Framework for the Final Year B. Pharm. (Credit Based System)

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No	Semester- VII	Credits	Contact hrs/week	Weightage		Marks
	Subject			**Continuous internal assessment**	**End Semester Examination**	
1	Pharmaceutical Chemistry - III	3	3	30	70	100
2	Pharmaceutical Analysis- III	3	3	30	70	100
3	Pharmacology-III	3	3	30	70	100
4	Pharmaceutics - IV	3	3	30	70	100
5	Pharmacognosy & Phytochemistry -II	3	3	30	70	100
6	Pharmaceutical Jurisprudence	3	3	30	70	100
	Total	**18**	**18**	**180**	**420**	**600**
	Practicals					
7	Pharmaceutical Analysis Lab - III	2	4	15	35	50
8	Pharmaceutics Lab - IV	2	4	15	35	50
9	Pharmacology Lab - II	2	4	15	35	50
10	Pharmacognosy & Phytochemistry Lab - II	2	4	15	35	50
	Total	**8**	**16**	**60**	**140**	**200**
	Total Teaching Hours~~s~~.		**34**			
	Total Credits	**26**				
	Total Marks			**240**	**560**	**800**

No.	Semester -VIII					
1	Pharmaceutical Chemistry-IV	4	4	30	70	100
2	Pharmaceutics-V	4	4	30	70	100
3	Biopharmaceutics & Pharmacokinetics	4	4	30	70	100
4	Pharmacognosy & Phytochemistry-III	4	4	30	70	100
5	Clinical Pharmacy	2	2	15	35	50
	Total	**18**	**18**	**135**	**315**	**450**
	Practicals					
6	Pharmaceutical Chemistry Lab - III	2	4	15	35	50
7	Pharmaceutics Lab - V	2	4	15	35	50
8	Pharmacognosy & Phytochemistry Lab - III	2	4	15	35	50
	Total	**6**	**12**	**45**	**105**	**150**
	Total Teaching Hours.		**30**			
	Total Credits	**24**				
	Total Marks			**180**	**420**	**600**

The revised total number of credits for the B. Pharm. Course from Semester I to Semester VIII is 198

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Scheme of Examination

No	Semester-VII	No of papers	End Semester Examination			Internal Assessment			Maximum marks	Minimum marks for passing the subject
						Periodic Test		Continuous Evaluation		
	Subject - Theory		**Duration (hrs)**	**Maximum marks**	**Minimum for passing**	**Duration (hrs)**	**Maximum marks**	**Maximum marks**		
1	Pharmaceutical Chemistry - III	1	3	70	28	1	15	15	100	40
2	Pharmaceutical Analysis - III	1	3	70	28	1	15	15	100	40
3	Pharmacology - III	1	3	70	28	1	15	15	100	40
4	Pharmaceutics - IV	1	3	70	28	1	15	15	100	40
5	Pharmacognosy & Phytochemistry - II	1	3	70	28	1	15	15	100	40
6	Pharmaceutical Jurisprudence	1	3	70	28	1	15	15	100	40
	Practicals									
7	Pharmaceutical Analysis Lab - III	1	4	35	14	4	8	7	50	20
8	Pharmaceutics Lab - IV	1	4	35	14	4	8	7	50	20
9	Pharmacology Lab -II	1	4	35	14	4	8	7	50	20
10	Pharmacognosy & Phytochemistry Lab - II	1	4	35	14	4	8	7	50	20

No	Semester-VIII	No of papers	End Semester Examination			Internal Assessment			Maximum marks	Minimum marks for passing the subject
						Periodic Test		Continuous Evaluation		
	Subject - Theory		Duration (hrs)	Maximum marks	Minimum for passing	Duration (hrs)	Maximum marks	Maximum marks		
1	Pharmaceutical Chemistry-IV	1	3	70	28	1	15	15	100	40
2	Pharmaceutics- V	1	3	70	28	1	15	15	100	40
3	Biopharmaceutics and Pharmacokinetics	1	3	70	28	1	15	15	100	40
4	Pharmacognosy & Phytochemistry - III	1	3	70	28	1	15	15	100	40
5	Clinical Pharmacy	1	2	35	14	1	8	7	50	20
	Practicals									
6	Pharmaceutical Chemistry Lab-III	1	4	35	14	4	8	7	50	20
7	Pharmaceutics Lab- V	1	4	35	14	4	8	7	50	20
8	Pharmacognosy & Phytochemistry Lab- III	1	4	35	14	4	8	7	50	20

Syllabus

Final Year B.Pharm. Sem. VII

Pharmaceutical Chemistry – III **3 Hrs/Week**

~~Sr.~~ ~~No.~~Unit	TOPIC~~opic~~	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*~~, mitomycin C~~, 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:** A~~a~~mantadine*, rimantadine, oseltamivir, zanamivir, acyclovir and its prodrugs, ganciclovir, famciclovir, penciclovir, idoxuridine, vidarabine~~, azidothymidine*, stavudine~~ Reverse transcriptase inhibitors: , azidothymidine*, stavudine, lamivudine, zalcitabine, didanosine, abacavir, Non-nucleosides reverse-transcriptase inhibi~~e~~tors: delaviridine, nevirapine, efavirenz, Enfuviritide. 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)**	3 2
3.	**Cardiovascular Drugs**	**21**
3.1	Cardiac Glycosides Digitalis glycosides (digitoxin, digoxin, lanatoside C)	1
3.2	**Antianginal Agents** Antianginal agents: Amyl nitrite, isosorbide dinitrate, pentaerythritol tetranitrate, verapamil, bepridil, diltiazem, nifedipine*, amlodipine, nimodipine, nicardipine, dipyridamole*	2
3.3	**Antiarrythmic Agents** Antiarrhythmic agents: quinidine, procainamide*, disopyramide, lidocaine, tocainide, mexilitine, encainide, amiodarone, propafenone, verapamil, diltiazem, propranolol, sotalol*	2
3.4	**Diuretics** • Site 1. Carbonic anyhydrase inhibitors: acetazolamide*, methazolamide, brinzolamide, ethoxzolamide • Site 2. High celing or loop diuretics: Sulphamoyl anthranilic acids like furosemide*,	4

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	azosemide and ~~and~~ bumetanide and phenoxyacetic acids ethacrynic acid* • Site 3. Thiazide and Thia~~a~~izide 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.	1
3.5	**Agents affecting Renin-Angiotensin Pathway and Calcium Blockers** • ACE Inhibitors- captopril* enalapril, benazepril, ramipril, Lisinopril • Angiotensin II receptor blockers- losartan, valsartan, candesartan, telmisartan, • Calcium channel blockers- verapamil bepridil, diltiazem, nifedipine, amlodipine, nimodipine, nicardipine, • Renin Inhibitors- aliskiren **(self study)** • Aldosterone antagonists: spironolacone, eplerenone **(self study)**	2 1 1
3.6	**Vasodilators/Sympatholytics** • Vasodilators- Hydralazine* diazoxide • 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	2
3.7	**Antihyperlipoproteinemics** Clofibrate*, gemfibrozil, ciprofibrate, HMG-CoA reductase inhibitors: lovastatin, atorvastatin, simvastatin, rosuvastatin, niacin, ezetimibe.	2
3.8	**Thrombolytics, Anticoagulants, Antiplatelets** W~~w~~arfarin* dicoumarol, anisidione, phenindione, aspirin, triflusal, indobufen **(self study)**, dipyridamole, cilostazol, ticlopidine clopidogrel, abciximab **(self study)**	2 1
4	**Antihistaminics** Antihistaminies:H_1 and H_2 receptors Emphasis to be on the second generation H_1 antagonists such as fexofenidine, astemazole, loratidine, cetrizine, mizolastine, and acrivastine, H_2 receptor antagonists like cimetidine **(self study)** ranitidine*, famotidine, nizatidine, proton pump inhibitors like omeprazole, rabeprazole, pantoprazole and lansoprazole.	3 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 ~~acarbose,~~ voglibose, and miglitol. • Insulin analgoues: Lispro insulin, glargine insulin	3 1
6	**Anaesthetics**	3
6.1	**General:** Halothane, isoflurane*, enflurane, sevoflurane, ketamine, propofol, thiopental.	
6.2	**Local:** • Amino esters – procaine, tetracaine, benzocaine* • Amino amides – lidocaine*, mepivacaine, bupivacaine, ropivacaine	

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	• Amino ethers – pramoxine • Amino ketones – dyclonine • Alcohols – benzyl alcohol, eugenol	
	Total	**45**

*Synthesis to be taught

Latest ~~e~~Editions of the following books to be adopted.

1. An Introduction to Medicinal Chemistry, Graham L. Patrick, Oxford University Press.
2. Fundamentals of Medicinal Chemistry, Gareth Thomas, Wiley, New York.
3. The Organic Chemistry of Drug Design and Drug Action, Richard B.Silverman, Academic Press.
4. Foye's Principles of Medicinal Chemistry, Thomas L. Lemke, David A Williams, Lippincott Williams & Wilkins.
5. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, John M. Beale, John H. Block, Lippincott Williams & Wilkins.
6. Medicinal Chemistry, Ashutosh Kar, New Age International Publishers.
7. Introduction to Medicinal Chemistry, Alex Gringauz, Wiley.
8. The Organic Chemistry of Drug Synthesis, Daniel Lednicer, Lester A. Mitscher, John Wiley and Sons.
9. Pharmaceutical Chemistry, Volume 1, Organic Synthesis, H. J. Roth & A. Kleemann, Ellis Horwood Series in Pharmaceutical Technology, Halsted Series.
10. Synthesis of Essential Drugs, Ruben Vardanyan and Victor Hruby, Elsevier.
11. Pharmaceutical Substances: Syntheses, Patents, Applications, Kleemann & Engel, Thieme Publications.

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Pharmaceutical Analysis – III **3 Hrs/week**

Unit	TOPIC	~~Hrs~~Hours
1.0	**Multicomponent analysis by UV Spectroscopy**	**2**
1.1	• Assay as a single component sample • Corrected interference • Assay after solvent extraction • Simultaneous Equation method • Absorbance Ratio method • Difference Spectroscopy method • Derivative Spectroscopy	2
2.0	**Concepts of Chromatography**	**6**
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) • Numericals related to column performance.	3
3.0	**High Performance Liquid chromatography (HPLC)**	**4**
3.1	**Instrumentation:** • Mobile phase reservoir • Pumps (reciprocating, displacement, pneumatic) ***(Self study-~~30 min~~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),***	3

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	Visualisation techniques, factors affecting resolution, Pharmaceutical applications of TLC and Preparative TLC. • **HPTLC**-Advantages of HPTLC over TLC and HPLC ***(Self study-0.5 hr)*** • Instrumentation-Applicator, photodensitometry, photodocumentation.	
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)***	
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.	3
9.0	**Hyphenated techniques**	**2**
	Significance, interfaces and applications of • LC-MS • GC-MS ***(Self study-1 hr)***	2
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: **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 min)***	3

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11	**Analytical method Validation as per ICH guidelines. *(Self study- 0.5 hr)***	**2**
	Total	**45**

Latest eEditions of the following books to be adopted.

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 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.

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Pharmacology – III **3 Hrs/Week**

Unit~~Sr.No.~~	TOPIC~~opic~~	Hours
1	**Drugs acting on Central Nervous System**	23
1.1	Aliphatic alcohols	1
1.2	General and Local anesthetics	3
1.3	Sedatives, Hypnotic and anxiolytic agents	2
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	3
1.8	Opioid analgesics	2
1.9	CNS stimulants	2
1.10	SELF STUDY: Physiology of CNS and central neurotransmitters	4
2	Autacoids; Drug therapy of inflammation	10
2.1	Histamine, bradykinin and their antagonists	2
2.2	Serotonin, agonists and antagonists	1
2.3	Lipid derived autacoids, Eicosanoids and platelet activating factor	1
2.4	NSAIDs	2
2.5	Pharmacotherapy of Asthma	2
2.6	SELF STUDY: Pharmacotherapy of Gout	2
3	**Drugs acting on gastrointestinal tract**	9
3.1	Antacids and Drugs for peptic ulcers	2
3.2	Emetics, antiemetics and Prokinetics	2
3.3	Drugs for constipation and diarrhoea	2
3.4	Drugs for Inflammatory Bowel Diseases	1
3.5	SELF STUDY: Innervations and hormones of GIT: Neuronal control and hormonal control	2
4	**Principles of Toxicology**	3
4.1	Heavy metals (Lead, Mercury, Arsenic)Poisoning,	1
4.2	Pesticide and Opioid Poisoning and treatment	1
4.3	SELF STUDY: Environmental toxicants	1
	Total	45

Latest editions of the 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, VallabhPrakashan, New Delhi.
7. B.G.Katzung-Basic and Clinical Pharmacology, Appleton and Lange publications.
8. Ghosh M.N. Fundamentals of Experimental Pharmacology Hilton & Company, Kolkata.

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Pharmaceutics – IV **3 Hrs/Week**

Unit~~No.~~	TOPIC~~opic~~	Hour
1	**Introduction to sterile dosage forms - Parenteral products**	**16**
1.1	Various routes of parenteral administration, pyrogens, vehicle,- WFI preparation, purity, storage and distribution, vehicles other than WFI, additives in parentertal products	4
1.2	*Self study* *Containers - glass and plastics- types and evaluation, , rubber closures and testing*	2
1.3	Personnel, facilities- layout, environmental control cleanliness classes, air handling (HVAC systems), HEPA filters, laminar flow	3
1.4	SVP – formulation considerations, types, product procedures, freeze drying	3
1.5	LVP – types, formulation aspects, packaging	2
1.6	QA & QC- sterility test, pyrogen/ endotoxin test, particulate evaluation, leaker test	2
2	**Ophthalmic Products**	**9**
2.1	*Self study-Anatomy and physiology of eye (1h)* lachrymal system, tears, precorneal tear film, cornea, ocular bioavailability	2
2.2	Formulation and packaging of various ophthalmic products - solutions, suspension, ophthalmic ointments and gels, preservatives and efficacy test, additives	3
2.3	QA and QC sterility test, clarity, particle size for suspension, tests on ointments and collapsible tubes	2
2.4	Contact lens solutions: types of lenses, cleaning solution, disinfection solution, lubricants, multipurpose solutions and packages	2
3	**Oral sustained and controlled release systems**	**110**
3.1	Advantages of SR systems, biopharmaceutical consideration and dose calculation of drug *Self study-Calculation for dose–loading, ~~maintainance~~maintenance-(2h)*	3
3.2	Properties of drug with reference to the design of oral SR systems	2
3.3	Matrix and reservoir type of systems, dissolution controlled systems, diffusion controlled systems, ion exchange controlled systems	4
3.4	Evaluation of sustain release systems	~~1~~ 2
4	**Stability Studies**	**9**
4.1	Importance of stability studies, kinetic principles, Arrhenius equation and derivation of shelf life based on Arrhenius equation, limitations and advantages of Arrhenius equation Self study-Problems –(2h)	4
4.2	Degradation pathways- hydrolysis, oxidation, photolytic degradation, methods to enhance stability of drugs	2
4.3	Accelerated stability studies, introduction to ICH guidelines	2
4.4	*Self studies-Interactions with containers and closures (1h)*	1
	Total	45

Latest e~~E~~ditions of the following books to be adopted

1. Pharmaceutical Dosage forms, Parenteral Medications. Vol I.II.III, Ed. By Kenneth A. Avis, Leon Lachman, and H .A. Liberman. Marcel ~~dekker~~ Dekker INC.

~~1.~~2. Pharmaceutics. The science of dosage form design, Ed. M. E. Aulton, Churchill livingstone.

~~1.~~3. Modern Pharmaceutics, Ed. By Gilbert S. Banker and Christopher T. Rhodes. Marcel Dekker INC.

~~1.~~4. The theory and practice of Industrial Pharmacy, Ed. By Leon Lachman, H. A. Liberman, J. L. Kanig; Varghese Publishing House.

~~1.~~5. Remington, The science and practice of Pharmacy, Vols. I and II, B.L. Publications Pvt. Ltd.

~~1.~~6. Ophthalmic drug delivery systems, ~~ed~~ Ed by Ashim K. Mitra, Volume 58, Marcel Dekker INC.

~~1.~~7. Turco and Kings, Sterile Dosage Forms, Lea and Febiger, Philadelphia.

~~1.~~8. Michel J. Akers, Quality Control of Parenterals, Marcel Dekker

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~~1.~~9. Controlled Drug Delivery-Fundamentals and Applications, Robinson Joseph R., Lee Vincent H, Vol 29, Marcel Dekker INC.
~~1.~~10. Pharmacetuical Technology, Vols. I, II, RSR Murthy, Ashutosh Kar, New Age Int. Ltd.

Pharmacognosy & Phytochemistry – II **3 Hrs/Week**

~~Sr. No.~~Unit	TOPIC~~opics~~	Hours
	Drugs indicated in bold font are to be studied for detailed pharmacognostic scheme	
1	**Lipids (Waxes, fats, fixed oils)**	**10**
1.1	General introduction to lipids. Study of the following drugs with respect to sources, classification,general properties, methods of extraction, preservation, storage, composition, evaluation,therapeutic uses and general applications. – Arachis**, castor**, sesame**, linseed**, jojoba, olive, **almond**, mustard, cottonseed, coconut, safflower, sunflower, croton, neem, rice bran, wheatgerm, hydnocarpus, cod-liver oil. *Self study* • *Methods of storage and preservation of oils and fats.*	5 1
1.2	Detailed study of following lipids with respect to chemistry, sources, extraction & / or preparation, preservation, evaluation and therapeutic use - Kokum butter, coca butter, Shea butter, woolfat, spermaceti wax, **beeswax,** carnauba wax, lecithin and introduction to glycolipids. *Self study –* • *Spermaceti and its substitutes* • *Uses and examples of glycolipids*	2 2
2	**Tannins**	**4**
2.1	Introduction to the structures of simple phenolics and their occurrence. Introduction to tannins and their definition, classification, occurrence, chemistry, detection, estimation and therapeutic applications.	1
2.2	Study of sources, composition, extraction and applications of **Galls, catechu (pale & black**) & Kino. Study of following tannin containing members with respect to their sources, properties, and therapeutic applications - arjuna, ashoka, harda, behra, green tea, pomegranate peel. Study of urushiol from poison ivy. *Self study-* • *Role of tannins in healthcare with suitable examples*	2 1
3	**Alkaloids**:	**15**
3.1	Introduction to alkaloids- Definition, classification, properties, general methods of extraction, detection and estimation. Study of following drugs containing alkaloids with respect to their chemistry (structures), sources, salient features of extraction and specific tests for detection (if any) and biopotenial : Alkaloidal Amines – **Ephedra,** colchicum Tropane – belladonna, **datura**, stramonium, hyoscyamus, coca, **Ashwagandha** Indole- **Rauwolfia,** vinca, **nux vomica, ergot** Steroidal – **kurchi** Terpene – Aconite Quinazoline – **Vasaka**	6
3.2	Study of following drugs containing alkaloids with respect to their chemistry (structures), sources, salient features of extraction and specific tests for detection (if any) and biopotenial : Benzyl isoquinoline – **opium** Isoquinoline - Ipecac, hydrastine, berberine, curare alkaloids Quinoline - **cinchona** Pyridine-Piperidine – Tobacco, Lobelia, pepper Purine - cocoa, tea, coffee, cola Glycoalkaloids – Solanum	5

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	Imidazole – Pilocarpus	
3.3	Biosynthesis of lysergic acid, opium alkaloids, tropane alkaloids, colchicines, emetine, quinine. *Self study –* • *Pharmacopoeial status of any five alkaloidal drugs*	2 2
4	**Miscellaneous phytochemicals**	**3**
4.1	**Polyacetylenes** Introduction to composition & properties of polyacetylenes from matricaria **Sulphur containing compounds** Thiophenes from tagetes. Study of sources, structure and properties of sulphur containing compounds from Allium species (*A. cepa and A. sativum*). **Napthoquinones** Study of alkana, henna, and plumbago with respect to active constituents and uses. **Benzoquinone** Study of *Embelia ribes.*	3
5	**Glycosides**	**8**
5.1	Introduction to glycosides their occurrence, chemistry, extraction and uses a) Anthroquinone - Rubia, cochineal, **aloes**, hypericum, cascara, andira**, senna**, rhubarb. Biosynthesis of Aloe emodin *Self study –* • *Commercial uses and preparation of aloes*	5 1
5.2	Chemistry, extraction & uses of following classes of glycosides : b) Isothiocyanate - Brassica c) Cyanogenetic - bitter almond, wildcherry Biosynthesis of amygdaline	2
	Pesticides of natural origin	**3**
6.1	Detailed study of following pesticides of natural origin with respect to their merits demerits, sources, active constituents and applications - Neem, Pyrethrum & Tobacco *Self Study* • *Commercially available pesticides and their composition*	2 1
7.	**Nutraceuticals**	**2**
7.1	Introduction to nutraceuticals. Study of the following drugs as nutraceuticals with respect to biological source, probable active constituents and uses – Alfalfa, Arnica, Apricot pits, bran, Chamomile, Chicory, Cucumber, Fenugreek, Onion, Garlic, Hydrocotyle, Hibiscus, Hops, Honey, Marigold, Amla, Ginseng, Ashwagandha, Gingko biloba, Spirulina, Gymnema, Momordica, Tinospora. *Self study:* • *Study of marketed nutraceutical preparations (any 2)*	1 1
	Total	**45**

Latest ~~e~~Editions of the following books to be adopted.

1. Trease D. & Evans W.C.: Text Book of Pharmacognosy: W.B. Saunders.
~~1.~~2. Tyler V. E. Brady L. R. & Robbers J. E.: Pharmacognosy; Lea Feibger, USA.
~~1.~~3. Wallis T. E.; Text Book of Pharmacognosy; CBS Publishers, Delhi.
~~1.~~4. Kokate C. K., Purohit A. P. & Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
~~1.~~5. Harbone J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman & Hall, London.
~~1.~~6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
~~1.~~7. Vasudevan T. N. & Laddha K. S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
~~1.~~8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
~~1.~~9. Brain K. R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.
~~1.~~10. Iyengar M. A. & Nayak S. G.: Anatomy of Crude Drugs: Manipal Power Press, Manipal.
~~1.~~11. Iyengar M. A.: Pharmacognosy of Powdered Drugs; Manipal Power Press, Manipal.

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~~1.~~12. Kokate C. K. : Practical Pharmacognosy; Vallabh Prakashan.
~~1.~~13. Wagner, Bladt & Zgainski; ~~plant~~ Plant Drug Analysis; Springer Verlag.
~~1.~~14. Khandelwal K. R.: Practical Pharmacognosy Techniques and Experiments; Nirali Prakashan, Pune.
~~1.~~15. Vasudevan T. N. Laddha K. S.: Practical Pharmacognosy; New Vrinda Publishing House, Jalgaon.

Pharmaceutical Jurisprudence **3 Hrs/Week**

~~Topic No.~~Unit	~~Content~~TOPIC	Hours
1	**Historical perspectives including details of Chopra Committee and Hathi Committee**	1
2	**PHARMACY ACT 1948**	5
2.1	Definitions	~~1~~2
2.2	Pharmacy Council of India and State Councils : Composition and Functions	
2.3	Preparation of registers and qualifications for entry into registers	~~2~~3
2.4	Educational Regulations and Approval of Courses and Institutions	
2.5	Offences and Penalities	
3	**DRUGS AND COSMETICS ACT 1940 AND RULES 1945**	18
3.1	Definitions	2
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	~~4~~6
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 corresponding penalties	~~2~~3
3.13	Broad Content of various Schedules of the Drugs and Cosmetics Act; Schedule M and Schedule Y in moderate details	
3.14	Self-study : Case Studies	1
4.0	**DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT 1954**	3
4.1	Definitions	2
4.2	Prohibited Advertisements, Savings	
4.3	Self-study : Case studies	1
5	**NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT 1985**	3
5.1	Definitions	1
5.2	Narcotics Commissioner and other Officers	
5.3	Illicit Traffic and measures to prevent illicit traffic of opium	~~1~~2
5.4	Offences and corresponding penalties	
6	**DRUGS PRICES CONTROL ORDER ~~1995~~2013**	3
6.1	Background of DPCO 1995~~Definitions~~	3
6.2	Definitions ~~Calculation of prices for scheduled and non scheduled bulk drugs and formulations~~	
6.3	~~Drug Price Equalization Account~~ Calculation of prices for drug products	
6.4	~~Drug Price Equalization Account~~Current National Pricing Policy ~~-~~Micellaneous heads under the order	

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7	**MEDICINAL AND TOILET PREPARATION (EXCISE DUTIES ACT) 1955**	2
7.1	Definitions, restricted and unrestricted preparations	2
7.2	Manufacturing in bond and outside bond	
8	**FOOD SAFETY AND STANDARDS ACT 2006 AND RULES 2011**	2
8.1	Definitions : Food, Adulterant and Food additive	2
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	Packaging and Labeling of Foods	
9	**INDIAN PATENTS ACT 2005**	3
9.1	Background : Intellectual Property and its types	2
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	Self-study : Case studies	1
10	**BOMBAY SHOPS AND ESTABLISHMENTS ACT**	1
10.1	Definitions of Shops and Commercial Establishments and Provisions under the Act in Brief	1
11	**FACTORIES ACT 1954**	1
11.1	Definitions	1
11.2	Provisions under the Act in Brief	
12	**INDIAN PENAL CODE AND CODE OF CRIMINAL PROCEDURES**	1
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 and Australia.	2
13.2	Introduction to USFDA, European, ICH and WHO guidelines	
	Total	~~36~~45

Latest e~~E~~ditions of the following books to be adopted.

1. Govt. Of India Publications of above Acts and Rules.
2. Kuchekar B. S., Khadtare A. M., Itkar S. C., Forensic Pharmacy, Nirali Prakashan.
3. N. K. Jain, Textbook of Forensic Pharmacy, Vallabh Prakashan.
~~3.~~4. Mittal B. M.- A Textbook of Forensic Pharmacy, Vallabh Prakashan.
~~3.~~5. Deshpande S. W. -Drugs & Cosmetics Act.
~~3.~~6. Guarino Rechard A. – New Drug Approval Process, Marcel Decker.

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Pharmaceutical Analysis Lab. – III **4 Hrs/week**

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). e.g-Ibuprofen.
6. Determination of validation parameters by UV spectroscopy: e.g Ibuprofen, Paracetamol.
   Linearity
   Precision
   Accuracy
7. Separation and identification of compounds by TLC
8. Determination of pK_a by UV spectroscopy e.g. Phenylephrine HCl
9. Demonstration experiments:
   1. -Separation and identification of amino acids by paper chromatography.
10. -Development of mobile phase for TLC
11. -Working of HPLC, GC and HPTLC.
12. -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 Latest editions of the following books to be adopted.

1. A.H. Beckett and J.B. Stenlake, *Practical Pharmaceutical Chemistry*, 4th Edn., Part I and II, CBS Publishers and Distributors, India, 2005.
2. G. D. Christian, *Analytical Chemistry*, 6th Edn., John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd., 2008.
3. *Indian Pharmacopoeia*, The Indian Pharmacopeia Commission, Ghaziabad, Government of India, 2010.
4. United States Pharmacopeia
5. J. Mendham, R. C. Denney, J. D. Barnes, M.J. K. Thomas, *Vogel's Textbook of Quantitative Chemical Analysis*, 6th Edn., Pearson Education Ltd, 2002. (Seventh impression 2008)
6. D.G. Watson, *Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists*. 3rd Edn., Churchill Livingstone Elsevier, 2012.
7. L. R. Snyder, J. J. Kirkland, J. L. Glajch, *Practical HPLC Method Development*, 2nd Edn., Wiley-Interscience pPublication, John Wiley & Sons, Inc., Canada, 1997.
8. S. Ahuja and M. W. Dong, *Handbook of Pharmaceutical Analysis by HPLC*, Volume 6 of Separation Science and Technology, 1st Edn., Elsevier Academic Press, Indian edition, 2009.

Reference books and textbooks (Please refer latest editions if available)

1. A.H. Beckett and J.B. Stenlake, *Practical Pharmaceutical Chemistry*, 4th Edn., Part I and II, CBS Publishers and Distributors, India, 2005.
2. G. D. Christian, *Analytical Chemistry*, 6th Edn., John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd., 2008.
3. *Indian Pharmacopoeia*, The Indian Pharmacopeia Commission, Ghaziabad, Government of India, 2010.
4. United States Pharmacopeia
5. J. Mendham, R. C. Denney, J. D. Barnes, M.J. K. Thomas, *Vogel's Textbook of*

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Quantitative Chemical Analysis, 6th Edn., Pearson Education Ltd, 2002. (Seventh impression 2008)

6 D.G. Watson, *Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists*. 3rd Edn., Churchill Livingstone Elsevier, 2012.

7 L. R. Snyder, J. J. Kirkland, J. L. Glajch, *Practical HPLC Method Development*, 2nd Edn., Wiley-Interscience publication, John Wiley & Sons, Inc., Canada, 1997.

8 S. Ahuja and M. W. Dong, *Handbook of Pharmaceutical Analysis by HPLC*, Volume 6 of Separation Science and Technology, 1st Edn., Elsevier Academic Press, Indian edition, 2009.

Pharmaceutics Lab. – IV **4 Hrs/Week**

1. Preparation and monographic testing of Water for Injection IP.
~~1.~~2. Processing and monographic testing of Glass containers and rubber closures as per IP.
~~1.~~3. Product –Package interaction- quantitative estimation of preservative absorption by rubber closures.
~~1.~~4. Preparation and documentation of the following injections:
    a. Sodium chloride and Dextrose injection IP.
    ~~a.~~b. Calcium gluconate injection IP
    ~~a.~~c. Ascorbic acid injection IP.
    ~~a.~~d. Official injection using an oily vehicle
    ~~a.~~e. Official parenteral suspension
5. Preparation and documentation of following ophthalmic products:
    a. Sulphacetamide eye drops, BPC.
    ~~a.~~b. Official antibiotic eye ointment
    ~~a.~~c. Contact lens solution
6. Accelerated stability testing of Aspirin
7. Sterility test and environmental control(Demonstration)

Latest editions of the following books to be adopted.

~~Books~~

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

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Pharmacology Lab. – II **4 Hrs/Week**

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

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.

Toxicity studies

- Introduction to CPCSEA, OECD guidelines
- Introduction to acute, sub-acute and chronic toxicity studies

Latest editions of the following books to be adopted

1. Kulkarni S. K. Handbook of Experimental Pharmacology, VallabhPrakashan, 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.

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Pharmacognosy & Phytochemistry – Lab. – II **4 Hrs/Week**

1 Study of morphology, histology and powder characteristics of cinchona bark and, extraction, chemical tests and TLC of quinoline alkaloids from Cinchona. ~~1 Practical~~

2 Study of morphology, histology and powder characteristics and tests for alkaloids of Rauwolfia. ~~1 Practical~~

3 Study of morphology, histology and powder characteristics of leaflets of senna. Extraction, chemical test and TLC of anthraquinone glycosides from senna. ~~1 Practical~~

4 Study of morphology , histology and powder characteristics of seeds of nuxvomica and extraction, chemical test and TLC of alkaloids of nux vomica ~~1 Practical~~

5 Study of morphology and histology of Datura, Ephedra, Vasaka, Kurchi, Ashwagandha, Arjuna, linseed ~~7 Practicals~~

6 Microscopical examination of powder mixtures of drugs mentioned above. ~~2 Practicals~~

7 Extraction and quantification of any one alkaloid by U.V and Demonstration of HPTLC. ~~1 Practical~~

8 Morphological identification of twenty crude drugs and their salient morphological features
Arachis, Castor, Sesame, Almond, Mustard, Ashoka, Galls, Pale and black catechu, Colchicum, Coffee beans, Vinca leaf, Ergot/ long pepper, Rhubarb, Wild cherry bark, Neem seeds and leaves, Pyrethrum, Henna, Aconite, Pepper black, kokum. ~~1 Practical~~

~~Total~~ ~~15 Practicals~~

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Latest Editions of the following books to be adopted.

1. Trease D. & Evans W.C.: Text Book of Pharmacognosy: W.B. Saunders.
~~1.~~2. Tyler V. E. Brady L. R. & Robbers J. E.: Pharmacognosy; Lea Feibger, USA.
~~1.~~3. Wallis T. E.; Text Book of Pharmacognosy; CBS Publishers, Delhi.
~~1.~~4. Kokate C. K., Purohit A. P. & Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
~~1.~~5. Harbone J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman & Hall, London.
~~1.~~6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
~~1.~~7. Vasudevan T. N. & Laddha K.S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
~~1.~~8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
~~1.~~9. Brain K. R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.
~~1.~~10. Iyengar M. A. & Nayak S. G.: Anatomy of Crude Drugs: Manipal Power Press Manipal.
~~1.~~11. Iyengar M. A.: Pharmacognosy of Powdered Drugs; Manipal Power Press, Manipal.
~~1.~~12. Kokate C.K.: Practical Pharmacognosy; Vallabh Prakashan.
~~1.~~13. Wagner, Bladt & Zgainski; plant Drug Analysis; Springer Verlag.
~~1.~~14. Khandelwal K. R.: Practical Pharmacognosy Techniques and Experiments; Nirali Prakashan, Pune.
~~1.~~15. Vasudevan T. N. Laddha K. S.: Practical Pharmacognosy; New Vrinda Publishing House, Jalgaon.

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Final Year B. Pharm. Sem. VIII

Pharmaceutical Chemistry – IV **4 Hrs/Week**

~~Sr. No.~~Unit	~~Topic~~TOPIC	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**	**20**
1.1	Sedatives – Hypnotics Barbiturates: phenobarbital, butabarbital, amobarbital, secobarbital, pentobarbital; benzodiadepines: chlordiazepoxide, diazepam, nitrazepam*, temazepam, alprazolam, estazolam; zolpidem, eszopiclone, ramelteon (last 3 for self study – 1 hr).	3 ~~+1~~
1.2	Anticonvulsants Types of seizures (Self study- 1 hr) phenobarbital, mephobarbital, phenytoin, mephenytoin, ethotoin, trimethadione, ethosuximide, methsuximide, phensuximide, diazepam, clonazepam, carbamazepine*, valproic acid, vigabatrine, progabide, lamotrigine, tiagabine	3 ~~+1~~
1.3	Antidepressants MAO Inhibitors (self study – 1 hr) Iproniazide, moclobemide, phenelzine, tranylcypromine; imipramine*, chlorimipramine, amitriptyline, nortriptyline, doxepine* fluoxetine*, paroxetine, sertraline, escitalopram, amoxapine	3 ~~+1~~
1.4	Anxiolytics Oxazepam, buspirone, meprobamate, tybamate (last two for self study- 1 hr)	1 ~~+1~~
1.5	Antipsychotics chlorpromazine*, triflupromazine, thioridazine, fluphenazine, trifluperazine, chlorprothixen(self study), haloperidol* (synthesis for self study- 1 hr), droperidol , pimozide, risperidone, loxapine, clozapine, sulpiride	3 ~~+1~~
1.6	Antiparkinson's carbidopa, levodopa, selegiline, amantadine, benztropine, procyclidine, orphenadrine (last 3 for self study- 1 hr)	1~~+1~~
2	**ANS Drugs**	**17**
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*, pindolol, sotalol, timolol, atenolol, metoprolol, esmolol, acebutolol, carvedilol, labetalol* (last two for self study, including synthesis of labetalol) Other adrenergic agents (Self study-2 hrs) : amphetamine, pseudoephedrine, ephedrine, guanethidine, propylhexedrine, reserpine	7~~+2~~
2.2	Cholinergic Drugs Muscarinic agonists : methacholine, carbachol, bethanechol, pilocarpine Acetylcholineesterase inhibitors : physostigmine, neostigmine*, pyridostigmine, edrophonium, echothiophate, malathion, parathion, paraoxonC, sarin, pralidoxime AntiAlzheimer's : Tacrine*, donepezil, rivastigmine Cholinergic antagonists : Atropine, scopolamine, homatropine, ipratropium cyclopentolate*, dicyclomine*, benztropine, procyclidine, isopropamide, tropicamide	7~~+1~~

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	Ganglion blockers : (Self study- 1 hr) trimethaphan, mecamylamine, hexamethonium Neuromuscular blockers :(Self study) tubocurarine, gallamine, succinylcholine, decamethonium	
3.	**Analgesic Drugs**	12
3.1	Opioid peptides(Self study) Different types of opioid receptors, 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 Antidiarrhoeals (Self study-1 hr) : loperamide, diphenoxylate	5~~+1~~
3.2	NSAIDS paracetamol, aspirin, indomethacin, sulindac, mefenamic acid, ibuprofen, naproxen*, flurbiprofen, nabumetone, diclofenac*, piroxicam*, nimesulide, celecoxib, rofecoxib Cytokine inhibitors :(Self study-1 hr) infliximab, rituximab, anakinra, abatacept Drugs in Gout : colchicine, probenecid, sulfinpyrazole, allopurinol, febuxostat	5~~+1~~
4	**Drugs affecting Male and Female Health (Steroids)**	**5**
4.1~~4.~~	~~**Drugs affecting Male and Female Health (Steroids)**~~ 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	4~~+ 1~~
5	**Drugs affecting Hormonal Systems**	~~**6**~~**2 ~~+ 3~~**
5.1	Thyroid Hormones (Self study- 1 hr) levothyroxine, propylthiouracil, methimazole, carbimazole	
5.2	Adrenocorticosteroids cortisone, hydrocortisone, prednisone, prednisolone, dexamethasone and betamethasone, flurometholone, fluocinolone, triamcinolone, aldosterone, fludrocortisone	4
5.3	Calcium Homeostasis (Self study-1 hr) raloxiphene, alendronate, teriparatide	
	TOTAL	60

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Books

As prescribed for Pharm. Chem. – III

Pharmaceutics – V **4 Hrs/Week**

Unit~~No.~~	TOPIC~~opic~~	Hours
1	**Introduction to NDDS**	8
1.1	Limitations of conventional dosage forms, need of NDDS, concept of targeting, advantages of targeting DDS	2
1.2	Advantages, limitations, concept, design and one suitable application of a typical system – oral multiparticulate (microspheres and pellets), floating gastro-retentive systems, transdermal DDS (membrane permeation systems), ocular insert, colloidal DDS (liposomes, nanoparticles, microemulsions), implantable systems (intrauterine device) Introduction to concept of iontophoresis, sonophoresis	6
2	**Mucoadhesive drug delivery systems**	6
2.1	Mucoadhesion and theories, factors influencing mucoadhesion	2
2.2	*In vitro-in vivo* methods to study mucoadhesion	2
2.3	Bioadhesive polymers, systems with reference to various routes of administration (oral, buccal, nasal, pulmonary, rectal)	2
3	**Colonic targeting**	4
3.1	Physiology of colon, difficulties in colonic drug delivery	1
3.2	Approaches - prodrug, pH sensitive polymers, polysaccharides, time release systems, osmotic systems, azo polymers and evaluation	3
4	**Osmotic Systems**	3
4.1	Basic principles (osmosis)	1
4.2	Classification, design and release kinetics of oral osmotic pumps, osmotic implants, applications and evaluation	2
5	**Microencapsulation**	5~~6~~
5.1	Definition, need/ reasons, concepts of core and coat	1
5.2	Methods of microencapsulation - phase separation coacervation (various techniques), wurster process, spray drying and related processes, interfacial polymerization, multiorifice centrifugal process, pan coating, solvent evaporation	4~~5~~
6	**Quality Assurance** (discuss specimen documents)	8
6.1	Raw material control, actives and inactive, in process control, sanitization, environmental and microbiological control, packaging and labeling control, finished product control	2
6.2	cGMP	2
6.3	Q. C. standards of identity, purity, quality and potency	2
6.4	Statistical Quality Control - Q. C. Charts, sampling and sampling plans	2
7	**Documentation**	5
7.1	Need and importance of documentation, maintenance and retrieval of documents	3
7.2	*Self study-SOP and BMR of various formulations*	2
8	**Pilot plant scale up techniques**	5
8.1	Group's responsibilities, facilities, example of scaling up of manufacturing of tablets, liquids (suspension, solutions, emulsions) and semisolids	5
9	**Validation**	5~~6~~
9.1	Definition, Types, Qualification, Validation of raw materials Process Validation – steps and documentation ~~e.g.:~~ mixing and wet granulation Equipment validation – ~~e.g.:~~ mixer and granulator	3~~4~~
9.2	Validation of sterilization process and equipment – microbial death kinetic terms,	2

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	F value applications, steps for validating steam sterilization method	
10	**Production Management**	**7**
10.1	Pharma industry - current scenario, Site selection and development – factors to be considered in designing a facility	2
10.2	*Self study-Personnel – qualifications, selection, responsibilities and training*	1
10.3	Material management - vendor audit, warehousing, sales forecasting, inventory control, production planning, elements of cost and cost controls	4
11	**Factory Layout**	**4**
11.1	As per schedule M - general considerations/ steps,	1
11.2	Examples of Typical layout schemes for Tablets, capsule, liquids, sterile formulations manufacturing areas	3
	TOTAL	**60**

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Latest ~~e~~Editions of the following books to be adopted

1. The theory and practice of Industrial Pharmacy, Ed. Leon Lachman, H. A. Liberman, J. L. Kanig; Varghese Publishing House.
~~1.~~2. Remington, The science and practice of Pharmacy, Vols. I and II, B. L. Publications Pvt. Ltd.
~~1.~~3. Cole Graham, Pharmaceutical Production Facilities, Design and Applications.
~~1.~~4. Pharmaceutical Process Validation, Nash Robert A., Berry Ira R., Volume 57, Marcell Dekker INC, New York.
~~1.~~5. Pharmaceutical dosage forms: Parenteral medications. Vols. I, II, III, Ed Kenneth A. Avis, Leon Lachman and H. A. Liberman, Marcel Dekker INC.
~~1.~~6. Pharmacetuical Technology, Vols. I, II, R S R Murthy, Ashutosh Kar, New Age Int. Ltd.
~~1.~~7. Advances in controlled and novel drug delivery, Ed. N. K. Jain, CBS publishers and distributors.
~~1.~~8. Modern Pharmaceutics, Ed. Gilbert S. Bankerand Christopher T. Rhodes. Marcel Dekker INC.
~~1.~~9. Targeted and controlled drug delivery, Novel carrier systems, S. P. Vyas and R. K. Khar., CBS publishers and Distributors.
~~1.~~10. Controlled and novel drug delivery, Ed N. K. Jain, CBS publishers and distributors.
~~1.~~11. Controlled drug delivery, concepts and advances; S. P. Vyas and R. K. Khar, Vallabh Publishers.
~~1.~~12. 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.
~~1.~~13. Nanoparticulate Drug Delivery Systems, Thasu Deepak, Dellers Michael, Pathak Yashwant, Volume 166, Marcel Dekker INC., New York.
~~1.~~14. Microencapsulation., Methods and Industrial Applications., D. Benita Simon, Marcel Dekker, INC, New York.
~~1.~~15. Controlled and Novel Drug Delivery, Jain N. K., CBS publishers and Distributors, New Delhi.
~~1.~~16. Ophthalmic drug delivery systems, Ed. Ashim K. Mitra, Volume 58, Marcel Dekker INC.

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Biopharmaceutics & Pharmacokinetics **4 Hrs/Week**

Unit~~No.~~	~~Topic~~TOPIC	Hrs
1	**INTRODUCTION**	5
~~1~~	~~**INTRODUCTION**~~	
1.1	Introduction to the subject of biopharmaceutics and p~~P~~harmacokinetics. Emphasis on the importance in drug discovery, development and clinical pharmacy and applications. Definitions: ADME, Bioavailability, Bioequivalence	2
1.2	Drug Transport: Different mechanisms of drug transport, physiology of cell membrane and passage of drugs across cell membrane.	3
2	**ABSORPTION**	10
~~2~~	~~**ABSORPTION**~~	
2.1	Routes of drug administration: Emphasis on Oral, parenteral and Extravascular routes (Self study)	2
2.2	Factors affecting drug absorption: Physicochemical factors (Emphasis on pH partition theory and solubility)	3
2.3	Factors affecting drug absorption: Physiological factors (Emphasis on physiology of GIT)	3
2.4	Factors affecting drug absorption: Formulation and Dosage form factors (Self study)	2
3	**DISTRIBUTION**	5
~~3~~	~~**DISTRIBUTION**~~	
3.1	Factors affecting distribution: Physiological barriers, Tissue permeability and perfusion limited distribution	2
3.2	Volume of Distribution – Concept, dependence on site/fluid of measurement, limits of values of volume of distribution	1
3.3	Protein Binding of drugs and its significance	2
4	**METABOLISM/Biotransformation**	8
~~4~~	~~**METABOLISM/Biotransformation**~~	
4.1	Phase I and Phase II reactions (self study)	3
4.2	Factors affecting drug metabolism: Age, species difference, genetic difference, induction and inhibition, drug- drug interaction	2
4.3	First pass metabolism, concept of clearance , hepatic clearance and factors affecting hepatic clearance, Hepatic extraction ratio, limits of values of organ clearance	3
5.	**EXCRETION**	**4**
5.1	Renal excretion, Renal clearance and factors affecting renal clearance, Excretion ratio	2
5.2	Non hepatic and non-renal routes of elimination	2
6	**DISSOLUTION**	**7**
6.1	Introduction to Biopharmaceutical Classification System of drugs	2
6.2	Theories of dissolution, Dissolution rate and methods of enhancing dissolution rate.	~~2~~3
6.3	Official and unofficial methods of dissolution rate testing. Application to different dosage forms (self study)	~~3~~2
7	**PHARMACOKINETICS**	**16**
7.1	Pharmacokinetics: Introduction to compartmental and physiological models. Introduction to the one compartmental open model and its assumptions. Concept	3

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	of zero order and first order rate kinetics	
7.2	Mathematical treatment of pPharmacokinetics upon (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
7.3	Mathematical treatment of pharmacokinetics upon (One compartment open model) extravascular dosing. Absorption rate constant, absorption half life, bioavailability. ~~Introduction of the concept of a~~Area under the curve~~, the trapezoidal rule~~ and the method of residuals. Concept of Cmax and tmax.	3
7.4	Introduction to the R~~r~~ate of excretion method and Sigma minus method for urine analysis after IV administration	2
7.5	Discussion of linear and nonlinear kinetics and description of factors resulting in non linear kinetics.	2
7.6	Application of PK principles through simple problems. (3 hours self study)	4
8	**BIOAVAILABILITY AND BIOEQUIVALENCE**	5
8.1	Concept of absolute and relative bioavailability	1
8.2	Methods of assessment and enhancement of bioavailability (1 hour self study)	2
8.3	Bioequivalence: Study designs, Introduction to the concept of biowaiver (1 hour self study)	2
	TOTAL	**60**

Latest e~~E~~ditions of the following books to be adopted

1. Leon Shargel, Susanna Wu – Pong, Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Singapore.
~~1.~~2. Brahmankar D.M and Jaiswal Sunil B, Biopharmaceutics and Pharmacokinetics – A Treatise, Vallabh Prakashan.
~~1.~~3. Robert E. Notari, Biopharmaceutics and Pharmacokinetics – An Introduction, Marcel Dekker Inc., New York.
~~1.~~4. Milo Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics~~"~~, ~~1991,~~ USA.
~~1.~~5. Malcom Roland, Thomas Tozer, Clinical Pharmacokinetics: Concept and Application, A Lea – Febiger book, USA
~~1.~~6. Banakar~~,~~ Umesh, Pharmaceutical Dissolution Testing, Volume 49, Marcel Dekker Inc, New York.

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Pharmacognosy & Phytochemistry – III **4 Hrs/Week**

~~Sr.No~~ Unit~~:~~	TOPIC~~epic~~	Hours
	Drugs highlighted in bold font are to be studied for detailed pharmacognostic scheme	
1	**Volatile Oils**	**11**
1.1	General introduction, composition, chemistry, general methods of extraction, therapeutic uses and commercial applications of volatile oils. Introduction to terpeneless volatile oils. Study of sources, composition of volatile oils, salient features of extraction (if any) and applications of the following : a. Umbelliferous fruits (Anise, Caraway, **Dill**, Ajowan, **Fennel**, **Coriander,** Cumin). Biosynthesis of mono and sesquiterpenoid derivatives occurring in volatile oils. *Self study* *Comparative study of morphology and microscopy of Umbelliferous fruits*	4 1
1.2	Study of sources, composition of volatile oils, salient features of extraction (if any) and applications of the following : b. Hydrocarbon volatile oil – Turpentine oil c. Alcohol – Peppermint, **Cardamom,** Rose oil, Peppermint d. Aldehyde volatile oil - Lemon and Orange peel oil, Lemongrass e. Ketone volatile oil - Camphor, spearmint (mint oils) f. Ester volatile oil - Oil of Wintergreen g. Ether volatile oil - **Eucalyptus oil** h. Miscellaneous - Sandalwood, Sassurea, Star anise, Jatamansi, Valerian, Vetiver, Phenyl propanoids - **Cinnamon, Cassia cinnamon, clove**, nutmeg. *Self study* • *Oils used in perfume industry any 2 examples* • *Marketed formulations containing the volatile oils mentioned above (any 5)*	4 2
2.	**Steriodal and Triterpenoidal drugs**	**9**
2.1	Introduction to steroidal and saponin glycosides with respect to their chemistry, general chemical tests. Detailed study of drugs with respect source, chemistry & biopotential of the following drugs - **Liquorice**, Quillaia, **Asparagus**, Ginseng, **Dioscorea**, Agave, Fenugreek, Bacopa, Hydrocotyle, Smilax, Sapindus, *Acacia concinna.*	5
2.2	Introduction to cardiac glycosides with respect to their classification, chemistry & general chemical tests. Detailed study of drugs with respect source, chemistry & biopotential of the following drugs – ***Digitalis lanata, Digitalis purpurea***, Strophanthus, Squill, Nerium, Thevetia. *Self Study:* • *Morphological and histological differences between different species of Diascorea, Digitalis, Brahmi*	2 2
3.	**Resins and resin combinations**	**5**
3.1	Introduction of resins as pathological products, definition, general properties, composition and applications. Study of occurrence, composition, uses and specific tests for identification of the following natural resins - Colophony, Myrrh, Benzoin, Balsams of Tolu and Balsam of Peru, Guggul, Asafoetida.	3
3.2	Introduction of metabolic resins and their methods of extractions. Study of details of chemistry (structures of principal components), sources and uses of the following resins - Cannabis, Turmeric, Ginger, Capsicum, Shellac. *Self Study:* • *Morphology and microscopy of Ginger* • *Preparation of Ginger and Turmeric for market*	1 1
4	**Phenyl propanoids and related compounds**	**6**

4.1	Biosynthesis of phenyl propanoids. Examples of monomeric , dimeric and related phenylpropanoid derivatives e.g., lignans, lignins and flavonoids.	1
4. 2	Flavonoids: Introduction to flavonoids, classification, chemical tests occurrence & their biopotential as exemplified by orange peel , garcinia, soyabean, liquorice, cranberry, buckwheat.	3
4.3	Study of following drugs with respect to sources, constituents and uses – Podophyllum, Psoralea, Ammi majus, Phyllanthus *Self study:* • *Differences between two species of Podophyllum* • *Differences between two species of Tinospora* • *Herbal photosensitizer and photoprotective agents*	1 1
5.	**Iridoids & Miscellaneous phytochemicals**	**5**
5.1	**Iridoids** General introduction to iridoids. Study of Gentian, piccrohiza. **Modified Triterpenoids** Quassia, tinospora, Artemisia, Taxus, , Andrographis. **Tetraterpenoids** General introduction to tetraterpenoids. Study of carotenoids- lutein, crocin, zeaxanthin, and lycopene with respect to sources, chemistry, and biopotential. *Self study:* • *All sources and applications of lycopene*	4 1
6	**Traditional drugs**	**6**
6.1	Study of following traditional drugs with respect to common names, sources, and traditional uses & observed pharmacological activities of the following drugs - punarnava (*Boerhavia diffusa*), shankpusphi (*Convolvulus microphylla*), Leshun (*Allium sativum*), Guggul (*Commiphora mukul*), Kalmegh (*Andrographis paniculata*), Tulsi (*Ocimum sanctum*), valerian(*Valerian officinalis*), Artemisia(*Artemisia annua*), Chirata (*Swertia chirata*), Ashoka (*Saraca indica*)	3
6.2	Study of all traditional drugs listed in Sec. 6.1, with respect to phytoconstituents. *Self study:* • *Study of marketed formulations containing traditional drugs (any two)*	2 1
7	**Study of Herbal Excipients & Cosmetics**	**6**
7.1	Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.	3
7.2	Herbal Cosmetics - Importance of herbals as surfactants (soapnut), hair conditioners and hair colorants (henna, hibiscus, tea), herbals for skin care (aloe vera gel, turmeric, lemon peel, vetiver). *Self study:* • *Study of two examples of each type of excipient from natural sources*	2 1
8.	**Study of herbal formulations & Ayurvedic formulations**	**5**
8.1	Formulations based on substances of natural origin – Challenges and salient features of preparation of herbal formulations	2
8.2	**Ayurvedic Formulations –**Introduction to Ayurvedic formulations like aristas, asava, gutika, taila, churna, avaleha, ghrita. Introduction to the concept of detoxification in Ayurveda. *Self study:* • *Examples of Ayurvedic formulations (any two)*	2 1
9	**Standardization, Regulations & Intellectual Property Rights of Herbal and Ayurvedic, Siddha & Unani (ASU) drugs**	**7**
9.1	Standardisation : Detailed study of Quality control of herbal drugs as per WHO guidelines. Safety parameters, toxicity concerns and herb- drug interactions. *Self study:*	2 1

	• *Examples of Herbal drug interactions* • *Study of five examples of markers from each class of phytoconstituents for standardization*	
9.2	Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule T & Y of Drugs & Cosmetics Act for ASU drugs. Overview of Global regulatory issues. Indian and International patent laws, proposed amendments as applicable to herbal /natural products and processes, Intellectual Property Rights with special reference to phytoconstituents. *Self study:* • *Search on one case study of patent related to herb*	3 1
	Total	**60**

Latest ~~e~~Editions of the following books to be adopted.

1. Trease D. & Evans W.C.: Text Book of Pharmacognosy: W. B. Saunders.
~~1.~~2. Tyler V. E. Brady L. R. & Robbers J. E.: Pharmacognosy; Lea & Feibger, USA.
~~1.~~3. Wallis T. E.; Text Book of Pharmacognosy; CBS Publishers, Delhi.
~~1.~~4. Kokate C. K., Purohit A. P. & Gokhale S. B.: Pharmacognosy; Nirali Publications, Pune.
~~1.~~5. Harbone J. B.: Phytochemical Methods: A guide to modern techniques Analysis: Chapman & Hall, London.
~~1.~~6. Bruneton J.: Pharmacognosy, Phytochemistry, Medicinal Plants: Intercept Limited.
~~1.~~7. Vasudevan T. N. & Laddha K. S.: A Textbook of Pharmacognosy, Vrinda Publication House, Jalgaon.
~~1.~~8. The Indian Pharmacopeia: The Controller of Publication; Delhi.
~~1.~~9. Brain K. R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.
~~1.~~10. Iyengar M. A. & Nayak S. G.: Anatomy of Crude Drugs: Manipal Power Press, Manipal.
~~1.~~11. Iyengar M. A.: Pharmacognosy of Powdered Drugs; Manipal Power Press, Manipal.
~~1.~~12. Kokate C. K.:Practical Pharmacognosy; Vallabh Prakashan.
~~1.~~13. Wagner, Bladt & Zgainski; Plant Drug Analysis; Springer Verlag.
~~1.~~14. Khandelwal K. R.: Practical Pharmacognosy Techniques and Experiments; Nirali Prakashan, Pune.
~~1.~~15. Vasudevan T. N. Laddha K. S.: Practical Pharmacognosy; New Vrinda Publishing House, Jalgaon.
~~16.~~ Pulok ~~k~~K. Mukherjee , GMP for botanicals (Regulatory and Quality Issues on Phytomedicines).
16. Editor Robert Verpoorte, Business Horizons New Delhi.
17. Pulok K Mukherjee, Quality control of herbal drugs, an approach to evaluation of botanicals, Business Horizons, New Delhi.

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Clinical Pharmacy **2 Hrs/Week**

Unit~~Sr. No.~~	TOPIC~~epic~~	Hours
1	Concept of Clinical Pharmacy, Community pharmacy and hospital pharmacy (Definition, scope and objectives), Patient Counselling: Role of Pharmacist in patient counselling	3
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	3
4	Drug interactions: Types, General Considerations and Mechanisms	3
5	**Drug use in special population**	
5.1	Drugs used in Geriatrics	2
5.2	Drugs used in Paediatrics	1
5.3	Drugs used in Pregnancy	1
6	Therapeutic Drug Monitoring: Definition, indications and strategies	2
7	**Drug discovery & development:**	
7.1	Preclinical development	1
7.2	Clinical development 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)	4
7.3	Good Clinical Practice (GCP): Concept and importance	1
7.4	Definitions of essential documents; SOP, protocol, Investigator's brochure, informed consent forms and case report forms	1
7.5	Introduction to BA/BE studies	2
7.6	SELF STUDY: - Pharmacovigilance: Definition, scope and aims of Pharmacovigilance	4
~~7.7~~	~~SELF STUDY: Pharmacovigilance: Definition, scope and aims of Pharmacovigilance~~	~~4~~
	Total	30

Latest editions of the following books to be adopted

1. Clinical Pharmacy and Therapeutics, Roger Walker, Clive Edwards, Churchill Livingstone.
~~1.~~2. Clinical Pharmacy, Dr.Tipnis, Dr. Bajaj, Career Publications.
~~1.~~3. Clinical Pharmacology, P.N. Benett, M. J. Brown, Churchill Livingstone.
~~1.~~4. Text Book of Clinical Pharmacy Practice, G. Parthisarathi, Karin Nyfort Hansen, Milap C. Nahata, Orient Longman.

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Pharmaceutical Chemistry Lab. – III **4 Hrs/Week**

Synthesis of the following Drugs and Drug Intermediates

1. Diels – Alder Reaction using Maleic Acid + Furan
2. Synthesis of Benzilic Acid: Conventional Method and Green Modification as in Green Chemistry DST Monograph
3. Synthesis of Benzoin from Benzaldehyde using Thiamine, Ref: Green Chemistry – V. K. Ahluwalia, pg. no. 2.5
4. Three Component Synthesis of Pyrimidone using Ethylacetoacetate, Benzaldehyde and Urea as per Green Chemistry DST Monograph
5. Synthesis of Dibenzylidene Acetone using LiOH as per Green Chemistry DST Monograph
6. Synthesis of Benzoic Acid using Cannizaro Reaction of Benzaldehyde, Ref: Green Chemistry, V. K. Ahluwalia pg. No. 65.
7. Hofmann rearrangement: Anthranilic acid from Phthalimide.
8. Reduction reaction: PABA from *p*-nitrobenzoic acid.
9. Synthesis of Benzocaine from PABA

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Pharmaceutics Lab. – V **4 Hrs/Week**

1. Preparation and *in vitro* release evaluation of sustained release oral granules/tablets-using hydrophobic and hydrophilic matrix materials.
2. Dissolution testing of marketed formulations of conventional tablets containing freely soluble and poorly soluble drug(selection of medium).
3. Calculations of pharmacokinetic parameters (plasma samples provided).
4. Preparation and evaluation of mucoadhesive buccal films (including mucoadhesive strength).
5. Preparation and evaluation of film coated modified release/colon specific dosage form.
6. Microencapsulation of solid and liquid core using phase separation coacervation technique and evaluation of microcapsules.
7. Validation of process-dissolution/mixing.
8. Assignment on SOP's of dissolution apparatus/tablet press/coating equipment.
9. Assignment on excipient/API specifications.

Books

All books listed in the theory syllabus as well as current editions of IP, BP and USP

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Pharmacognosy & Phytochemistry Lab. – III **4 Hrs/Week**

1 Study of morphology, histology, powder characteristics of Fennel and Coriander
Extraction and detection of volatile oil from fennel. 1 Practical
2 Study of morphology, histology, powder characteristics of Liquorice
Extraction and detection of saponin glycosides and flavonoids from Liquorice 1 Practical
3 Study of morphology, histology, powder characteristics of Clove. Extraction of clove oil and detection of Eugenol by TLC and potassium euginate test. 1 Practical
4 Study of morphology, histology, powder characteristics of, Ginger, Quassia, Kalmegh, Eucalyptus, Cinnamon 5 Practicals
5 Microscopical examination of powder mixtures of drugs mentioned above. 3 Practicals
6 Extraction and detection by TLC of curcumin from turmeric. 1 Practical
8 Morphological identification any twenty samples and their salient morphological features
Anise and Star anise, Caraway, Dill, Ajowan, Cumin, Citrus peel, Sandalwood, Sassurea, Jatamansi, Valerian, Nutmeg and mace, Vetiver, Dioscorea, Fenugreek, Brahmi, Shikakai, Soapnut, Squill, Digitalis, Turmeric, Soyabean, Capsicum, Podophyllum, Picrorhiza, Punarnava, Apricot, Amla, Karela 1 Practical
9 Qualitative evaluation of phytoconstituents from herbal formulation with respect to volatile oils, saponin glycosides, cardiac glycosides, flavanoids. 2 Practicals
Total 15 Practicals

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. Brain K. R. & Turner T. D.: The Practical Evaluation of Phytopharmaceuticals: Wright, Scientica, Bristol.
10. Iyengar M. A. & Nayak S. G.: Anatomy of Crude Drugs: Manipal Power Press Manipal.
11. Iyengar M. A.: Pharmacognosy of Powdered Drugs; Manipal Power Press, Manipal.
12. Kokate C.K.: Practical Pharmacognosy; Vallabh Prakashan.
13. Wagner, Bladt & Zgainski; Plplant Drug Analysis; Springer Verlag.
14. Khandelwal K. R.: Practical Pharmacognosy Techniques and Experiments; Nirali Prakashan, Pune.
15. Vasudevan T. N. Laddha K. S.: Practical Pharmacognosy; New Vrinda Publishing House, Jalgaon.

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