AC 14.6.2018

Item Number : 4.53

UNIVERSITY OF MUMBAI

Bachelor of Pharmacy

B. Pharm. Choice Based Credit System (CBCS)

Third Year B. Pharm. and Final Year B. Pharm

(Semester V to Semester VIII),

from Academic Year 2018 -19 and 2019-20

From Coordinator's Desk:

To meet the challenge of ensuring excellence in engineering education, the issue of quality needs to be addressed, debated taken forward in a systematic manner. Accreditation is the principal means of quality assurance in higher education. The major emphasis of accreditation process is to measure the outcomes of the program that is being accredited. In line with this Faculty of Technology of University of Mumbai has taken a lead in incorporating philosophy of outcome based education in the process of curriculum development.

Faculty of Technology, University of Mumbai, in one of its meetings unanimously resolved that, each Board of Studies shall prepare some Program Educational Objectives (PEO's), give freedom to affiliated Institutes to add few (PEO's) course objectives course outcomes to be clearly defined for each course, so that all faculty members in affiliated institutes understand the depth approach of course to be taught, which will enhance learner's learning process. It was also resolved that, maximum senior faculty from colleges and experts from industry should to be involved while revising the curriculum. I am happy to state that, each Board of studies has adhered to the resolutions passed by Faculty of Technology, developed curriculum accordingly. In addition to outcome-based education, **Choice Based Credit and Grading System** is also introduced to ensure quality of engineering education.

Choice Based Credit and Grading System enables a much-required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning not in teaching. It also focuses on continuous evaluation which will enhance the quality of education. University of Mumbai has taken a lead in implementing the system through its affiliated Institutes. Faculty of Technology has devised a transparent credit assignment policy adopted ten points scale to grade learner's performance. Credit grading-based system was implemented for First Year of B. Pharmacy from the academic year 2016-2017. Subsequently this system was carried forward for Second Year B. Pharmacy in the academic year 2017-2018, Third Year in the academic years 2018-2019 and Final Year B. Pharmacy in the academic year 2019-2020.

Dr. S. K. Ukarande
Dean – Faculty of Science and Technology,
Member - Academic Council
University of Mumbai, Mumbai

SEMESTER VII

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_701_T	Pharmaceutical Chemistry II	4	4	20	80	100
BPH_C_702_T	Pharmacognosy III	4	4	20	80	100
BPH_C_703_T	Pharmaceutical Analysis III	4	4	20	80	100
BPH_C_704_T	Pharmacology III	4	4	20	80	100
BPH_C_705_T	Pharmaceutical Jurisprudence	3	3	20	80	100
BPH_E_7xx_T	Choice Based Course V	2	2	10	40	50
	TOTAL Theory	**21**	**21**	**110**	**440**	**550**
BPH_C_706_L	Pharmacognosy Lab II	2	4	10	40	50
BPH_C_707_L	Pharmaceutical Analysis Lab III	2	4	10	40	50
BPH_C_708_L	Pharmacology Lab II	2	4	10	40	50
	TOTAL Lab	**6**	**12**	**30**	**120**	**150**
	TOTAL SEM VII	**27**	**33**	**140**	**560**	**700**

SEMESTER VIII

Course Code	Name	Credits	Hr/Wk	Weightage Internal	Weightage End Semester Exam	Total Marks
BPH_C_801_T	Pharmaceutical Chemistry III	4	4	20	80	100
BPH_C_802_T	Pharmaceutics IV	4	4	20	80	100
BPH_E_8xx_T	Choice Based Course VI	4	4	20	80	100
BPH_E_8xx_T	Choice Based Course VII	4	4	20	80	100
	TOTAL Theory	**16**	**16**	**80**	**320**	**400**
BPH_C_803_L	Pharmaceutical Chemistry Lab II	2	4	10	40	50
BPH_C_804_L	Pharmaceutics Lab IV	2	4	10	40	50
BPH_E_805_D	Project	6	12	-	200	200
	TOTAL Lab	**10**	**20**	**20**	**280**	**300**
	TOTAL SEM VIII	**26**	**36**	**100**	**600**	**700**

SYLLABUS FOR Final. Y. B. Pharm.

SEMESTER-VII

BPH_C_701_T – Pharmaceutical Chemistry II- (4 Hr/Wk)

Course Objective

1. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of anticancer agents
2. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of antiviral agents
3. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of cardiovascular drugs like antianginal agents, antiarrhythmic agents, diuretics, drug affecting the RAS pathway, vasodilators, antihyperlipidemic agents drugs
4. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of antihistaminics
5. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of hypoglycemic agents and insulin analogs

Course Outcome

Students will gain knowledge in the thurst areas chemotherapy for cancer, antiviral diseases, cardiovascular drugs like antianginal agents, antiarrhythmic agents, diuretics, drug affecting the RAS pathway, vasodilators, antihyperlipidemic agents. They will be apply this knowledge in research areas.

No	Details	Hours
	Discussion of the following classes of drugs including classification, chemical nomenclature, structure including stereochemistry, generic names, SAR and metabolism, molecular mechanism of action, synthesis(*) and rational development if any	
1	**Anti-Cancer agents:** • Alkylating agents like mechlorethamine , chlorambucil* (self study), melphalan*, cyclophosphamide*, busulfan, carmustine, lomustine, streptozocin, dacarbazine and procarbazine, timozolomide • Antimetabolites like azaserine, methotrexate*, pralatrexate, azacytidine, 5-fluorouracil, cytarabine (Ara–C), 6-MP and 6-TG. • Antibiotics like dactinomycin, daunorubicin, doxorubicin , bleomycin and other natural products like vincristine, vinblastine, paclitaxel, docetaxel, topotecan, irinotecan (only highlights of structure to be discussed for bleomycin and natural products) • Platinum compounds like cisplatin and oxaliplatin • Histone Deacetylase Inhibitors: romidepsin, vorinostat • Tyrosine Kinase Inhibitors: imatinib, dasatinib, lapatinib • Combination therapy for breast cancer, leukemia **(Self study)**	7 1
2.	**Antivirals agents including anti-HIV agents:** Amantadine*, rimantadine, oseltamivir, zanamivir, acyclovir and its prodrugs, ganciclovir, famciclovir, penciclovir, idoxuridine, vidarabine Reverse transcriptase inhibitors: , azidothymidine*, stavudine, lamivudine, zalcitabine, didanosine, abacavir, Non-nucleosides reverse-transcriptase inhibitors: delaviridine, nevirapine, efavirenz. HIV-protease inhibitors: raltegravir, saquinavir, ritonavir, (only highlights of structure of protease inhibitors). Drugs like nelfinavir, lopinavir, atazanavir, amprenavir, telaprevir and Combination anti-therapy **(Self Study)**	4 2
3.	**Cardiovascular Drugs**	
3.1	**Antianginal Agents**	3

	Antianginal agents: Amyl nitrite, isosorbide dinitrate, pentaerythritol tetranitrate, verapamil, bepridil, diltiazem, nifedipine, dipyridamole*	
3.2	**Antiarrythmic Agents** Antiarrhythmic agents: quinidine, procainamide*, disopyramide, lidocaine, mexilitine, amiodarone, propafenone, verapamil, diltiazem, propranolol, sotalol*	4
3.3	**Diuretics** • Site 1. Carbonic anyhydrase inhibitors: acetazolamide*, methazolamide, brinzolamide, ethoxzolamide • Site 2. High celing or loop diuretics: Sulphamoyl anthranilic acids like furosemide*, azosemide and bumetanide and phenoxyacetic acids ethacrynic acid* • Site 3. Thiazide and Thiazide like diureties, chlorthiazide***(self study)** hydrochlorthiazide, benzthiazide, methyclothiazide, trichlormethiazide, chlorthalidone, metolazone, quinethazone, indapamide • Site 4. Potassium sparing diureties such as spironoloactone, eplerenone **(self study)** triamterene and amiloride. Osmotic diuretics- mannitol, isosorbide.	4 1
3.4	**Agents affecting Renin-Angiotensin Pathway and Calcium Blockers** • ACE Inhibitors- captopril* Lisinopril, perindopril • Angiotensin II receptor blockers- losartan, valsartan, , telmisartan, olmesartan, azilsartan. • Also valsartan + sacubitril combination • Calcium channel blockers- verapamil , diltiazem, nifedipine, amlodipine, nimodipine, , cilnidipine, benidipine, efonidipine • Renin Inhibitors- aliskiren**(self study)** • Aldosterone antagonists: spironolacone, eplerenone **(self study)**	4 1 1
3.5	**Vasodilators/Sympatholytics** • Vasodilators- Hydralazine* • Non-selective beta blockers- propranolol, nadolol • Selective beta-1 blockers- acebutalol, atenolol, esmolol • Selective alpha-2 blockers- prazosin* terazosin • Mixed alpha-beta blockers- carvedilol, labetalol • K-channel agonists- Minoxidil	4
3.6	**Antihyperlipoproteinemics** Clofibrate*, gemfibrozil, gemfibrate, fenofibrate • HMG-CoA reductase inhibitors: lovastatin, atorvastatin, simvastatin, rosuvastatin, ezetimibe.	3
4	**Antihistaminics** Antihistaminies:H_1 and H_2 receptors, general SAR of classical H1 antihistaminics, Emphasis to be on the second generation H_1 antagonists such as fexofenidine, , loratidine, cetrizine, , andacrivastine, ebastine and bepotastine; combination of H1 antihistaminics and monteleukast H_2 receptor antagonists like cimetidine ranitidine*, famotidine, nizatidine, lafutidine; proton pump inhibitors like omeprazole, rabeprazole, pantoprazole and lansoprazole.	4 1
5	**Hypoglycemics and Insulin Analogues** Hypoglycemics (Insulin not to be discussed) • Biguanides e.g. metformin • Sulfonylureas: 1st Generation like tolbutamide, chloropropamide, tolazamide and acetohexamide***(self study);** 2nd Generation like glyburide* glypizide and glimepride,glyclazide and meglitinides like repaglinide, nateglinide. • Thiazolidinediones such as troglitazone, ciglitazone, rosiglitazone and pioglitazone. • GLP-1 agonists and DPP-IV inhibitors- exenatide and liraglutide (no structures), saxagliptin, vildagliptin, sitagliptin, linagliptin • β – Glucosidase inhibitors like voglibose, and miglitol. Insulin analgoues:Lisproinsulin, glargineinsulin	4
	Total	**48**

*Synthesis to be taught

Latest editions of the following books to be adopted.

12. An Introduction to Medicinal Chemistry, Graham L. Patrick, Oxford University Press.
13. Fundamentals of Medicinal Chemistry, Gareth Thomas, Wiley, New York.

14. The Organic Chemistry of Drug Design and Drug Action, Richard B.Silverman, Academic Press.
15. Foye's Principles of Medicinal Chemistry, Thomas L. Lemke, David A Williams, Lippincott Williams & Wilkins.
16. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, John M. Beale, John H. Block, Lippincott Williams & Wilkins.
17. Medicinal Chemistry, Ashutosh Kar, New Age International Publishers.
18. Introduction to Medicinal Chemistry, Alex Gringauz, Wiley.
19. The Organic Chemistry of Drug Synthesis, Daniel Lednicer, Lester A. Mitscher, John Wiley and Sons.
20. Pharmaceutical Chemistry, Volume 1, Organic Synthesis, H. J. Roth & A. Kleemann, Ellis Horwood Series in Pharmaceutical Technology, Halsted Series.
21. Synthesis of Essential Drugs, Ruben Vardanyan and Victor Hruby, Elsevier.
Pharmaceutical Substances: Syntheses, Patents, Applications, Kleemann& Engel, Thieme Publications.

BPH_C_702_T – Pharmacognosy III- (4 Hr/Wk)

Course Objectives

1. To introduce the learner to the chemistry, sources, cultivation and collection of crude drugs containing phytoconstituents like steroidal, triterpenoidal, anthraquinone, flavonoid glycosides and alkaloids.
2. To introduce the learner to the biosynthesis of alkaloids obtained from different amino acids
3. To introduce the learner to glycoproteins with the representative examples and their utility in diagnosis or therapeutics.
4. To make the learner aware of regulatory requirements for manufacture and sale of Ayurvedic, Siddha and Unani (ASU) Medicines and Phytopharmaceuticals, monographs of herbal drugs
5. To make the learner understand formulation aspects and challenges of Herbal formulations, standardization and interactions of drugs of natural origin
6. To apply the spectroscopic techniques in characterization of phytoconstituents of both aliphatic and aromatic nature

Course Outcomes

Upon completion of the course student will be able to:

1. Write the source, composition, general methods of extraction, evaluation, chemical tests, therapeutic uses of crude drugs containing phytoconstituents like steroidal, triterpenoidal, anthraquinone, flavonoidal glycosides, alkaloids glycoproteins.
2. Write the biosynthesis of biosynthesis of alkaloids obtained from different amino acids
3. Understand regulatory requirements for manufacture and sale of Ayurvedic, Siddha and Unani (ASU) Medicines and Phytopharmaceuticals, monographs of herbal drugs
4. Apply the knowledge of excipients from natural origin and pharmaceutical technology to herbal formulation and understand the challenges in herbal formulation
5. Understand the concept of herbal drug standardization and its application to herbal formulation
6. Apply the knowledge of pharmacology to understand pharmacodynamic and pharmacokinetic interactions of herbal drugs with food
7. Apply spectroscopic techniques to characterize small molecules both from the categories of aromatic and aliphatic nature

No.	Details	Hours
1	**Steriodal and Triterpenoidal glycosides** • Detailed study of drugs with respect source, chemistry, and therapeutic application of the following drugs – Liquorice, Asparagus, Dioscorea, Fenugreek, Brahmi, Ginseng • Introduction to cardiac glycosides with respect to their classification, chemistry & general chemical tests. Detailed study of drugs with respect source, chemistry cultivation and collection, preparation & biopotential of the following drugs – *Digitalis lanata*, *Digitalis purpurea*, Squill • Extraction, Identification and Analysis of Phytoconstituents – Liquorice constituents • Commercial application of Diosgenin **Interactive Session** • Potency, marketed preparation of all cardiac glycosides • Composition and indication of Fenugreek containing formulations	6 1
2	**Alkaloids** Introduction to alkaloids - Classification, properties, general methods of extraction. • Study of following drugs containing alkaloids with respect to their sources, chemistry (structures), salient features of extraction and specific tests for detection (if any) and therapeutic applications of: a. Alkaloidal Amines – Ephedra, colchicum b. Tropane - Datura, Coca, Ashwagandha c. Indole - Rauwolfia, Vinca, Ergot	8

	d. Steroidal –Kurchi e. Quinazoline – Vasaka f. Benzyl isoquinoline – Opium g. Isoquinoline - Ipecac, *Berberis aristata* h. Quinoline - cinchona i. Pyridine-Piperidine –Pepper, Tobacco j. Purine - Tea, Coffee, Cocoa k. Imidazole – Pilocarpus l. Glycoalkaloids- Solanum • Isolation, Identification and Analysis of Phytoconstituents Piperine, Caffeine **Interactive Session** • Market products and their therapeutic uses of Atropine, Pilocarpine, Vasaka, Kurchi, Ephedra, Pepper	 1 1
3	**Biosynthesis** of lysergic acid, tropane alkaloids, emetine, quinine,	2
4	**Glycoproteins** – Castor, Pea and Oats	2
5	**Glycosides** a) Anthracene derivative – Study of aloes, senna, rhubarb, with respect to Occurrence, chemistry, salient features of cultivation, collection, preparation, chemical test and uses. b) Source, chemistry and uses of Rubia, St. John`s wort **Occurrence, Chemistry, Test and Uses of** a) Isothiocyanate – Brassica, cabbage b) Cyanogenetic - bitter almond, wild cherry bark, Biosynthesis of amygdaline Isolation, Identification and Analysis of Phytoconstituents – Anthraquinone- Aloe emodin	3 2
6	**Detailed study of Flavonoids and Coumarins:** **a.** Introduction, classification, chemical tests occurrence & their biopotential as exemplified by Orange Peel, Soyabean, Buckwheat, Psoralea. b. Monomeric, dimeric and related phenylpropanoid derivatives e.g., lignans- Podophyllum • Isolation, Identification and Analysis of Phytoconstituents - Rutin	3
7	**Interactions with DONO :** **Concept of pharmacokinetic interaction and pharmacodynamic interactions** herb- drug interactions – 3 examples each of synergistic and antagonistic interactions herb- food interactions – 3 examples each of synergistic and antagonistic interactions eg . Hypercium, Liquorice, Coffee, Ginseng, Ginkgo biloba, Digitalis, Garlic, Pepper & Ephedra.	3
8	**Use of spectroscopy techniques in characterization of phytoconstituents**. a. Citral b. Rutin c. Gallic acid	2
9	**Standardization of herbal drugs using various type of markers with examples.** Application of various chromatographic techniques in standardization of herbal products with two examples. Stability testing of herbal medicines with respect to marker analysis. **Interactive session** Standardization of polyherbal formulation with respect to respective marker constituents emphasizing on simultaneous estimation.	3 1
10	**Monograph of herbal drugs & excipients** in Indian Pharmacopoeia (Two examples each) **Interactive session** Comparative study of herbal monographs in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia.	2 2
11	**Regulatory Issues - ASU formulations, patent and proprietary medicine and Phytopharmaceuticals** Schedule T & Y of Drugs & Cosmetics Act for ASU drugs and phytopharmaceuticals	2
12	**Study of herbal formulations & Ayurvedic formulations** a. Ayurvedic Formulations –Introduction to Ayurvedic formulations like aristas, asava, gutika,taila, churna, avaleha, bhasma, ghrita. b. Introduction to the concept of detoxification in Ayurveda (2eg). c. Herbal formulations: Challenges in the preparation and evaluation of Herbal tablets, capsules, liquid oral, semisolid dosage forms	3

	d. NDDS of Herbal medicine: Limitation of conventional formulations, challenges in development of NDDS of Herbal medicine, Phytosomes with one example each **Interactive session** Phytopharmaceuticals in the market: Study of any two formulations under each category with respect to their ingredients used and activities / claims of each ingredient used in them	1
	TOTAL	48

Books:

Latest editions of the following books to be adopted.

1. Trease D. & Evans W.C.: Text Book of Pharmacognosy: W.B. Saunders.
2. Tyler V. E. Brady L. R. & Robbers J. E.: Pharmacognosy; Lea Feibger, USA.
3. Wallis T. E.; Text Book of Pharmacognosy; CBS Publishers, Delhi.
4. Kokate C. K., Purohit A. P. & Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
5. Harbone J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman & Hall, London.
6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
7. Vasudevan T. N. & Laddha K. S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
9. R. S. Guad, S. J. Surana, G. S. Talele, S. G. Talele, Mr. S. B. Gokhale. Natural Excipients, Pragati Books Pvt. Ltd., 2006
10. Biren Shah, Avinash Seth, Textbook of Pharmacognosy and Phytochemistry , Elsevier Health Sciences,
11. Ashutosh Kar, Pharmacognosy And Pharmacobiotechnology, New Age International, 2003
12. Quality Control Methods for Medicinal Plant Materials, World Health Organization World Health Organization, 1998 - Botanical drug industry
13. WHO Monographs on Selected Medicinal Plants, World Health Organization World Health Organization, 1999
14. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, ESCOP, European Scientific Cooperative on Phytotherapy, Thieme, 2003 -
15. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, Max Wichtl CRC Press, 2004 - Health & Fitness
16. Pulok K. Mukherjee Evidence-Based Validation of Herbal Medicine, Elsevier, 17-Feb-2015
17. Adverse Effects of Herbal Drugs 2, Springer Science & Business Media, 06-Dec-2012
18. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals, Pulok K. Mukherjee Business Horizons, 2002
19. Brain K. R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.
20. Iyengar M. A. & Nayak S. G.: Anatomy of Crude Drugs: Manipal Power Press, Manipal
21. Iyengar M. A.: Pharmacognosy of Powdered Drugs; Manipal Power Press, Manipal

BPH_C_703_T – Pharmaceutical Analysis III- (4 Hr/Wk)

Course Objectives

On completion of this course, the learner should be able to apply the principles of spectroscopy for multicomponent analysis and describe working principle, instrumentation and applications of chromatographic and characterization techniques.

Course Outcomes

The learner should be able to:

1. Explain various methods used for multicomponent analysis of drugs by UV spectroscopy.
2. Summarize chromatographic and hyphenated techniques used for the separation, identification and quantification of analytes.
3. Describe the working of proton ^{1}H NMR spectroscopy and mass spectrometry.
4. Interpret spectral data to predict structure of a given compound.
5. Summarize the parameters of ICH guidelines for analytical method validation.

No.	Details	Hours
1.0	**Multicomponent analysis by UV Spectroscopy**	**4**
1.1	• Assay as a single component sample • Corrected interference • Assay after solvent extraction • Simultaneous Equation method	4

	• Absorbance Ratio method • Difference Spectroscopy method • Derivative Spectroscopy	
2.0	**Concepts of Chromatography**	**7**
2.1	*Terminologies:* stationary phase, mobile phase, retention time, gradient and isocratic elution, normal and reverse phase chromatography, planar chromatography, retention factor, chromatogram, internal standard, reference standard, working standard, tailing factor (symmetry factor), asymmetry factor, resolution, signal to noise ratio, column chromatography, preparative chromatography, adsorption chromatography and partition chromatography.	3
2.2	• Classification of chromatographic methods ***(Self study-0.5 hr)*** • Quantitative analysis (Peak height, peak areas, calibration curve, internal standard, and area normalization) • Optimization of column performance (Column efficiency and band broadening, shape of peak-Gaussian, Plate height, Number of theoretical plates, van Deemter equation, Capacity factor, Selectivity factor, Tailing factor, peak width, and Resolution)	3
2.3	Numericals and justification based problems related to column performance	1
3.0	**High Performance Liquid chromatography (HPLC)**	**4**
3.1	**Instrumentation:** • Mobile phase reservoir • Pumps (reciprocating, displacement, pneumatic) ***(Self study-0.5 hr)*** • Sample injection systems (Rheodyne injector and autosampler) • Column types (analytical, guard and preparative columns) and column packing (porous, pellicular and monolithic), • Detectors (Concept of solute and bulk property detector-Refractive index ,UV-Vis, Phototodiode array, fluorescence, , Electrochemical, Evaporative Light Scattering), • Difference between UPLC and HPLC ***(Self study-0.5 hr)*** • Applications, Advantages and Limitations of HPLC ***(Self study-0.5 hr)***	4
4.0	**Gas chromatography (GC)**	**3**
4.1	• Introduction **Instrumentation** • Carrier gas supply • Sample injection system including Head space analysis • Columns (Packed, Open tubular columns, Capillary columns) and column ovens ***(Self study-0.5 hr)*** • Detectors (Thermal conductivity, Electron capture, Flame ionization) Applications, Advantages and Limitations of GC ***(Self study-0.5 hr)***	3
5.0	**Planar chromatography**	**3**
5.1	• **Paper chromatography**-Principle, Developmental techniques (Ascending, Descending, Radial and Two-dimensional), Spray reagents and Pharmaceutical applications ***(Self study-0.5 hr)*** • **TLC**-Principle, types of adsorbents, Developmental techniques ***(Self study-0.5 hr),*** Visualisation techniques, factors affecting resolution, Pharmaceutical applications of TLC and Preparative TLC. • **HPTLC:** Instrumentation- Applicator, photodensitometry, photodocumentation, • Advantages of HPTLC over TLC and HPLC ***(Self study-0.5 hr)***	3
6.0	**Ion exchange chromatography, Ion Pair and Size Exclusion chromatography**	**3**

6.1	Principle, Stationary phases, Mobile phases and Applications ***(Self study-0.5 hr)***	3
7.0	**Nuclear Magnetic Resonance Spectroscopy (^{1}H-NMR)**	**8**
7.1	**^{1}H-NMR phenomenon-** spinning nucleus, precessional motion, precessional frequency, gyromagnetic ratio, energy transitions and relaxation processes, NMR Spectra, Chemical shift, shielding and deshielding, Vanderwaal's deshielding, Deuterium exchange, Chemical and magnetic equivalence , anisotropic effect (eg. Alkanes, alkenes, alkynes, carbonyl, aromatic and cyclohexane), Solvents, Reference compounds and internal standards.	2
7.2	**Measurement of chemical shift:** • Scales used. • Factors affecting chemical shift (Electronegativity-Shielding and Deshielding, Vanderwaal's deshielding, anisotropic effect) • Instrumentation of NMR Spectrometer (including schematic representation) ***(Self study-0.5 hr)*** • Principle of FT NMR (including representation of conversion of time domain spectra to frequency domain spectra)	3
7.3	**Spin-spin coupling-Spin-Spin splitting:** • N+1 rule (Pascal's triangle), theory of spin-spin splitting, formation of doublet, triplet and quartet due to possible spin orientations, inverted tree diagram, Coupling constants & values for alkyl, alkenyl , aromatic). Information obtained from proton NMR-Chemical shift, splitting, coupling constant, integration. ***(Self study-0.5 hr)***	3
8.0	**Mass Spectrometry**	**4**
8.1	Principle & basic theory- Mass spectrum, relative abundance, mass to charge ratio, molecular ion, fragment ion (daughter ion), metastable ion, base peak, isotope peak, mass to charge ratio.	1
8.2	**Instrumentation:** • Basic components of mass spectrometer (including block diagram). • Ionisation methods: Electron Ionisation, Chemical Ionisation, Desorption Ionisation (MALDI), Fast Atomic Bombardment, Atmospheric Pressure Ionisation (Electrospray, APCI, APPI). • Analysers: Quadrupole, Ion Trap and Time of Flight.	2
8.3	Examples of different mass fragmentation pathways	1
9.0	**Hyphenated techniques**	**2**
	Significance, interfaces and applications of • LC-MS • GC-MS ***(Self study-1 hr)***	
10.0	**Structure Elucidation by spectral techniques using UV, IR, 1H-NMR and Mass spectrometry**	**8**
10.1	UV-Woodward Fieser rules for predicting λ_{max} (acyclic & cyclic dienes, and α, β unsaturated ketones (acyclic and 6 membered ring). (**Note**-only alkyl substituents to be studied). ***(Practice problems-Self study-0.5 hr)***	2
10.2	Elucidation of structure of a compound using IR and ^{1}H NMR data- Problems for simple organic compounds with molecular formula given ***(Practice problems-Self study-0.5 hr)***	3
10.3	Mass spectrometry:	3

	Fragmentation: Representation of fragmentation process, Basic types of fragmentation: • Fissions (homolytic and heterolytic, α and β fission). • Rearrangement (Mclafferty, Retro Diel-Alders, 4 membered cyclic rearrangement), • Nitrogen rule and Even electron rule. ***(Practice problems-Self study-0.5 hr)***	
11	**Analytical method Validation.** ***(Self study- 0.5 hr)***	**2**
11.1	Analytical method Validation as per ICH guidelines.	
	Total	**48**

Books:

1. D. A. Skoog, F. J. Holler and S. R. Crouch, Principles of Instrumental Analysis, Saunders College Publishing, USA.
2. K. A. Connors, A Textbook of Pharmaceutical Analysis, John Wiley and Sons, Canada.
3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, ,Vol. 6, Part I and II, CBS Publishers and Distributors, India.
4. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, Saunders College Publishing, USA.
5. G. D. Christian, Analytical Chemistry, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
6. H.H. Willard, L. L. Merrit and J. A. Dean, Instrumental Method of Analysis, CBS Publishers & Distributors, New Delhi.
7. Ashutosh. Kar, Pharmaceutical Drug Analysis, New Age International (P) Ltd. Publishers, India.
8. S. S. Mahajan, Instrumental Methods of Analysis, Popular Prakashan Pvt Ltd., India.
9. G. R. Chatwal and S. K. Anand, Instrumental methods of chemical analysis, Himalaya Publishing House Pvt. Ltd.
10. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission, Ghaziabad, Government of India.
11. United States Pharmacopeia
12. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
13. D. G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists. Churchill Livingstone Elsevier.
14. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
15. R. Kellnar, J. M. Mermet, M. Otto, M. Valcarceland, H. M. Widmer, Analytical Chemistry: A modern approach to analytical science, Wiley-VCH, USA.
16. J. W. Munson, Pharmaceutical Analysis: Modern methods (in two parts), Marcel Dekker Inc., USA.
17. W. Kemp, Organic Spectroscopy, Palgrave Publishers Ltd., New York, USA.
18. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi.
19. D. B. Troy and P. Beringer, Remington-The Science and Practice of Pharmacy, Vol-I & II, Wolters Kluwer/ Lippincott Williams & Wilkins (Indian edition), New Delhi.
20. 20 J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
21. J. R. Dyer, Applications Of Absorption Spectroscopy Of Organic Compounds, Prentice- Hall of India Pvt Ltd, New Delhi, India.
22. D. L. Pavia, G. M. Lampman, G. S. Kriz and J. R. Vyvyan, Introduction to Spectroscopy, Brooks/Cole Cengage Learning, Australia.
23. Y. R. Sharma, Elementary organic spectroscopy-Principles and Chemical Applications, S. Chand & Company Ltd, New Delhi, India.
24. L. R. Snyder, J. J. Kirkland, J. L. Glajch, Practical HPLC Method Development, Wiley-Interscience publication, John Wiley & Sons, Inc., Canada.
25. S. Ahuja and M. W. Dong, Handbook of Pharmaceutical Analysis by HPLC, Volume 6 of Separation Science and Technology, Elsevier Academic Press, Indian edition.

BPH_C_704_T – Pharmacology III- (4 Hr/Wk)

Course prerequisites

- Knowledge of anatomy, physiology and pathophysiology of diseases/disorders of central nervous system and gastrointestinal system
- Concept of Inflammation
- Information on endogenous receptors in the human body

Course objectives

1. To educate on different drugs acting on central nervous system and its associated diseases.
2. To educate on pharmacology of anti-inflammatory drugs.
3. Impart knowledge on pharmacology of drugs used in inflammatory disorders like asthma and gout.
4. Educate on autacoids and drugs impacting autacoids' actions.
5. To provide understanding about drugs used in GIT associated disorders.
6. To convey principles of toxicity with briefing on common toxicants.

Course outcomes

1. Explain pharmacology of drugs acting on central nervous system and associated diseases.
2. Classify and explain pharmacology of anti-inflammatory drugs, make use of knowledge of these drugs to justify their use in asthma and gout.
3. Discuss the pharmacology of drugs used in gastrointestinal disorders.
4. Know the toxic effects of heavy metals, drugs and environmental toxicants.

No	Details	Hours
1	Drugs acting on Central Nervous System	24
1.1	Aliphatic alcohols	2
1.2	General and Local anaesthetics	4
1.3	Sedatives, Hypnotic and anxiolytic agents	3
1.4	Antiepileptic drugs	2
1.5	Drugs Used in Parkinson's disease	2
1.6	Drugs used in Alzheimer's disease	2
1.7	Antipsychotic, antidepressant, anti-mania drugs	4
1.8	Opioid analgesics	3
1.9	CNS stimulants	2
2	Autacoids; Drug therapy of inflammation	13
2.1	Histamine, bradykinin and their antagonists	2
2.2	Serotonin, agonists and antagonists	2
2.3	Lipid derived autacoids, Eicosanoids and platelet activating factor	2
2.4	NSAIDs	3
2.5	Pharmacotherapy of Asthma	2
2.6	Pharmacotherapy of Gout	2
3	Drugs acting on gastrointestinal tract	8
3.1	Antacids and Drugs for peptic ulcers	3
3.2	Emetics, anti-emetics and Prokinetics	2
3.3	Drugs for constipation and diarrhoea	2
3.4	Drugs for Inflammatory Bowel Diseases	1
4	Principles of Toxicology	3
4.1	Heavy metals (Lead, Mercury, Arsenic) Poisoning,	2
4.2	Pesticide and Opioid Poisoning and treatment	1
	TOTAL	**48**

Books:
Latest editions of following books to be adopted

1. Goodman & Gilman's Pharmacological Basis of Therapeutics, McGraw Hill Companies Inc.
2. Satoskar R.S. Bhandarkar S.D. & Rege N.N. Pharmacology & Therapeutics, Popular Prakashan.
3. Rang & Dale Pharmacology, Churchill Livingstone.
4. Lippincott's Illustrated Reviews: Pharmacology- Lippincott-Raven Howland & Nyeets Publishers NY.
5. Laurence D.R. & Bennett Clinical Pharmacology, Elsevier NY.
6. Kulkarni S.K. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
7. B.G.Katzung-Basic and Clinical Pharmacology, Appleton and Lange publications.
8. Ghosh M.N. Fundamental of Experimental Pharmacology. Hilton and company, Kolkata

BPH_C_705_T – Pharmaceutical Jurisprudence- (3 Hr/Wk)

Course Objectives

To impart knowledge on important legislations related to the profession of Pharmacy

Course Outcomes

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

1. Interpret Pharmaceutical Legislation
2. Understand pricing of drugs & pharmaceuticals
3. Summarize offences & penalties concerned with laws for drugs and pharmaceuticals
4. Gain an insight into Drug Regulatory Affairs

No.	Details	Hours
1	Pharmaceutical Legislation – A brief review of Historical perspectives, Study of Drugs Enquiry Committee (Chopra Committee), Hathi Committee, Dr Mashelkar Committee	**1**
2	**PHARMACY ACT 1948**	
2.1	Definitions	**0.5**
2.2	Pharmacy Council of India and State Councils: Composition and Functions	
2.3	Registration of Pharmacists: Preparation of registers and qualifications for entry into registers	**2**
2.4	Educational Regulations and Approval of Courses and Institutions	
2.5	Offences and Penalties	
2.6	Pharmacy Practice Regulations, 2015	**1**
3	**DRUGS AND COSMETICS ACT 1940 AND RULES 1945**	
3.1	Definitions	**0.5**
3.2	Advisory Bodies: DTAB and DCC: Composition and Function	**2**
3.3	Analytical Bodies: Drug control Laboratories and Government Analyst	
3.4	Executive Bodies: Licensing Authorities, Controlling Authorities, Drug Inspectors and Customs Collectors	
3.5	Provisions regarding Import of Drugs	**3**
3.6	Provisions regarding Manufacture of Drugs	
3.7	Provisions regarding Sale of Drugs	
3.8	Labeling and Packing of Drugs	**1**
3.9	Provisions applicable to Manufacture, Sale, labeling and Packing of Ayurvedic Drugs	**1**

3.10	Provisions applicable to Import, Manufacture, Sale, labeling and Packing of Homeopathic Drugs	**1**
3.11	Provisions applicable to Import, Manufacture, Sale, labeling and Packing of Cosmetics	**1**
3.12	Offences and penalties	**1**
3.13	Schedules to the Drugs and Cosmetics Act & Rules (in brief), Schedule M and Schedule Y in moderate details	**1**
3.14	Self-study: Case Studies	
4.0	**DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT 1954 & RULES 1955**	**2**
4.1	Definitions	
4.2	Prohibited Advertisements, Savings	
4.3	Self-study: Case Studies	
5	**NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT & RULES 1985**	**2**
5.1	Definitions	
5.2	Narcotics Commissioner and other Officers	
5.3	Illicit Traffic and measures to prevent illicit traffic of opium	
5.4	Essential Narcotic Drugs, Recognized Medical Institutions	
5.4	Offences and penalties	
6	**DRUGS PRICES CONTROL ORDER 2013**	**2**
6.1	Definitions	
6.2	Calculation, fixation, revision of ceiling / retail price for a scheduled formulation and its monitoring	
6.3	Display of prices of non-scheduled formulations and price list thereof and Sale of splitSS quantities of formulations	
6.4	Manufacturer, distributor or dealer not to refuse sale of drug	
6.5	National List of Essential Medicines and Schedule I	
6.6	Draft Pharmaceutical Policy – 2017	
7	**MEDICINAL AND TOILET PREPARATIONS (EXCISE DUTIES ACT) 1955**	**2**
7.1	Definitions, restricted and unrestricted preparations	
7.2	Manufacturing in bond and outside bond	
8	**FOOD SAFETY AND STANDARDS ACT 2006 AND RULES 2011**	**3**
8.1	Definitions: Food, Adulterant and Food additive	
8.2	Authorities and bodies: Food Safety and Standards Authority of India, Central Advisory Committee, Food safety Officer, Commissioner of Food Safety in the State, Analytical Laboratories and Food Analysts	
8.3	Different Food Safety and Standards Regulations	
8.4	Food Safety and Standards (Packaging and Labeling) Regulation, 2011	

9	**INDIAN PATENTS ACT 2005**	**4**
9.1	Intellectual Property and its types, PCT, Different Laws related to Intellectual Property in India	
9.2	Definitions, features of a patent	
9.3	Criteria for patentability and inventions not patentable in India	
9.4	Process of patenting in India	
9.5	Working of Patents, Compulsory Licences	
9.5	Self-study: Case Studies	
10	**BOMBAY SHOPS AND ESTABLISHMENTS ACT**	
10.1	Definitions of Shops and Commercial Establishments and Provisions under the Act in Brief	**1**
11	**FACTORIES ACT 1954**	
11.1	Definitions	**1**
11.2	Provisions under the Act in Brief	
12	**INDIAN PENAL CODE AND CODE OF CRIMINAL PROCEDURES**	
12.1	Provisions pertaining to different courts, jurisdiction and power	**1**
12.2	Provisions governing entry, search, arrest, bailable and non-bailable offences, cognizable and non-cognizable offences	
13	**INTRODUCTION TO DRUG REGULATORY AFFAIRS**	**2**
13.1	Brief overview of Drug Regulatory Agencies of US, Australia, Europe, UK, Japan	
13.2	Introduction to USFDA, European, ICH and WHO guidelines	
	TOTAL	**38**

Books:

Latest editions of the following

1. Kuchekar B. S., Khadtare A. M., Itkar S. C., Pharmaceutical Jurisprudence, Nirali Prakashan.
2. N.K. Jain, Pharmaceutical Jurisprudence, Vallabh Prakashan.
3. Mittal B. M., Forensic Pharmacy, Vallabh Prakashan
4. Deshpande S. W. & Nilesh Gandhi, Drugs & Cosmetics Act; 9th Edition;2018
5. Government of India Publications of above Acts and Rules
6. www.fda.gov
7. www.tga.gov.au
8. www.ema.europa.eu
9. www.mhra.gov.uk
10. www.ich.org
11. www.who.int

BPH_C_706_L – Pharmacognosy Lab II- (4 Hr/Wk)

Course Objectives

1. To study crude drugs representative to major parts of plants for their morphological features and microscopic characters including histology, powder characteristics.
2. To apply the knowledge of microscopic characters of the crude drugs in ascertaining genuinely of powdered formulations.
3. To extract and perform qualitative chemical tests belonging to various classes of phytoconstituents viz. Anthraquinone Glycosides, Cardiac Glycosides, Flavonoids, Cyanogenetic Glycosides, Alkaloids, Triterpenoid and Steroidal Glycosides, Saponins, Tannins.

4. To apply knowledge of analytical procedures in quantitative determination of total Aldehyde content / Phenol content / total alkaloids from crude drugs
5. To understand principles involved and carry out extraction of active constituents
6. To identify crude drugs based on the morphological characters and quote some formulations available in market with their therapeutic utility

Course outcomes

At the end of the course the learner will be able to

1. Identify crude drugs based on morphological characters, microscopic characters and give biological source with the chemical constituents and therapeutic uses
2. Apply the knowledge of microscopic characters in ascertaining the genuinely of powdered formulations.
3. Extract and perform qualitative chemical rests on the crude drugs containing Anthraquinone Glycosides, Cardiac Glycosides, Flavonoids, Cyanogenetic Glycosides, Alkaloids, Triterpenoid and Steroidal Glycosides, Saponins, Tannins
4. Apply analytical procedures and principles for quantitative determination of total Aldehyde content / Phenol content / total alkaloids from crude drugs
5. Understand principles involved apply these for carrying out extraction of active constituents
6. Identify crude drugs based on the morphological characters and quote some formulations available in market with their therapeutic utility

No.	Details	Hours
1	Study of morphology, histology, powder characteristics, Extraction Chemical test, and TLC. (TLC of any 5 drugs) Clove, Fennel, Senna, Cinnamom bark, Ephedra, Kurchi, Liquorice	20
2	To ascertain the authenticity of the powder formulation using microscopy containing drugs listed in topic 1. Qualitative Phytochemical Tests of all phytoconstituents – Anthraquinone Glycosides, Cardiac Glycosides, Flavonoids, Cyanogenetic Glycosides, Alkaloids, Triterpenoid and Steroidal Glycosides, Saponins, Tannins,	8
3	Monograph analysis of 1 herbal drug or 1 herbal excepient from IP	4
4	Estimation of Aldehyde content / Phenol content / total alkaloids from crude drug (Beckett)	4
5	Exercise involving isolation & detection of active principles of any two – Piperine / Caffeine/ eugenol / embelin / rutin)	8
6	To study morphological characters and one marketed formulation of Arjuna, Vasaka, Brahmi, Fenugreek, Garlic, Guggul, Asafoetida, Pepper, Ergot, Mint, Jatamansi, Lemon grass, Digitalis, Vinca, Aloe vera, Vidang, Myrobalans, Dill, Cumin, Lemon grass.	4
	TOTAL	**48**

Books:

1. Trease D. & Evans W. C.: Textbook of Pharmacognosy: W. B. Saunders.
2. Tyler V.E., Brady L.R. & Robbers J. E.: Pharmacognosy; Lea Febiger, USA.
3. Wallis T. E.; Textbook of Pharmacognosy; CBS Publishers, Delhi.
4. Kokate C.K., Purohit A. P. &Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
5. Harborne J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman& Hall, London.
6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
7. Vasudevan T.N. & Laddha K.S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
9. Brain K.R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.

BPH_C_707_L – Pharmaceutical Analysis Lab III- (4 Hr/Wk)

Course Objectives

On performing the following experiments, the learner should be able to operate the instruments, understand their functioning, prepare solutions accurately, conduct analysis using appropriate instrument, calculate, report and interpret the results of analysis.

Course Outcomes

The learner should be able to:

1. Record, calculate and interpret data obtained by UV spectrophotometric analysis for pK_a determination and concentration determination by multicomponent analysis techniques.
2. Apply ICH guidelines to validate an analytical method by UV spectroscopy and interpret results obtained.
3. Develop and optimize mobile phase composition for qualitative analysis by TLC and interpret qualitative analysis data by TLC and paper chromatography.
4. Outline working and application of column chromatography, HPLC and GC.

No.	Details
1.	UV spectrophotometric estimation of two components formulation by simultaneous equation method, Eg- Caffeine and Sodium benzoate injection.
2.	UV spectrophotometric estimation of two components formulation by absorbance ratio method, Eg- Caffeine and Sodium benzoate injection.
3.	UV spectrophotometric estimation of formulation by Difference spectroscopy: Eg: Phenylephrine HCl ophthalmic solution.
4.	Assay of Trimethoprim in cotrimoxazole tablets
5.	Determination of concentration of sample by UV spectroscopy (Construction of calibration curve using linear regression analysis). Eg-Ibuprofen.
6.	Determination of validation parameters by UV spectroscopy: Eg-Ibuprofen, Paracetamol. • Linearity • Precision • Accuracy
7.	Separation and identification of compounds by TLC
8.	Determination of pKa by UV spectroscopy eg. Phenylephrine HCl
9.	Demonstration experiments: • Separation and identification of amino acids by paper chromatography. • Development of mobile phase for TLC • Working of HPLC, GC and HPTLC. • Separation of compounds by column chromatography

Note: Examples of drugs are provided for reference purpose only. Any other suitable drug can also be used.

Books:

1. A.H. Beckett and J.B. Stenlake, *Practical Pharmaceutical Chemistry*, 4th Edn., Part I and II, CBS Publishers and Distributors, India.
2. G. D. Christian, *Analytical Chemistry*, 6th Edn., John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
3. Indian Pharmacopoeia, The Indian Pharmacopeia Commission, Ghaziabad, Government of India.
4. United States Pharmacopeia.
5. J. Mendham, R. C. Denney, J. D. Barnes, M.J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
6. D.G. Watson, *Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists*. 3rd Edn., Churchill Livingstone Elsevier.
7. L. R. Snyder, J. J. Kirkland, J. L. Glajch, *Practical HPLC Method Development*, 2nd Edn., Wiley-Interscience publication, John Wiley & Sons, Inc., Canada.
8. S. Ahuja and M. W. Dong, Handbook of Pharmaceutical Analysis by HPLC, Volume of Separation Science and Technology, Elsevier Academic Press, Indian edition.

BPH_C_708_L– Pharmacology Lab II- (4 Hr/Wk)

Course prerequisites:

- Ability to perform *in vitro* "dose response" experiments using cock ileum.

Course objectives:

1. Practical training on performing Bioassay of acetylcholine and atropine using cock ileum.
2. Demonstration of oxytocin bioassay and behavioural experiments using interactive CDs.
3. Information on Regulatory and toxicity guidelines.

Course outcomes:

1. Define Bioassay, list the types, methods and applications of bioassay and perform *in vitro* bioassay using cock ileum and record, calculate and interpret unknown concentration of agonist/antagonist/drug.

2. Observe preclinical models which provide evidences on drug/lead pharmacological activity.
3. Relate to and apply the ethical, regulatory and toxicity guidelines/rules (ICH, OECD, CPCSEA, Schedule Y) in drug/lead testing using preclinical animals.

No.	Details
1.	**Experiments:** 1. Bioassay of Acetylcholine using suitable isolated tissue preparation e.g. Cock ileum 2. Bioassay of Atropine using suitable isolated tissue preparation e.g. Cock ileum
2.	**Demonstrations: (with kymograph recordings or audio-visual aids)** 1. Bioassay of oxytocin 2. Behavioral Pharmacology Demonstrations/ Simulated experiments (CDs). • To study effect of drugs on locomotor activity in rodents using actophotometer. • To study the muscle relaxant property of drug using Rota-rod. • To study analgesic activity of drug using an analgesiometer. • To study anticonvulsant activity of drugs using maximal electroshock/ chemically induced seizures. • To study phenothiazines induced catalepsy using suitable animal model.
3.	**Toxicity studies** • Introduction to CPCSEA, OECD guidelines • Introduction to acute, sub-acute and chronic toxicity studies

Books:

Latest editions of the following books to be adopted:

1. Kulkarni S. K. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
2. Ghosh M.N. Fundamentals of Experimental Pharmacology Hilton & Company, Kolkata.
3. S. B. Kasture. A handbook of Experiments in Pre-Clinical Pharmacology, Career Publications.
4. W. L. M. Perry, Pharmacological Experiments on isolated preparations, E & S Livingstone, Edinburg & London.
5. Patil C. R. X-cology (Software), Pragati Book Co. Pvt. Ltd, Pune.

ANY ONE SUBJECT FROM THE FOLLOWING 2 CREDIT SUBJECTS TO BE CHOSEN AS ELECTIVE FOR A TOTAL OF 2 CREDITS

BPH_E_709_T – Intellectual Property Rights- (2 Hr/Wk)

Course Objectives

The course is framed to impart knowledge to the learners so that they get conversant with the Fundamentals of Intellectual property Rights (IPR), their types and governing laws.

Course Outcomes

1. Correlate the knowledge of IPR with respect to pharmaceutical products.
2. Apply knowledge of IPR in designing strategy for pharmaceutical product development.

No.	Details	Hours
1	Intellectual Property Rights (IPR) – Introduction, definition, need history	2
2	Patents – Introduction, Indian Patent Act (1970), Patent and claim drafting, Process of filing and prosecution, Rights achieved, Patentability with respect to Regional/ country's Requirement, Opposition of Patent Self-Study - Case Study Presentations	8 1
3	Industrial Design – Introduction, filing and prosecution	2
4	Geographical Indication - Introduction, filing and prosecution	1
5	Natural biodiversity Act and Depository Bodies – Introduction and filing procedure	1
6	Patent Filing under PCT (Paris Convention Treaty/Patent Convention Treaty) - Introduction, filing and prosecution, territorial specificity	3
7	Trademark – Introduction, filing and prosecution, opposition to trademark	3
8	Copyright – Introduction, filing and prosecution	1
9	Role of IPR in pharmaceutical product launch	1
10	IPR infringement and remedies	1
	TOTAL	24

Books:

1. Intellectual Property Law, P. Narayanan, , Eastern Law House, Revised Edition, 2017.
2. www.wipo.int (World Intellectual Property Organization)
3. Indian Patent Act (www.ipindia.nic.in)

BPH_E_710_T – Green Chemistry and Catalysis- (2 Hr/Wk)

Course Objective

1. To introduce the learner with principles of green chemistry.
2. To study the source, disposal and prevention of chemical waste.
3. To learn basic level environmental management system.
4. To learn and select various kinds of catalysis with respect to industrial case studies.

Course Outcomes

The learner should be able to:

1. Know the terms involved in green chemistry.
2. Understand the concept and techniques of waste management.
3. Know various guidelines of environmental management system.
4. Outline type of catalysis and their uses.
5. Learn greener process designing.

No.	Details	Hours
1	Principles and Concepts of Green Chemistry	**2**
1.1	Introduction and Twelve principles	
1.2	Sustainable development and green chemistry	
1.3	Atom economy, Atom economic reactions like rearrangement and addition reactions, Atom uneconomic reactions like substitution, elimination	
1.4	Reducing and measuring toxicity, E-Factor	
2	Waste: Production, problems and prevention	**3**
2.1	Introduction, Problems caused by waste	
2.2	Sources of waste from chemical industry, cost of waste	
2.3	Waste minimization techniques: Approach, Process design, minimizing waste from existing resources	
2.4	Treatment of waste: Physical, Chemical, Biotreatment	
2.5	Design for degradation: Degradation and surfactants, DDT, Polymer	
2.6	Polymer recycling: Separation and sorting, Incineration, Mechanical and chemical recycling of monomers	
3	Environmental Management Systems (EMS) ISO 4000, The European Eco-Management and Audit Scheme (EMAS)	**2**
3.1	Introduction to Life Cycle assessment system (LCA): Four stages, carbon foot printing	
3.2	Eco labels, Integration Pollution Prevention and Control (IPPC), REACH	
4	Catalysis and Green Chemistry	**4**
4.1	Introduction to catalysis, comparison of catalyst types	
4.2	Heterogeneous catalysts: Basics, Zeolites and bulk chemical industry, heterogeneous catalyst in Fine chemicals and pharmaceutical Industry, Catalytic converters	
4.3	Homogeneous catalysts: Basics, Transition metal catalysts, Greener lewis catalyst, asymmetric catalyst	
4.4	Phase transfer catalysis: Basics, hazard reduction, C-C bond formation, oxidation using H_2O_2	
4.5	Biocatalysis, Photocatalysis	
5	Use of solvents	**4**
5.1	Organic solvents and volatile organic compounds, solvent free system, Supercritical fluids, $scCO_2$,scH_2O	
5.2	Water as reaction solvent	
5.3	Ionic liquids as solvent and catalyst, Fluorous biophase solvents,	
5.4	Greenness of solvent a comparison	
6	Renewable resources	**2**
6.1	Biomass as renewable resource, Energy: from biomass, solar power, fuel cells	
6.2	Chemicals from renewable feedstock: from fatty acids, polymers, natural resources	
7	Emerging Greener technology	**3**
7.1	Photochemical reactions: Advantages and challenges, examples	
7.2	Microwave assisted chemistry: Microwave heating and examples	

7.3	Sonochemistry, Electrochemistry with examples	
8	Designing green process	**2**
8.1	Conventional reactors: Batch reactors, continuous reactors	
8.2	Inherently safer design using concept of minimization, simplification, substitution, moderation, limitation	
8.3	Process intensification: PI equipment with examples of intensified processes	
8.4	In-process monitoring, Process safety	
9	Industrial case studies: Methyl Methcrylate, acetic acid manufacturing, Vitamin C, Dyes, Naproxen, Ibuoprofen	**2**
	TOTAL	**24**

Books:

1. Green Chemistry: An Introductory Text, Mike Lancaster, 2nd edition, RSC publishing.
2. Green Chemistry: Theory and Practice, Anastas P T and Warner J C, Oxford University Press.
3. Introduction to Green Chemistry, Ryan M. A., Tinnesand M., American Chemical Society (Washington).
4. Handbook of Green Chemistry and Technology, Clarke J and Macquarrie D, Blackwell.

BPH_E_711_T – Preformulation Studies- (2 Hr/Wk)

Course Objectives

On completion of the course the learner will be able to understand the importance of physicochemical properties of a drug candidate in design and development of an effective, stable, acceptable and safe formulation

Course Outcomes

At the end of the course the learners will be able to:

1. Explain physicochemical principles relevant to pharmaceutical dosage forms.
2. Comprehend the importance of solubility, stability and compatibility of drug substances with different excipients
3. Understand the role of preformulation studies in drug discovery, drug and product development

No	Details	Hours
1	**Drug Discovery and Development Process in the Pharmaceutical Industry-** Need, Hurdles faced, Scheme of Steps in New Drug Development Process. **The concept of preformulation -**Goals and scope of preformulation, Basic information for designing preformulation studies. **Principal areas of Preformulation research**	**3**
2	**Bulk Characterization**	**10**
2.1	Organoleptic properties: Appearance, odour and taste, Hygroscopicity	1
2.2	Crystallinity & Polymorphism: Crystal morphology & Crystal habit, Pseudopolymorphism (solvates), True polymorphism. Methods to characterize polymorphs-Melting point determination, Hot-stage microscopy, Differential scanning calorimetry and thermal analysis, PXRD (basic principles of the methods only)	3
2.3	Fine particle characterization - Particle size distribution measurements, Microscopy, sieve analysis. Laser diffraction method (basic principle) Particle Size Reduction, effect of milling and micronization,	3
2.4	Powder flow and Compression properties**:** Bulk density, void volume, Carr's compressibility, Hausner's ratio, Angle of repose. Deformation behaviour of particles under the influence of applied forces-Elastic & Plastic deformation, Fragmentation, Punch filming (sticking).	3
3	**Solubility**	**7**
3.1	Aqueous solubility: Intrinsic solubility (K_0), pK_a determination, pH solubility profile and Common ion effect, effect of temperature, Techniques of solubilization-Co solvents, Chelating agents, Surfactants Complexation.	4
3.2	Dissolution: Intrinsic dissolution rate, Measurement of intrinsic dissolution rate Partition coefficient ($K_{o/w}$): Significance in preformulation studies as predictor of *in vivo* absorption, methods to determine partition coefficient	3
4	**Stability** Temperature, Order of reaction, Hydrolysis, Oxidation, photolysis **(Self-study with follow up)** Solid-state stability: bulk stability, effect of high humidity Compatibility in presence of excipients Solution phase stability: pH stability profile	**3**

5	Preformulation aspects for development of Tablets and Monophasic liquid dosage forms	**1**
	TOTAL	**24**

Books:

1. M.E. Aulton. Pharmaceutics: The Design and manufacture of medicines. Third edition. 2007. Churchill Livingstone Elsivier.
2. David B. Troy, Paul Beringer. Remington's - The Science and Practice of Pharmacy. Twenty first Edition. 2006. Lippincot Williams & Wilkins.
3. Mark Gibson. Pharmaceutical Preformulation and Formulation: A Practical Guide from candidate selection to commercial dosage form. Second edition. Informa Healthcare.
4. Leon Lachman, Herbert A. Lieberman. Theory and Practice of Industrial Pharmacy. Special Indian edition. 2009; CBS Publishers.
5. Herbert Lieberman, Leon Lachman, Joseph B. Schwartz. Pharmaceutical Dosage Forms: Tablets, Volume 1. 1989. Second Edition. Marcel Dekker Inc. NY

SEMESTER-VIII

BPH_C_801_T – Pharmaceutical Chemistry III- (4 Hr/Wk)

Course Objectives

1. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of CNS active drugs like sedatives/hypnotics, anticonvulsants, antidepressants, anxiolytics and antipsychotics
2. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of ANS active drugs like adrenergic and cholinergic agents
3. Learn structure including stereochemistry, chemical name, SAR, metabolism, mechanism of action and selected synthesis of testosterons and adrenocorticoids

Course Outcome

Students will gain knowledge in the thurst areas of CNS, ANS active drugs, analgesic agents and male female hormones. They will be apply this knowledge in research areas.

No.	Details	Hours
	Discussion of the following classes of drugs including classification, chemical nomenclature, structure including stereochemistry, generic names, SAR and metabolism, molecular mechanism of action, synthesis(*) and rational development if any	
1	**CNS Drugs**	
1.1	Sedatives – Hypnotics Benzodiadepines: chlordiazepoxide, diazepam, nitrazepam*, temazepam, alprazolam, estazolam; zolpidem, eszopiclone, ramelteon (last 3 for self study – 1 hr).	3
1.2	Anticonvulsants Types of seizures (Self study- 1 hr) phenytoin, mephenytoin, ethotoin, trimethadione, diazepam, clonazepam, carbamazepine*, valproic acid, vigabatrine, progabide, lamotrigine, tiagabine	3 1
1.3	Antidepressants imipramine*, chlorimipramine, amitriptyline, nortriptyline, doxepine* fluoxetine*, paroxetine, sertraline, escitalopram, amoxapine	3
1.4	Anxiolytics Oxazepam, buspirone	1
1.5	Antipsychotics chlorpromazine*, triflupromazine, thioridazine, fluphenazine, trifluperazine, chlorprothixen(self study), droperidol , pimozide, risperidone, loxapine, clozapine, sulpiride	4
1.6	Antiparkinson's carbidopa, levodopa, selegiline, amantadine, benztropine, procyclidine, orphenadrine (last 3 for self study- 1 hr)	1
2	**ANS Drugs**	
2.1	Adrenergic Drugs Alpha adrenergic agonists: phenylephrine*, naphazoline, xylometazoline, oxymetazoline, methyldopa, clonidine, guanabenz, guanafacine Beta agonists : Isoproterenol, colterol, metaproterenol, terbutaline*, albuterol, isoxsuprine, ritodrine Alpha antagonist : tolazoline, phentolamine, phenoxybenzamine, prazosin, doxazosin Beta Antagonists : pronethalol, propranolol*, sotalol, timolol, atenolol, metoprolol, esmolol, acebutolol, carvedilol, labetalol* (last two for self study, including synthesis of labetalol) Other adrenergic agents (Self study-2 hrs) : pseudoephedrine, ephedrine, guanethidine, propylhexedrine, reserpine	7
2.2	Cholinergic Drugs Muscarinic agonists : methacholine, carbachol, bethanechol, pilocarpine Acetylcholineesteraseinhibitors : physostigmine, neostigmine*, pyridostigmine, edrophonium, echothiophate, malathion, parathion, pralidoxime AntiAlzheimer's :Tacrine*, donepezil, rivastigmine	7

	Cholinergic antagonists : Atropine, scopolamine, homatropine, ipratropium cyclopentolate*, dicyclomine*, benztropine, procyclidine, isopropamide, tropicamide Neuromuscular blockers :(Self study) tubocurarine, gallamine, succinylcholine, decamethonium	
3.	**Analgesic Drugs**	
3.1	Opioid peptides(Self study) Different types of opioid receptors, Potuguese and Becket Casy model, agonists, partial agonists and antagonists of these receptors Morphine, codeine, levorphanol, buprenorphine, phenazocine, pentazocine, meperidine*, alpha and beta prodine, pheniridine, anileridine, fentanyl, methadone, dextropropoxyphene*, tramadol, nalorphine, naloxone, naltrexone, flupirtine Antidiarrhoeals (Self study-1 hr) : loperamide, diphenoxylate	6
3.2	NSAIDS paracetamol, aspirin, indomethacin, sulindac, mefenamic acid, ibuprofen, naproxen*, nabumetone, diclofenac*, piroxicam*, nimesulide, celecoxib, valdecoxib. Cytokine inhibitors :(Self study-1 hr) infliximab, rituximab, anakinra, abatacept Drugs in Gout : colchicine, probenecid, sulfinpyrazone, allopurinol, febuxostat	5
4	**Drugs affecting Male and Female Health (Steroids)**	
4.1	Testosterone, 17-alphamethyltestosterone, oxymesterone, fluoxymesterone, stanazolol, danazol (Self study) estradiol, ethinyl estradiol, mestranol, medroxyprogesterone acetate, megestrol acetate, norethindrone, norgestrel, diethylstilbestrol*(Synthesis for self study), clomiphene (Self study), tamoxifen, anastrozole, letrozole, exemestane (Self study-1 hr) medroxy progesterone acetate, megesterol acetate, norethindrone and norgestrel	3
4.2	Adrenocorticosteroids cortisone, hydrocortisone, prednisone, prednisolone, dexamethasone and betamethasone, flurometholone, fluocinolone, triamcinolone, aldosterone, fludrocortisone	2
	TOTAL	**48**

Books:
Same as prescribed for Pharm. Chem. – III

BPH_C_802_T – Pharmaceutics IV- (4 Hr/Wk)

Course Objectives

To provide detailed insights into formulation and technology of sterile products including parenterals and ophthalmic dosage form, to orient students about oral sustained and controlled release systems, to introduce important pharmacokinetics models and parameters and to familiarize students with the concept of Pilot plant, Validation, cGMP etc. as important quality management systems in the pharmaceutical industry.

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Apply the knowledge of sterile technology in designing safe and effective injectables and ophthalmic products
2. Study the rationale for oral SR/CR products, principles of design, development and evaluation of SR formulations
3. Understand the concepts of validation and pilot plant scale up for large scale manufacturing operations
4. Understand the concept of biopharmaceutics and significance of various pharmacokinetic parameters

No.	Details	Hours
1	**Introduction to sterile dosage forms - Parenteral products**	**12**
1.1	Various routes of parenteral administration, pyrogens, vehicle, Water for Injection (WFI) - preparation, purity, storage and distribution, vehicles other than WFI, additives in parenteral products.	3
1.2	Containers - glass and plastics- types and evaluation, rubber closures – characteristics and testing.	2
1.3	Personnel, Manufacturing facilities- layout, environmental control, cleanliness classes, air handling (HVAC systems), HEPA filters, laminar flow	2
1.4	SVP: formulation considerations- solutions, suspensions, product procedures, freeze drying.	2
1.5	LVP – types, formulation aspects, packaging, FFS technology.	2
1.6	QA & QC- sterility test, pyrogen/ endotoxin test, particulate evaluation, leaker test.	1

2	**Ophthalmic Products**	**5**
2.1	Physiology of eye, lachrymal system, tears, precorneal tear film, cornea, ocular bioavailability	1
2.2	a) Formulations - additives and packaging of various ophthalmic products - solutions, suspension, ophthalmic ointments and gels, preservatives and efficacy test b) Contact lens solutions: types of lenses, cleaning solution, disinfection solution, lubricants, multipurpose solutions and packages	3
2.3	QA and QC - sterility test, clarity, particle size for suspension, tests on ointments and collapsible tubes	1
3	**Oral sustained and controlled release systems**	**6**
	Need, definitions, Advantages of SR & CR systems, biopharmaceutical considerations; Properties of drug with reference to the design of oral SR systems Dose calculation of drug, calculation for dose- loading and maintenance	2
3.2	Matrix and reservoir type of systems, dissolution-controlled systems, diffusion-controlled systems, ion exchange-controlled systems	3
3.3	Evaluation of sustained release systems	1
4	**Microencapsulation**	**5**
4.1	Definition, need/ reasons, concepts of core and coat	1
4.2	Methods of microencapsulation - phase separation coacervation (various techniques), Wurster process, spray drying and related processes, interfacial polymerization, multiorifice centrifugal process, pan coating, solvent evaporation; extrusion & spheronization Evaluation of microcapsules	4
5	**Introduction to Industrial Pharmacy**	**6**
5.1	Pilot plant scale up techniques: Need, components, Factors considered while scaling up of formulations: Mention the points for tablets, liquids (suspension, solutions, emulsions) and semisolids	2
5.2	Validation: Definition, Types- Prospective, concurrent, Retrospective and revalidation. Qualification of equipment-design, installation, operational, performance	2
5.3	Factory Layout: schedule M - general considerations/ steps, Examples of Typical layout schemes for Tablets, capsule, liquids, sterile formulations manufacturing areas **(Individual layouts- Assignment with follow up)**	2
6	**Introduction to NDDS**	**8**
6.1	Advantages of NDDS, concept of targeting-Active & Passive targeting	1
6.2	Concept, design and one suitable application of a typical system of following NDDS: a) Floating gastro-retentive systems, b) Colon targeted drug delivery systems, c) Mucoadhesive drug delivery systems, d) Osmotic systems, e) Transdermal DDS (membrane permeation systems), f) Ocular inserts, g) Colloidal DDS (liposomes, nanoparticles, microemulsions),	7 **1 hour for each system**
8	**Introduction to Pharmacokinetics**	**6**
8.1	Definitions: Pharmacokinetics, ADME, bioavailability absolute and relative, bioequivalence. Emphasis on the importance in drug discovery, development and clinical pharmacy	1
8.2	Pharmacokinetics: Introduction to compartmental and physiological models. Introduction to the one compartmental open model and its assumptions	1
8.3	One compartment open model: IV bolus dosing: importance of volume of Distribution. Clearance, elimination rate constant, half-life, area under the curve (trapezoidal rule)	2
8.4	One compartment open Model: Extra-vascular dosing. Absorption rate constant, absorption half -life, bioavailability. Introduction of the Concept of Cmax, T_{max}, area under the curve, the trapezoidal rule and the method of Residuals.	2
	TOTAL	**48**

Books:
Latest Editions

1. The theory and practice of Industrial Pharmacy, Ed. Leon Lachman, H. A. Liberman, J. L. Kanig; Varghese Publishing House.
2. Remington, The science and practice of Pharmacy, Vols. I and II, B. L. Publications Pvt. Ltd.
3. Cole Graham, Pharmaceutical Production Facilities, Design and Applications.
4. Pharmaceutical Process Validation, Nash Robert A., Berry Ira R., Volume 57, Marcell Dekker INC, New York.

5. Pharmaceutical Dosage Forms: Parenteral medications. Vols. I, II, III, Ed Kenneth A. Avis, Leon Lachman and H. A. Liberman, Marcel Dekker INC.
6. Pharmacetuical Technology, Vols. I, II, R S R Murthy, Ashutosh Kar, New Age Int. Ltd.
7. Pharmaceutical dosage forms: Parental medications, Vol. I, II, III, ed. by Kenneth A. Avis, Leon Lachman and H. A. Liberman, Marcel Dekker Inc., 1986.
8. Pharmaceutics. The Science of dosage form design ed. by M. E. Aulton, 2 nd ed., Churchill Livingstone, 2002.
9. Modern Pharmaceutics, 4 th ed. Revised and Expanded ed. by Gilbert S. Banker and Christopher T. Rhodes, Marcel Dekker INC., 2002.
10. The theory and practice of industrial pharmacy, ed. by Leon Lachman, H. A. Liberman, J. I. Kanig, 3 rd ed., Verghese Publishing house, 1987.
11. Ophthalmic drug delivery, ed. by Ashim K. Mitra, 1993, Marcel Dekker INC.
12. Turco and Kings, Sterile Dosage forms, 3 rd Edn., Lea & Febiger, Philadelphia, 1985.
13. Michael J. Akers, Quality Control of Parenterals, Marcel Dekker
14. Controlled drug delivery – Fundamentals and Applications", Robinson Joseph R., Lee Vincent H., Vol. 29, Marcel Dekker Inc
15. Leon Shargel, Susanna Wu – Pong, Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Singapor
16. Brahmankar D.M and Jaiswal Sunil B, Biopharmaceutics and Pharmacokinetics – A Treatise, Vallabh Prakashan.

Note: References to latest amendments of Schedule M and Schedule U of Drugs and Cosmetics Act 1940 to be made wherever it is appropriate

BPH_C_803_L – Pharmaceutical Chemistry Lab II- 4 Hr/Wk)

Course Objectives

1) To introduce the learner to various hands-on experimental organic synthetic techniques including column chromatography and thin layer chromatography.
2) To learn characterization of intermediates and final products by TLC and IR
3) To review important topics such as cyclization, reduction, rearrangement, condensation reactions.
4) To introduce the learner to the concepts of green chemistry.
5) To study the source, disposal and prevention of chemical waste.

Course Outcomes

The learner should be able to

1) Design and perform various unit operations of organic synthetic reactions
2) Characterize reaction intermediates and final products.
3) Know the theoretical concepts behind organic synthesis.
4) Understand the concept and techniques of waste management.

Synthesis of the following Drugs and Drug Intermediates

1. Synthesis of Benzilic Acid: Conventional Method and Green Modification as in Green Chemistry DST Monograph
2. Three Component Synthesis of Pyrimidone using Ethylacetoacetate, Benzaldehyde and Urea as per Green Chemistry DST Monograph
3. Hofmann rearrangement: Anthranilic acid from Phthalimide.
4. Reduction reaction: PABA from *p*-nitrobenzoic acid.
5. Pechmann condensation for coumarin synthesis using clay catalyst (Clay catalyzed solid state synthesis of 7-hydroxy-4-methylcoumarin).
6. Synthesis of resacetophenone (Ref. Vogel page 983)
7. Synthesis of 4-methylcarbostyryl (old syllabus experiment)
8. Synthesis of Phenytoin
9. Synthesis of Hippuric Acid (https://www.linfield.edu/assets/files/chem/Courses/CHEM%20322/3bAmide_synthesis_2015.pdf)

Or Synthesis of adipic acid (Ref. DST Monograph pg. 38)

Monitoring the progress of any two reactions by using TLC: Aim is to only monitor the completion of the reaction under consideration. Student can comment on status of the reaction (completion/ incompletion) using TLC; they must develop the solvent system

Books:

1. Vogel's A Text book of Practical Organic Chemistry by Vogel, Longman group limited, London.
2. Practical Organic Chemistry by Mann FC & Saunders BC, Longman Group Limited, London.
3. Laboratory Techniques in Organic Chemistry, Ahluwalia V.K. I.K. Publishers.
4. Green Chemistry, V. K. Ahluwalia.

5. New Trends in Green Chemistry, V K Ahluwalia and M Kidwai, KluwerAcademic Publishers
6. Monograph on Green laboratory Experiments, Grenn Chemistry Task Force Committee, DST.
7. Practical Organic Synthesis: A Student's Guide - Reinhart Keese, Martin Brändle, Trevor Toube.
8. Advanced practical Medicinal Chemistry by Ashutosh Kar, New Age International Publications.

BPH_C_804_L – Pharmaceutics Lab IV- (4 Hr/Wk)

Course Objectives

To train the learner with the practical aspects of formulation, manufacturing and quality control tests of parenteral and ophthalmic products.

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Demonstrate the intricacies of formulation and development of parenterals and ophthalmic products.
2. Understand and know about quality control and documentation of a manufacturing process.
3. Know about the pharmacopoeial tests for these products and their packaging materials.
4. Explain the concept of dissolution testing as an important quality control tool and relate to its importance from regulatory point of view.
5. Apply pharmacokinetic principles of oral routes of administration.
6. Demonstrate oral and written communication skills and ability to plan the experimentation with proper time management

EXPERIMENTS

No.	Details
1	Preparation & Testing of WFI as per IP
2	Processing and monographic testing of Glass containers and rubber closures as per IP.
3	Preparation and documentation of the following injections: a. Calcium Gluconate injection IP b. Ascorbic acid injection IP. c. Sodium chloride & Dextrose Injection IP
4	Preparation and documentation of following ophthalmic products: a. Sulphacetamide eye drops, IP b. Official antibiotic eye ointment (any one)
5	Preparation and *in vitro* release evaluation of sustained release oral tablets (matrix type)
6	Dissolution testing of marketed formulations of conventional tablets containing poorlywater soluble drug (selection of medium)
7	Calculations of pharmacokinetic parameters -i.v. administration (plasma samples provided).
8	Microencapsulation of solid/liquid core using phase separation coacervation technique
9	Preparation and evaluation of mucoadhesive buccal formulation (tablet/film)
10	Validation of process- mixing/milling
11	Assignment on SOP's of dissolution apparatus/tablet press/coating equipment
12	Assignment on excipient/API specifications. (One example of each)

Books:
All books listed in the theory syllabus as well as Current editions of IP, BP and USP.

BPH_E_805_D– Project- (12 Hr/Wk)

ANY TWO SUBJECTS FROM THE FOLLOWING 4 CREDIT SUBJECTS TO BE CHOSEN AS ELECTIVES FOR A TOTAL OF 8 CREDITS

BPH_E_806_T – Phytopharmaceutical Technology- (4 Hr/Wk)

Course Objectives

1. To make learners aware of various terms used in Phytopharmaceuticals and understand the concept of standardization of natural products utilized in cosmetics, medicine and as nutraceuticals.
2. To understand industrial preparation of standardized extracts and isolation of phytoconstitutents.
3. To give an insight towards various Conventional and Novel Drug Delivery Systems (NDDS) of Herbal medicines and the challenges faced along with the bioavailability aspects of Herbal formulations.
4. To introduce the concepts of QC and QA of Phytopharmaceuticals.
5. To learn role of herbs as Nutraceutical remedies for common disorders and in cosmeticeuticals.
6. To study the regulatory requirements for phytopharmaceuticals and Traditional Digital Knowledge Library (TKDL)

Course Outcomes

Upon completion of the course learners will be able to –
1. Understand terms related to phytopharmaceuticals and standardization of Natural Products.
2. Explain industrial preparation of standardized extracts, isolation of phytoconstitutents and their applications.
3. Discuss the challenges faced in formulation of conventional and NDDS of herbal medicines.
4. Explain the applications of QC and QA of Phytopharmaceuticals.
5. To suggest the use of herbs as nutraceuticals in common disorders and cosmeticeuticals.
6. Describe the regulatory requirements for phytopharmaceuticals.

No	Topics	Hours
1	**Introduction to the terms** Phytopharmaceutical Technology – Phytopharmaceuticals, Active ingredient, Botanical Drug Substance, Ethnomedicine, Herbal Medicine, Phytomedicine, Phytopharmaceutical Science, Regulatory affairs, Traditional medicine, Folklore medicine, Herbal medicine, Finished herbal product, Pharmaco-vigilance of herbals, Phytopharmacoepidemology and Phytopharmacoeconomics.	3
2	**Herbal Extracts** Processing and authentication, Introduction to Preparation and Types of extracts with suitable examples – liquid, solid, semisolid, dried and powdered Large scale industrial method for preparation of extracts, Process and equipment: Names of equipment and their uses, merits and demerits in the unit operations of size reduction, Extraction, Filtration, Evaporation/ Distillation, Drying of Extracts	8
3	**Formulations and drug delivery system** A) Methods of preparations and evaluation of Herbal Tablets, Capsules, topical and liquid oral dosage forms. Study of any two examples of formulations under each dosage form with respect to their formulae and activities / claims of each ingredient used in them. B) NDDS of Herbal medicine: Limitation of Conventional, Challenges in Development of NDDS of Herbal medicine, Phytosomes, Nanocarriers, Transdermal with one example each. Use of Bio-enhancers in formulation development of herbal products. Labeling of Phyto-pharmaceuticals. Preservation of Phyto-pharmaceuticals	8
4	**Quality Assurance and Quality Control of Phytopharmaceuticals** A) For Herbal Extracts: Q.A by cultivation and Breeding, Standardized extracts –Quantitative standardization using different types of Marker Compound. Stability testing of Herbal extracts. B) For Formulations: Stability of herbal formulation, Bioavailability of Phytoconstituents from Herbal Formulations – Factors affecting bioavailability and pharmacokinetics of some herbal drugs and phytoconstituents.	4
5	**Herbs as Phytopharmaceutical Products** Occurrence, Structure, Pharmacology, Metabolism and Pharmacokinetics, Therapeutic uses, Recommended doses and Marketed preparations, Toxicity and Regulatory status of the following – Ephedra Alkaloids, Ginger, Garlic, Kava kava, Ginkgo Biloba, Valerian, Chammomile, Echinacea, Panax Ginseng, Cranberry, Acoruscalamus, Comfrey, Tomato, Liquorice, Senna, Cascara.	8
6	**Non-Nutritive Sweeteners from Natural sources** Preparation, evaluation and salient features of Steveosides, Thaumatin, Glycyrrhizin.	2
7	**Herbal Cosmeceuticals** Role of Herbs and phytoconstituents in the following categories of cosmetic preparations. Formulation aspects of the following cosmetic preparations and their market potential • Skin cosmetics – herbs used as Fairness agents- Turmeric (Curcumin), Uvaursi (Arbutin) Moisturizers – Aloe vera (mannans), Coriander seed oil (SELENOL)	8

	Anti-ageing agents- **Rose and rosehip** (*Rosa canina*), **Chamomile** (*Matricariachamomilla*) Face packs -Apricot, Orange peel • Colour cosmetics advantages of natural dyes and colourants– Onosmaechioides, Carthamine, Bixin - their use in lipsticks, rouges, eye shadows • Cosmetic products for eyes – Butcher's broom, Chammomile • Hair cosmetics – Colouring of hair- Tea extracts, Amla, Henna Herbs used in improving health of hair -shampoos, oils, conditioners. (Any two examples) • Dental hygiene Products: *Salvadorepersica*, clove, neem	
8	**Industrial production and estimation of the following phytoconstituents** Preparation of their derivatives and products Alkaloids -Berberine Carotenoids- Capsanthin Flavonoids- Naringenin, Hesperidin Terpenoids- Citral, Forskolin, Gymnemic acid Steroids -Diosgenin Carbohydrates-Pectin	**4**
9	**Regulatory issues in Phytomedicine** Indian and International requirements. TKDL (Traditional Knowledge Digital Library), Certification of Phytodrug industry. (DSHE) Dietary Supplement Health and Education. Acts related to banned or restricted phytoingredients. Standardization Regulation for labeling purpose.	**3**
	TOTAL	**48**

References:

1. Evidence-Based Validation of Herbal Medicine edited by Pulok K. Mukherjee Business Horizons Publishers
2. Phytotherapies: Efficacy, Safety, and Regulation. Ed Iqbal Ramzan John Wiley and Sons
3. Contemporary Phytomedicines. Amritpal Singh Saroya, CRC press
4. Journal of Ethnopharmacology 140 (2012) 513–518: www.elsevier.com/locate/jethpharm Pharmacovigilance of herbal medicine Shaw Debbiea,, Ladds Graeme B, Duez Pierrec, Williamson Elizabeth D, Chan Kelvine,F
5. Textbook of Pharmacognosy by Trease & Evans.
6. Textbook of Pharmacognosy by Tyler, Brady & Robber.
7. Pharmacognosy by Kokate, Purohit and Gokhale
8. Essential of Pharmacognosy by Dr. S.H. Ansari
9. Pharmacognosy & Phytochemistry by V.D.Rangari
10. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
11. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002
12. Toxicology and Clinical Pharmacology of Herbal Products,Steven B. Karch, Humana Press
13. Herbal Principles in Cosmetics Properties and Mechanisms of Action, Bruno Burlando, Luisella Verotta, Laura Cornara, and Elisa Bottini-Massa, CRC Press.

BPH_E_807_T – Clinical Pharmacy- (4 Hr/Wk)

Course Prerequisites

- Understanding of Pharmacology and its applications.

Course Objectives

1. Introduction to clinical pharmacy, Role of clinical pharmacist, patient case history, presentation of cases and counselling.
2. Educate on personalized drug therapy taking into consideration general and special population.
3. Teach basics of ADRs and pharmacovigilance.
4. Introduce the concept of therapeutic drug monitoring and its importance in therapy areas like epilepsy, cardiovascular disorders, and others
5. Introduce the concepts of pharmacoepidemiology and pharmacoeconomics

Course Outcomes

1. Relate to the role of pharmacist in different setups like clinics, pharmacies and in the community and appraise the crucial role of pharmacists in patient counselling and eventually in drug adherence and compliance to therapy.
2. Discuss the types, risk factors, classification, methods of detection, monitoring and reporting of ADRs, drug interactions, pharmacovigilance and TDM in normal as well as special populations.
3. Outline the process of drug discovery and development, Ethical Guidelines/Schedules, Role of Ethics Committee, essential documents in clinical trials/research, BA-BE studies and, apply and appreciate the role of GCP in conduct of clinical research.
4. Identify and analyze the trends in drug use to optimize health outcomes.

No.	Details	Hours
1	**Introduction to Clinical Pharmacy:** Concept of Clinical Pharmacy, Community pharmacy and hospital pharmacy (Definition, scope and objectives)	**4**
2	**Pharmacist-Patient Interaction**	**4**
2.1	Patient Counselling: Role of Pharmacist in patient counselling	2
2.2	Patient Compliance, Methods of assessment of compliance, Reason for patient noncompliance, Strategies to improve compliance, Precaution and directions for medication, Administration instructions	2
3	**Adverse Drug reactions:** Epidemiology, Classification, Risk factors, Monitoring, Detecting and reporting of ADR	**5**
4	**Drug interactions:** Types, General Considerations and Mechanisms	**3**
5	**Drug use in special population**	**6**
5.1	Drugs used in Geriatrics	2
5.2	Drugs used in Paediatrics	2
5.3	Drugs used in Pregnancy	2
6	**Therapeutic Drug Monitoring:** Definition, indications and strategies	**2**
7	**Drug discovery & development**	**14**
7.1	Preclinical development	2
7.2	Clinical development-	5
	a. History, terminologies, types of clinical research, phases of clinical trials, role of clinical trial in new drug developments. Ethical issues in clinical trials: Principle of regulatory requirements, responsible conduct, supervision of ethics, (Informed Consent, Independent Ethics Committee, Institutional Review Board)	
7.3	Good Clinical Practice (GCP): Concept and importance	1
7.4	Definitions of essential documents; SOP, protocol, Investigator's brochure,	2
7.5	Introduction to BA/BE studies	2
7.6	Pharmacovigilance: Definition, scope and aims of Pharmacovigilance	2
8	**Pharmacoepidemiology:** Definition, types, methods, factors affecting drug utilization, applications of pharmacoepidemiology	**4**
9	**Pharmacoeconomics and outcomes Research:** Theories and methodologies of pharmacoeconomics and outcomes research, applications to pharmacotherapy and managed health care	**6**
	Total	**48**

Books:

Latest editions of the following books to be adopted

1. Clinical Pharmacy and Therapeutics, Roger Walker, Clive Edwards, Churchill Livingstone.
2. Clinical Pharmacy, H. P. Tipnis, A. Bajaj, Career Publications.
3. Clinical Pharmacology, P.N. Benett, M. J. Brown, Churchill Livingstone.
4. Text Book of Clinical Pharmacy Practice, G. Parthisarathi, Karin Nyfort Hansen, Milap C. Nahata, Orient Longman.
5. Strom BI, Limmel SE. Textbook of Pharmacoepidemiology. Chichester, West Sussex, England: John Wiley & Sons Ltd; 2006.
6. Rascati, Karen L. Essentials of Pharmacoeconomics. Philadelphia, Pa.: Lippincott Williams and Wilkins, 2009.

7. M. F. Drummond, M. J. Sculpher and G. W. Torrance, Methods for the economic evaluation of health care programmes. Oxford University Press, USA, 2005.
8. Brenda Waning; Michael Montagne; William W McCloskey, Pharmacoepidemiology: Principles and practice, New York, McGraw-Hill, 2001.

BPH_E_808_T – Pharmacovigilance- (4 Hr/Wk)

Course Prerequisites

- Basic/core courses in Pharmacology.

Course Objectives

1. Provide an opportunity for the student to learn about development of pharmacovigilance.
2. Learn the basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance.
3. Train students on establishing pharmacovigilance programme in an organization.
4. Various methods that can be used to assess adverse drug reactions generate safety data and signal detection.
5. Regulatory aspects of pharmacovigilance.

Course Outcomes

1. Relate to the role of pharmacovigilance and its prevalence in different setups.
2. Discuss the different facets of ADRs in normal as well as special populations with their relation to pharmacovigilance methods.
3. Integrate knowledge of resources of drug information, safety data and drug utilization.
4. Outline the regulatory processes in pharmacovigilance.
5.

No.	Details	Hours
1	**Introduction to Pharmacovigilance**	**6**
1.1	History and development of Pharmacovigilance	0.5
1.2	Importance of safety monitoring of Medicine	0.5
1.3	WHO international drug monitoring programme	1
1.4	Pharmacovigilance Program of India (PvPI)	1
1.5	Vaccine safety surveillance	1
	Vaccine Pharmacovigilance, Vaccination failure	
1.6	Establishing pharmacovigilance programme	2
	Establishing in a hospital	
	Establishment & operation of drug safety department in industry	
	Contract Research Organizations (CROs)	
	Establishing a national programme	
2	**Adverse drug reactions**	**9**
2.1	Definitions and classification of ADRs	1
2.2	Detection and reporting	3
2.3	Methods in Causality assessment	2
2.4	Severity and seriousness assessment	1
2.5	Predictability and preventability assessment	1
2.6	Management of adverse drug reactions	1
3	**Pharmacogenomics of adverse drug reactions: Drug safety evaluation in special population**	**6**
3.1	Pediatrics	2
3.2	Pregnancy and lactation	2
3.3	Geriatrics	2
4	**Pharmacovigilance methods**	**10**
4.1	Passive surveillance – Spontaneous reports and case series	7

	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	
4.2	Communication in pharmacovigilance	3
	Effective communication in Pharmacovigilance	
	Communication in Drug Safety Crisis management	
	Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	
5	**Drug dictionaries and coding in pharmacovigilance**	**10**
5.1	WHO adverse reaction terminologies	2
	MedDRA and Standardized MedDRA queries	
	WHO drug dictionary	
5.2	Information resources in pharmacovigilance	2
	drug information resources	
	Specialized resources for ADRs	
5.3	Basic terminologies used in pharmacovigilance	1
	Terminologies of adverse medication related events	
	Regulatory terminologies	
5.4	Drug utilization:	2
	Need, types of drug utilization studies	
	Drug use evaluation	
5.5	Medication safety data: Safety data generation	3
	Pre-clinical phase	
	Clinical phase	
	Post approval phase	
6	**Regulatory Aspects of Pharmacovigilance**	**7**
6.1	ICH Guidelines for Pharmacovigilance	4
	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	
6.2	CIOMS	1
	CIOMS Working Groups	
	CIOMS form	
6.3	CDSCO (India) and Pharmacovigilance	2
	D & C Act and Schedule Y	
	Differences in Indian and global pharmacovigilance requirements	
	TOTAL	**48**

Books:

Latest editions of the following books to be adopted

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.

2. Practical Drug Safety from A to Z, 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, Eds 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, PharmaMed Press/BSP Books.
12. http://www.cioms.ch/
13. http://cdsco.nic.in/
14. http://www.who.int/vaccine_safety/en/
15. http://www.ipc.gov.in/PvPI/pv_home.html
16. http://apps.who.int/medicinedocs/pdf/s4876e/s4876e.pdf

BPH_E_809_T – Pharmaceutical Regulatory Affairs- (4 Hr/Wk)

Course Objectives

The course is framed to impart knowledge to the learners so that they get conversant with drug regulatory practices and procedures followed at national and international level for registration and approval.

Course Outcomes

The learner should be able to:
1. Understand the basics of new drug and generic product development.
2. Apply knowledge of regulatory requirements for preparing the documents for registration of pharmaceutical product in India and overseas.
3. Understand various harmonized practices and integrate the knowledge required for various certifications.

No.	Details	Hours
1	**Drug Regulatory Affairs**	**4**
	1.1 Introduction to Drug Regulatory Affairs(DRA)	1
	1.2 DRA in Pharmaceutical Industry	1
	1.3 Regulatory bodies across the world and different markets and brief introduction of registration process in UK, Australia, Brazil, Canada, Japan, ASEAN countries, Commonwealth of Independent States, -Russian Commonwealth (CIS)	2
2	**Indian Regulations**	**9**
	2.1 Indian Pharmacopoeia (IP) commission - Introduction, IP review process with mentioning monograph and IP reference substances (RS)	3
	2.2 Pharmacovigilance Programme of India (PVPI)	1
	2.3 Central Drug Standard Control Organization (CDSCO), Drug Controller General of India (DCGI), Food and Drugs Administration (FDA), Centre Drugs Laboratory(CDL)- Structure, role, function and strategies of these organizations	3
	2.4 Procedure for obtaining test license (Form 29 and form 11), Export NOC, Loan License/Contract manufacturing	2
3	**US Regulations**	**11**
	3.1 USFDA - Structure, role and function	1
	3.2 Drug price competition and patent term restoration act (Hatch Waxman Act 1984)- scope and objective	3
	3.3 Type of filings- Type of application and relevant forms - Investigational New Drug (IND), New Drug Application (NDA), Supplemental new drug application (SNDA), Abbreviated NDA (ANDA), Biologic License Application (BLA)	2
	3.4 Orange book Therapeutic Equivalent (TE) codes, Patent term and exclusivity	
	3.5 21 CFR- Brief introduction and mention of 21 CFR Part 11	2
	3.6 Post Approval changes and SUPAC guidelines - Brief introduction	1
	3.7 Drug master file (DMF) and different types	1
		1
4	**European Regulations (EU)**	**10**
	4.1 EMEA- Structure role and function	2

	4.2 Types of filing- Centralized, Decentralized, Mutual recognition procedure, National 4.3 Type of applications for marketing authorization - New drug, Hybrid drug, Generic, similar biologic, Fixed combination 4.4 Active Substance master file (ASMF) – Brief introduction, Certificate of suitability (COS) 4.5 Post Approval changes and handling variations	3 2 2 1
5	International Council for Harmonization (ICH) 5.1 Introduction- Composition, Role and responsibilities 5.2 ICH guidelines- Quality (Q), Safety (S), Efficacy (E), Multidisciplinary (M) 5.3 ICH quality guidelines – Terminologies 5.4 Introduction of ICH , multidisciplinary M4 guidelines	**4** 1 1 1 1
6	GMP certification and ISO	**3**
7	Clinical Trials 7.1 Regulatory perspective of clinical trials and brief overview of schedule Y and amendments 7.2 ICMR guidelines, Institutional Ethics committee for biomedical research (IRB/IEC) 7.3 Bioavailability and bioequivalence study, Biowaiver- Regulatory requirement	**4** 1 1 2
8	Intellectual Property rights and type Patent Act 1970, TRIPS, WTO, GATT and PCT- Definition and Goals	**3**
	TOTAL	48

Books:

1. New Drug Approval: Accelerating Global Registrations by Richard A Guarino, MD, 5th Edition, Drugs and the Pharmaceutical Sciences, Vol.190.
2. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.
3. 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.
4. Intellectual Property Law, P. Narayanan, , Eastern Law House, Revised Edition, 2017.
https://www.ich.org
https://www.fda.gov
https://www.ema.europa.eu
https://www.cdsco.nic.in
https://www.icmr.nic.in
https://www.gov.uk

BPH_E_810_T – Lead Optimization – Strategies and Methods- (4 Hr/Wk)

Course Objectives

1. To introduce the learner to the concepts of druggability and physicochemical/ADME/Toxicity property optimization in new drug discovery.
2. To study the fundamentals, structure modification strategies and methods of determination of various physicochemical and pharmacokinetic properties of lead compounds.

Course Outcomes

The learner should be able to:

1. Understand the importance of druggability and physicochemical/ADME/Toxicity property optimization in new drug discovery.
2. Understand the fundamentals of various physicochemical and pharmacokinetic properties and their significance in lead optimization.
3. Know various strategies for structure modification for optimizing druggability of lead molecules.
4. Describe different methods of determination of various physicochemical and pharmacokinetic properties of lead compounds.

No.	Details	Hours
1	**Drug-like Properties**	**4**
1.1	Introduction, drug-likeness and Drug Discovery	
1.2	Property profiling and optimization	
1.3	Rules for rapid property profiling from structure	
1.4	Lead-like compounds	
1.5	Strategies for integrating drug-like properties into Drug Discovery	
2	**Lipophilicity and pKa**	**4**
2.1	Fundamentals, effects and structure modification strategies	
2.2	Lipophilicity determination Methods: in silico lipophilicity methods, experimental lipophilicity methods, in-depth lipophilicity methods	

2.3	pKa determination methods: in silico methods, experimental methods, in-depth methods	
3	**Solubility**	**4**
3.1	Fundamentals of solubility, dissolution rate, structural properties affecting solubility, kinetic solubility and thermodynamic solubility	
3.2	Effects of solubility, IV formulations, solubility classification, effects of physiology on solubility and absorption	
3.3	Structure modification strategies to improve solubility, strategies for improving dissolution rate, salt forms	
3.4	Methods for solubility determination: solubility calculation methods and commercial software, kinetic solubility methods, thermodynamic solubility methods	
4	**Permeability**	**4**
4.1	Permeability fundamentals: passive diffusion permeability, endocytosis permeability, active uptake permeability, paracellular permeability, efflux permeability, combined permeability	
4.2	Permeability effects: effect of permeability on bioavailability, effect of permeability on cell-based activity assays	
4.3	Permeability structure modification strategies	
4.4	Methods for permeability determination: in silico permeability methods, in vitro permeability, in depth permeability methods	
5	**Transporters**	**4**
5.1	Transporter fundamentals	
5.2	Transporter effects, efflux transporters: p-glycoprotein (MDR1, ABCB1) , breast cancer resistance protein (BCRP, ABCG2), multidrug resistance protein 2 (MRP2, ABCC2) , efflux transporters in the BBB	
5.3	Uptake transporters, structure modification strategies	
5.4	Methods: in silico transporter methods, in vitro transporter methods, in vivo methods for transporters	
6	**Blood Brain Barrier**	**4**
6.1	BBB fundamentals: BBB permeation mechanisms, brain distribution mechanisms, brain–CSF barrier, interpreting data for brain penetration	
6.2	Effects of brain penetration	
6.3	Structure–BBB penetration relationships, structure modification strategies to improve brain penetration	
6.4	Methods for determining BBB: in silico methods, in vitro methods, in vivo methods,	
7	**Metabolic Stability, Plasma Stability, Solution Stability**	**6**
7.1	Metabolic stability fundamentals: Phase I metabolism, Phase II metabolism, metabolic stability effects	
7.2	Structure modification strategies for metabolic stability: Phase I, Phase II, consequences of chirality on metabolic stability	
7.3	Plasma Stability: fundamentals, effects, structure modification strategies to improve plasma stability	
7.4	Solution Stability: fundamentals, effects, structure modification strategies to improve solution stability	
7.5	Methods: *In silico* metabolic stability methods, in vitro metabolic stability methods, plasma stability methods, solution stability methods	
8	**Plasma Protein Binding**	**3**
8.1	Plasma Protein Binding Fundamentals: consequences of chirality on PPB	
8.2	Plasma Protein Binding Effects: Impact of PPB on distribution, clearance and pharmacology	
8.3	Structure modification strategies for PPB	
8.4	Methods for determining PPB: in silico methods, in vitro Methods	
9	**Cytochrome P450 inhibition**	**4**
9.1	CYP inhibition fundamentals and effects	
9.2	Structure modification strategies to reduce CYP inhibition	
9.3	Reversible and irreversible CYP inhibition	
9.4	Methods for determining CYP inhibition: in silico methods, in vitro methods	
10	**hERG Blocking**	**3**
10.1	hERG Fundamentals, hERG blocking effects	

10.2	hERG Blocking Structure–Activity Relationship, structure modification strategies for hERG	
10.3	hERG methods: In silico hERG methods, in vitro hERG methods, in vivo hERG methods	
11	**Toxicity**	**4**
11.1	Toxicity Fundamentals: toxicity terms and mechanisms	
11.2	Structure modification strategies to improve safety	
11.3	Methods: in silico toxicity methods, in vitro toxicity assays, in vivo toxicity	
12	**Pharmacokinetics**	**4**
12.1	Pharmacokinetic parameters: volume of distribution, Area Under the Curve, clearance, half-life, bioavailability	
12.2	Effects of plasma protein binding on PK parameters, tissue uptake	
12.3	Using PK data in drug discovery	
12.4	Pharmacokinetic methods: PK dosing (single-compound dosing, cassette dosing), PK sampling and sample preparation, instrumental analysis	
	Total Hours	**48**

Books:

1. Drug-like Properties: Concepts, Structure Design and Methods from ADME to Toxicity Optimization, Li Di, Edward Kerns, Academic Press.
2. Lead Optimization for Medicinal Chemists: Pharmacokinetic Properties of Functional Groups and Organic Compounds, Florencio Zaragoza Dörwald, Wiley-VCH.
3. Pharmacokinetics and Metabolism in Drug Design, Volume 31, Dennis A. Smith, Han van de Waterbeemd, Don K. Walker, Series Editors - Raimund Mannhold, Hugo Kubinyi and Gerd Folkers, Wiley-VCH.

BPH_E_811_T – Novel Drug Delivery Systems- (4 Hr/Wk)

Course Objectives

To provide the learner with knowledge of basic principles and the different types of Novel Drug Delivery Systems

Course Outcomes

Upon completion of the course, the learner shall be able to:
1. Understand the basic concept of NDDS
2. Discuss the different NDDS for different routes-oral, transdermal, ocular, transmucosal and implantable
3. Explain the need and concepts of targeting and active & passive targeting
4. Elaborate on principles and targeting systems for brain, colon, lymphatics and tumors
5. Discuss the various multiparticulate systems for targeting

No.	Details	Hours
1.0	Fundamentals of Novel drug delivery systems: Basic Concepts, Advantages and Disadvantages, Limitations of conventional dosage forms	1
2.0	Polymers: Introduction, classification, Role and applications in NDDS, Biodegradable and biocompatible polymers.	3
3.0	**Particulate NDDS:** Microspheres, liposomes, nanoparticles, aquasomes, niosomes, dendrimers-Classification, components & design, methods of preparation, characterization and applications of each system.	4
3.0	**Oral Controlled Drug Delivery Systems:** a) Matrix and reservoir systems- Diffusion and dissolution-controlled systems b) Multiparticulate drug delivery systems (Pellets)- need and significance of pelletization, techniques- pan coating, extrusion and spheronization, equipments, evaluation c) Osmotic Systems- Basic principles, classification- Implantable osmotic pumps, oral osmotic pumps, applications & evaluation d) Gastroretentive drug delivery systems (GRDDS)- Regional variability in intestinal absorption and concept of absorption window, Design of GRDDS technologies- low density (Floating systems), Swelling and expanding systems, Mucoadhesive systems, high density systems. Evaluation of GRDDS.	8
4.0	**Ocular drug delivery systems:**	4

	Limitations of conventional systems, *in situ* gelling systems, Ocular inserts: Non-erodible and Erodible inserts, Particulate systems for ocular delivery-liposomes & nanoparticles, ocular iontophoresis, evaluation. One example of each system	
5.0	**Transdermal Drug Delivery Systems (TDDS):** Permeation through skin, factors affecting permeation, Advantages and disadvantages of TDDS, basic components of TDDS, Different types of TDDS and release control mechanism, pressure sensitive adhesives, Evaluation	4
6.0	**Transmucosal drug delivery systems**: Concept of bioadhesion/ mucoadhesion, Advantages and disadvantages of transmucosal drug delivery, Bioadhesive polymers, Theories of mucoadhesion, Factors affecting mucoadhesion, transmucosal permeability, Formulation considerations: emphasis on buccal drug delivery, Evaluation of mucoadhesive strength	4
7.0	**Parenteral Controlled drug delivery systems**- Need and Various approaches, Details of Implantable Systems – Characteristics desired, routes employed, diffusion-controlled systems, activation-controlled systems and feedback-regulated systems. One example of each. Biocompatibility issues of implantable systems	5
8.0	**Nasal and Pulmonary Drug Delivery Systems**-Advantages and limitations; Nasal drug delivery-absorption pathways of intranasally administered drugs, permeation enhancers, intranasal formulations, nose-to-brain delivery Pulmonary delivery- Weibel model of Lungs (Pulmonary tree), aerosol deposition mechanisms and pattern in lungs, concepts of mass median aerodynamic diameter (MMAD) and Fine particle fraction (FPF); Delivery systems (nebulised, systems, pMDIs and DPIs), Active and Passive devices, Evaluation methods.	7
9.0	. **Targeted drug delivery systems:** a) Introduction to targeting, concepts of active and passive targeting. b) Particulate systems for targeting- microspheres, aquasomes, niosomes, dendrimers, and solid lipid nanoparticles, liposomes c) Targeting to colon: Difficulties in colonic targeting, Approaches of colon targeting, Evaluation d) Targeting to Brain: Blood brain barrier (BBB), transport through BBB, factors affecting drug permeation through BBB, strategies for brain drug delivery e) Lymphatic targeting-need and approaches- f) Targeting to tumor – EPR effect, ligand-based active targeting with two examples	8
	TOTAL	**48**

Books:

Latest editions

1. Advances in controlled and novel drug delivery, ed. by N. K. Jain, CBS publishers and distributors, 2001.
2. Modern Pharmaceutics, 4th ed. Revised and Expanded, ed. by Gilbert S. Banker and Christopher T. Rhodes, Marcel Dekker INC., 2002
3. Targetted and controlled drug delivery, Novel carrier systems, S. P. Vyas and R. K. Khar, CBS publishers and distributors, 2002.
4. Controlled and novel drug delivery, ed. by N. K. Jain, CBS publishers and distributors, 1997.
5. Controlled drug delivery, concepts and advances, S. P. Vyas and R. K. Khar, Vallabh Publishers, 2002.
6. The theory and practice of industrial pharmacy, ed. by Leon Lachman, H. A. Liberman, J. L. Kanig, 3rd ed., Verghese Publishing house, 1987.
7. The science and practice of pharmacy, 21st ed., Remington, Vol I and II, B. L. Publications Pvt. Ltd., 2005.
8. Bioadhesive Drug Delivery Systems – Fundamentals, Novel Approaches, and Development, Mathiowitz Edith, Chickering III, Donald E., Lehr Claus-Michael, Volume 98, Marcel Dekker Inc., New York, 1995.
9. Nanoparticulate Drug Delivery Systems, Thassu Deepak, Dellers Michael, Pathak Yashwant, Volume 166, Marcel Dekker Inc., New York, 2007.
10. Microencapsulation – Methods and Industrial Applications", Benita Simon, 2nd Edition, Marcel Dekker Inc., New York, 2006.
11. Controlled and Novel Drug Delivery, Jain N. K., 1st Edition, CBS Publishers and Distributors, New Delhi, 2004.
12. Targeted and Controlled Drug Delivery- Novel Carrier Systems", Vyas S. P., Khar R. K., 1st Edition, CBS Publishers and Distributors, New Delhi, 2002.
13. Ophthalmic Drug Delivery Systems, Mitra, Ashim K., Volume 58, Marcel Dekker Inc., New York, 1993.
14. Encyclopedia of Pharmaceutical Technology, Swabrick, Boylan, Volumes 1,6,8,9,10,12,13,14,15,16,17,18,19,20, Marcel Dekker Inc., New York.