pharmacognosy by Tyler, Brady & Robber.
14. Pharmacognosy by Kokate, Purohit and Gokhale
15. Essential of Pharmacognosy by Dr.S.H.Ansari
16. Pharmacognosy & Phytochemistry by V.D.Rangari
17. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
18. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
19. Society of Chemistry.
20. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
21. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
22. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

B. Pharm. – Semester VII
INSTRUMENTAL METHODS OF ANALYSIS

Course Code: BPHT701

L-4, T-2, P-0, C-5

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

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

Course Content:

UNIT –I

10 Hours

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

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

UNIT –II

10 Hours

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III

10 Hours

Introduction to chromatography

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

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

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

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

UNIT –IV

08 Hours

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

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

UNIT –V

07 Hours

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

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

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.

B. Pharm. – Semester VII
INDUSTRIAL PHARMACY-II

Course Code: BPHT702

L-4, T-2, P-0, C-5

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

- Know the process of pilot plant and scale up of pharmaceutical dosage forms
- Understand the process of technology transfer from lab scale to commercial batch
- Know different Laws and Acts that regulate pharmaceutical industry
- 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>.

B. Pharm. – Semester VII

PHARMACY PRACTICE

Course Code: BPHT703

L-4, T-2, P-0, C-5

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

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

Unit I:

10 Hours

Hospital and its organization

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

Hospital pharmacy and its organization

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

Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

Community Pharmacy

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

Unit II:

10 Hours

Drug distribution system in a hospital

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

Hospital formulary

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

Therapeutic drug monitoring

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

Medication adherence

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

Patient medication history interview

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

Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III:

10 Hours

Pharmacy and therapeutic committee

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

Drug information services

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

Patient counseling

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

Education and training program in the hospital

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

Prescribed medication order and communication skills

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

Unit IV

8

Hours

Budget Preparation and implementation: Budget preparation and implementation

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

Over the counter (OTC) sales: Introduction and sale of over the counter, and Rational use of common over the counter medications.

Unit V

7 Hours

Drug store management and inventory control

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

Investigational use of drugs: Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

Interpretation of Clinical Laboratory Tests Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

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*, 4th ed. 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:

Therapeutic drug monitoring. ISSN: 0163-4356

Journal of pharmacy practice. ISSN: 0974-8326

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

Pharmacy times (Monthly magazine)

B. Pharm. – Semester VII
NOVEL DRUG DELIVERY SYSTEMS

Course Code: BPHT704

L-4, T-2, P-0, C-5

Objectives: Upon completion of the course student shall be able

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

Course content:

Unit-I **10 Hours**

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

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

Unit-II **10 Hours**

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

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

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

Unit-III **10 Hours**

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

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

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

Unit-IV **08 Hours**

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

Unit-V **07 Hours**

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

B. Pharm. – Semester VII
INSTRUMENTAL METHODS OF ANALYSIS

Course Code: BPHP751

L-0, T-0, P-4, C-2

4 Hours/Week

Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds

Estimation of dextrose by colorimetry

Estimation of sulfanilamide by colorimetry

Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy

Assay of paracetamol by UV- Spectrophotometry

Estimation of quinine sulfate by fluorimetry

Study of quenching of fluorescence

Determination of sodium by flame photometry

Determination of potassium by flame photometry

Determination of chlorides and sulphates by nephelo turbidometry

Separation of amino acids by paper chromatography

Separation of sugars by thin layer chromatography

Separation of plant pigments by column chromatography

Demonstration experiment on HPLC

Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

11. Instrumental Methods of Chemical Analysis by B.K Sharma
12. Organic spectroscopy by Y.R Sharma
13. Text book of Pharmaceutical Analysis by Kenneth A. Connors
14. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
15. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
16. Organic Chemistry by I. L. Finar
17. Organic spectroscopy by William Kemp
18. Quantitative Analysis of Drugs by D. C. Garrett
19. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
20. Spectrophotometric identification of Organic Compounds by Silverstein

B. Pharm. – Semester VII PRACTICE SCHOOL

Course Code: BPHP752

L-0, T-0, P-12, C-6

Every candidate shall undergo practice school for a period of 150 hours spread over and evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

Various domains shall be:

- Pharmaceutical Industry/Hospital.
- Production unit,
- Quality Control department,
- Quality Assurance department,
- Analytical laboratory,
- Chemical manufacturing unit,
- Pharmaceutical R&D,
- Hospital (Clinical Pharmacy),
- Clinical Research Organization,
- Community Pharmacy, etc

Each individual student shall be liable to face 05 seminars of ten marks each and get evaluated for the internal assessment for a total of 05 marks.

The End semester examination shall comprise of evaluation of individual student by the duly constituted program committee/ academic review committee for the total of 150 marks.

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

B. Pharm. – Semester VIII
BIOSTATISTICS AND RESEARCH METHODOLOGY

Course Code: BPHT801

L-4, T-2, P-0, C-5

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 - Pharmaceutical 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, Experimental Design Technique, plagiarism

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

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

Unit-IV 8 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

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

Unit-V 7 Hours

Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. 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

B. Pharm. – Semester VIII
SOCIAL AND PREVENTIVE PHARMACY

Course Code: BPHT802

L-4, T-2, P-0, C-5

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

- Acquire high consciousness/realization of current issues related 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 to health 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
3. Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
4. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
5. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D,
6. Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
7. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
8. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

Research in Social and Administrative Pharmacy, Elsevier, Ireland

B. Pharm. – Semester VIII
PHARMA MARKETING MANAGEMENT

Course Code: BPHT803

L-4, T-2, P-0, C-5

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; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, 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.

B. Pharm. – Semester VIII
PHARMACEUTICAL REGULATORY SCIENCE

Course Code: BPHT804

L-4, T-2, P-0, C-5

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

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

Course content:

Unit I **10Hours**

New Drug Discovery and development

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

Unit II **10Hours**

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). 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

B. Pharm. – Semester VIII **PHARMACOVIGILANCE**

Course Code: BPHT805

L-4, T-2, P-0, C-5

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

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

Course Content

Unit I 10 Hours Introduction to Pharmacovigilance History and development of Pharmacovigilance, Importance of safety monitoring of Medicine, WHO international drug monitoring programme, Pharmacovigilance Program of India (PvPI)

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

Basic terminologies used in pharmacovigilance

Terminologies of adverse medication related events Regulatory terminologies

Unit II

10 hours

Drug and disease classification

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

Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance,

Basic drug information resources, Specialised resources for ADRs

Establishing pharmacovigilance programme

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

Unit III

10 Hours

Vaccine safety surveillance

Vaccine Pharmacovigilance, Vaccination failure, Adverse events following immunization

Pharmacovigilance methods

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

Communication in pharmacovigilance

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

Unit IV

8 Hours

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 Pharmacoepidemiology 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 Nyfort Hansen, 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.who.unc.edu/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

B. Pharm. – Semester VIII
QUALITY CONTROL AND STANDARDIZATION OF HERBALS

Course Code: BPHT806

L-4, T-2, P-0, C-5

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

- know WHO guidelines for quality control of herbal drugs
- know Quality assurance in herbal drug industry
- know the regulatory approval process and their registration in Indian and international markets
- appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms, WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use

Unit II **10 hours**

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

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

WHO Guidelines on GACP for Medicinal Plants.

Unit 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.

B. Pharm. – Semester VIII
COMPUTER AIDED DRUG DESIGN

Course Code: BPHT807

L-4, T-2, P-0, C-5

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, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III

10 Hours

Molecular Modeling and virtual screening techniques

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

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

UNIT-IV 08 Hours

Informatics & Methods in drug design: Introduction to Bioinformatics, chemo-informatics. 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 Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvold'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.

B. Pharm. – Semester VIII
CELL AND MOLECULAR BIOLOGY (Elective subject)

Course Code: BPHT808

L-4, T-2, P-0, C-5

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

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

Course content:

Unit I

10Hours

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

Unit II

10 Hours

DNA and the Flow of Molecular Information, DNA Functioning, DNA and RNA, Types of RNA, Transcription and Translation

Unit III

10 Hours

Proteins: Defined **and** Amino Acids, Protein Structure, Regularities in Protein Pathways, Cellular Processes, Positive Control and significance of Protein Synthesis

Unit IV

08 Hours

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

Unit V

07 Hours

Cell Signals: Introduction, Receptors for Cell Signals, Signaling Pathways: Overview Mis-regulation of Signaling Pathways Protein-Kinases: Functioning

Recommended Books (latest edition):

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

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

B. Pharm. – Semester VIII

COSMETIC SCIENCE

Course Code: BPHT809

L-4, T-2, P-0, C-5

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 cosmeceuticals.

Antiperspirants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products: Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils. Chemistry and formulation of Para-phenylene 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, b and syndet bars. Evolution and skin benefits.

UNIT V

07 Hours

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body 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 cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

B. Pharm. – Semester VIII
PHARMACOLOGICAL SCREENING METHODS

Course Code: BPHT810

L-4, T-2, P-0, C-5

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

1. Appreciate the applications of various commonly used laboratory animals.
2. Appreciate and demonstrate the various screening methods used in preclinical research
3. Appreciate and demonstrate the importance of biostatistics and research methodology
4. 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

Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, anti-asthmatics,

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

Unit –III

10 Hours

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

Unit –IV

05 Hours

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, 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

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

B. Pharm. – Semester VIII
ADVANCED INSTRUMENTATION TECHNIQUES

Course Code: BPHT811

L-4, T-2, P-0, C-5

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 Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

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

UNIT-III

10 Hours

Calibration and validation-as per ICH and USFDA guidelines **Calibration of following Instruments:** Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV

08 Hours

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

B. Pharm. – Semester VIII
DIETARY SUPPLEMENTS AND NUTRACEUTICALS

Course Code: BPHT812

L-4, T-2, P-0, C-5

1. **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 :
2. Understand the need of supplements by the different group of people to maintain healthy life.
3. Understand the outcome of deficiencies in dietary supplements.
4. Appreciate the components in dietary supplements and the application.
5. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

UNIT I

07 hours

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

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

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

UNIT II
hour

15

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

Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, leutin Sulfides: Diallyl sulfides, Allyl trisulfide. Polyphenolics: Resveratrol Flavonoids- Rutin , Naringin, Quercetin, Anthocyanidins, catechins, Flavones Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum

Phyto estrogens: Isoflavones, daidzein, Geobustin, lignans Tocopherols Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III

07 hours

Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. Dietary fibres and complex carbohydrates as functional food ingredients..

UNIT IV

10 hours

Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence,

Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α -Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole. Functional foods for chronic disease prevention

UNIT V

06 hours

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

References:

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

B. Pharm. – Semester VIII
(PROJECT WORK)
Elective course on Pharmaceutical Product Development

Course Code: BPHP851

L-0, T-0, P-16, C-8

Unit-I

10 Hours

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

Unit-II

10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories Solvents and solubilizers, Cyclodextrins and their applications, Non - ionic surfactants and their applications, Polyethylene glycols and sorbitols, Suspending and emulsifying agents, Semi solid excipients

Unit-III

10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories Tablet and capsule excipients Directly compressible vehicles Coat materials Excipients in parenteral and aerosols products Excipients for formulation of NDDS Selection and application of excipients in pharmaceutical formulations with specific industrial applications

Unit-IV

08 Hours

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

Unit-V

07 Hours

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

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.

6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis andH.A. Libermann.
13. Advanced Review Articles related to the topics.