JSS MAHAVIDYAPEETHA

College of Pharmacy
JSS Academy of Technical Education

C-1/A, Sector-62, Noida-201301

Affiliated to A.P.J. Abdul Kalam Technical University, Uttar Pradesh, Lucknow
Approved by Pharmacy Council of India (PCI), New Delhi

Course Handout

2022-23

Class: Third Year B. Pharm

(Semester V & VI)

Name : _____

Roll No.: _____

JSS MAHAVIDYAPEETHA
College of Pharmacy
JSS Academy of Technical Education
C-1/A, Sector-62, Noida-201301
Affiliated to A.P.J. Abdul Kalam Technical University, Uttar Pradesh, Lucknow

VISION

To be a leader in pharmacy education, training and research.

MISSION

- ✓ Providing Knowledge and skill of pharmaceutical sciences to its students
- ✓ Advancing the knowledge, skill and attitude of faculty members for transformational research activities in the pharmaceutical sciences.

Academic Calendar 2022-23

Third Year B. Pharm

1. Commencement of Classes

B. Pharm – V Semester **1st September 2022**

2. Sessional Examination Schedule

I	II	III
1st Week of October 2022	**1st Week of November 2022**	**1st Week of December 2022**

3.

Closure of Term: **10th January 2023**

End Semester Examination:

4. Theory Examination **15th Dec- 10th January 2023**

Practical Examination **09th – 14th December 2022**

5. Commencement of VI Semester Classes: **21 January 2023**

6. Sessional Examination Schedule

I	II	III
4th Week February of 2023	**2nd Week of March 2022**	**2nd Week of April 2022**

7. Closure of Term: **25th May 2023**

8. End Semester Examination:

Theory Examination **15th May – 05th June 2023**

Practical Examination **01st – 10th June 2023**

9. Commencement of VII Semester Classes: **01st August 2023**

Program Educational Objectives (PEOs):

PEO 1: To acquire the theoretical knowledge of pharmaceutical sciences PEO 2: To acquire practical skills in

- isolation of medicinal compounds from natural sources
- synthesis and analysis of medicinal compounds
- screening medicinal compounds for pharmacological activities
- formulation of pharmaceutical dosage forms and their evaluation

PEO 3: To develop competent Pharmacists with ethical attitude, research intuition, leadership qualities, to participate in public health programs and engage in life-long learning.

Program Outcomes (POs):

1. Ability to acquire knowledge of pharmaceutical sciences
2. Ability to design and conduct experiments, to analyze and interpret data
3. Ability to demonstrate effective planning, develop and implement plans within time frame.
4. Ability to function effectively individually and on teams, including diverse and multidisciplinary, to accomplish a task.
5. Ability to understand and appreciate the role of pharmacist in healthcare services.
6. Understanding of professional, ethical, legal, security and social issues and responsibilities.
7. Ability to understand contemporary issues relating to pharmacy profession and challenges ahead.
8. Awareness of ethical and professional responsibilities.
9. Possess the necessary interpersonal and communication skills to be a productive member of the team in work environment.
10. Ability to use current techniques, skills, and modern tools.
11. A strong background and motivation to pursue life-long learning

1. Course Details V Semester

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial PharmacyI– 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 PharmacyI – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
BP509P	Report on Hospital Training - I	-	-	2
	Total	**27**	**5**	**28**

2. Course Details VI Semester

Course Code	Name of the Course	No. of hours	Tutorial	Credit Points
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	3	1	4
BP606T	Quality Assurance– Theory	3	1	4
BP607P	Medicinal Chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
BP610P	Report on Industrial Training	-	-	2
	Total	**30**	**6**	**32**

2. Attendance and Progress

A candidate is required to put in atleast 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.

3. Evaluation:

a. Internal assessment: Continuous mode

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

Table 1: Scheme for awarding internal assessment: Continuous mode

THEORY		
Criteria	**Maximum Marks**	
Attendance	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher Interaction	3	1.5
Total	**10**	**5**
PRACTICALS		
Attendance		2
Based on Practical Records, Regular viva voce, etc.		3
Total		**5**

Table 2: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	4	2
90–94	3	1.5
85–89	2	1
80–84	1	0.5
Less than 80	0	0

b. Sessional Exams

Three 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 best two Sessional exams shall be computed for internal assessment as per the requirements.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly, Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations
For subjects having University examination

I. Long Essay(Answer 1 out of 2) = 1 x 10 = 10

II Short Essay (Answer 2 out of 3) = 2 x 5 = 10
III. Short Answers (Answer 5 out of 6) = 5 x 2 = 10

Total =30 marks

For subjects having Non-University Examination

I. Long Essay (Answer 1 out of 2) = 1 x 10 = 10
II. Short Essay (Answer 2 out of 3) = 2 x 5 = 10
III. Short Answers (Answer 5 out of 6) = 5 x 2 = 10

Total =30 Marks

Question paper pattern for Practical Sessional Examinations

I. Synopsis = 10
II. Experiments = 25
III. Viva voce = 05

Total = 40 marks

4. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to VIII shall be conducted by the university except for the subjects notified as non-university examinations.

Table 3: Scheme for internal assessments and university examination -Semester-V

Course code	Name of the course	Sessional examination				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial PharmacyI– 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 and Phytochemistry II– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial Pharmacy I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP508P	Pharmacognosy and Phytochemistry II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP509P	Report on Hospital Training - I	-	-	-	-	100	-	100
Total		**65**	**105**	**17 Hrs**	**170**	**580**	**27 Hrs**	**750**

Table 4: Scheme for Sessional examinations and university examination - Semester-VI

Course code	Name of the course	Sessional examination				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	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
BP607P	Medicinal Chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP610P	Report on Industrial Training	-	-	-	-	100	-	100
Total		**75**	**120**	**18 Hrs**	**195**	**655**	**30 Hrs**	**850**

5. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. programme if he/she secures at least 50% marks in that particular course including internal assessment. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

6. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified (in promotion and award of grades), then he/she shall reappear for the university examination of that course. However, his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

7. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the Internal assessment. The re-conduct of the sessional exam should be completed before the commencement of next semester theory examinations.

Question pattern for university theory examinations for 75 marks paper

I. Long Essay (Answer 2 out of 3) = 2 x10 =20
II. Short Essay (Answer 5 out of 7) = 5 x 7 = 35
III. Short Answers (Answer all) = 10 x 2 =20

Total = 75 marks

Question pattern for university theory examinations for 50 marks paper

I. Long Answers (2 out of 3) = 2 x 10 = 20
II. Short Answers (6 out of 8) = 6 x 5 =30

Total = 50 marks

---

8. Grading of performance

Letter grades and grads points allocations

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.

Table 5: Letter grades and grade points equivalent to percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	A+	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent in any form of evaluation/examination, letter grade allocated to him/her should be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

9. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of. 7.50 and
above First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

10. Attendance: The marks is allotted based on the attendance percentage (Table 2)

11. Chamber consultation hours: Any time during college hours.

12. Tutorial Class: Objective of the tutorial is to enhance the learning ability and help students in better understanding of the subject. This provides a best opportunity for the students to clarify their subject doubts. This involves discussions, presentations on specified topics, assignments and evaluation.

BP501T. MEDICINAL CHEMISTRY – II (Theory)

Teacher: **45 Hours (3 Hrs/ week)**

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 (*)

	Topic	Hrs
UNIT- I	**Antihistaminic agents:** Histamine, receptors and their distribution in the Human body **H_1–antagonists:** Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium **H_2-antagonists:** Cimetidine*, Famotidine, Ranitidine **Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole **Anti-neoplastic agents:** **Alkylating agents:** Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa **Antimetabolites:** Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine **Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin **Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate **Miscellaneous:** Cisplatin, Mitotane.	**10**

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 **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	**10**
UNIT-III	**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	**10**
UNIT-IV	**Drugs acting on Endocrine system:** Nomenclature, Stereochemistry and metabolism of steroids **Sex hormones:** Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol **Drugs for erectile dysfunction:** Sildenafil, Tadalafil **Oral contraceptives:** Mifepristone, Norgestril, Levonorgestrol **Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone **Thyroid and antithyroid drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.	**08**

UNIT-V	**Antidiabetic agents:** **Insulin and its preparations** **Sulfonyl ureas:** Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride **Biguanides:** Metformin **Thiazolidinediones:** Pioglitazone, Rosiglitazone **Meglitinides:** Repaglinide, Nateglinide **Glucosidase inhibitors:** Acrabose, Voglibose **Local Anesthetics: SAR of Local anesthetics** **Benzoic Acid derivatives:** Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine **Amino Benzoic acid derivatives:** Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate **Lidocaine/Anilide derivatives:** Lignocaine, Mepivacaine, Prilocaine, Etidocaine **Miscellaneous:** Phenacaine, Diperodon, Dibucaine*	**07**

Theory Sessional examination syllabus

Sessional No.	**Syllabus**
	Chapters no.
I	1, 2
II	3, 4
III	5

Recommended Books (Latest Editions)

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

BP 502 T. Industrial Pharmacy I (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

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

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

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

Course content:

	Topic	Hrs
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.	**07**
UNIT-II	**Tablets:** a. **Introduction**, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling. b. **Tablet coating**: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. c. **Quality control tests**: In process and finished product tests. **Liquid orals:** Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia.	**10**
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.	**08**

	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, equipment's 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. Quality control tests of parenteral products. **Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations.	**10**
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; Quality control and stability studies. **Packaging Materials Science:** Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.	**10**

Theory Sessional examination syllabus

Sessional examination No.	Syllabus Chapters no.
I	1, 2
II	3,4
III	5

BP 506 P. Industrial PharmacyI (Practical)

Teacher: **60 Hours (4 Hrs/ week)**

List of Experiments:

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

Recommended Books (Latest Editions)

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

BP503. T. PHARMACOLOGY-II (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

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 student shell 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:

Topics		Hrs
UNIT-I	**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**
UNIT-II	**1. Pharmacology of drugs acting on cardio vascular system** a. Drug used in the therapy of shock. b. Haematinics, 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.	**10**
UNIT-III	**Autocoids and related drugs** a. Introduction to autacoids and classification b. Histamine, 5-HT and their antagonists. c. Prostaglandins, Thromboxane's and Leukotrienes. d. Angiotensin, Bradykinin and Substance P. e. Non-steroidal anti-inflammatory agents f. Anti-gout drugs g. Antirheumatic	**10**

UNIT-IV	**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.	**08**
UNIT-V	**1. Pharmacology of drugs acting on endocrine system** a. Androgens and Anabolic steroids. b. Estrogens, progesterone and oral contraceptives. c. Drugs acting on the uterus. **2. Bioassay** a. Principles and applications of bioassay. b. Types of bioassay c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT	**07**

Theory Sessional examination syllabus

Sessional examination No.	Syllabus
	Unit
I	1, 2
II	3,4
III	5

BP 507 P. PHARMACOLOGY-II (Practical)

Teacher/s: **60 Hours (4 Hrs/ week)**

List of Experiments:

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

11. Determination of 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 spasmolytic using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

Recommended Books (Latest Editions)

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

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

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 subject student shall be able to –

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:

Topics		Hrs
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.	**07**
UNIT-II	General introduction, composition, chemistry & chemical classes, bio sources, therapeutic uses and commercial applications of following secondary metabolites: **Alkaloids:** Vinca, Rauwolfia, Belladonna, Opium, **Phenylpropanoids and Flavonoids:** Lignans, Tea, Ruta **Steroids, Cardiac Glycosides & Triterpenoids**: Liquorice, Dioscorea, Digitalis **Volatile oils**: Mentha, Clove, Cinnamon, Fennel, Coriander, **Tannins:** Catechu, Pterocarpus **Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony **Glycosides:** Senna, Aloes, Bitter Almond **Iridoids, Other terpenoids & Naphthoquinones:** Gentian, Artemisia, taxus, carotenoids	**14**
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	**06**

UNIT-IV	**Industrial production, estimation and utilization of the following phytoconstituents:** Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine.	**10**
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.	**08**

Theory Sessional examination syllabus

Sessional examination No.	Syllabus
	Chapters no.
I	1, 2
II	3 ,4
III	5

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

Teacher/s: **60 Hours (4 Hrs/ week)**

List of Experiments:

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

Recommended Books (Latest Editions)

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007.
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.

7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

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:

Topics		Hrs
UNIT-I	**Drugs and Cosmetics Act, 1940 and its rules 1945:** a. Objectives, Definitions, Legal definitions of schedules to the Act and Rules b. Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. c. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs d. 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.	**10**
UNIT-II	**Drugs and Cosmetics Act, 1940 and its rules 1945:** a. Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) b. Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties c. Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. d. 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	**06**
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:**	**10**

	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)	**08**
UNIT-V	**Pharmaceutical Legislations –** A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee. **Code of Pharmaceutical ethics:** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath. **Medical Termination of Pregnancy Act** **Right to Information Act** **Introduction to Intellectual Property Rights (IPR)**	**07**

Theory Sessional examination syllabus

Sessional examination No.	Syllabus
	Chapters no.
I	1,2
II	3,4
III	5

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-byM.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).

BP601T. MEDICINAL CHEMISTRY – III (Theory)

Teacher: **45 Hours (3 Hrs/ week)**

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 the 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 (*)

		Hrs
UNIT-I	**Antibiotics** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. **β-Lactam antibiotics:** Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin **Tetracyclines:** Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline	**10**
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. **Antimalarial:** Etiology of malaria. **Quinolines:** SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. **Biguanides and dihydro triazines**: Cycloguanil pamoate, Proguanil. **Miscellaneous:** Pyrimethamine, Artesunate, Artemether, Atovaquone.	**10**

UNIT- III	**Anti-tubercular Agents:** **Synthetic anti tubercular agents:** Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* **Anti-tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine, Streptomycin, Capreomycin sulphate. **Urinary tract anti-infective agents:** **Quinolones:** SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin,Moxifloxacin. **Miscellaneous:** Furazolidine, Nitrofurantoin*, Methanamine **Antiviral agents:** Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Ganciclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.	**10**
UNIT-IV	**Antifungal agents:** **Antifungal antibiotics:** Amphotericin-B, Nystatin, Natamycin, Griseofulvin **Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate.* **Anti-protozoal Agents:** Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine. **Anthelmintic:** Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin. **Sulphonamides and Sulfones:** Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine. **Folate reductase inhibitors**: Trimethoprim*, Cotrimoxazole. **Sulfones:** Dapsone*.	**08**
UNIT-V	**Introduction to Drug Design** Various approaches used in drug design. Physiochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques. **Combinatorial Chemistry:** Concept and applications of combinatorial Chemistry: Solid phase and solution phase synthesis.	**07**

Theory Sessional examination syllabus

Sessional No.	Syllabus
	Chapters no.
I	1, 2
II	3, 4
III	5

BP607P. MEDICINAL CHEMISTRY- III (Practical)

Teacher: **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 physiochemical 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 (Lipinski's 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. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP602 T. PHARMACOLOGY-III (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

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 the course the student shall 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
3. Appreciate correlation of pharmacology with related medical sciences.

Course Content:

	Topic	Hrs
UNIT-I	**Pharmacology of drugs acting on Respiratory system** a. Anti -asthmatic drugs b. Drugs used in the management of COPD c. Expectorants and antitussives d. Nasal decongestants e. Respiratory stimulants **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.	**10**
UNIT-II	**Chemotherapy:** General principles of chemotherapy. a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole. c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides	**10**
UNIT-III	**Chemotherapy:** a. Antitubercular agents b. Antileprotic agents c. Antifungal agents d. Antiviral drugs e. Anthelmintics f. Antimalarial drugs g. Antiamoebic agents	**10**

UNIT-IV	**Chemotherapy:** Urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy. **Immunopharmacology:** Immunostimulants. Immunosuppressant. Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars.	**08**
UNIT-V	**Principles of toxicology** a. Definition and basic knowledge of acute, subacute and chronic toxicity. b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity c. General principles of treatment of poisoning d. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning. **Chronopharmacology** a. Definition of rhythm and cycles. b. Biological clock and their significance leading to chronotherapy.	**07**

Theory Sessional examination syllabus

Sessional examination No.	**Syllabus Chapters no.**
I	1, 2
II	3,4
III	5

BP 608 P. PHARMACOLOGY-III (Practical)

Teacher: **60 Hours (4 Hrs/ week)**

List of Experiments:

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

Recommended Books (Latest Editions)

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

BP603T. HERBAL DRUG TECHNOLOGY (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

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 student shell 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:

Topics		Hrs
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:** Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy. Preparation and standardization of Ayurvedic formulations viz. Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.	**10**
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:** Alfa-alfa, 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.	**08**
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.	**10**

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:** Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy. Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem. **Regulatory Issues:** Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.	**10**
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 page, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.	**07**

Theory Sessional examination syllabus

Sessional examination No.	Syllabus
	Unit
I	1, 2
II	3,4
III	5

BP609P. HERBAL DRUG TECHNOLOGY (Practical)

Teacher/s: **60 Hours (4 Hrs/ week)**

List of Experiments:

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

Recommended Books (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BP604T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

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

Objectives: Upon completion of the subject 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:

Topics		Hrs
UNIT-I	**Introduction to Biopharmaceutics:** **Absorption;** Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from non per-oral extra-vascular routes. **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.	**10**
UNIT-II	**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.	**10**
UNIT-III	**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. Intravenous Injection (Bolus), Intravenous infusion and Extra vascular administrations. Pharmacokinetics parameters – K_E , t1/2,Vd, AUC, Ka, Clt and CL_R- definitions, methods of eliminations, understanding of their significance and application.	**10**

UNIT-IV	**Multicompartment models:** Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.	**08**
UNIT V	**Nonlinear Pharmacokinetics:** Introduction, Factors causing Non-linearity. Michaelis-Menten method of estimating parameters, Explanation with example of drugs.	**07**

Theory Sessional examination syllabus

Sessional examination No.	**Syllabus**
	Chapters no.
I	1, 2
II	3 ,4
III	5

Recommended Books (Latest Editions)

1. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew, B.C.Y.U. 4th edition Prentice-Hall International edition. USA.
2. Biopharmaceutics and Pharmacokinetics-A Treatise by D.M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi.
3. Handbook of Clinical Pharmacokinetics by Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
4. Biopharmaceutics by Swarbrick, Lea and Febiger, USA.
5. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, PharmaMed Press, Hyderabad.
6. Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Sarfaraz Niazi, PharmaMed Press, Hyderabad.
7. Basic Pharmacokinetics by Mohsen A. Hedaya, CRC Press, NY.
8. Biopharmaceutics and Pharmacokinetics by V. Ventashewarlu, PharmaMed Press, Hyderabad.
9. Clinical Pharmacokinetics, Concepts and Applications by Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence by Abdou H.M, Mack, Publishing Company, Pennsylvania, 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics: An Introduction by Robert F. Notari, 4th edition, Marcel Dekker Inc., New York.

BP605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

Scope:

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

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

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

Course Content:

Topics		Hrs
UNIT-I	**Brief introduction** to Biotechnology with reference to Pharmaceutical Sciences. **Enzyme Biotechnology**- Methods of enzyme immobilization and applications. **Biosensors**- Working and applications of biosensors in Pharmaceutical Industries. **Brief introduction to Protein Engineering**. **Use of microbes** in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. **Basic principles of genetic engineering**.	**10**
UNIT-II	• Study of cloning vectors, restriction endonucleases and DNA ligase. • Recombinant DNA technology. Application of genetic engineering in medicine. • Application of r DNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin. • Brief introduction to PCR	**10**

UNIT-III	**Types of immunity**- humoral immunity, cellular immunity. Structure of Immunoglobulins. Structure and Function of MHC. **Hypersensitivity reactions**, Immune stimulation and Immune suppressions. General method of the preparation of bacterial infections, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. Storage conditions and stability of official vaccines. **Hybridoma technology**- Production, Purification and Applications, Blood products and Plasma Substitutes.	**10**
UNIT-IV	**Immuno-blotting techniques**- ELISA, Western blotting, Southern blotting. Genetic organization of Eukaryotes and Prokaryotes. Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. Introduction to Microbial biotransformation and applications. Mutation: Types of mutation/mutants.	**08**
UNIT-V	Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. Large scale production fermenter design and its various controls. Study of the production of - Penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin. Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.	**07**

Theory Sessional examination syllabus

Sessional examination No.	Syllabus
	Chapters no.
I	1,2
II	3,4
III	5

Recommended books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606T. PHARMACEUTICAL QUALITY ASSURANCE (Theory)

Teacher/s: **45 Hours (3 Hrs/ week)**

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, the student shall be able to understand:

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to pharmaceutical industries
4. Understand the responsibilities of QA & QC departments

Course Content:

Topics		Hrs
UNIT-I	**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	**10**
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.	**10**

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.	**10**
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.	**08**
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.	**07**

Recommended Books: (Latest Edition)

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

BP610P. REPORT ON INDUSTRIAL TRAINING

Training of students at an industrial establishment or an approved research laboratory. The industrial training shall include: in case of industry- different sections and subsections of the industry, an idea about the functioning of the industry, product range of the industry and various approvals of the industry; in case of research laboratory- different departments of the laboratory, an idea about the interdisciplinary coordination, contribution of the laboratory to the society and various approvals of the laboratory. A proper report of the same shall be submitted by the students, which shall be subsequently evaluated to assess the impact of the visit.

May be performed at the end of the 5th semester.