JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University) (Accredited 'A+' Grade by NAAC)



JSS COLLEGE OF PHARMACY, ROCKLANDS, OOTY

(ISO 9001:2015 Certified)



(Academic Year : 2021 - 2022)

Course: III . B. PHARM

Vision

To be preeminent colleges in shaping society-worthy and SMART Pharmacy Professionals of global repute

Mission

- To adopt and lead the transformation of pharmacy education, practice and research nationally and globally.
- To inspire and nurture students to become exemplary professionals to serve the global society
- To develop competencies among students and empower them to meet the changing needs of the profession
- To impart quality education and practice to promote and advance public health
- To impart holistic and value-based education to produce new generation humane pharmacy professionals
- To address the sustainable health care challenges through innovative measures and technologies

Programme Educational Objectives

- 1. To acquire the theoretical knowledge of Pharmaceutical Sciences
- **2.** To acquire practical skills in
- Isolation and identification of medicinal compounds from natural sources
- Synthesis and analysis of medicinal compounds
- Screening for pharmacological activities
- Formulation of pharmaceutical dosage forms and their evaluation
- Comprehensive pharmaceutical care to patients
- 3. To demonstrate the leadership qualities, ethical attitude and to engage in life-long learning
- **4.** To acquire skills for designing the research questions, protocol, data analysis and reporting research outcomes

Programme Outcomes

- 1. Pharmacy Knowledge
- 2. Planning abilities
- 3. Problem analysis
- 4. Modern tool usage
- 5. Leadership skills
- 6. Professional Identity
- 7. Pharmaceutical Ethics
- 8. Communication
- **9.** Pharmacist and society
- 10. Environment and sustainability
- **11.** Lifelong learning

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1. EXCERPT FROM JSS ACADEMY OF HIGHER EDUCATION & RESEARCH REGULATIONS

Medium of instruction and examinations

Medium of instruction and examination shall be in English.

Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree is 208. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Project over the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

Course of study

The course of study for II B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to II The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to II.

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial Pharmacy I– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial Pharmacy I – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	27	5	26

Table – I:	Course	of study	for	semester	V
	Course	or study	101	SCHICSLEI	•

	Name of the course	No. of hours		Crodit
Course	Name of the course	No. of hours	Tutorial	points
code				-
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory– Theory	3	1	4
BP606T	Quality Assurance – Theory	3	1	4
BP606P	Medicinal chemistry III – Practical	4	-	2
BP607P	Pharmacology III – Practical	4	-	2
BP608P	Herbal Drug Technology – Practical	4	-	2
	Total	30	6	30

Table – II: Course of study for semester VI

End semester examinations

The End Semester Examinations for each theory and practical course through semesters III to IV shall be conducted by the university.

		Tuble	III. Ucili					
		Internal Assessment			End Sem	lester		
Course	Name of the course					Exams		Total
code		Continuous	Session	al Exams	Total	Marks	Duration	Marks
		Mode	Marks	Duration				

Table - III: Semester V

BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial Pharmacy I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Biotechnology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial Pharmacy I— Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
	Total	65	105	17 Hrs	170	480	27 Hrs	650

Table – IV: Semester VI

Course		Intern	Internal Assessment				End Semester Exams		
code	Name of the course	Continuo	Sessiona	Exams	Total	Marks	Duration	Marks	
		us Mode	Marks	Duration	TOtal		Duration		
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100	
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100	
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100	
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100	
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100	
BP606T	Quality assurance – Theory	10	15	1 Hr	25	75	3 Hrs	100	
BP606P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50	
BP607P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50	
BP608P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50	
	Total	75	120	18 Hrs	195	555	30 Hrs	750	

Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table - V: Scheme for awarding internal assessment: Continuous mode

	Theory				
Crite	ria	Maximu	ım Marks		
Attendance (Refer Table – VI)		4	2		
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)			1.5		
Student – Teacher interaction		3	1.5		
Total			5		
	Practical				
Attendance (Refer Table – VI)		2			
Based on Practical Records, Regular viva v	oce, etc.	3			
Total			5		
Table – VI: Guidelines for the allotment of marks for attendance					
Percentage of Attendance Theory Pract		ctical			
95 - 100	4	2			

90 - 94	3	1.5
85 — 89	2	1
80 - 84	1	0.5
Less than 80	0	0

Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Question Paper Pattern for Theory Sessional Examinations

For subjects having University Examination				
I. Multiple Choice Questions (MCQs)				
(Answer all the questions)		=	10 X 1	= 10
I. Long Answers (Answer 1 out of 2)		=	1 x 10	= 10
II. Short Answers (Answer 2 out of 3)		=	2 X 5	= 10
	Tota	1 =	_	30 marks
For subjects having Non University Examination				
I. Long Answers (Answer 1 out of 2)		=	1 x 10	= 10
II. Short Answers (Answer 4 out of 6)		=	4 x 5	= 20
	Total	=	-	30 marks
Question paper pattern for practical sessional examinati	ons			
I. Synopsis		=		10
II. Experiments		=		25
III. Viva voce		=		05

Table – VII. Tentative schedule of end semester examinations						
Semester	For Regular Candidates	For Failed Candidates				
V	November / December	May / June				
VI	May / June	November / December				

Total

=

40 marks

Question paper pattern for end semester theory examinations

For 75 marks paper

(Answer all the questions)		
I. Multiple Choice Questions (MCQs)	=	$20 \times 1 = 20$
I. Long Answers (Answer 2 out of 3)	=	$2 \times 10 = 20$
II. Short Answers (Answer 7 out of 9)	=	7 X 5 = 35
III.	Total =	75 marks
Question paper pattern for end semester	practical examin	ations
I. Synopsis	= 05	
II. Experiments	= 25	
III. Viva voce	= 05	
Total =	35 mai	rks

Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

SYLLABUS OF III B.PHARM. (SEMESTER - V)

BP501T. MEDICINAL CHEMISTRY – II (Theory)

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

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

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

Course Content:

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

UNIT- I

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

H1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine Succinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Cromolyn sodium H2-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole.

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*,

Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, hydrochloride, Doxorubicin hydrochloride, Bleomycin Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate Miscellaneous: Cisplatin, Mitotane.

UNIT – II

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole. **Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

10 Hours

45 Hours

10 Hours

5 Hours

7

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, **Loop diuretics:** Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

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

UNIT- III

10 Hours

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

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

UNIT – V Antidiabetic agents:

Insulin and its preparations

Biguanides: Metformin.

07 Hours

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine. **Amino Benzoic acid derivatives**: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine. Miscellaneous: Phenacaine, Diperodon, Dibucaine.

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.

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

2. Foye's Principles of Medicinal Chemistry.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide. **Glucosidase inhibitors:** Acrabose, Voglibose. **Local Anesthetics:** SAR of Local anesthetics

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

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

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

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

Course content:

3 hours/ week

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

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

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

Tablets:

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

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

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

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

UNIT-III

Capsules:

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

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

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

UNIT-IV

Parenteral Products:

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

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

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

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion

fluids. Ouality control tests of parenteral products.

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

UNIT-V

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

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

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

10 Hours

10 Hours

10 Hours

08 Hours

07 Hours

BP 506 P. Industrial Pharmacy I (Practical)

4 Hours/week

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

Recommended Books: (Latest Editions)

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

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

BP503T. PHARMACOLOGY-II (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I

- 1. Pharmacology of drugs acting on cardio vascular system
- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

10 hours

UNIT-II

- 1. Pharmacology of drugs acting on cardio vascular system
- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders
- 2. Pharmacology of drugs acting on urinary system
- a. Diuretics
- b. Anti-diuretics.

UNIT-III

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

UNIT-IV

4. Pharmacology of drugs acting on endocrine system

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

UNIT-V

5. Pharmacology of drugs acting on endocrine system

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.
- 6. Bioassay
- a. Principles and applications of bioassay.
- b. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis histamine and 5-HT
- c. Types of bioassay

BP507P. PHARMACOLOGY-II (Practical) 4Hrs/Week

- 1. Introduction to in-vitro pharmacology and physiological salt solutions.
- 2. Effect of drugs on isolated frog heart.
- 3. Effect of drugs on blood pressure and heart rate of dog.
- 4. Study of diuretic activity of drugs using rats/mice.
- 5. DRC of acetylcholine using frog rectus abdominis muscle.
- 6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
- 7. Bioassay of histamine using guinea pig ileum by matching method.
- 8. Bioassay of oxytocin using rat uterine horn by interpolation method.

10 hours

10 hours

08 hours

07 hours

9. Bioassay of serotonin using rat fundus strip by three-point bioassay.

10. Bioassay of acetylcholine using rat ileum/colon by four-point bioassay.

11. Determination of PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).

12. Determination of PD2 value using guinea pig ileum.

13. Effect of spasmogens and spasmolytics using rabbit jejunum.

14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.

15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares (Expharma, Excology etc.,) and videos

Recommended Books (Latest Editions)

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

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45 Hours

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

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

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents

- 2. to understand the preparation and development of herbal formulation.
- 3. to understand the herbal drug interactions
- 4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I

Metabolic pathways in higher plants and their determination

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

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

UNIT-II

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

7 Hours

14 Hours

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

UNIT-III

Isolation, Identification and Analysis of Phytoconstituents

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

UNIT-IV

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

UNIT V

Basics of Phytochemistry

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

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander

- 2. Exercise involving isolation & detection of active principles
- a. Caffeine from tea dust.
- b. Diosgenin from Dioscorea
- c. Atropine from Belladonna
- d. Sennosides from Senna
- 3. Separation of sugars by Paper chromatography
- 4. TLC of herbal extract
- 5. Distillation of volatile oils and detection of phytoconstitutents by TLC

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

Recommended Books: (Latest Editions)

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

- 2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan,
- 4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
- 5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
- 7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
- 8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
- 9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
- 10. The formulation and preparation of cosmetic, fragrances and flavours.
- 11. Remington's Pharmaceutical sciences.

06 Hours

10 Hours

8 Hours

12. Text Book of Biotechnology by Vyas and Dixit.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory) 45 Hours

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

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

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

Course Content:

UNIT-I

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under

license or permit. Offences and penalties.

Manufacture of drugs - Prohibition of manufacture and sale of certain drugs,

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

UNIT-II

Drugs and Cosmetics Act, 1940 and its rules 1945.

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

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

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

UNIT-III

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

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

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

UNIT-IV

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

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

National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

10 Hours

08 Hours

10 Hours

10 Hours

13

UNIT-V

07 Hours

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

Recommended books: (Latest Edition)

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

<u>VI SEMESTER</u>

BP601T. MEDICINAL CHEMISTRY - III (Theory)

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

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

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

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

UNIT - I

10 Hours

Antibiotics

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

- β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams
- Aminoglycosides: Streptomycin, Neomycin, Kanamycin

45 Hours

Tetracyclines: Tetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

Antibiotics

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

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate. Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

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

UNIT - IV08 Hours Antifungal agents:

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

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

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

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

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides:

Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate. Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

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

07 Hours

10 Hours

10 Hours

4 Hours / week

I Preparation of drugs and intermediates

1 Sulphanilamide

2 7-Hydroxy, 4-methyl coumarin

- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

II Assay of drugs

1 Isonicotinic acid hydrazide

- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave

irradiation technique

IV Drawing structures and reactions using chem draw®

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

Recommended Books (Latest Editions)

- 1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- 2. Foye's Principles of Medicinal Chemistry.
- 3. Burger's Medicinal Chemistry, Vol I to IV.
- 4. Introduction to principles of drug design- Smith and Williams.
- 5. Remington's Pharmaceutical Sciences.
- 6. Martindale's extra pharmacopoeia.
- 7. Organic Chemistry by I.L. Finar, Vol. II.
- 8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.

9. Indian Pharmacopoeia.

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

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

10 hours

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

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

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases

2. comprehend the principles of toxicology and treatment of various poisonings and

3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I

1. Pharmacology of drugs acting on Respiratory system

- a. Anti -asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives

BP 608 P. PHARMACOLOGY-III (Practical)	4Hrs/Week
a. Definition of rhythm and cycles.b. Biological clock and their significance leading to chronotherapy.	
 c. General principles of treatment of poisoning d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning. 6. Chronopharmacology 	
 UNIT-V 5. Principles of toxicology a. Definition and basic knowledge of acute, subacute and chronic toxicity. b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity 	07 hours
 3. Chemotherapy I. Urinary tract infections and sexually transmitted diseases. m. Chemotherapy of malignancy. 4. Immunopharmacology a. Immunostimulants b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars 	
g. Antiamoebic agents	08 hours
 a. Antitubercular agents b. Antileprotic agents c. Antifungal agents d. Antiviral drugs e.Anthelmintics f. Antimalarial drugs 	
UNIT-III 3. Chemotherapy	10 hours
 UNIT-II 3. Chemotherapy a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole. c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides 	10 hours
 d. Nasal decongestants e. Respiratory stimulants 2. Pharmacology of drugs acting on the Gastrointestinal Tract a. Antiulcer agents. b. Drugs for constipation and diarrhoea. c. Appetite stimulants and suppressants. d. Digestants and carminatives. e. Emetics and anti-emetics. 	

- 1. Dose calculation in pharmacological experiments
- 2. Antiallergic activity by mast cell stabilization assay

3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.

18

4. Study of effect of drugs on gastrointestinal motility

5. Effect of agonist and antagonists on guinea pig ileum

- 6. Estimation of serum biochemical parameters by using semi- autoanalyser
- 7. Effect of saline purgative on frog intestine
- 8. Insulin hypoglycemic effect in rabbit
- 9. Test for pyrogens (rabbit method)
- 10. Determination of acute oral toxicity (LD50) of a drug from a given data
- 11. Determination of acute skin irritation / corrosion of a test substance
- 12. Determination of acute eye irritation / corrosion of a test substance
- 13. Calculation of pharmacokinetic parameters from a given data
- 14. Biostatistics methods in experimental pharmacology (student's t test, ANOVA)

15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

*Experiments are demonstrated by simulated experiments/videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier

2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill

3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics

4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins

5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,

9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

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

1. understand raw material as source of herbal drugs from cultivation to herbal drug product

- 2. know the WHO and ICH guidelines for evaluation of herbal drugs
- 3. know the herbal cosmetics, natural sweeteners, nutraceuticals
- 4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming.

Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

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

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

11 Hours

UNIT-II

Nutraceuticals

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

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

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

UNIT-III

Herbal Cosmetics

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

Herbal excipients:

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

Herbal formulations :

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

UNIT-IV

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs. **Patenting and Regulatory requirements of natural products:**

a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem. **Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs -Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

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

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipment's, standard operating procedures, health and hygiene, documentation and records.

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.

2. Determination of the alcohol content of Asava and Arista

3. Evaluation of excipients of natural origin

4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.

5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.

6. Monograph analysis of herbal drugs from recent Pharmacopoeias

7 Hours

10 Hours

10 Hours

07 Hours

8. Determination of Phenol content

9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.

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

3. Pharmacognosy by Kokate, Purohit and Gokhale

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

5. Pharmacognosy & Phytochemistry by V.D.Rangari

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

7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business

Horizons Publishers, New Delhi, India, 2002.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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

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

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.

2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.

4. Understand various pharmacokinetic parameters, their significance & applications.

Course Content:

UNIT-I

Introduction

Biopharmaceutics to Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs UNIT- II 10 Hours

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

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

UNIT-III

10 Hours

10 Hours

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - KE ,t1/2,Vd,AUC,Ka, Clt and CLRdefinitions methods of eliminations, understanding of their significance and Application **UNIT-IV** 08 Hours

Multicompartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settings. 07 Hours

UNIT-V

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

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.

2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari

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

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

5. Pharmacokinetics: ByMilo Glbaldi Donald, R. Mercel Dekker Inc.

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

7. Biopharmaceutics; By Swarbrick

8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and

9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.

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

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

12. Remington's Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvnia

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

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

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

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

Unit I

10 Hours

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

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

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

d) Brief introduction to Protein Engineering.

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

Lipase, Protease, Penicillinase.

f) Basic principles of genetic engineering.

Unit II

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

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

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

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

d) Brief introduction to PCR

10 Hours

Types of immunity- humoral immunity, cellular immunity

a) Structure of Immunoglobulins

b) Structure and Function of MHC

c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.

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

e) Storage conditions and stability of official vaccines

f) Hybridoma technology- Production, Purification and Applications

g) Blood products and Plasma Substitutes.

Unit IV

08 Hours

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

b) Genetic organization of Eukaryotes and Prokaryotes

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

d) Introduction to Microbial biotransformation and applications.

e) Mutation: Types of mutation/mutants.

Unit V

07 Hours

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

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

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

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

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.

2. RA Goldshy et. al., : Kuby Immunology.

3. J.W. Goding: Monoclonal Antibodies.

4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.

5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.

6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.

7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi.

BP606T PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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

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

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

Course content:

UNIT – I

10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration **NABL accreditation:** Principles and procedures

UNIT - II

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

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

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

UNIT – III Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

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

UNIT - IV

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

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

UNIT - V

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

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.

2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.

3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications.

4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh

5. How to Practice GMP's – P P Sharma.

6. ISO 9000 and Total QualityManagement – Sadhank G Ghosh

7. The International Pharmacopoeia - Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms

8. Good laboratory Practices – Marcel Deckker Series

9. ICH guidelines, ISO 9000 and 14000 guidelines

07 Hours

10 Hours

10 Hours

08 Hours

DETAILS OF SUBJECT TEACHERS

S. No	Name of the Subject	Name of the Teacher	Designation and Department	Mobile No.	e-mail
1.	Medicinal Chemistry-II	Dr. S. Gomathi	Asoct. Professor, Dept. of Pharm. Chemistry	9790095279	gomathiswaminathan@jssuni.edu.in
2.	Industrial Pharmacy-1	Dr.V.Senthil	Professor, Dept. of Pharmaceutics	9842650602	senthil.v@jssuni.edu.in
3.	Pharmacology-II	Mr.B.Shivarama krishnan	Asst. Professor, Dept. of Pharmacology	9620001429	shivaram.krishna@jssuni.edu.in
4.	Pharmacognosy-II	Dr Kalakotla Shanker	Asst. Professor, Dept. of Pharmacognosy	8374602737	drshankar@jssuni.edu.in
5.	Pharmaceutical Jurisprudence	Ms.S.Priyadarshini	Lecturer, Dept. of Pharmacognosy	9443801876	priya@jssuni.edu.in
6.	Pharmaceutical Biotechology	Dr. P. Vasanth raj	Asst. Professor, Dept. of Pharmacy Practice	9500793944	vasanth@jssuni.edu.in
7.	Medicinal Chemistry-III	Dr. S. Jubie	Asoct. Professor, Dept. of Pharm. Chemistry	9894618588	jubie@jssuni.edu.in
8.	Biopharmaceutics and Pharmacokinetics	Mr. R.Arun	Lecturer, Dept. of Pharmaceutics	7402222019	arun.r@jssuni.edu.in

Name of the Subject	Medicinal Chemistry-II (Theory)
· · · · · · , · · ·	
Name of the Faculty	Dr. Comathy Subramanian M. Pharm Ph.D.
Name of the faculty	Dr. Gomatry Subramanian, Th. Fharm., Th.D.,
Designation Department	Assistant Professor, Donartmont of Pharmacoutical Chemistry
Designation, Department	Assistant Professor, Department of Pharmaceutical Chemistry
Mobile Number	9486433876
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Scope, Course Objectives and Course Outcomes

Scope: This course is designed to impart knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on chemistry, mechanism, structure activity relationships and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: The primary objectives of this course are to

- 1. To study the fundamentals of Medicinal Chemistry
- 2. To understand the chemistry of drugs with respect to their biological activity
- 3. To help the students to understand the mechanism, drug metabolic pathways and therapeutic value of drugs.
- 4. To know the general structural features of drugs and structural activity relationship of important class of drugs
- 5. To write the chemical synthesis of important drugs

Course Outcomes (COs): At completion of Medicinal Chemistry-II, students will be able to:

- CO 1 : Recognize the structure of drugs
- CO 2 : To predict the therapeutic action of drugs
- CO 3 : Understand chemical synthetic reactions for selected drugs
- CO 4 : Knowledge on the structural activity relationship and structural influences on pharmacological actions
- CO 5 : Describe the mechanism, use and mode of application of the important drugs

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No. of Hours of other Activities	Total No. of Lecture Hours
Ι	24	3	27
II	21	3	24
Total No. of Hours	45	6	51

I SESSIONAL: 24 Lectures + 3 Activities

Lecture	Lecture Details	Hours
No.		
Unit-1: A	NTI-HISTAMINIC AGENTS & ANTI-NEOPLASTIC AGENTS	(10)
1.	Anti-Histaminic Agents: Histamine, receptors and their distribution	
2.	H1-antagonists: Diphenhydramine HCl*, Dimenhydrinate, doxylamine succinate,	
	clemastine fumarate, diphenylphyraline HCl, ,	05

З.	Tripelenamine HCl, chlorcyclizine HCl, meclizine HCl, buclizine HCl, Chlorpheniramine maleate	
Tutorial-1		
3.	triprolidine HCI*, phenidamine tartarate, Promethazine HCI, trimeprazine tartarate, cyproheptadine HCI	
4.	Azatidine maleate, astemizole, loratadine, cetirizine, cromolyn sodium	
5.	H2-antagonists: Cimetidine*, famotidine, ranitidine	
6.	Gastric proton pump inhibitors: omeprazole, lansoprazole	
7.	Anti-Neoplastic agents: Alkylating agents: Meclorethamine*, cyclophosphamide, melphalan, chlorambucil, busulfan, thiotepa.	05
8.	Antimetabolites : mercaptopurine*, thioguanine, fluorouracil, floxuridine, cytarabine, methotrexate*, azathioprine.	
9.	Antibiotics: Dactinomycin, Daunorubicin HCI, Doxorubicin HCI, Bleomycin	
10.	Plant products: Etoposide, Vinblastin sulphate, vincristine sulphate Miscellaneous: Cisplatin, Mitotane.	
Unit-II:	ANTI-ANGINAL AGENTS, DIURETICS & ANTI- HYPERTENSIVES	(10)
1.	Anti-anginal agents:	03
	Vasodilators: Amyl nitrite, Nitroglycerine*, Pentaerythritol tetranitrate, Isosorbide	
	dinitrite*, dipyridamole.	
2.	Calcium channel blockers: Verapamil, bepridil HCl, Diltiazem HCl, Nifedipine.	
3.	Amlodipine, Felodipine, nicardipine, nimodipine	
4.	Diuretics: Carbonic anhydrase inhibitors : Acetazolamide*, methazolamide, dichlorphenamide.	04
5.	Thiazides: chlorthiazide*, hydrochlorthiazide, hydroflumethiazide, cyclothiazide.	
6.	Loop diuretics: Furosemide*, bumetanide, Ethacrynic acid	
7.	Potassium sparing diuretics: Spiranolactone, triamterene, amiloride.	
8.	Anti-hypertensive agents:	03
	Timolol, captopril, Lisinopril, enalapril, benzapril HCl, Quinapril HCl	
9.	Methyldopate HCI*, clonidine HCI, Guanethidine monosulphate Guanbenz acetate	
10.	Sodium nitroprusside, diazoxide, Minoxidil, reserpine, hydralazine HCl.	
Unit-III :	ANTI-ARRHYTHMIC DRUGS, ANTI-HYPERLIPIDEMICS &	(10)
	CHF DRUGS	
1.	Anti-arrhythmic drugs:	~ ~
	Quinidine sulphate, procainamide HCI,	04
2.	disopyramide phosphate* Phenytoin sodium	
3.	lidocaine HCl, tocainide HCl	
4.	Mexiletine HCI, Lorcainide HCI, Amiodarone, Sotalol.	
Activity1	Descriptive Test	
Activity2	MCQ Test (Unit-I)	
Activity3	MCQ Test (Unit-II)	

I SESSIONAL: 21 Lectures + 3 Activities

Lecture	Lecture Details	Hours
No.		
5.	ANTI-HYPERLIPIDEMIC AGENTS: Clofibrate, lovastatin, cholesteramine and cholestipol.	06
6.	Coagulant: Menodione, Acetomenadione	
7.	Anti-coagulant: Warfarin*, Anisindione	
8.	DRUGS USED IN CONGESTIVE HEART FAILURE: Digoxin	
9.	Digitoxin, Nesiritide,	
10.	bosentan, tezosentan	
Unit-IV	DRUGS ACTING ON ENDOCRINE SYSTEM	(08)

1.	Sex hormones: testosterone, nandralone, progestrones	02
2.	Oestriol, oestradiol, oestrione, diethyl stilbestrol	
3.	Drugs for erectile dysfunction: Sildenafil, levonorgestrol	04
4.	Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol	
5.	Corticosteroids: Cortisone, hydrocortisone, prednisolone	
6.	Betamethasone, dexamethasone	
7.	Thyroid and anti-thyroid drugs: L-thyroxine, L-thyronine	02
8.	Propylthiouracil, methimazole	
Unit-V:	ANTI-DIABETIC AGENTS & LOCAL ANESTHETICS	(07)
1.	Anti-diabetic agents: Insulin and its preparations	
	Sulphonyl urea's: Tolbutamide*, Chlorpropamide, glipizide, glimepiride	03
2.	Iniazolialineationes: Proglitazone, Kosiglitazone Meglitinides: Penaglinide, Nateglinide	
3	Glucosidase inhibitors. Acrabose Voglibose	
4	Local anesthetics: SAR of local anesthetics	
5	Benzoic acid derivatives: Cocaine hexylcaine menrylcaine cyclomethycaine	04
5.	piperocaine	•••
6.	Amino benzoic acid derivatives: Benzocaine*, butamben, procaine*, butacaine,	
	propoxycaine, tertracaine, benoxinate	
7.	Lidocaine/anilide derivatives: lignocaine, mepivacaine, prilocaine, etidocaine	
Activity	Miscellaneous: Phenacaine, diperidon, dibucaine*	
Activity-	inco test	
	MCO Tort	
Activity-	inco test	
2 Activity	Descriptive Test	
Activity-		
3		

Text Books

- 1. Foye's Principles of Medicinal Chemistry, 5th Edition.
- 2. Burger's Medicinal Chemistry, Vol. I to IV.
- 3. Textbook of Medicinal Chemistry, Volume I by Ilango and Valentina

Reference Books

- 1. Wilson and Gisvold's Organic medicinal and Pharmaceutical Chemistry, 11th Edition.
 - 2. Introduction to principles of drug design- Smith and Williams.
 - 3. Remington's Pharmaceutical Sciences, 20th Edition.
 - 4. Martindale's extra pharmacopoeia.
 - 5. Organic Chemistry by I.L. Finar, Vol. II.
 - 6. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
 - 7. Indian Pharmacopoeia 1996 and 2007 Editions.

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Name of the Subject	Pharmacology II (Theory)
Name of the Faculty	Mr. B. Shivaramakrishnan M.Pharm
Designation, Department	Assistant Professor, Department of Pharmacology
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Scope, Course Objectives and Course Outcomes

Scope: Pharmacology II provides an opportunity for the students to learn about different classes of drugs with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, routes of administration, precautions, contraindications and interaction with other drugs.

Objectives: The primary objectives of this course are to

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

Course Outcomes (COs): At completion of this course it is expected that the students will be able to

CO 1 : Identify and explain the pharmacodynamics and pharmacokinetic properties of drugs of various categories

- CO 2 : Recognize the adverse effects of drugs
- CO 3 : Avoid adverse drug reactions
- CO 4 : Recognize indications of different drugs and avoid contraindications
- CO 5 : Provide vital information to patients about drugs during patient counselling
- CO 6 : Design & execute animal experiments to identify the pharmacological properties of known drugs and unknown samples.

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	26	5	31
II	20	5	25
Total No. of Hours	46	10	56

LECTURE PLAN – Abstract

Lecture No.	Lecture Details	Hours
Unit-1: Pl	harmacology of drugs acting on cardiovascular system	
1.	Introduction to haemodynamics & electrophysiology of heart	
2.	Drugs used in congestive heart failure	
3.	Anti-hypertensive drugs	
4.	Anti-anginal drugs	10
5.	Anti-arrhythmic drugs	
6.	Anti-hyperlipidemic drugs	
Unit-2: Pl	harmacology of drugs acting on cardiovascular system	
1.	Drugs used in the therapy of shock	
2.	Haematinics	
3.	Coagulants	
4.	Anti-coagulants	06
5.	Fibrinolytics	
6.	Anti-platelet drugs	
7.	Plasma volume expanders	
Unit-3: Pl	harmacology of drugs acting on Urinary system	
1.	Diuretics	
2.	Anti-diuretics	04
Unit-4: A	utocoids & Related drugs	
1.	Introduction to autacoids and classification	
2.	Histamine	
3.	5-HT and their antagonist	
4.	Prostaglandins	
5.	Thromboxanes and Leukotrienes	06
6.	Angiotensin	
Activity-1	MCQ Test	
Activity-2	MCQ Test	
Activity-3	MCQ Test	
Activity-4	MCQ Test	
Activity-5	Revision	

Lecture No.	Lecture Details	Hours
Unit-4: Autocoids & Related drugs		
1.	Bradykinin and Substance P	_
2.	Non-steroidal Anti-inflammatory agents	_
3.	Anti-gout drugs	04
4.	Anti-rheumatic drugs	
Unit- 5: F	harmacology of drugs acting on endocrine system	
1.	Basic concepts in endocrine pharmacology	_
2.	Anterior pituitary hormones- analogues and their inhibitors	
3.	Thyroid hormones- analogues and their inhibitors	
4.	Hormones regulating plasma calcium level- Parathormone, Calcitonin & Vitamin-D	
5.	Insulin and Glucagon	08
6.	ACTH and Corticosteroids	
7.	Oral Hypoglycemic agents	
Unit- 5: P	harmacology of drugs acting on endocrine system	
8.	Androgens and Anabolic steroids	
9.	Estrogen & progesterone	
10.	Oral contraceptives	04
11.	Drugs acting on uterus	
Unit-6: B	ioassay	
1.	Principles and Applications of bioassay	
2.	Types of bioassay	
3.	Bioassay of Insulin, Oxytocin, Vasopressin, ACTH	04
4.	Bioassay of d-tubocurarine, Digitalis, Histamine and 5-HT	
Activity-1	MCQ Test	•
Activity-2	MCQ Test	
Activity-3	Class Test	
Activity-4	Revision	
Activity-5	Exam Preparation & Time management skills	

II SESSIONAL: 20 Lectures + 5 Activities

Text Books

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
- 2. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology.

Reference Books

- 1. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill.
- 2. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 3. K.D.Tripathi. Essentials of Medical Pharmacology. JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 4. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

Name of the Subject	Industrial Pharmacy-1 (BP502T)
Course/ Semester	B.Pharm, Vth Semester
Name of the Faculty	Dr V.Senthil, M.Pharm, Ph.D, PGDCA
Designation, Department	Professor, Pharmaceutics
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Scope, Course Objectives and Course Outcomes

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

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

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.

2. Know various considerations in development of pharmaceutical dosage forms

3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course Outcomes (COs): At completion of this course it is expected that the students will be able to CO 1: Define the important of preformulation

CO 2: The students to understand the formulation and manufacturing aspects of various dosage forms

CO 3: The students will learn how to use the physicochemical properties of the drug/ excipients

CO 4: To development of pharmaceutical dosage forms.

CO5: Describe the common measure use in quality.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	23	3	23
n	22	3	22
Total No. of Hours	45	6	51

I SESSIONAL

LECTURE PLAN 23 Lectures+ 3 Activities

Lecture No.	Lecture Details		
UNIT-1	Preformulation Studies	(08)	Hours
1.	Introduction		
2.	Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.		
3.	a. Physical properties: particle size, shape		08
4.	flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism		
5.	b. Chemical Properties: Hydrolysis, oxidation, reduction, Racemisation, polymerization,		

6.	BCS classification of drugs	
7.	Application of preformulation considerations in the development of <i>solid, liquid dosage</i> forms and its impact on stability of dosage forms.	
8.	Application of preformulation considerations in the development of <i>oral and parenteral dosage</i> forms and its impact on stability of dosage forms.	
UNIT-2	Tablets(10)	
9.	Tablets: a. Introduction	
10.	Ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets	
11.	Granulation methods, compression and processing problems	
12.	Equipment's and tablet tooling.	10
13.	b. Tablet coating: Types of coating, coating materials, formulation of coating materials,	10
14.	Method of coating, equipment employed and Defects in coating.	
15.	c. Quality control tests: In process and finished product tests	
16.	Liquid orals: Formulation and manufacturing consideration of solutions, suspensions and emulsions; Filling and packaging	
17.	evaluation of liquid orals official in pharmacopoeia	
Activity1	MCQ Test	
Activity2	MCQ Test	
UNIT -3	Capsules (08)	
18.	Capsules: a. Hard gelatin capsules: Introduction, Extraction of gelatin and production of hard gelatin capsule shells. Filling,	
19.	Finishing and special techniques of formulation of hard gelatin capsules.	
20.	In process and final product quality control tests for capsules.	06
21.	b. Soft gelatin capsules: Nature of shell and capsule content, importance of base adsorption and minimum/gram factors, production,	00
22.	In process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules	
Activity 3	MCQ Test	

II SESSIONAL: 22 Lectures + 3 Activities

23.	Pellets: Introduction, formulation requirements, pelletization process,	02
24.	equipment's for manufacture of pellets	02
UNIT-4	Parenteral Products (10)	
25.	Parenteral Products: a. Definition, types, advantages and limitations.	10
26.	Preformulation factors and essential requirements, vehicles, importance of isotonicity	
27.	b. Production procedure, production facilities and controls]

28.	c. Formulation of injections, sterile powders	
29.	Formulation of injections, emulsions, suspensions	
30.	large volume parenteral and lyophilized products	
31.	Sterilization.	
32.	d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.	
33.	Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions;	
34.	Evaluation of ophthalmic preparations	
UNIT-5	Cosmetics (10)	
35.	Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream	
36.	vanishing cream, tooth pastes,	10
37.	Hair dyes and sunscreens.	
38.	Packaging Materials Science: Materials used for packaging of pharmaceutical products	
39.	factors influencing choice of containers,	
40.	legal and official requirements for containers	
41.	Stability aspects of packaging materials, Quality control tests	
42.	Pharmaceutical Aerosols: Definition, propellants, containers	
43.	Valves, Types of aerosol systems;	
44.	formulation and manufacture of aerosols;	
Activity1	MCQ Test	
Activity1	MCQ Test	
Activity1	MCQ Test	

Recommended Books: (Latest Editions)

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

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Name of the Subject	Pharmacognosy and Phytochemistry - II
Name of the Faculty	Dr Kalakotla Shankar
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Scope, Course Objectives and Course Outcomes

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

Objectives: The primary objectives of this subject are,

- 6. To be familiar with the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
- 7. To understand the preparation and development of herbal formulation.
- 8. To understand the herbal drug interactions
- 9. To carryout isolation and identification of phytoconstituents

Course Outcomes (COs): At completion of this subject, it is expected that the students will be able to

- CO 1: Define the basic metabolic pathways in higher plants and their role in the production of secondary metabolites
- CO 2: Define the general introduction, composition, chemistry & chemical classes, bio sources, therapeutic uses and commercial applications of secondary metabolites.
- CO 3: Isolate, Identify and Analysis of various significant Phytoconstituents present in herbals

CO 4: Produce, estimate and utilize the phytoconstituents at Industrial level

CO 5: Extract, isolate, purify, and identify the phytoconstituents by applying the latest techniques like Spectroscopy, chromatography and electrophoresis.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	27	03	30
II	18	03	21
Total No. of Hours	45	06	51

Lecture No.	Lecture Details	Hours
METAB	OLIC PATHWAYS	(07)
Unit-1:	Metabolic pathways in higher plants and their determination	
1.	Introduction to Pharmacognosy II & Metabolic pathways	07
2.	Shikimic acid pathway and formation of different secondary metabolites	
3.	Acetate pathways- Acetate melonate pathway and formation of different secondary	
4	Acetate-Mevolanate pathway and its secondary metabolities	
5.	Amino acid pathway and formation of different secondary metabolites	
6.	Study of utilization of radioactive isotopes in the investigation of Biogenetic studies	
METABO	LITES	(14)
Unit-2:	General introduction, composition, chemistry & chemical classes,	
biosouro	res therapeutic uses and commercial application of metabolities	
2	Constal introduction about alakaloids. Vince and Pauwolfia	
5.	Belladonna, Onium	14
4. 5	Phenyl Propanoids and Flavonoids- Lingans, Tea and Ruta	
5.	Steroids Cardiac alvoorides & Triterpenoids - Liquorice	
0. 7	Dioscorea Digitalis	
8	Volatile oils: Mentha clove	
9.	Cinnamon, Fennel, Coriander	
10.	Tannins: Catechu, Pterocarpus	
11.	Resins: Benzoin, Guggul, Ginger	
12.	Asafoetida, Myrrh, Colophony	
13.	Glycosides: Senna, Aloes	
14.	Bitter almond	
15.	Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia	
16.	Taxus, Carotenoids	
PHYTOCO	ONSTITUENTS	(06)
Unit-3:	solation, identification and analysis of phytoconstituents	
1.	Terpenoids: Menthol, Citrol, Artemisin	
2.	Glycosides: Glycyrhetinic acid & Rutin	
3.	Alkaloids: Atropine, Quinine	06
4.	Reserpine, Caffeine, Podophyllotoxin, Curcumin	00
Activity1	MCQ Test (Metabolic pathways)	
Activity2	MCQ Test (Metabolites)	
Activity3	MCQ Test (Phytoconstituents)	

I SESSIONAL : 24 Lectures + 3 Activities

II SESSIONAL : 17 Lectures + 2 Activities

Lecture	Lecture Details	Hours
No.		
INDUSTRI	AL ASPECTS OF PHYTOCONSTITUENTS	(10)
Unit-4: Industrial production, estimation and utilization of phytoconstituents		
5.	Forskolin	

6.	Sennoside	
7.	Artemisinin	
8.	Diosgenin	
9.	Digoxin	
10.	Atropine	10
11.	Podophyhllotoxin	
12.	Caffeine	
13.	Taxol	
14.	Vincristine and vinblastin	
PHYTOCH	EMISTRY	(08)
Unit-5: Bas	sics of Phytochemistry	
9.	Modern methods of extraction: General Extraction techniques	
10.	Soxhlet extraction, SCFE	
11.	Counter current extraction, Micro oven assisted extraction	08
12.	Extraction of volatile oils	
13.	Application of spectroscopy in the isolation, purification identification of crude drugs - UV, IR	
14.	Application of spectroscopy in the isolation, purification identification of crude drugs - NMR, MS	
7.	Chromatography in the isolation, purification and identification of drugs	
Activity-1	MCQ Test (Industrial aspects of Phytoconstituents)	
Activity-2	MCQ Test (Phytochemistry)	
Activity-3	MCQ Test	

Text Books

- 1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 4. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007

Reference Books

- 1. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
- 2. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
- 3. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
- 4. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
- 5. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
- 6. The formulation and preparation of cosmetic, fragrances and flavours.
- 7. Remington's Pharmaceutical sciences.
- 8. Text Book of Biotechnology by Vyas and Dixit.
- 9. Text Book of Biotechnology by R.C. Dubey.

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Name of the Subject	Pharmaceutical Jurisprudence
Name of the Faculty	Ms S.Priyadharshini M.Pharm
Designation, Department	Lecturer, Department of Pharmacognosy
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Scope, Course Objectives and Course Outcomes

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

Objectives: The primary objectives of this course are to gain knowledge about:

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

Course Outcomes (COs): At completion of this course it is expected that the students will be able to CO 1: Define the rules and regulations laid under Drugs and Cosmetics Act, 1940

CO 2: Define the Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

CO 3: Detail different Schedules of Drugs and Cosmetics and how various acts and rules are administered

CO 4: Understand the pharmacy education regulations, registration process and various rules and regulations implemented on narcotic drugs, medicinal and toilet preparations and Magic remedies.

CO 5: To understand the process of Drug Price Control, Intellectual Property Rights and Right to information. CO 6: Follow various ethics related to Pharmacy Profession.

LECTURE PLAN

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	28	11	39
II	38	22	60
Total No. of Hours	66	33	99

I SESSIONAL : 25 Lectures + 3 Activity + 8 Tutorials

Lecture	Lecture Details	Hours
No.		
PHARMACEUTICAL JURISPRUDENCE		
Unit-1:	Drugs and Cosmetics Act, 1940 and its rules 1945	
1.	Objectives, Definitions, Legal definitions of schedules to the act and rules	

2.	Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties	
3.	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,v	10
4.	Conditions for grant of license and conditions of license for manufacture of drugs,	
	Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan	
	license and repacking license.	
Unit-2:	Drugs and Cosmetics Act, 1940 and its rules 1945.	
8.	Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)	09
9.	Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties	
10.	Labeling & Packing of drugs- General labeling requirements and specimen labels for	
	drugs and cosmetics, List of permitted colors. Offences and penalties.	
11.	Administration of the act and rules – Drugs Technical Advisory Board, Central drugs	
	Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing	
	authorities, controlling authorities, Drugs Inspectors	
Unit-3	Pharmacy Act –1948	
17.	Objectives, Definitions, Pharmacy Council of India; its constitution and functions,	
	Education Regulations, State and Joint state pharmacy councils; its constitution and	
	functions, Registration of Pharmacists, Offences and Penalties	
Madiation	Land Tailet Drenovetion A st. 1977	
Medicina	al and Tollet Preparation Act –1955	
1.	Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of	
	alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary	
	Preparations. Offences and Penalties.	
Activity		03

II SESSIONAL - 24 Lectures + 14 Activity + 9 Tutorials

Unit 3: Na	rcotic Drugs and Psychotropic substances Act-1985 and Rules:	
1.	Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	04
Unit 4:	Study of Salient Features of Drugs and magic remedies Act and its rules	
1.	Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted	
	advertisements, Offences and Penalties	
Prevention of Cruelty to animals Act-1960:		
1.	Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking	
	of Animals, Performance of Experiments, Transfer and acquisition of animals for	10
	experiment, Records, Power to suspend or revoke registration, Offences and Penalties	
National Pharmaceutical Pricing Authority		
1.	Drugs Price Control Order (DPCO)2013. Objectives, Definitions, Sale prices of bulk	
	drugs, Retail price of formulations, Retail price and ceiling price of scheduled	
	formulations, National List of Essential Medicines (NLEM)	
Unit 5:	Pharmaceutical Legislations	
1.	A brief review, Introduction, Study of drugs enquiry committee, Health survey and	
	development committee, Hathi committee and Mudaliar committee	
Code of Ph	armaceutical ethics	

D efinition, Pharmacist in relation to his job, trade, medical profession and his profession,	
Pharmacist's oath 08	
Medical Termination of pregnancy act	
Right to information Act	
Introduction to Intellectual Property Rights (IPR)	02
ACTIVITY	
Seminars	
Mind mapping	
Flow chart reading	
Assignments	
Tests	
Mind games on schedules and years	

Text Books

1. Forensic Pharmacy by B. Suresh

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

Reference Books

- 1. Forensic Pharmacy by B. Suresh
- 2. Text book of Forensic Pharmacy by B.M. Mithal
- 3. Hand book of drug law-by M.L. Mehra
- 4. A text book of Forensic Pharmacy by N.K. Jain

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VI - SEMESTER

Name of the Subject	Medicinal Chemistry III (Theory)
Name of the Faculty	Dr.Jubie S M.Pharm., Ph.D
Designation, Department	Associate Professor, Department of Pharmaceutical Chemistry
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Scope, Course Objectives and Course Outcomes

Scope: This course is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs.the subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR).Prodrug concept, combinatorial chemistry and Computer aided drug design

(CADD). The subject also emphasized on the chemistry, mechanism of action, metabolism, adverse effects, structure activity relationships (SAR), therapeutic uses and synthesis of important drugs..

- **Objectives:** The primary objectives of this course are to
 - 1. Study the concepts of drug design and QSAR.
 - 2. Learn the mechanism of action and pharmacokinetic properties of drugs.
 - 3. Outline the synthesis of drugs.
 - 4. Learn the SAR of drugs
 - 5. Study the applications of prodrugs

Course Outcomes (COs): At completion of this course it is expected that the students will be able to

- 1. Understand the importance of drug design and different techniques of drug design.
- 2. Understand the chemistry of drugs with respect to their biological activity.
- 3. Know the metabolism, adverse effects and therapeutic value of drugs.
- 4. Know the concept of prodrugs and their applications.
- 5. Acquire the knowledge about the SAR of drugs.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	23	-	23
II	22	-	22
Total No. of Hours	45	-	45

I SESSIONAL : 23 Lectures

Lecture	Lecture Details	Hours
No.		
Unit-1:	Antibiotics	
1.	Beta lactam antibiotics-Penicillins	
2.	Beta lactam antibiotics-Cephalosporins	
3.	Beta lactam antibiotics-Cephalosporins	
4.	Beta lactamase inhibitors	
5.	Monobactams	10
6.	Amino glycosides	
7.	Streptomycin, Neomycin, Kanamycin	
8.	Tetracyclines	
9.	Tetracycline,Oxytetracycline,	
10.	Chlortetracycline, Minocycline, Doxycycline	
Unit-2: A	Antibiotics, Prodrugs & Antimalariais	
18.	Macrolides- Erythromycin, Clarithromycin & Azithromycin	
19.	Miscellaneous- Chloramphenicol*, Clindamycin.	
20.	Prodrugs-Basic concepts	
21.	Applications of Prodrugs	
22.	Applications of Prodrugs (cont)	
23.	Antimalarials- Etiology of Malaria & SAR	10
24.	Quinolines- Quinine sulphate, Chloroquine*, Amodiaquine,	
25.	Quinolines- Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine	
26.	Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.	
10.	Miscellaneous- Pyrimethamine, Artesunete, Artemether, Atovoquone	
Unit-3:	Anti-tubercular Agents, Urinary tract anti-infective agents, Antiviral	

agents		03
1.	Anti tubercular agents	
2.	Synthetic anti tubercular agents-Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*	
3.	Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.	

II SESSIONAL : 22 Lectures

Lecture	Lecture Details	Hours
No.		
Unit-3: Anti-tubercular Agents, Urinary tract anti-infective agents, Antiviral		
agents (cont)		
1.	Urinary Tract Anti-infective agents-Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin,	07
2.	Quinolones: Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin	
3.	Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.	
4.	Antiviral agents: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride	
5.	Anti viral agents- Acyclovir*, Gancyclovir, Zidovudine, Didanosine,	
6.	Anti viral agents- Zalcitabine, Lamivudine, Loviride, Delavirding,	
7.	Anti viral agents Ribavirin, Saquinavir, Indinavir, Ritonavir.	
Unit-4: A	Antifungal agents, Anti-protozoal Agents, Anthelmintics	
8.	Antifungal antibiotics: Amphotericin-B. Nystatin. Natamycin. Griseofulvin.	
9.	Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole	
	Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole,	
	Naftifine hydrochloride, Tolnaftate*.	
10.	Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.	08
11.	Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin	
12.	Sulphonamides and Sulfones Historical development, chemistry, classification and SAR of Sulfonamides:	
13.	Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.	
14.	Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.	
15.	Sulfones: Dapsone*.	
Unit-5: I	ntroduction to Drug Design	
12.	Introduction to drug design- various approaches in drug design	
13.	Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient	
14.	Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.	07
15.	Pharmacophore modeling.	
16.	Docking techniques	
17.	Combinatorial Chemistry: Concept and applications chemistry	
18.	Solid phase and solution phase synthesis.	

Text books

- Wilson and Gisvold's Organic Medicinal and Pharmaceutical chemistry.
 Foye's Principles of Medicinal Chemistry.

Reference books

- 1. Burger's Medicinal Chemistry, Vol I to IV istry
- 2. Introduction to principles of drug design-Smith and Williams
- 3. Remington's Pharmaceutical Sciences. 4. Martindale's extra pharmacopoeia

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Name of the Subject	Pharmacology III (Theory)
Name of the Faculty	Mr. B. Shivaramakrishnan M.Pharm
Designation, Department	Assistant Professor, Department of Pharmacology
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Scope, Course Objectives and Course Outcomes

Scope: Pharmacology III provides an opportunity for the students to learn about different classes of drugs with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, routes of administration, precautions, contraindications and interaction with other drugs.

Objectives: The primary objectives of this course are to

- 1. Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- 2. Comprehend the principles of toxicology and treatment of various poisonings and
- 3. Appreciate correlation of pharmacology with related medical sciences.

Course Outcomes (COs): At completion of this course it is expected that the students will be able to

- CO 1 : Identify and explain the pharmacodynamics and pharmacokinetic properties of drugs of various categories
- CO 2 : Recognize the adverse effects of drugs
- CO 3 : Avoid adverse drug reactions
- CO 4 : Recognize indications of different drugs and avoid contraindications
- CO 5 : Provide vital information to patients about drugs during patient counselling
- CO 6 : Design & execute animal experiments to identify the pharmacological properties of known drugs and unknown samples.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	28	1	29
II	25	5	30
Total No. of Hours	53	06	59

I SESSIONAL: 28 Lectures + 1 Activity

Lecture	Lecture Details	Hours
No.		
Unit-1: Ph	armacology of drugs acting on Respiratory system	
7.	Anti-asthmatic drugs	
8.	Expectorants and Anti-tussives	
9.	Nasal decongestants	
10.	Respiratory stimulants	
Unit-2: Ph	armacology of drugs acting on Digestive system	
12.	Anti-ulcer agents	05
13.	Drugs for Constipation and Diarrhea	
14.	Appetite stimulants and Suppressants	-
15.	Digestants and Carminatives	-
16.	Emetics and Anti-emetics	-
Unit-3: Cł	emotherapy	
27.	General Principles of Chemotherapy	
28.	Sulfonamides and Cotrimoxazole	-
29.	Antibiotics - Penicillins & Cephalosporins	-
30.	Chloramphenicol & Macrolide antibiotics	
31.	Quinolones & Fluoroquinolones	18
32.	Tetracylines	
33.	Aminoglycosides	
34.	Antitubercular drugs	
35.	Antileprotic drugs	
36.	Anti-amoebic drugs	
37.	Antiviral drugs	
38.	Antimalarial drugs	
39.	Anti-amoebic drugs	
40.	Antifungal drugs	1
Activity1	Class Test	

II SESSIONAL: 25 Lectures + 5 Activities

Lecture No.	Lecture Details	
Unit-4: Chen	notherapy & Immunopharmacology	
15.	Anthelmentics	1
16.	Urinary tract infections and sexually transmitted diseases	1
17.	Chemotherapy of malignancy	10
18.	Immunostimulants	1
19.	Immunosupressants	1
20.	Protein Drugs, Monoclonal Antibodies	1
21.	Target drugs to antigen, Biosimilars	1
Unit-5: Princ	iples of Toxicology	

16.	Acute, subacute and chronic toxicity- Definitions & Basics	
17.	Genotoxicity, Carcinogenicity, Teratogenicity & Mutagenicity- Definitions & Basics	~~
18.	General principles of treatment of poisoning, Clinical symptoms and management of Barbiturate poisoning	07
19.	Clinical symptoms and management of Morphine, organophosphorus compound poisoning	
20.	Clinical symptoms and management of lead, mercury and arsenic poisoning	
Unit-6 : Chro	nopharmacology	
19.	Definition of rhythms and cycles	
20.	Biological clock and their significance leading to chronotherapy	03
Revision		05
Activity-1	MCQ Test	
Activity-2	MCQ Test	
Activity-3	Class Test	
Activity-4	Class Test	
Activity-5	Exam Preparation & Time management skills	

Text Books

- Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone 3. Elsevier
- 4. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology.

Reference Books

- Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill. 5.
- Goodman and Gilman's, The Pharmacological Basis of Therapeutics 6.
- K.D.Tripathi. Essentials of Medical Pharmacology. JAYPEE Brothers Medical Publishers (P) Ltd, New 7. Delhi.
- 8. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher ***

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Name of the Subject	Herbal Drug Technology	
Name of the Faculty	Ms S Priyanka M.Pharm, PhD	
Designation, Department	Assistant Professor, Department of	
	Pharmacognosy	
Mobile Number	9486604970	
e-Mail i.d.	rajendirankrish@jssuni.edu.in	

Scope, Course Objectives and Course Outcomes

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

Objectives: The primary objectives of this subject are,

1. To understand raw material as source of herbal drugs from cultivation to herbal drug product

2. To know the WHO and ICH guidelines for evaluation of herbal drugs

3. To know the herbal cosmetics, natural sweeteners, nutraceuticals

4. To appreciate patenting of herbal drugs, GMP.

Course Outcomes (COs): At completion of this subject, it is expected that the students will be able to

CO1: Define the principal involved in Indian Systems of Medicine, Preparation and standardization of Ayurvedic formulations

CO2: Define the Market, growth, scope of nutraceuticals and significance of herbal-drug and herb-food Interactions

CO 3: Define Herbal Cosmetics, Herbal excipients Herbal formulations

CO 4: Patenting and Regulatory requirements of natural products, Regulatory Issues WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

CO 5: Present scope and future prospects of Herbal industry, Good Manufacturing Practice of Indian systems of medicine

LECURE PLAN – Abstract

Sessional	No. of Hours of Didactic LectureNo of Hours of other Activities		Total No. of Lecture Hours
I	21	03	24
II	24	03	27
Total No. of Hours	45	05	51

I SESSIONAL : 21 Lectures + 3 Activities

Lecture	re Lecture Details	
No.		
INDIAN	I SYSTEMS OF MEDICINE	(11)
Unit-1: He	erbs as raw materials	
7.	Herbs as raw materials: Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation	11
8.	Source of Herbs	
9.	Selection, identification and authentication of herbal materials	
1(Processing of herbal raw material	
11	Biodynamic Agriculture: Good agricultural practices in cultivation of medicinal plants including Organic farming	
12	Pest and Pest management in medicinal plants	
13	Biopesticides/Bioinsecticides	
14	Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy	
15	Preparation of Ayurvedic formulations	
16	Standardization of Ayurvedic formulations	
17	Standardization of Ayurvedic formulations	
NUTRA	CEUTICALS	(07)
Unit-2: Ni	itraceuticals and Herbal-Drug and Herb-Food Interactions	
41.	General aspects, market, growth, scope of nutraceuticals	
42.	Health benefits and role of Nutraceuticals in Diabetes, CVS diseases, Cancer	
43.	Health benefits and role of Nutraceuticals in Irritable bowel syndrome and various Gastro intestinal diseases.	07
44.	Study of Alfaalfa, Chicory, Ginger, Fenugreek, Garlic as health food	

45.	Study of Honey, Amla, Ginseng, Ashwagandha, Spirulina as health food	
46.	General introduction to Herbal-Drug and Herb-Food Interactions	
47.	Study of Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra and their possible side effects and interactions	
HERBA	L COSMETICS	(10)
Unit-3: He	erbals used in cosmetics	
5.	Sources and description of fixed oils, waxes, gums used in cosmetics	
6.	Sources and description of colours, perfumes used in cosmetics	
7.	Sources and description of protective agents, bleaching agents, antioxidants used in cosmetics	03
Activity1	MCQ Test (Indian Systems of Medicine)	
Activity2	MCQ Test (Nutraceuticals)	
Activity3	MCQ Test (Herbal Cosmetics)	

II SESSIONAL : 24 Lectures + 3 Activities

Lecture No.	Lecture Details	
HERBAL	COSMETICS	
Unit-3: Herb	als used in cosmetics (Continued for II Sessional)	
22.	Significance of substances of natural origin as excipients	
23.	Colorants and sweeteners	
24.	Binders and diluents	
25.	Viscosity builders and disintegrants	
26.	Flavors & perfumes	
27.	Conventional herbal formulations: Syrups, mixtures and tablets	07
28.	Novel dosage forms: Phytosomes	
EVALUA	TION OF DRUGS	(10)
Unit-4: Regu	latory Issues	
15.	WHO guidelines for the assessment of herbal drugs	
16.	ICH guidelines for the assessment of herbal drugs	
17.	Stability testing of herbal drugs.	10
18.	Patenting of natural products	
19.	Regulatory requirements of natural products	
20.	Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy	
21.	Patenting aspects of Traditional Knowledge and Natural Products.	
22.	Case study of Curcuma	
23.	Case study of Neem	
24.	Cosmetics Act for ASU drugs.	
HERBAL	INDUSTRY	(07)
Unit-5: Regu	latory Issues	
1.	General Introduction to Herbal Industry	
2.	Present scope and future prospects of Herbal Industry	
3.	A brief account of plant based industries and institutions involved in work on	
	medicinal and aromatic plants in India	
4.	Schedule T – Good Manufacturing Practice of Indian systems of medicine	
5.	Components of GMP (Schedule – T) and its objectives	

6.	Infrastructural requirements, working space, storage area, machinery and equipments of Herbal Industry	
7.	Standard operating procedures, health and hygiene, documentation and records of of	
	Herbal Industry	
Activity-1	MCQ Test (Herbal Cosmetics)	
Activity-2	MCQ Test (Evaluation of Drugs)	
Activity-3	MCQ Test (Herbal Industry)	

Text Books

- 1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
- 2. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 3. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 4. Pharmacognosy & Phytochemistry by V.D.Rangari

Reference Books

- 1. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
- 2. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

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Name of the Subject	Biopharmaceutics and Pharmacokinetics (Theory)
Name of the Faculty	Mr. Arun R M.Pharm.,
Designation, Department	Lecturer, Department of Pharmacy Practice
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Scope, Course Objectives and Course Outcomes

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

Objectives: The primary objectives of this course are to

- 1. Discuss the fundamentals of biopharmaceutics and pharmacokinetics
- 2. Explain how various physicochemical characteristics of drugs, physiological characteristics and dosage form factors impact the biopharmaceutics and pharmacokinetic parameters
- 3. Help the students to understand the concepts of bioavailability and bioequivalence
- 4. Equip the students to calculate all possible pharmacokinetic parameters by using various pharmacokinetic models for any given data
- 5. Enable the students to apply the theoretical knowledge into clinical practice

6. Familiarize and train the students with software and electronic computational tools for pharmacokinetic calculations

Course Outcomes (COs): At completion of this course it is expected that the students will be able to

- CO 1 : Define the basic concepts in biopharmaceutics and pharmacokinetics
 - CO 2 : Critically interpret biopharmaceutic studies including drug product equivalency
 - CO 3 : Use raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolism and excretion
 - CO 4 : Design and evaluate dosage regimens of the drugs using pharmacokinetic andbiopharmaceutic parameters
 - CO 5 : Identify potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them
 - CO 6 : Use software for various pharmacokinetic data analysis

LECTURE PLAN – Abstract

	No. of Hours of Didactic Lecture			
Sessional	Biopharmaceutics	Pharmacokinetics	No of Hours of other Activities	Total No. of Lecture Hours
I	17	14	3	34
II	10	15	2	27
III	06	13	9	28
Total No. of Hours	33	42	14	89

I SESSIONAL : 31 Lectures + 3 Activities

Lecture	Lecture Details	Hours
No.		
BIOPH	ARMACEUTICS	(09)
Unit-1:	Introduction to Biopharmaceutics	
	Orientation to the subject	01
1.	Introduction to Biopharmaceutics	
Unit-2:	Absorption of Drug	
1.	Oral Drug Absorption: Introduction, Rate limiting step in bioavailability, Anatomical and physiological consideration of the GIT	
2.	Introduction to Biopharmaceutics	••
3.	Carrier mediated transport – active transport, Facilitated diffusion, Ion-pair formation, Pore transport, Endocytosis	08
4.	Physiological factors governing GI drug absorption	
5.	Physicochemical factors governing GI drug absorption (cont)	
6.	Formulation factors governing GI drug absorption	
7.	Absorption of drug from Non per OS extra-vascular routes	
8.	Absorption of drug from Non <i>per</i> OS extra-vascular routes (cont)	
PHARM	IACOKINETICS	(14)
Unit-6: Ir	ntroduction to Pharmacokinetics	
1.	Introduction, Mathematical model	
2.	Drug levels in blood	05
3.	Pharmacokinetic models	
4.	Compartment models	

5.	Noncompartmental models, Physiological model	
Unit-7: O	ne Compartment Open Model	
1.	Intravenous injection – bolus – plasma data	
2.	Intravenous injection – bolus – plasma data (cont)	
3.	Intravenous injection – bolus – urine data	
4.	Intravenous injection – bolus – urine data (cont)	
5.	Intravenous injection – bolus – urine data (cont)	09
6.	Intravenous injection – infusion	
7.	Intravenous injection – infusion (cont)	
8.	Intravenous injection – infusion (cont)	
9.	Intravenous injection – infusion (cont)	
BIOPHARMACEUTICS (08)		
Unit-3: Di	stribution of Drugs	
1.	Tissue permeability of drugs, Binding of drugs	
2.	Apparent volume of distribution	08
3.	Apparent volume of distribution (cont)	
4.	Protein binding of drugs, factors Affecting protein – drug binding	
5.	Protein binding of drugs, factors Affecting protein – drug binding (cont)	
6.	Kinetics of protein binding	
7.	Kinetics of protein binding (cont)	
8.	Clinical significance of protein – drug binding	
Activity1	Mind Mapping on Selected Topic(s)	
Activity2	MCQ Test (Biopharmaceutics)	
Activity3	MCQ Test (Pharmacokinetics)	

II SESSIONAL : 25 Lectures + 2 Activities

Lecture	Lecture Details	Hours
No.		
BIOPHARI	MACEUTICS	(10)
Unit-5: B	Bioavailability and Bioequivalence	
29.	Introduction, Objectives of Bioavailability studies, Relative and Absolute Bioavailability, Bioavailability study protocol	
30.	Bioequivalence studies	
31.	Bioequivalence studies (cont)	
32.	Methods of assessment of bioavailability	10
33.	Methods to enhance bioavailability	
34.	Methods to enhance bioavailability (cont)	
35.	in-vitro drug dissolution: mechanisms (theories) of dissolution, measurement of dissolution rates	
36.	Official and unofficial methods of dissolution, control of variables in dissolution testing	
37.	<i>in-vitro</i> and <i>in-vivo</i> Correlation, limitations of dissolution test	
38.	Factors influencing the rate of dissolution	
PHARMAG	COKINETICS	(15)
Unit-7: On	e Compartment Open Model: (cont)	
25.	Extravascular administration	
26.	Extravascular administration (cont)	

27.	Extravascular administration (cont)	06
28.	Extravascular administration (cont)	
29.	Extravascular administration (cont)	
30.	Extravascular administration (cont)	
Unit-10: No	onlinear Pharmacokinetics	
21.	Introduction, Factors causing non-linearity	
22.	Michaelis - Menton method of estimating parameters	
23.	Michaelis-Menton method of estimating parameters (cont)	05
24.	Michaelis-Menton method of estimating parameters (cont)	
25.	Michaelis-Menton method of estimating parameters (cont)	
Unit-11: Noncompartmental Pharmacokinetics		
21.	Introduction, Statistical Moment Theory	
22.	Mean Residence Time (MRT) for various compartment models	04
23.	Mean Residence Time (MRT) for various compartment models (cont)	
24.	Physiological pharmacokinetic model	
Activity-1	MCQ Test (Biopharmaceutics)	· · · ·
Activity-2	MCQ Test (Pharmacokinetics)	

III SESSIONAL : 19 Lectures + 9 Activities

Lecture No.	Lecture Details	Hours
BIOPHAR	AMACEUTICS	(06)
Unit-4: Drug	Elimination	
1.	Biotransformation of drugs	
2.	Biotransformation of drugs (cont)	
3.	Renal excretion of dugs	06
4.	Factors affecting renal excretion of dugs	
5.	Renal clearance	
6.	Non renal routes of excretion of drugs	
PHARMA	COKINETICS	(13)
Multiple – D	Dosage Regimens	
1.	Repetitive intravenous injections – One compartment open model	
2.	Repetitive intravenous injections – One compartment open model (cont)	
3.	Repetitive extravascular dosing – One compartment open model	05
4.	Repetitive extravascular dosing – One compartment open model (cont)	
5.	Multiple Dosage Regimen – Two compartment open model	
Multicompartment Models		
1.	Two compartment open model – i.v. bolus (cont.)	
2.	Two compartment open model – i.v. bolus (cont.)	
3.	Two compartment open model – i.v. bolus (cont.)	
4.	Two compartment open model – i.v. infusion (cont.)	08
5.	Two compartment open model – i.v. infusion (cont.)	
6.	Two compartment open model – oral administration	
7.	Two compartment open model – oral administration (contd.)	
8.	Two compartment open model – oral administration (contd.)	
Activity 1	Unit Test – 1	
Activity 2	Unit Test – 2	
Activity 3	Unit Test – 3	
Activity 4	Unit Test – 4	

Activity 5	Unit Test – 5
Activity 6	MCQ Test -1
Activity 7	MCQ Test -2
Activity 8	MCQ Test -3
Activity 9	Revision Exam – 1

Text Books

- 5. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
- 6. Biopharmaceutics and Pharmacokinetics; By Robert F Notari.
- 7. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Inernationaledition.USA.
- 8. Biopharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, VallabhPrakashanPitampura, Delhi.
- 9. Biopharmaceutics and Pharmacokinetics, V Venkateswarulu, Pharma Book Syndicate.

Reference Books

- 1. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- 2. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 3. Biopharmaceutics; By Swarbrick.
- 4. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Toezer.
- 5. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- 6. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- 7. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- 8. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

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Name of the Subject	Pharmaceutical Quality Assurance (Theory)
Name of the Faculty	Dr. Jeyaprakash MR M.Pharm., Ph.D
Designation, Department	Associate Professor, Department of Pharmaceutical Analysis
Mobile Number	9952335392
e-Mail i.d.	jpvis7@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

Scope: This course conveys the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It also explains the current requirement of Quality standards, cGMP, QC tests, ICH guidelines, Complaints and documentation requirements. It also deals with the packing material quality and requirement as per the regulatory affairs requirement.

Objectives: The primary objectives of this course are to

- 1. It reveals the basic aspects of quality assurance
- 2. Explain the various types of quality requirements.
- 3. It helps the young community to understand the concept of GLP
- 4. The subject concept detail the raw materials and warehouse management process

Course Outcomes (COs): At completion of this course it is expected that the students will be able to

CO 1: Different types of Quality Management system

CO2: GMP and its individual criterion requirements

CO3: Good Laboratory Practices requirements

CO4: Complaints and Document maintenance and its handling procedure in pharmaceutical industry

CO5: Different types of analytical instruments and calibration procedures

Sessional	No. of Hours of Didactic Lecture Pharmaceutical Quality Assurance	No of Hours of other Activities	Total No. of Lecture Hours
I	20	04	24
II	25	04	29
Total No. of Hours	45	08	53

LECTURE PLAN – Abstract

I SESSIONAL : 31 Lectures + 2 Activities

Lecture	No.	Lecture Details	Hours
Unit 1: Quality Assurance and Quality Management concepts, Total Quality			10
Management (TQM), ICH Guidelines, Quality by design (QbD), Quality by design			
(QbD), ISO 9000 a	(QbD), ISO 9000 & ISO14000, NABL accreditation		
1	Orientation towards subje	ect and syllabus (Activity 1)	
2	Definition and concept of	f Quality control, Quality assurance and GMP	
3	(TQM): Definition, element	nts, philosophies	
4	ICH Guidelines: purpose,	participants, process of harmonization	
5	Brief overview of QSEM		
6	Special emphasis on Q-se	ries guidelines, ICH stability testing guidelines	
7	QbD: Definition, overview, Elements of QbD program, tools		
8	ISO 9000 & ISO14000: Overview, Benefits, Elements,		
9	Steps for ISO registration		
10	NABL Principles and pro-	cedure	
11	Assignment 1		02
Unit 2: Organization and personnel, Premises, Equipments and raw materials10			10
1	Personnel responsibilities,	training,	
2	Hygiene and personal records		
3	Premises: Design, construction and plant layout, maintenance,		
4	Sanitation,		
5	Environmental control,		
6	Utilities and maintenance of sterile areas,		
7	Control of contamination		

8	Equipments selection,	
9	Purchase specifications	
10	Maintenance of stores for raw materials,	
11	ASSIGNMENT 1	02

II SESSIONAL : 25 Lectures + 3 Activities

Lecture No.	Lecture Details Hours	
Unit-3: Quality Co	ontrol and Good Laboratory Practices	10
1	Quality control test for containers	
2	Rubber closures and secondary packing materials	
3	GLP General Provisions	
4	Organization and Personnel, Facilities,	
5	Equipment,	
6	Testing Facilities Operation,	
7	Test and Control Articles,	
8	Protocol for Conduct of a Nonclinical Laboratory Study	
9	Records and Reports	
10	Disqualification of Testing Facilities	
	Assignment 3	02
Unit 4: Complaint	s and Document maintenance in pharmaceutical industry	08
1	Complaints and evaluation of complaints,	
2	andling of return good	
3	Recalling and waste disposal	
4	Batch Formula Record	
5	Master Formula Record	
6	SOP	
7	Quality audit, Quality Review	
8	Quality documentation, Reports and documents, distribution records	
9	Assignment 4	
Unit 5: Calibration and Validation, Warehousing 07		07
1	Introduction, definition and general principles of calibration	
2	qualification and validation, importance and scope of validation	
3	types of validation	
4	validation master plan. Calibration of pH meter	
5	Qualification of UV-Visible spectrophotometer	
6	General principles of Analytical method Validation.	
7	Good warehousing practice, Materials management	
8	Assignment 5	02

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.

2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.

3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.

4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh

5. How to Practice GMP's – P P Sharma.

6. ISO 9000 and Total Quality Management – Sadhank G Ghosh

7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms

8. Good laboratory Practices – Marcel Deckker Series

9. ICH guidelines, ISO 9000 and 14000 guidelines

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Name of the Subject	Pharmaceutical Biotechnology (Theory)
Name of the Faculty	Dr. P. Vasanth raj M.Pharm., Ph.D
Designation, Department	Asst. Professor, Department of Pharmaceutical

	Biotechnology
Mobile Number	9500793944
e-Mail i.d.	vasanth@jssuni.edu.in

Scope, Course Objectives and Course Outcomes

Scope: This course aims to provide knowledge that includes a multidisciplinary approach in which students can follow the requirements of large-scale industry-related operations as well as high-end independent research on Biotechnology. The course covers a broad range of competencies required to understand different biological concepts of rDNA technology, genomics, proteomics, protein engineering, fermentation and immunology.

Objectives: The primary objectives of this course are to

Explain how genomes are structured in higher species

- 1. Describe functional classes of the DNA and Gene families.
- 2. Understand how recombinant DNA technology works
- 3. Explain the development and implementation of the DNA and cDNA libraries.
- 4. Get an insight into primary and secondary organs of the Immune system.
- 5. Describe different technologies for microorganism to produce useful commodity.

Course Outcomes (COs): At completion of this course it is expected that the students will be able to CO 1: Gain insight into the theory and manipulation of genomes.

- CO 2 : Classify and explain the structure and general characteristics of genes.
- CO 3 : Understand various basic concepts about fermentation technology
- CO 4 : Get insight into the role and function of diverse immune cells
- CO 5 : Describe antigenicity and its influencing factors.
- CO 6 : Explain immunity mediated by cell, development of monoclonal antibody, and hypersensitivity.

LECTURE PLAN – Abstract

Sessional	No. of Hours of Didactic Lecture	No of Hours of other Activities	Total No. of Lecture Hours
I	28	03	31
II	17	02	19
Total No. of Hours	45	05	50

I SESSIONAL: 28 Lectures + 3 Activities

Lecture	Lecture Details	Hours
No.		
Unit-1		
	Orientation to the subject	10
1.	Brief introduction to Pharmaceutical Biotechnology	
2.	Enzyme Biotechnology-Methods of enzyme immobilization and applications	
3.	Enzyme Biotechnology-Methods of enzyme immobilization and applications (Cont)	
4.	Biosensors-Working and applications of biosensors in Pharmaceutical Industries	
5.	Biosensors-Working and applications of biosensors in Pharmaceutical Industries (Cont)	
6.	Brief introduction to Protein Engineering	

7.	Use of microbes in industry-Production of Amylase, Catalase	
8.	Use of microbes in industry-Production of Peroxidase, Lipase	
9.	Use of microbes in industry-Production of Protease, Penicillinase	
10.	Basic principles of genetic engineering	
Unit-2		
17.	Study of cloning vectors	
18.	Study of restriction endonucleases	
19.	Study of DNA ligase	
20.	Application of genetic engineering in medicine	
21.	Interferon by r DNA technology	10
22.	Hepatitis -B by r DNA technology	
23.	Insulin by r DNA technology	
24.	Brief introduction to PCR	
25.	Types of immunity and Humoral immunity	
26.	Cellular immunity	
Unit-3		
48.	Structure of Immunoglobulin's	
49.	Structure and Function of MHC	
50.	Hypersensitivity reactions	10
51.	Immune stimulation and Immune suppressions	
52.	General method of the preparation of vaccines and other products	
53.	General method of the preparation of vaccines and other products (Cont)	
54.	General method of the preparation of vaccines and other products (Cont)	
55.	General method of the preparation of vaccines and other products (Cont)	
Activity1	MCQ Test	
Activity2	MCQ Test	
Activity3	MCQ Test	

II SESSIONAL: 17 Lectures + 2 Activities

Lecture	Lecture Details	Hours
No.		
56.	Storage conditions and stability of official vaccines	
57.	Hybridoma technology-Production, Purification and Applications	
Unit-4	•	
31.	Immuno blotting techniques	
32.	Genetic organization of Eukaryotes	
33.	Genetic organization of Prokaryotes	08
34.	Microbial genetics	
35.	Plasmids	
36.	Transposons	
37.	Microbial biotransformation and applications	
38.	Mutation	
Unit-5	•	
26.	Types of mutation/mutants	
27.	General requirements of fermentation	
28.	General requirements of fermentation (Cont)	07
29.	Large scale production fermenter design and its various controls	

30.	Study of the production of Penicillin's and Griseofulvin	
31.	Study of the production of Citric acid and Glutamic acid	
32.	Study of the production of Vitamin B12	
Activity-1	MCQ Test	
Activity-2	MCQ Test	

Text Books

- 1. Biotechnology by Singh B.D.
- 2. B.R. Glick and J.J.Pasternak: Molecular Biotechnology: Principles and Applicationsof RecombinantDNA: ASM Press Washington D.C.
- 3. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio

Reference Books

- S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell ScientificPublication
 Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology,2ndedition, Aditya books Ltd., New Delhi

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JSS Academy of Higher Education & Research, Mysuru (Accredited 'A⁺' Grade by NAAC) JSS College of Pharmacy, Ooty – 643 001

(An ISO 9001:2015 certified Institution)

III B. PHARM, V Semester (AY- 2021-22) (First Half: July - Dec 2021)

Day	9-10 AM	10-11 AM	11-12 PM	12-1 PM	1-2 PM	2-5 PM (PRACTICAL)
Monday		PC-II (T)	IP (T)	MC II (T)		Batch I -PC-II (SRK) (P) Batch V- IP (VS) (P)
,		(SRK)	(VS)	(GS)		Batch II- PCOG (<i>KS</i>) (P) (Batch-III & IV-Library)
Tuesday	PJ (<i>Tu</i>)	IP(T)	PJ (T)	PC-II (T)		Batch II- PC-II (SRK) (P) Batch III-IP (VS) (P)
lacoudy	(SP)	(VS)	(SP)	(SRK)		Batch I-PCOG (<i>KS</i>) (P) (Batch-IV & V-Library)
Wednesday		IP (T)	PCOG(T)	PC-II (<i>Tu</i>)	X	Batch III-PC-II (SRK) (P) Batch IV- IP (KGR) (P)
		(VS)	(KS)	(SRK)	RE₽	Batch V-PCOG (KS) (P) (Batch-I & II-Library)
Thursday	IP (Tu)	PJ (T)	MC-II (T)	PCOG (T)	H B	Batch IV-PC-II (SRK) (P) Batch II-IP (KGR) (P)
marsaay	(VS)	(SP)	(GS)	(KS)	NU	Batch III-PCOG (KS) (P) (Batch-I & V-Library)
Friday		PJ (T)	MC-II (T)	PC-II (T)	L L L	Batch V-PC-II (SRK) (P) Batch I-IP (VS) (P)
inady		(SP)	(GS)	(SRK)		Batch IV-PCOG (KS) (P) (Batch-II & III-Library)
Saturday		MC-II (<i>Tu</i>) (GS)	PCOG (T) <i>(KS)</i>	PCOG (<i>Tu</i>) (KS)		Sports/Library

T- Theory, P- Practical, Tu-Tutorial

Subject in charge:

Industrial Pharmacy-I

2.

3.

- 1. Medicinal Chemistry-II (BP501T) (MC-II): Dr. G
 - (MC-II): Dr. Gomathi S (GS) (T)
 - (BP502T) (IP)

(IP) : Dr.V.Senthil (VS) (T&P)

- Pharmacology-II (BP503T) (PC-II) : Mr.B.Shivaramakrishnan (SRK) (T&P)
- 4. Pharmacognosy & Phytochemistry II (BP504T) (PCOG) : Dr. Kalakotla Shankar (KS) (T&P)
- 5. Pharmaceutical Jurisprudence (BP505T) (PJ) : Ms S. Priyadharshini (SP) (T)

Class-in-Charge: Dr.V.SENTHIL, Professor, Dept. of Pharmaceutics [senthil.v@jssuni.edu.in, Mob: 9842650602]



JSS Academy of Higher Education & Research, Mysuru

(Accredited ' A^+ ' Grade by NAAC) JSS College of Pharmacy, Ooty – 643 001

(An ISO 9001:2015 Certified Institution)

III B. PHARM (VI Semester AY- 2021-22)

Day	9-10 AM	10-11 AM	11-12 PM	12-1 PM	1-2 PM	2-5 PM (PRACTICAL)	Sub ect
Monday	PB (T)	PC-III(T)	BP(T)	QA(T)		Batch I-PC-III (SRK) Batch III-MC-III (SJ)	in
	(PV)	(SRK)	(RA)	(MRJ)		Batch II-HDT (SP) (Batch-IV & V-Library)	cha
Tuesday	PB (T)	PC-III <i>(Tu)</i>	BP(T)	MC-III(T)		Batch II-PC-III (SRK) Batch IV-MC-III (SJ)	ge:
Tuesday	(PV)	(SRK)	(RA)	(SJ)		Batch I-HDT <i>(SP)</i> (Batch-III & V-Library)	
Wodposday	РВ (Т)	HDT(T)	PB (T)	PC-III(T)	EAK	Batch III-PC-III (SRK) Batch I-MC-III (SJ)	
weunesuay	(PV)	(SP)	(PV)	(SRK)	BR	Batch V-HDT (SP) (Batch-IV & II-Library)	
Thursday	BP(Tu)	QA(T)	MC-III(T)	HDT(T)	Н	Batch IV-PC-III (SRK) Batch V-MC-III (SJ)	
mursuay	(RA)	(MRJ)	(SJ)	(SP)	Ž	Batch III-HDT (SP) (Batch-I & II-Library)	
Eridov	HDT <i>(Tu)</i>	QA(T)	HDT(T)	MC-III(T)		Batch V-PC-III (SRK) Batch II-MC-III (SJ)	
Fluay	(SP)	(MRJ)	(SP)	(SJ)		Batch IV-HDT (SP) (Batch-I & III-Library)	
Saturday	QA(Tu)	PC-III(T)	BP(T)	MC-III <i>(Tu)</i>		Sports/Library	a di i
Saturday	(MRJ)	(SRK)	(RA)	(SJ)		Sports/Library	edic

Chemistry-III

Dr. S. Jubie *(SJ)* (T&P)

2. Pharmacology -III (PC-III) : Mr. B.Shivaramakrishnan *(SRK)* (T&P) 3. Herbal Drug Technology (HDT) : Dr. S.Priyanka (SP) (T&P) 4. Biopharmaceutics and Pharmacokinetics (BP) : Mr. R. Arun *(RA)* (T) 5. Quality Assurance (QA) : Dr. M.R.Jeyprakash (MRJ) (T) 6. Pharmaceutical Biotechology (PB) : Dr. P. Vasanth raj (PV) (T) Class-in-Charge: Dr.V.SENTHIL, Professor, Dept. of Pharmaceutics [senthil.v@jssuni.edu.in, Mob: 98426 50602]

7.STUDENT SUPPORT SERVICES

Student	Person/s	Responsibilities	
Services	Responsible		
		Making decisions on behalf of the faculty, staff, students and alumni to achieve the stated mission and vision of the college.	
Principal	Dr. Dhanabal S	Effectively organizing and allocating the human and financial resources of the college to achieve the stated mission and vision of the college.	
	I diamswarry	Implementing and enforcing the policies of the College and the university.	
		Representing and advocating on behalf of the faculty, staff, students and alumni to the university.	
		✤Supervision, coordination and delivery of teaching programs	
Vice	Dr. Afzal A	Management of programs to improve the knowledge, skill and attitude of staff	
Principal	Mohammed	Responsibility for general discipline matters of students	
		Centre for continuous learning for professional excellence (CCLPE)	
		Contribute to the overall management of the college	
	Mr. Basavalinga	Coordinating a range of functions, such as finance, human resources and other support areas that contributes significantly to the management function within the college.	
Administrative		Managing the delivery of a particular service or function (e.g. finance, library, human resources, facilities)	
Officer	Develuting	Performing routine administrative activities	
		Providing basic physical and emotional care for students	
		Assisting with coordination and planning of student routines	
		Providing routine customer service tasks such as reception and providing straightforward advice about the college	
		Providing routine support tasks with respect to college maintenance	
		Coordinating the day to day routine operational requirements of a college office	
		Assuming responsibilities for the general cleanliness and maintenance of the college	

10. GRIEVANCE REDRESSAL COMMITTEE

S. No.	Name	Position	Contact No.
1.	Dr. S Ponnusankar, Professor	Chairman	9489613428
2.	Dr. Afzal A Mohammed, Vice Principal	Co-Chairman	9486687029
3.	Dr.K.Gowthamrajan, Professor,	Member	9443089812
4.	Dr. Krishnaveni Nagappan, Professor	Member	9442083447
5.	Dr. K P.Arun, Associate Professor	Member	9994934663
6.	Dr A Justin, Assistant Professor,	Member	9942932150
7.	Dr. S Saravanan, Assistant Professor	Member	9585625948
8.	Mr.Basavanna, Administrative Officer	Member	9489044575

<u> 11.ANTI – RAGGING COMMITTEE</u>

As per the decision of the Hon'ble Supreme Court of India in writ petition No. (C) 656 / 1998, "RAGGING IS PROHIBITED". If an incident of ragging comes to the notice of the authority concerned, the accused student(s) will be given an opportunity to explain and if the explanation is not satisfactory the authority will exple him / her from the institution. In this view, an anti – ragging committee is constituted in our institution (as per the regulation notified by AICTE, New Delhi vide F. NO. 37-3/Legal/IACTE/2009 dated July 1, 2009) with the following members. The details of their names and telephone numbers are given here for your assistance. In case of any untoward incidents pertaining to ragging must be immediately brought to the knowledge of the members to curb ragging at its inception stage itself.

Name of the Staff	Designation	Mobile Phone Number	E-mail. i.d.
Dr. S.P. Dhanabal	Principal & Chief Warden	94890 44577	spdhanabal@jssuni.edu.in
Dr. Afzal Azam	Vice-Principal & Deputy Chief Warden	09486687029	<u>afzal@jssuni.edu.in</u>
Dr. S. Ponnusankar	Professor	94896 13428	drsponnusankar@jssuni.edu.in
Dr. N. Krishnaveni	Professor & Warden (Girl's Hostel)	94420 83447	<u>krisath@jssuni.edu.in</u>
Dr. GNK Ganesh	Associate Professor	94421 91918	gnk@jssuni.edu.in
Dr. Arun K P	Associate Professor & Warden (Boy's Hostel)	99949 34663	<u>kparun@issuni.edu.in</u>
Mr. H.K. Basavalingadevaru	Administrative Officer & Residential Warden (Boy's Hostel)	94890 44575	<u>basavanna@issuni.edu.in</u>
Dr. JSK. Nagarajan	Assistant Professor	9443257841	jsk.nagarajan@ <u>jssuni.edu.in</u>
Dr. B. Gowramma	Associate Professor	94421 11172	gowramma@jssuni.edu.in
Dr. S Gomathy Subramanian	Assistant Professor	9486433876	gomathys@jssuni.edu.in

SAY NO TO RAGGING - MAKE OUR CAMPUS RAGGING FREE