Where talent meets opportunity

SRI SATYA SAI UNIVERSITY
OF TECHNOLOGY AND MEDICAL SCIENCES

SYLLABUS REVISION

Name of School-Faculty of Pharmacy

Department/Program- Pharmacy/(B.Pharma & M.Pharma)

2017-18 TO 2021-22

www.sssutms.co.in

Opp.Oilfed Plant, Bhopal-Indore Road,Sehore (M.P), Pin - 466001

(+91) 07562-292740 | 7562292720

Sri Satya Sai University of Technology and Medical Sciences, Sehore
Faculty of Pharmacy
Minutes of Board of studies Meeting

A Meeting faculty members of the department is organized in School of Pharmacy, SSSUTMS as per the details below:

Date : May 18, 2018

Place : Dean, Faculty of Pharmacy Cabin

Agenda I: Regarding approval of change in curriculum of B.Pharmacy III Year & M.Pharm II year Pharmaceutics/Pharmacology (choice based credit semester system) as per latest gazette notification no.-362 dated 11/12/2014 of PCI New Delhi.
Agenda II: Regarding approval of B.Pharma IV year Non-CBCS.
Agenda III: A new value added course "Hematological interpretation" & "Modern Techniques involved in synthesis and analysis of drug" are implemented after taking the feedback from all sukeholders for increasing the skill of students.
Decision: It was decided to introduce update syllabus/Scheme of B.Pharmacy III Year, M.Pharm II year Pharmaceutics/Pharmacology (choice based credit semester system) as per latest gazette notification of PCI New Delhi & approval for continuing Non-CBCS curriculum for B.Pharma IV year & Value added courses.

Following Members were presem

Dr. Ashok Kumar Budhwani (Subject Expert)
Dr. Jitendra Malik (Subject Expert)
Dr. Neelesh Chaubey (Chairman)
Dr. Hemant Sharma (Member)
Dr. C.K. Tyagi (Member)
Mr. Harish Pandey (Member)
Dr. Sunil Shah (Member)
Mr. Narendra Patel (Member)
Mr Jitendra Sigh Lodhi (Member)
Mr. Pradeep Patra (Member)
Mr. Yogendra Malviya (Member)
Miss Deepika Sahu (Member)
Mrs. Jyoti Jamaliya (Member)
Mr. Firoz Khan (Member)
Mr. Wazid Ali (Member)
Mr.Dinesh Somwanshi (Member)
Mr.Dharmendra Siloriya (Member)
Mrs. Sujata Kushwaha (Member)
Miss Deepshikha Gunwan (Member)
Miss Sana Sahil (Member)

Minutes of meeting was forwarded to the academic council for the information.

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Chairman
(BOS)

SRI SATYA SAI

University of Technology and Medical Sciences

(ESTABLISHED UNDER GOVT OF M.P. AND REGISTERED UNDER UGC 2(F) 1956)
Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Choice Based Credit System

Scheme

Bachelor of Pharmacy - V Semester (2016-17)

(4 YDC.)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Periods/ Hours			Total Credits	
			Theory			Practical							
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Lab Work	Assignment/ Quiz	L	T	P		
1	BP501	Medicinal Chemistry II	75	15	10	-	-	-	3	1	0	4	
2	BP502	Industrial Pharmacy-I	75	15	10	35	10	5	3	1	4	6	
3	BP503	Pharmacology II	75	15	10	35	10	5	3	1	4	6	
4	BP504	Pharmacognosy and Phytochemistry- II	75	15	10	35	10	5	3	1	4	6	Total Marks
5	BP505	Pharmaceutical Jurisprudence	75	15	10	-	-	-	3	1	0	4	
			375	75	50	105	30	15	15	5	12	26	650

L : Lecture T : Tutorial P : Practical

(As Per PCI New-Delhi)

Note: A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. program if he/she secures at least 50% marks in that particular course including internal assessment

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BP501 MEDICINAL CHEMISTRY-II (Theory)

45 Hours

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

10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody
H1-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines 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, Levocetrazine Cromolyn sodium.

H_2-antagonists: Cimetidine*, Famotidine, Ranitidine.

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

Anti-neoplastic agents:
Alkylating agents: Mechlorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa
Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine,Cytarabine, Methotrexate*, Azathioprine
Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin
Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate
Miscellaneous: Cisplatin, Mitotane.

UNIT – II **10 Hours**

Anti-anginal:
Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbidedinitrite*, Dipyridamole.
Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazemhydrochloride, 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, Benazeprilhydrochloride, 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, Cholestaramine andCholestipol
Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*,Anisindione, clopidogrel
Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide Bosentan, Tezosentan

UNIT- IV **08 Hours**

Drugs acting on Endocrine system
Nomenclature, Stereochemistry and metabolism of steroids
Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol,Oestrione, Diethylstilbestrol.
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.

UNIT – V **07 Hours**

Antidiabetic agents: Insulin and its preparations
Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride, Biguanides: MetforminThiazolidinediones:Pioglitazone, RosiglitazoneMeglitimides: Repaglinide,

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Nateglinide. Glucosidaseinhibitors: 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.*

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 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

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BP502 INDUSTRIAL PHARMACY-I (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence ofpharmaceutical 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: **3hours/week**

UNIT-I

07 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study ofphysicochemical characteristics of drug substances.

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

b. **Chemical Properties:** Hydrolysis, oxidation, reduction, racemisation, polymerizationBCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

10 Hours

Tablets:

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

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

Quality control tests: In process and finished product tests

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

UNIT-III

08 Hours

Capsules:

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

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

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

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UNIT-IV

10 Hours

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.
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 eyedrops, eye ointments and eye lotions; methods of preparation: labeling, containers; evaluation of ophthalmic preparations.

UNIT-V

10 Hours

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

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

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

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BP 502 P. INDUSTRIAL PHARMACY (Practical)

(4 hours/week)

1. Preformulation study for prepared granules
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets-film coating of tablets/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 &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 by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

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BPS03 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 10hours

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.

UNIT-II 10hours

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 10hours

3. Autacoids 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.

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e. Non-steroidal anti-inflammatory agents
f. Anti-gout drugs
g. Antirheumatic drugs.

UNIT-IV

08hours

5. 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

07hours

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

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BP 503 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.
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 PA$_2$ value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 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 software's and video.

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 Lippincon 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.

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BP504 : PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how thesecondary 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 **7 Hours**

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 **14 Hours**

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

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Ligums, Tea, Rutu

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond.

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III **06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

a) **Terpenoids:** Menthol, Citral, Artemisin

b) **Glycosides:** Glycyrrhetinic acid & Rutin

c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine

d) Resins: Podophyllotoxin, Curcumin

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UNIT IV **10 Hours**

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

UNIT V **8 Hours**

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

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BP 504 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 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. Saunders & Co., London, 2009.
2. Mohammad Ali, Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996). 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.

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BP505 PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Scope: This course is designed to impart basic knowledge on several importantlegislations 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
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 **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the act and rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

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

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

UNIT-II 10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

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

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penaltiesLabeling & 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 analysis, Licensing authorities, controlling authorities, Drugs Inspectors.

UNIT-III **10 Hours**

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

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

Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives,Definitions,

Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation,opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV **08 Hours**

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

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

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

UNIT-V **07 Hours**

Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquirycommittee, 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 Editions)

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).

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SRI SATYA SAI

University of Technology and Medical Sciences

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Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Choice Based Credit System

Scheme [4 YDC,]

Bachelor of Pharmacy - VI Semester [2016-17]

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Periods/ Hours			Total Credits	
			Theory			Practical							
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Lab Work	Assignment/ Quiz	L	T	P		
1	BP601	Medicinal Chemistry III	75	15	10	35	10	5	3	1	4	6	
2	BP602	Pharmacology III	75	15	10	35	10	5	3	1	4	6	
3	BP603	Herbal Drug Technology	75	15	10	35	10	5	3	1	4	6	
4	BP604	Biopharmaceutics and Pharmacokinetics	75	15	10	-	-	-	3	1	-	4	
5	BP605	Pharmaceutical Biotechnology	75	15	10	-	-	-	3	1	-	4	Total Marks
6	BP606	Quality Assurance	75	15	10	-	-	-	3	1	-	4	
			450	90	60	105	30	15	18	6	12	30	750

L : Lecture T : Tutorial P : Practical

(As Per PCI New-Delhi)

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Note: A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. program if he/she secures at least 50% marks in that particular course including internal assessment

BP601 MEDICINAL CHEMISTRY – III (Theory)

45 Hours

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

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

10 Hours

Antibiotics

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

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design

Antimalarials: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Arremether, Atovoquone.

UNIT – III

10 Hours

Anti-tubercular Agents

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

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine 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*, Methenamine.

Antiviral agents: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV

08 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, Diloxamide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

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

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*

UNIT – V

07 Hours

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet'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.

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BP 601 MEDICINAL CHEMISTRY- III (Practical)

(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 ROS)

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. Vogels rganic 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.

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BP603 PHARMACOLOGY-III (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 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 poisoningsand
3. Appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10 hours**

1. 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

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.

UNIT-II **10 hours**

Chemotherapy

a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III **10 hours**

Chemotherapy

a. Antitubercular agents

b. Antileprotic agents
Anti-fungal agents
c. Antiviral drugs. Anthelmintics

f. Antimalarial drugs
g. Antiamoebic agents

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UNIT-IV

08 hours

Chemotherapy

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

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

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

UNIT-V

07 hours

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
c. General principles of treatment of poisoning
d. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

6. Chronopharmacology

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

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BP 602 PHARMACOLOGY-III (Practical)

(4hrs/week)

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)

**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,
2. Churchil Livingstone Elsevier
3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
5. 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
6. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
7. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
8. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
11. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

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BP 803 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 **06 Hours**

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs

Selection, identification and authentication of herbal materials Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

UNIT-II **05 Hours**

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

b) Preparation and standardization of Ayurvedic formulations viz Arishta and Asawas, Ghutikas,Churna, Lehya and Bhasma.

UNIT-III **07 Hours**

Nutraceuticals

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

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

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

UNIT-IV **10 Hours**

Herbal Cosmetics

ources 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- V **10 Hours**

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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-VI **07 Hours**

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

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

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

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

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BP 643 HERBAL DRUG TECHNOLOGY (Practical)

(4 hours/ week)

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of Ash value
3. Determination of moisture content of crude drugs
4. Determination of Extractive values of crude drugs
5. Determination of the alcohol content of Asava and Arista
6. Preparation of herbal cosmetics
7. Preparation and standardization of herbal formulation
8. Determination of swelling index and foaming index
9. Monograph analysis of herbal drugs from recent Pharmacopoeias
10. Analysis of fixed oils

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.

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SSSUTMS SEHORE (M.P.)

BP 604 BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

Scope: This subject 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: Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics.
2. Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
3. Critically evaluate biopharmaceutic studies involving drug product equivalency
4. Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

Course Content:

UNIT-I **10 Hours**

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 of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding, Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II **10 Hours**

Drug Elimination renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

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

UNIT- III **10 Hours**

Pharmacokinetics: Introduction to Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations,

Calculations of K_a, K_e From plasma and urinary excretion data

UNIT- IV **08 Hours**

Multicompartment *mmr models*: Two compartment open model. IV bolus

***Multiple – Dosage Regimens*:**

a). Repitirive Intravenous injections – One Compartment Open Model

b). Repitirive Extravascular dosing – One Compartment Open model

UNIT- V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters, Biotransformation of drugs

Recommended **Books:** (Latest Editions)

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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 International edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R, Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescot 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 Febiger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebon F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

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BP 605 PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

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 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

10 Hours

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 products:
d) Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.
e) Brief introduction to PCR

Types of immunity- humoral immunity, cellular immunity

Unit III

10 Hours

a) Structure ructure 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

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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.

Unit V 07 Hours

a. Types of mutation/mutants.
b) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
c) Large scale production fermenter design and its various controls.
d) Study of the production of - penicillins, citric acid, Vitamin B12, Gluconic acid, Griseofulvin.

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 Goldsby 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., Whitaker A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

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BP 606 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 covers 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 Q5EM, 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 procedure

UNIT – II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

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

UNIT – III **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing Material terials.

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

UNIT – IV **08 Hours**

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

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

UNIT – V **07Hours**

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

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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 Dekkker Series.

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University of Technology and Medical Sciences

(ESTABLISHED UNDER GOVT OF M.P. AND REGISTERED UNDER UGC 2(F) 1956)
Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Credit Based Semester System

Scheme

Master of Pharmacy - III Semester (Pharmaceutics)
(2 YDC, Session-2017-2018)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Credits Hours		Total Credits	Marks
			Theory			Practical						
			End Sem	Mid Sem Test (Internal)	Continuous Mode	End Sem	Mid Sem Test (Internal)	Continuous Mode	L	P		
1.	MPH 301T	Research Methodology and Biostatistics*	75	15	10	-	-	-	4	-	4	100
2.	MPH 302T	Journal Club	-	25	-	-	-	-	1	-	1	25
3.	MPH 303T	Discussion / Presentation (Proposal Presentation)	-	50	-	-	-	-	2	-	2	50
4.	MPH 304P	Research work*	-	-	-	350	-	-	-	28	14	350
Total			75	90	10	350			7	28	21	525

L : Lecture P : Practical

*Non University Examination
(As Per PCI New-Delhi)

Journal Club: Review submission of Major Research Project report submission (topic for the same should be other than major research Topic (Dissertation)). Students have to submit report of 25 Pages in Soft Copy to Head Computer College.

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Semester III

MPH301T/MPL301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology : Research, objective, requirements, practical difficulties, review of literature, study design, types of studies,strategies to eliminate errors/bias, controls, randomisation, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size,factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA. Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence,non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication,control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility : Goals, veterinary care, quarantine, surveillance, diagnosis,treatment and control of disease,personal hygiene,location of animal facilities to laboratories, anesthesia,euthanasia,physical facilities, environment,animal husbandry,record keeping,SOPs,personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

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Credit Based Semester System

Scheme

Master of Pharmacy - IV Semester (Pharmaceutics)
(2 YDC, Session-2017-2018)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Credits Hours		Total Credits	Marks
			Theory			Practical						
			End Sem	Mid Sem Test (Internal)	Continuous Mode	End Sem	Mid Sem Test (Internal)	Continuous Mode	L	P		
1	MPH 401T	Journal club	-	25	-	-	-	-	1	-	1	25
2	MPH 402T	Discussion / Final Presentation	-	75	-	-	-	-	3	-	3	75
3	MPH 403P	Research work and Colloquium	-	-	-	400	-	-	-	31	16	400
Total				100		400			4	31	20	500

L : Lecture

P : Practical

(As Per PCI New-Delhi)

Journal Club: Parent Submission, Manuscript Submission / Conference/ Seminar/ Workshop/ Presentation

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Credit Based Semester System

Scheme

Master of Pharmacy - III Semester (Pharmacology)
(2 YDC, Session-2017-2018)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Credits Hours		Total Credits	Marks
			Theory			Practical						
			End Sem	Mid Sem Test (Internal)	Continuous Mode	End Sem	Mid Sem Test (Internal)	Continuous Mode	L	P		
1.	MPL 301T	Research Methodology and Biostatistics*	75	15	10	-	-	-	4	-	4	100
2.	MPL 302T	Journal Club	-	25	-	-	-	-	1	-	1	25
3.	MPL 303T	Discussion / Presentation (Proposal Presentation)	-	50	-	-	-	-	2	-	2	50
4.	MPL 304P	Research work*	-	-	-	350	-	-	-	28	14	350
		Total	75	90	10	350			7	28	21	525

L : Lecture P : Practical

*Non University Examination
(As Per PCI New-Delhi)

Journal Club: Review submission or Minor Research Project report submission (topic for the same should be other than major research Topic (Dissertation)). Students have to submit report of 25 Pages in Soft Copy + Hard Copy to College.

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Semester III

MPH301T/MPL301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology : Research, objective, requirements, practical difficulties, review of literature, study design, types of studies,strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample site,factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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UNIT – IV

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UNIT – V

Declaration of Helsinki: History, Introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

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Credit Based Semester System

Scheme

Master of Pharmacy - IV Semester (Pharmacology)
(7 YDC, Session-2017-2018)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Credits Hours		Total Credits	Marks
			Theory			Practical						
			End Sem	Mid Sem Test (Internal)	Continuous Mode	End Sem	Mid Sem Test (Internal)	Continuous Mode	L	P		
1	MPL 401T	Journal club	-	25	-	-	-	-	1	-	1	25
2	MPL 402T	Discussion / Final Presentation	-	75	-	-	-	-	3	-	3	75
3	MPL 403P	Research work and Colloquium	-	-	-	400	-	-	-	31	16	400
Total				100		400			4	31	20	500

L : Lecture P : Practical

(As Per PCI New-Delhi)

Journal Club: Patent Submission/ Manuscript Submission / Conference/ Seminar/ Workshop/ Presentation

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MODERN TECHNIQUES INVOLVED IN SYNTHESIS AND ANALYSIS OF DRUGS

PROGRAMME:III/IV B.PHARMACY(ACADEMIC YEAR:2018-2019 ONWARDS)

DURATION:30 HOURS

S.NO	EXPERIMENT	DURATION
01	Synthesis and characterisation of Benzimidazole using parallel synthsizer	4hrs
02	Study of drug molecules by using ChemSketch software	4hrs
03	TLC analysis of selected medicinal compounds	3hrs
04	Chemistry of Remdesivir and Falpiravir	2hrs
05	Microwave extraction and isolation of piperine from black paper	4hrs
06	Determination of pKa value of selected drugs	3hrs
07	Computation tools for studying ADMET properties of drug designing	4hrs
08	Lipinskii rule of five for studying physiochemical properties of drug molecule	3hrs
09	Assay of Glipizide Tablets	3hrs

*NOTE:

Assessment test on skill development course will be conducted on final day after omplition of course.

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Approved by Madhya Pradesh Private University Regulatory Commission

Hematological Interpretations

Course duration: 35 hrs

Aim: To develop independent capabilities in a student to learn and apply the knowledge of hematology through interpretation of test results in identifying blood related problems and their diagnosis.

Objectives:

- To train a student so as to ensure higher competency in clinical pathology dealing with blood (blood related diseases, their causes, processes and effects).
- He/she is expected to perform collection of blood from different sites depending on age of patient and procedures to be done.
- He/she is expected to perform routine hematological evaluation such as complete blood count (hemoglobin estimation, bleeding time, clotting time, Random blood sugar, total RBC count, total WBC count and Differential WBC count) of collected blood samples.
- He/she is expected to have an understanding of collection and interpretation of data. He/she is expected to have an understanding of normal ranges and altered values, diseases in which they are altered and processes involved.
- He/she is expected to deal with correct professional handling, examination, interpretation.

Skills:

To develop confidence in graduate students to handle and to manage laboratory and research responsibilities in future.

Course Content:

1. Introduction and scope of hematology
2. Physiology of Blood
   a. Blood cells
      i. RBC
      ii. WBC
      iii. Platelets

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b. Plasma

3. HematologyTests: complete blood count tests
4. Interpretation of complete blood count tests

   a. Normal values
   b. Altered values
   i. Conditions in which values are increased
   ii. Conditions in which values are decreased

5. Blood disorders and disease processes

Approach: Topics to be covered as lectures, demonstrations and seminars.

Reference Books:

- Textbook of Haematology by Tejindar Singh
- Bethesda Handbook of Clinical Hematology 3rd Edition
- Hematology for Students and Practitioners by Ramnik Sood
- Practicals and Quick Review by Ganga S.Pilli
- For Applied aspects : Textbook of Oral Pathology by Shafer
- Text book of human physiology by Chatterjee

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Sri Satya Sai University of Technology and Medical Sciences, Sehore
Faculty of Pharmacy
Minutes of Board of studies Meeting

A Meeting faculty member of the department is organized in School of Pharmacy, SSSUTMS as per the details below:

Date : May 15, 2019

Place : Dean, Faculty of Pharmacy Cabin

Agenda I: Regarding approval of change in curriculum of B.Pharmacy IV Year (choice based credit semester system) as per latest gazette notification dated 11/12/2014 of PCI New Delhi.

Agenda II: New value added course "Recent Trends in Experimental Pharmacology and Analysis of Drugs" & "Interview Competence and Group Discussion" is implemented after taking the feedback from all stakeholders for increasing the skill of students.

Decision: It was decided to introduce update syllabus/Scheme of B.Pharmacy IV Year, (choice based credit semester system) as per latest gazette notification of PCI New Delhi.
New value added course "Recent Trends in Experimental Pharmacology and Analysis of Drugs" & "Interview Competence and Group Discussion" are approved.
Following Members were present

Dr. Ashok Kumar Budhwani (Subject Expert)
Dr. Jitendra Malik (Subject Expert)
Dr. Neelesh Chaubey (Chairman)
Dr. Hemant Sharma (Member)
Dr. C.K. Tyagi (Member)
Mr. Harish Pandey (Member)
Dr. Sunil Shah (Member)
Mr. Narendra Patel (Member)
Mr Jitendra Sigh Lodhi (Member)
Mr. Pradeep Patra (Member)
Mr. Yogendra Malviya (Member)
Miss Deepika Sahu (Member)
Mrs. Jyoti Jamaliya (Member)
Mr. Firoz Khan (Member)
Mr. Wazid Ali (Member)
Mr.Dinesh Somwanshi (Member)
Mr.Dharmendra Siloriya (Member)
Mrs. Sujata Kushwaha (Member)
Miss Deepshikha Gunwan (Member)
Miss Sana Sahil (Member)

Minutes of meeting was forwarded to the academic council for the information.

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Chairman
(BOS)

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Choice Based Credit System

Scheme (4 YDC,)

Bachelor of Pharmacy - VII Semester (2016-17)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Periods/ Hours			Total Credits	
			Theory			Practical							
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Lab Work	Assignment/ Quiz	L	T	P		
1	BP701	Instrumental Methods of Analysis	75	15	10	35	10	5	3	1	4	6	
2	BP702	Industrial Pharmacy-II	75	15	10	-	-	-	3	1	-	4	
3	BP703	Pharmacy Practice	75	15	10	-	-	-	3	1	-	4	
4	BP704	Novel Drug Delivery System	75	15	10	-	-	-	3	1	-	4	
5	BP705	Practice School*	-	-	-	125	-	25	-	-	12	6	Total Marks
			300	60	40	160	10	30	12	4	16	24	600

L : Lecture T : Tutorial P : Practical

* The subject experts at college level shall conduct examinations

(As Per PCI New-Delhi)

Note: A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. program if he/she secures at least 50% marks in that particular course including internal assessment

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BP701INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to Underst and the interaction of matter with electromagnetic radiations and its applications in drug analysis. Underst and the chromatographic separation and analysis of drugs. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectralz shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

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

UNIT –II **10 Hours**

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations.

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications.

Flame Photometry- Principle, interferences, instrumentation and applications.

Atomic **absorption spectroscopy**- Principle, interferences, instrumentation and applications.

Nepheloturbidometry- Principle, instrumentation and applications.

UNIT –III 10 Hours

Introduction to chromatography

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

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

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

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

UNIT –IV **08 Hour**

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

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

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UNIT –V **07 Hours**

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

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

BP 701INSTRUMENTAL METHODS OF ANALYSIS (Practical)

(4 hours/week)

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2. Estimation of dextrose by colorimetry
3. Estimation of sulfanilamide by colorimetry
4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5. Assay of paracetamol by UV- Spectrophotometry
6. Estimation of quinine sulfate by fluorimetry
7. Study of quenching of fluorescence
8. Determination of sodium by flame photometry
9. Determination of potassium by flame photometry
10. Determination of chlorides and sulphates by nephelo turbidometry
11. Separation of amino acids by paper chromatography
12. Separation of sugars by thin layer chromatography
13. Separation of plant pigments by column chromatography
14. Demonstration experiment on HPLC
15. Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K. Sharma.
2. Organic spectroscopy by Y.R Sharma.
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors.
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel.
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake.
6. Organic Chemistry by I. L. Finar.
7. Organic spectroscopy by William Kemp.
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

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BP 702 INDUSTRIAL PHARMACY-II (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product commercialization from laboratory to market

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

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different laws and acts that regulate pharmaceutical industry in India and US
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I **10 Hours**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to Platform technology.

UNIT-II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation , confidentiality agreement , licensing, MoUs , legal issues.

UNIT-III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure(IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP.

UNIT-V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization(CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

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Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http.//en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http://www.cgmp.com/ra.htm.

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BP 703 PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice ofHospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

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

Unit I: **10 Hours**

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

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

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

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

Unit II: **10 Hours**

a) Drug distribution system in a hospital Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

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

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

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

e) Patient medication history interview Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management Financial, materials, staff, and infrastructure requirements.

Unit III **10 Hours**

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

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

Patient counseling
Definition of patient counseling: steps involved in patient counseling, and Special cases that require the pharmacist.
Education and training program in the hospital Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.
Prescribed medication order and communication skills Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

UNIT IV **8 Hours**

Budget preparation and implemenation
Budget preparation and implementation
Clinical Pharmacy: Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.
Dosing pattern the drug delivery based on pharmacokinetic and disease pattern.
Over the counter (OTC) sales
Introduction and sale of over the counter, and Rational use of common over the counter medications.

Unit V **7 Hours**
Drug store management and inventory control: Organization of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure
Investigational use of drugs: Description, principals involved classification, control, identification, role of hospital pharmacist, advisory committee.
Interpretation of Clinical Laboratory Tests Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakashan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of ClinicalPharmacy Practice-essential concepts and skills*, 1sted. Chennai: OrientLongman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2006.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*. 10th ed. India: CBS Publishers & Distributers; 2006.

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BP 704 NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able. To understand various approaches for development of novel drug delivery systems. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation.

Course content:

Unit-I **10 Hours**

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

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

Unit-II **10 Hours**

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

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

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

Unit-III **10 Hours**

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

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

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

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Unit-IV **08 Hours**

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

Unit-V **07 Hours**

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome--Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages ,development of intra uterine devices (IUDs) and applications.

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

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Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Choice Based Credit System

Scheme (4 yDC.)

Bachelor of Pharmacy - VIII Semester (2016-17)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Periods/ Hours			Total Credits	
			Theory			Practical							
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Lab Work	Assignment/ Quiz	L	T	P		
1	BP801	Biostatistics and Research Methodology	75	15	10	-	-	-	3	1	-	4	
2	BP802	Social and Preventive Pharmacy	75	15	10	-	-	-	3	1	-	4	
3	BP803E	Pharmaceutical Marketing*	75 + 75 = 150	15 + 15 = 30	10 + 10 = 20	-	-	-	3+3=6	1+1=2	-	4+4=8	Total Marks
4	BP804E	Pharmaceutical Regulatory Science*											
5	BP805E	Pharmacovigilance*											
6	BP806E	Quality Control and Standardizations of Herbals*											
7	BP807E	Computer Aided Drug Design*											
8	BP808E	Cell and Molecular Biology*											
9	BP809E	Cosmetic Science*											
10	BP810E	Experimental Pharmacology*											
11	BP811E	Advanced Instrumentation Techniques*											
12	BP812	Project Work	-	-	-	150	-	-			12	6	
			300	60	40	150	00	00	12	4	12	22	550

L : Lecture T : Tutorial P : Practical

(As Per PCI New-Delhi)

* Elective (Any Two)

Note: A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. program if he/she secures at least 50% marks in that particular course including internal assessment

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SBP801 BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory) 45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and.Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Objectives: Upon completion of the course the student shall be able to Know the operation of M.S. Excel, SPSS, R and MINITAB', DoE (Design of Experiment) Know the various statistical techniques to solve statistical problems Appreciate statistical techniques in solving the problems.

Course content:

Unit-I **10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation -Pharmaceuticals examples

Unit-II **10 Hours**

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x= a + by, Multiple regression, standard error of regression- Pharmaceutical Examples

Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problems .Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples.

Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference.

Unit-III **10 Hours**

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal- Wallistest, Friedman Test.

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism,

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

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

Unit-IV **8 Hours**

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using

Excel, SPSS, MINITAB*, DESIGN OF EXPERIMENTS, R -Online Statistical Software's to Industrial and Clinical trial approach.

Unit-V **7Hours**

Design and Analysis of experiments:
Factorial Design: Definition, 2^3, 2^4design. Advantage of factorial design
Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Gupta
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Panneerselvam.
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

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BP 802SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

Scope: The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives: After the successful completion of this course, the student shall be able to: Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide. Have a critical way of thinking based on current healthcare development. Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

Course content:

Unit I: **10 Hours**

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health.

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II: **10 Hours**

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia. hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: **10 Hours**

National health programs, its objectives, functioning and outcome of the following:

HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National. Programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV: **08 Hours**

National health intervention programme for mother and child. National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V: **07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

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Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition. 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita DHiremath Dhanunjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications.
5. Park Textbook of Preventive and Social Medicine, K. Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

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BP803E: PHARMACEUTICAL MARKETING (Theory)

45 Hours

Scope: The pharmaceutical industry not only needs highly qualified researchers, chemist, technical people but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management. The career in product management starts from having hands on experience in sales and marketing only.

Course Objective: The course aim is to provide an understanding of marketing concepts and techniques and the application of the same in the pharmaceutical industry.

Unit I

10 Hours

Marketing: Definition, general concepts, and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior, industrial buying behavior.

Pharmaceutical market: Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

Unit II

10 Hours

Product decision: Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III

10 Hours

Promotion: methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit IV

10 Hours

Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V

10 Hours

Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price

management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi .
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Meenakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Namakumari, S: Marketing Management: Global Perspective, Indian Context,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

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BP804 E: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, drug products in regulated countries like US, EU, Japan, Australia and Canada. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products in regulated countries.

Objectives: Upon completion of the subject student shall be able to; Know about the process of drug discovery and development. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I **10Hours**

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

Unit II **10Hours**

Regulatory Approval Process Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA / ANDA.

Regulatory authorities and agencies Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III **10Hours**

Registration of Indian drug product in overseas market: Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

Unit IV **8Hours**

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

Unit V **07Hours**

Regulatory Concepts Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

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Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD. 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory ComplianceBy Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John Gallin and Frederick P. Ognibene.
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

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BP 803EPHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives: At completion of this paper it is expected that students will be able to (know, do, and appreciate): Why drug safety monitoring is important. History and development of pharmacovigilance National and international scenario of pharmacovigilance Dictionaries, coding and terminologies used in pharmacovigilanceDetection of new adverse drug reactions and their assessment International standards for classification of diseases and drugs Adverse drug reaction reporting systems and communication in pharmacovigilance Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation Pharmacovigilance Program of India (PvPI) ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning CIOMS requirements for ADR reporting Writing case narratives of adverse events and their quality.

Course Content

UNIT I — 10 Hours

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events.
- Regulatory terminologies

UNIT I I — 10 Hours

Drug and disease classification

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

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Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs .

Establishing pharmacovigilance programme

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

Unit III 10 Hours

- Vaccine safety surveillance
- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization.

Pharmacovigilance methods

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

Communication in pharmacovigilance

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

UnitIV 8Hours

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports

- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies.

Unit V 07Hours

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta. Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Waller, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& Barlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/

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17. http://www.ipc.gov.in/PvPI/pv_home.html

BP 806 E: QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

45 hours

Scope: In this subject the student learns about the various methods and guidelines forevaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

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

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

Unit I **10 hours**

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

Unit II **10 hours**

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP intraditional system of medicine.WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

EU and ICH guidelines for quality control of herbal drugs.Research Guidelines for Evaluating the Safety and **Efficacy of Herbal Medicines**

Unit IV **08hours**

Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.
Role of chemical and biological markers in standardization of herbal products

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Recommended Books: (Latest Editions

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals, Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Applications of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva. 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.

WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

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BP 807 E: COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand, Design and discovery of lead molecules, The role of drug design in drug discovery process, The concept of QSAR and docking, Various strategies to develop new drug like molecules. The design of new drug molecules using molecular modeling software

Course Content

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies.

UNIT-II **10 Hours**

Quantitative Structure Activity Relationship (QSAR) SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III **10 Hours**

Molecular Modeling and virtual screening techniques

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

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

UNIT-IV **08 Hours**

Informatics & Methods in drug design Introduction to Bioinformatics, chemo informatics, ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V **07 Hours**

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics, Energy Minimization methods and Conformational Analysis, global conformational minima determination.

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Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC, "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro Ikovas A, Burckhalter JH, "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" JohnWiley& Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H. eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York

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BP808E: CELL AND MOLECULAR BIOLOGY (Theory) 45 Hours

Scope: Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function. This is done both on a microscopic and molecular level. Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organismssuch as humans, plants, and sponges.

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

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

Course content:

Unit I 10 Hours

a) Cell and Molecular Biology: Definitions theory and basics and Applications.
b) Cell and Molecular Biology: History and Summation.
c) Theory of the Cell? Properties of cells and cell membrane.
d) Prokaryotic versus Eukaryotic
e) Cellular Reproduction
f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II 10 Hours

a) DNA and the Flow of Molecular Structure
b) DNA Functioning
c) DNA and RNA
d) Types of RNA
e) Transcription and Translation

Unit III 10 Hours

a) Proteins: Defined and Amino Acids
b) Protein Structure
c) regularities in Protein Pathways
d) Cellular Processes
e) Positive Control and significance of Protein Synthesis

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Unit IV **08 Hours**

a) Science of Genetics
b) Transgenics and Genomic Analysis
c) Cell Cycle analysis
d) Mitosis and Meiosis
e) Cellular Activities and Checkpoints

Unit V **07 Hours**

a) Cell Signals: Introduction
b) Receptors for Cell Signals
c) Signaling Pathways: Overview
d) Misregulation of Signaling Pathways
e) Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Prabuher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.

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BPS091: COSMETIC SCIENCE (Theory)

45Hours

UNIT I

10Hours

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, Classification and application **Skin:**

Basic structure and function of skin. **Hair:** Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II

10 Hours

Principles of formulation and building blocks of skin care products: Face wash, Moisturizing cream, Cold Cream, Vanishing cream their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Antiperspants & deodorants- Actives & mechanism of action. Principles of formulation and building blocks of Hair care products: Conditioning shampoo, Hair conditioner, anti-dandruff shampoo, Hair oils. Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth, Teeth whitening, Mouthwash.

UNIT III

10 Hours

Sun protection. Classification of Sunscreens and SPF.
Role of herbs in cosmetics:
Skin Care: Aloe and turmeric
Hair care: Henna and amla.
Oral care: Neem and clove
Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

UNIT IV

08 Hours

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer, Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps,and syndet bars. Evolution and skin benfits.

UNIT V

07 Hours

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. .Antiperspirants and Deodorants- Actives and mechanism of action

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References

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.

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BP810 EXPERIMENTAL PHARMACOLOGY

PHARMACOLOGICAL SCREENING METHODS 45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies inexperimental animals including design, conduct and interpretations of results.

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

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research.
- Appreciate and demonstrate the importance of biostatistics and research methodology.
- Design and execute a research hypothesis independently.

Unit –I 08 Hours

Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthenasia.

Unit –II 10 Hours

Preclinical screening models

Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups.
Rationale for selection of animal species and sex for the study.

Study of screening animal models for
Diuretics, nootropics, anti-Parkinson's,antiasthmatics,

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

Unit –III 10 hours

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

Unit –IV

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants

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Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

Research methodology and Bio-statistics 05 Hours

Selection of research topic, review of literature, research hypothesis and study design

Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richa

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BP 811 E: ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative andquantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able tounderstand the advanced instruments used and its applications in drug analysis.understand the chromatographic separation and analysis of drugs. understand the calibration of various analytical instruments .know analysis of drugs using various analytical instruments. **Course Content:**

UNIT-I **10 Hours**

Nuclear Magnetic Resonance spectroscopy Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques– Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II **10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications

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

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

UNIT-III **10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

UNIT-IV **08 Hours**

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

Extraction techniques:General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V **07 Hours**

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

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Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel.
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake.
6. Organic Chemistry by I. L. Finar.
7. Organic spectroscopy by William Kemp.
8. Quantitative Analysis of Drugs by D. C. Garrett .
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi.
10. Spectrophotometric identification of Organic Compounds by Silverstein.

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BP 812 . DIETARY SUPPLEMENTS AND NUTRACEUTICALS

No. of hours :3 **Tutorial:1** **Credit point:4**

Scope : This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objective:

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to :

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

UNIT I

07 hours

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

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

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

UNIT II

15 hours

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

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lenin

b) Sulfides: Diallyl sulfides, Allyl trisulfide.

c) Polyphenolics: Resevretrol

d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones

e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum

f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans

g) Tocopherols

h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III

07 hours

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b) Dietary fibres and complex carbohydrates as functional food ingredients..

UNIT IV 10 hours

a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

c) Functional foods for chronic disease prevention.

UNIT V 06 hours

a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK, HACCP and GMPs on Food Safety. Adulteration of foods.

c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. E.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2 nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors 2000 Functional foods Woodhead Publ.Co.London.
7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA. Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea and Febig.

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Semester VIII – Elective course on Pharmaceutical Product Development

No of Hours: 3 **Tutorial:1** **Credit points:4**

Unit-I **10 Hours**

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

Unit-II **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

i. **Solvents and solubilizers**
ii. **Cyclodextrins and their applications**
iii. **Non - ionic surfactants and their applications**
iv. **Polyethylene glycols and sorbitols**
v. **Suspending and emulsifying agents vi. Semi solid excipients**

Unit-III **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

I. Tablet and capsule excipients
II. Directly compressible vehicles
iii. Coat materials
iv. Excipients in parenteral and aerosols products
v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

Unit-IV **08 Hours**

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

Unit-V **07 Hours**

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

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Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.

2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition,Informa Healthcare publishers.

3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman andLeon Lachman; Marcel Dekker, Inc.

4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.

5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.

6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.

7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40

8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.

9. Remington – The Science and Practice of Pharmacy, 20th Ed.

10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz

11. Pharmaceutical Dosage Forms – Disperse Systems Vol I to 3, H.A. Liberman, Martin, M.M and Gilbert S. Banker.

12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis andH.A. Libermann.

13. Advanced Review Articles related to the topics.

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IV/IV B.PHARMACY FOR THE ACADEMIC YEAR 2019-20 ONWARDS

TITLE : INTERVIEW COMPETANCE AND GROUP DISCUSSION No.of Hours : 30

OBJECTIVES : To create awareness of interview skills and group discussion and aid them to face the challenging corporate world.

The obejective of the course is to develop the student as effctive communicators and to face the corporate challenges confidently such as JAM session, interviews and group discussion.T he content will prepare the student to gain entrepreneurial and leadership traits and emerge as a daring,dashing and dianamic personality in all walks of there carrier.

COURSE OUTCOMES : On completion of the course,student will be able to

1	Undersatanding the purpose of professional interviews.
2	Identify the different types of professional interviews.
3	Obtain important tips on preparing for the professional interviews.
4	Articulate the impotance of self presentation.

S.NO	CONTENTS	PRESCRIBED HOURS
1	Importance of communications skills	2 hours
2	Importance of soft skills	2 hours
3	Social etiquette	2 hours
4	Telephone etiquette	2 hours
5	Basics of JAM skills	2 hours
6	Basics of inerview skils	2 hours
7	How to face an interview board	2 hours
8	Ten worst interview blunders	2 hours
9	Interviews skills mock practice-Questions and Answers	10 hours
10	Importance of group discussions	2 hours
11	Resume preparation	1 hours
12	Key to success in life	1 hours

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DEPARTMENT OF PHARMACOLOGY

SYLLABUS FOR SKILLS DEVELOPMENT COURSE ON

"RECENT TRENDS IN EXPERIMENTAL PHARMACOLOGY AND ANALYSIS OF HERBAL DRUGS"

Department :Pharmacology
Participants : IV/IV B.pharmacy students
Duration :30 hrs

COURSE OUTCOMES	
CO-1	To demostrate the significance of CPCSEA guidelines and to demostrate various routes of drug administration and blood collection techniques for laboratory animals.
CO-2	To summarize screening models for Psychotropic/neurotropic, learning and memory activities.
CO-3	To interupt various preclinical models for drugs acting on CVS and PNS.
CO-4	To compile analysis of herbal drugs, DNA barcoding.

1.CPCSEA Guidelines **4 hrs**
Goal and objectives,compositions,activities,IAEC –Functioning,requirements for animals house,maintenance of records.

2.Laboratory Animals **4 hrs**
Identification of animals species,sex,strain and breeding,Handeling of animals,routes of administration,dosing and blood collection techniques.

3.Animal House Facility **3 hrs**
Environment,physical facilities, animals procurement,quarintine,stabalization,seperation,breeding,housing,maintenace of laboratory animals,surveillance,diagnosis,treatment and control of disease,personal hygiene.

4.Psycotropic and Neurotropic activity **4 hrs**
Anti epileptic activity(electroconvulsiometer),anti aggressive activity(agressometer) ,behaviour (locomotor activity-actophotometer,hole board test),anxiolytic activity(elevated plus maze,open field test),anti,psycotic activity(CAR).

5.Nootropic or learning memory activity. **3 hrs**
Spatial long term memory(Elevated plus maze),Working memory(8-Arm radial maze),spatial working memory (Y Maze,Rectangular maze),Learning, memory and resoning(Hebbs William Maze and Lbyrnth Maze).

6.Cardiovascular activity: **5 hrs**
Anti-hypertensive activity by non-invasive blood pressure measurement techniques[NIBP]/Invasive blood pressure measurement(2-channel physiograph), anti-hyper-lipidmic activity(high fat diet inclused/streptozotocin).

7.Analgesic activity(EDDY'S hot plate/tail- flick analgesiometer),Anti-diabetic activity(allaxan/streptozotocin)/ Diuretic activity **3 hrs**

8.Analysis of herbal drugs and DNA bar coding of Herbs **2 hrs**

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Sri Satya Sai University of Technology and Medical Sciences, Sehore
Faculty of Pharmacy
Minutes of Board of studies Meeting

A Meeting faculty member of the department is organized in School of Pharmacy, SSSUTMS as per the details below:

Date : JUNE 05, 2017

Place : Dean, Faculty of Pharmacy Cabin

Agenda I: Regarding approval of change in curriculum of B.Pharmacy II Year & M.Pharm I year Pharmaceutics/Pharmacology (choice based credit semester system) as per latest gazette notification no.-362 dated 11/12/2014 of PCI New Delhi.

Agenda II: Regarding approval of B.Pharma III & IV year Non-CBCS & M.pharma II year (Pharmaceutics/Pharmacology) Non-CBCS.

Agenda III: A new value added course "Professional Ethics and Human value" & "Communication skills and soft skills "is implemented after taking the feedback from all stakeholders for increasing the skill of students.

Decision: It was decided to introduce update syllabus/Scheme of B.Pharmacy II Year, M.Pharm I year Pharmaceutics/Pharmacology (choice based credit semester system) as per latest gazette notification of PCI New Delhi & approval for continuing Non-CBCS curriculum for B.pharma III & IV year /M.Pharma II year & Value added courses.

Following Members were present

Dr. Ashok Kumar Budhwani (Subject Expert)
Dr. Jitendra Malik (Subject Expert)
Dr. Neelesh Chaubey (Chairman)
Dr. Hemant Sharma (Member)
Dr. C.K. Tyagi (Member)
Mr. Harish Pandey (Member)
Dr. Sunil Shah (Member)
Mr. Narendra Patel (Member)
Mr Jitendra Sigh Lodhi (Member)
Mr. Pradeep Patra (Member)
Mr. Yogendra Malviya (Member)
Miss Deepika Sahu (Member)
Mrs. Jyoti Jamaliya (Member)
Mr. Firoz Khan (Member)
Mr. Wazid Ali (Member)
Mr.Dinesh Somwanshi (Member)
Mr.Dharmendra Siloriya (Member)
Mrs. Sujata Kushwaha (Member)
Miss Deepshikha Gunwan (Member)
Miss Sana Sahil (Member)

Minutes of meeting was forwarded to the academic council for the information.

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Chairman
(BOS)

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University of Technology and Medical Sciences

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Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Choice Based Credit System

Scheme

Bachelor of Pharmacy - III Semester (2016-17)
(4 YDC,)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Periods/ Hours			Total Credits	
			Theory			Practical							
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Lab Work	Assignment / Quiz	L	T	P		
1	BP301	Pharmaceutical Organic Chemistry II	75	15	10	35	10	5	3	1	4	6	
2	BP302	Physical Pharmaceutics I	75	15	10	35	10	5	3	1	4	6	
3	BP303	Pharmaceutical Microbiology	75	15	10	35	10	5	3	1	4	6	
4	BP304	Pharmaceutical Engineering	75	15	10	35	10	5	3	1	4	6	Total Marks
			300	60	40	140	40	20	12	4	16	24	600

L : Lecture T : Tutorial P : Practical

(As Per PCI New-Delhi)

Note: A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. program if he/she secures at least 50% marks in that particular course including internal assessment

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BP301 PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

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

1. Write the structure, name and the type of isomerism of the organic compound.
2. Write the reaction, name the reaction and orientation of reactions.
3. Account for reactivity/stability of compounds.
4. Prepare organic compounds.

Course Content:

1. General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained.
2. To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences.

UNIT I **10 Hours**

Benzene and its derivatives

A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule

B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.

C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction

D. Structure and uses of DDT, Saccharin, BHC and Chloramine.

UNIT II **10 Hours**

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

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

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

UNIT III **10 Hours**

Fats and Oils

Fatty acids – reactions.

Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV **08 Hours**

Polynuclear hydrocarbons:

a. Synthesis, reactions

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b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V **07 Hours**

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

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BP301 PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

(4 hrs/week)

I Experiments involving laboratory techniques: -

- Recrystallization
- Steam Distillation

II Determination of following oil values (including standardization of reagents)

- Acid Value
- Saponification Value
- Iodine Value.

III Preparation of Compounds

1. Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol/Aniline by acylation reaction.
2. 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline.
3. Acetanilide by halogenation (Bromination) reaction.
4. 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
5. Benzoic acid from Benzyl chloride by oxidation reaction.
6. Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
7. 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
8. Benzil from Benzoin by oxidation reaction.
9. Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction.
10. Cinnamnic acid from Benzaldehyde by Perkin reaction.
11. P-Iodo benzoic acid from P-amino benzoic acid.

Recommended Books (Latest Editions):

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

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BP302 PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physical, physicochemical properties andprinciple involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

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

1. Understand various physicochemical properties of drug molecules in the designing the dosage form
2. Know the principles of chemical kinetics & to use them in assigning expiry date for formulation
3. Demonstrate use of physicochemical properties in evaluation of dosage forms.
4. Appreciate physicochemical properties of drug molecules in formulation research and development

Course Content:

UNIT-I **10 Hours**

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partiallymiscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II **10Hours**

States of Matter and properties of matter: State of matter, changes in the state of matter, latera heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols
– inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.
Physicochemical properties of drug molecules: Refractive index, optical rotation,dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III **08 Hours**

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

UNIT-IV **08Hours**

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

UNIT-V **07 Hours**

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

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BP 302 P. PHYSICAL PHARMACEUTICS – I (Practical)

(4hrs. /week)

1. Determination the solubility of drug at room temperature.
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. . Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubilitymethod
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical pharmacy by Alfred Martin
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosum J. Pharmaceutical calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-I to 3, MarcelDekker Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekker Inc.
7. Physical pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory manual of physical pharmaceutics, C.V.S. Subramanyam, J. Thimma setties
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. . Text book of Physical Pharmacy, by Gaurav Jain & Roop K. Khar

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BP 303 PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope: In the broadest sense, scope of microbiology is the study of all organisms that are invisible to the naked eye- that is the study of microorganisms. Microorganisms are necessary for the production of bread, cheese, beer, antibiotics, vaccines, vitamins, enzymes etc. Microbiology has an impact on medicine, agriculture, food science, ecology, genetics, biochemistry, immunology etc.

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

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. Importance of sterilization in microbiology, and pharmaceutical industry
3. Learn sterility testing of pharmaceutical products.
4. Microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

Unit I

10 Hours

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

Unit II

10 Hours

Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC).
Study of principle, procedure, merits, demerits and applications of Physical, chemical, gaseous radiation and mechanical method of sterilization.
Evaluation of the efficiency of sterilization methods,equipments employed in large scale sterilization. Sterility indicators.

Unit III

10 Hours

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

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV

08 Hours

Designing of aseptic area, laminar flow equipment; study of different sources of contamination in an aseptic area and methods of prevention clean area classification.
Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.
Assessment of a new antibiotic.

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Unit V

07 Hours

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

Preservation of pharmaceutical products using antimicrobial agents, Evaluation of microbial stability of formulations

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

Application of cell cultures in pharmaceutical industry and research.

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BP 303 P. PHARMACEUTICAL MICROBIOLOGY (Practical)

(4 hrs/week)

1. Introduction and study of different equipment and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dun, Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig. Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris. Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Prohisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan.
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthanarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi.
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

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BP 308 PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and scienceof various unit operations used in pharmaceutical industry.

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

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

Course content:

UNIT-I

10 Hours

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

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

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

UNIT-II

10 Hours

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

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

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

UNIT- III

08 Hours

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

Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silvers on Emulsifier

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UNIT-IV **08 Hours**

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

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

UNIT- V **07 Hours**

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

Recommended Books: (Latest Edition)

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

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BP 304 PHARMACEUTICAL ENGINEERING (Practical)

(4 hours/week)

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

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SRI SATYA SAI

University of Technology and Medical Sciences

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Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Choice Based Credit System

Scheme

Bachelor of Pharmacy - IV Semester (2016-17)
(4 YDC,)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Periods/ Hours			Total Credits	
			Theory			Practical							
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Lab Work	Assignment/ Quiz	L	T	P		
1	BP401	Pharmaceutical Organic Chemistry III	75	15	10	-	-	-	3	1	0	4	
2	BP402	Medicinal Chemistry I	75	15	10	35	10	5	3	1	4	6	
3	BP403	Physical Pharmaceutics II	75	15	10	35	10	5	3	1	4	6	
4	BP404	Pharmacology I	75	15	10	35	10	5	3	1	4	6	
5	BP405	Pharmacognosy and Phytochemistry I	75	15	10	35	10	5	3	1	4	6	Total Marks
			375	75	50	140	40	20	15	5	16	28	700

L : Lecture T : Tutorial P : Practical

(As Per PCI New-Delhi)

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Note: A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. program if he/she secures at least 50% marks in that particular course including internal assessment

BP401 PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

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

1. Understand the methods of preparation and properties of organic compounds.
2. Explain the stereo chemical aspects of organic compounds and stereo chemical reactions.
3. Know the medicinal uses and other applications of organic compounds.

Course Content

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

UNIT-I **10 Hours**

Stereo Isomerism

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

UNIT-II **10 Hours**

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

UNIT-III **10 Hours**

Heterocyclic compounds

Nomenclature and classification, Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene - Relative aromaticity, and reactivity of pyrrole, Furan unf thiophene.

UNIT-IV **8 Hours**

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

UNIT-V **07 Hours**

Reactions of synthetic importance

Metal hydride reduction (NaBH$_4$ and LiAlH$_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement, Claisen-Schmidt condensation

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Recommended Books (Latest Editions)

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

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BP 402 MEDICINAL CHEMISTRY-1 (Theory)

45 Hours

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 (sar) of different class of drugs.
4. Write the chemical synthesis of some drugs.

Course Content:

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

UNIT- I **10 Hours**

Introduction to Medicinal Chemistry History and development of medicinal chemistry Physicochemical properties in relation to biological action **Ionization**, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation **Bioisosterism**, Optical and Geometrical isomerism.

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

UNIT- II **10 Hours**

Drugs acting on Autonomic Nervous System
Adrenergic Neurotransmitters:
Biosynthesis and catabolism of catecholamine. Adrenergic receptors (Alpha & Beta) and their distribution.
Sympathomimetic agents: SAR of Sympathomimetic agents
Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,
M ethyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine. Agents with mixed mechanism: Ephedrine, Metaraminol.
Adrenergic Antagonists:Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide. **Beta adrenergic blockers:** SAR of beta blockers, Propranolol*, Metibranolol, Atenolol. Bevazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III **10 Hours**

Cholinergic neurotransmitters:
Biosynthesis and catabolism of acetylcholine.Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.**Parasympathomimetic agents: SAR of Parasympathomimetic agents.Direct acting agents:** Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.**Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):**
Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.
Cholinesterase reactivator: Pralidoxime chloride.**Cholinergic Blocking agents: SAR of cholinolytic**

agents. Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.**Synthetic cholinergic blocking agents:** Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV **08 Hours**

Drugs acting on Central Nervous System

Sedatives and Hypnotics:

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

Barbiturates: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscellaneous:Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

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

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

Fluro butersphenones: Haloperidol, Droperidol, Risperidone.

Bera amino kerones: Molindone hydrochloride.

Benzamides: Sulpiride.

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

Barbiturates: Phenobarbitone, Methabarbital

Hydantoins: Phenytoin*, Mephenytoin, Ethotoin

Oxazolidine diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide, Ethosuximide*

Urea and monocyclurates: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid , Gabapentin, Felbamate

UNIT-V **07 Hours**

Drugs acting on Central Nervous System

General anesthetics:

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

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

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

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

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

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

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BP402 P. MEDICINAL CHEMISTRY – 1 (Practical)

(4 hours/week)

I	**Preparation of drugs/ Intermediates**
1	1,3-pyrazole
2	1,3-oxazole
3	Benzimidazole
4	Benzotriazole
5	2,3- diphenyl quinoxaline
6	Benzocaine
7	Phenytoin
8	Phenothiazine
9	Barbiturate
II	**Assay of drugs**
1	Chlorpromazine
2	Phenobarbitone
3	Atropine
4	Ibuprofen
5	Aspirin
6	Furosemide

III **Determination of Partition coefficient for any two drugs**

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.

BP 403 PHYSICAL PHARMACEUTICS-II (Theory)

45 Hours

Scope: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

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

1. Understand various physicochemical properties of drug molecules in the designing the dosage form.
2. Know the principles of chemical kinetics & to use them in assigning expiry date for Formulation.
3. Demonstrate use of physicochemical properties in evaluation of dosage forms.
4. Appreciate physicochemical properties of drug molecules in formulation research and Development.

Course Content:

UNIT-I **07 Hours**

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

UNIT-II **10 Hours**

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

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

UNIT-III **10 Hours**

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

UNIT-IV **10 Hours**

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

UNIT-V **10 Hours**

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of

pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis. Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention.

BP 403 PHYSICAL PHARMACEUTICS- II (Practical)

(3 hrs/week)

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

Recommended Books: (Latest Editions)

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

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BP 404 PHARMACOLOGY-I (Theory)

45 Hrs

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

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

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

Course Content

UNIT-I

08 Hours

General Pharmacology

Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination.

UNIT-II

12 Hours

General Pharmacodynamics

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

Adverse drug reactions.

Drug interactions (pharmacokinetic and pharmacodynamic)

Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III 10 hours

Pharmacology of drug acting peripheral nervous system

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

UNIT-IV 08 Hours

Pharmacology of drugs acting on central nervous system

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

UNIT-V 07 Hours

Pharmacology of drugs acting on central nervous system

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

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(4hrs/week)

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

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

Recommended Books (Latest Editions)

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 experimenal pharmacology. VallabhPrakashan,

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45 Hours

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

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

1. To know the techniques in the cultivation and production of crude drugs.
2. To know the crude drugs, their uses and chemical nature.
3. Know the evaluation techniques for the herbal drugs.
4. To carry out the microscopic and morphological evaluation of crude drugs.

Course Content:

UNIT-I 10 Hours

Introduction to Pharmacognosy:
(a) Definition, history, scope and development of Pharmacognosy

(b) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

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

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II 10 Hours

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

UNIT-III 07 Hours

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in pharmacognosy. Edible vaccines

UNIT IV 10 Hours

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

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V 08 Hours

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

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

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopepridase, urokinase, streptokinase, pepsin).
Lipids(Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax
Marine Drugs:
Novel medicinal agents from marine sources

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BP 405 PHARMACOGNOSY-I (Practical)

(4 hours/week)

1. Analysis of crude drugs by chemical tests: (i)Tragacanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions)

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

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Scheme of Examination

Fifth Semester- Bachelor of Pharmacy

S.No.	Subject Code	Subject Name	Periods per week			Credits	Maximum Marks (Theory Slot)		Maximum Marks (Practical Slot)		Total Marks
			L	T	P		End Sem. Exam.	Mid Sem.	End Sem. Practical & Viva	Practical mid sem+ Viva+Practical Record	
1	BPH501	Pharmaceutics –VI (Cosmetic Technology)	3	1	2	4+2=6	70	30	60	40	200
2	BPH502	Pharmaceutics – VII Dispensing, Community and Hospital Pharmacy	3	1	2	4+2=6	70	30	60	40	200
3	BPH503	Pharmaceutical Chemistry - VI (Medicinal Chemistry-I)	3	1	2	4+2=6	70	30	60	40	200
4	BPH504	Pharmacognosy-III	3	1	2	4+2=6	70	30	60	40	200
5	BPH505	Pharmacology-II	3	1	2	4+2=6	70	30	60	40	200
		TOTAL	15	5	10	30	350	150	300	200	1000

Note: - One Credit Refers to one hour Teaching in Theory and two Hours in Practical
L: Lecture - T: Tutorial - P: Practical

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PHARMACEUTICS-VI (BPH501)
(COSMETIC TECHNOLOGY)

Unit – I

Fundamental of cosmetic science: Structure and functions of skin. Formulation considerations, preparation, packaging and evaluation of the following categories of cosmetics.

Face Preparations: Face powder, Compact powder, Talcum powder, Face packs.

Skin Preparation: Skin creams, Anti-wrinkle preparations, Vanishing creams, Cold creams, Cleansing creams, all-purpose creams, Anti-perspirant, / deodorant, Moisturizing and foundation formulation. Bleaching creams, Night and Massage creams, Hand creams.

Protective creams and gels: Sun-screen, Sunum, and Anti-sun burn preparation.

Unit –II

Structure and functions of hair & Hair Preparations: Formulation considerations, preparation, packaging and evaluation of the following categories of cosmetics.

Hair Preparations: Hair tonics, Hair conditioners, Hair lotions, Hair sprays, Hair dressings, Hair setting lotions and creams, Hair dyes, Bleaches, Hair waiving, Hair straighteners .

Shampoo and Bath preparations: Clear liquid shampoos, Dry shampoos, Acid-balanced shampoos, Egg shampoos, Anti-dandruff Shampoos, foam baths.

Unit –III

Herbal Cosmetics: Cosmetics containing Aloe, Bahul, Brahmi, Chandan, Cucumber, Haldi, Jatavansi, Khus, Mehandi, Neem, Reetha, Shikakai, Tulsi, Amica, Bhringraj and Volatile oils.

Unit-IV

Colored make-up preparations: Lipsticks, Rouge, Mascara, Eye make-up, Eye-liner, Eyebrow pencils.

Manicure Preparation: Nail polish, Nail lacquers and Nail bleaches.

Cosmetic for babies.

Unit-V

Dentifrices: Tooth powders, Tooth pastes, Denture cleansers.

Shaving Preparation: Lather shaving stick, Lather shaving creams, Shaving foams, Shaving gels, pre-and after shave lotions.

Text Books

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1. M. S. Balsam & Edward Sagarin (Eds.), Cosmetic Science and Technology, Vol. 1-3, Krieger Publishing company. Florida.
2. Jellinek, J.S. Formulation and Functions of Cosmetics, John Willey & Sons, New York.
3. R. K . Nema, K. S. Rathode, B.K. Dubey, Text Book of Cosmetics, CBS- Publishers & distributors, New Delhi.
4. Sunil Nanda, Arun Nanda & R.K. Khar, Cosmetic Technology, Birla publications Pvt. Ltd., Delhi.
5. B. M. Mithal and R.N. Saha, A handbook of cosmetics, Vallabh Prakashan, Delhi.
6. S.C. Bhatia, Perfumes, soaps, Detergents and Cosmetics Vol. 1 & 2, CBS Publishers and Distributors, New Delhi.

Reference Books

1. P.P. Sharma, Cosmetics- Formulation, Manufacturing & Quality control,Vandana Publications Pvt. Ltd, Delhi
2. Hildo Butler (Ed.), Poucher's Perfumes, Cosmetics & Soaps, Kluwer Academic Publishers, The Netherland.
3. E.G., Thomasen, Modern Cosmetics, Universal Publishing Corporation, Bombay.
4. Mac Chesney, J. C., Packaging of Cosmetic an Toiletries. Newness- Butterworth, London

Practical

LIST OF PRACTICALS:

1. Prepare, Pack and Evaluate Compact Powder.
2. Prepare and Face pack
3. Prepare and Evaluate Talcum Powder.
4. Prepare and Evaluate Vanishing Cream.
5. Prepare and Evaluate Cold Cream.
6. Prepare and Evaluate Cleansing Cream.
7. Prepare and Evaluate Sunscreen preparation.
8. Prepare and Evaluate After shave lotion.
9. Prepare and Evaluate Lather shaving cream.
10. Prepare and Evaluate Simple shampoo (Soap based).
11. Prepare and Evaluate Acid balanced shampoo.
12. Prepare and Evaluate Egg shampoo.
13. Prepare and Evaluate Anti-dandruff Shampoo..
14. Prepare and Evaluate Tooth Powder.
15. Prepare and Evaluate Tooth Paste.
16. Prepare, Pack and Evaluate Lipsticks.
17. Prepare, Pack and Evaluate Nail lacquer.
18. Prepare and submit Herbal preparations. (Atleast 5 different types)

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PHARMACEUTICS - VII (BPH502)
(DISPENSING, COMMUNITY AND HOSPITAL PHARMACY)

UNIT-I

Dispensing Pharmacy: Prescription, Handling of prescription, Sources of errors in prescription, Care required in dispensing prescriptions. Brief introduction of commonly used Latin terms in prescription.

General Dispensing Procedures including labeling of dispensed products.

UNIT-II

Principles involved and procedures adopted in dispensing, compounding container, storage, dose, some special label conditions (if any)- Powders, Tablets, Capsules, Solutions, Mixtures, Suspensions, Emulsions, Lotions, Liniments, Ophthalmic, Suppositories.

UNIT-III

Incompatibility in Prescription: Physical, Chemical and Therapeutic incompatibilities. Incompatibility of common occurrence and their correction.

Posology: Basis of posology, Detection of over doses in prescription, knowledge of prophylactic and therapeutic doses with route of administration.

UNIT-IV

Community Pharmacy: Organization and structure of retail and wholesale drug stores, Legal requirements for establishment and maintenance. Dispensing of proprietary products, Maintenance of records of retail and wholesaler, Patient counseling, Role of Pharmacist in community health care and education, Hazards of medication, Inventory control.

UNIT-V

Hospital Pharmacy: Organization and structure of a hospital pharmacy, responsibilities of Pharmacist in PTC, Drug monitoring and drug information.

Hospital Formulary: Contents, preparation and revision of hospital formulary.

LIST OF PRACTICALS:

1. Prepare and Dispense Simple Powder.
2. Prepare and Dispense Compound Powder.
3. Prepare and Dispense Simple Tablet.

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4. Prepare and Dispense effervescent granules.
5. Prepare and Dispense Dusting Powder.
6. Prepare and Dispense Simple Mixture containing Soluble substances only.
7. Prepare and Dispense Emulsion.
8. Prepare and Dispense Emulsion containing Volatile oils.
9. Prepare and Dispense Calamine lotion.
10. Prepare and Dispense turpentine liniment.
11. Prepare and Dispense prescription possessing Physical Incompability (Incomplete Solution).
12. Prepare and Dispense prescription possessing Physical Incompability (Precipitation).
13. Prepare and Dispense prescription possessing Chemical Incompability (Alkaloidal salts with alkaline substances).
14. Prepare and Dispense prescription possessing Chemical Incompability (Alkaloidal salts with soluble iodides).
15. Prepare and Dispense prescription possessing Chemical Incompability (Evolution of carbon dioxide).

BOOKS RECOMMENDED:

1. Allwodd M. C. and Fell J. T., Text book of Hospital Pharmacy, Blackwell Scientific Publication, Oxford.
2. Hassan W. E., Lea and Febiger, Philadelphia Hospital Pharmacy.
3. J.S. Qadry, R.K. Goyal & R.K. Parika, Merchant & Qadry's a text book of Hospital Pharmacy, B.S. Shah Prakashan, Ahmedabad.
4. Pratibha Nand & R.K. Khar, Text Book of Hospital & Clinical Pharmacy, Birla Publications Pvt Ltd., Delhi.
5. S.J. Carter (Ed.), Cooper & Gunn's Dispensing for Pharmaceutical Students, CBS Publishers & Distributors, New Delhi.
6. R.M. Mehta, Dispensing Pharmacy, Vallabh Prakashan, Delhi.
7. S.N. Sharma & N.K. Jain, the Concise Pharmaceutical Dispensing, Prakash B. Printers,Baroda.
8. N.K. Jain & G.D. Gupta, Modern Dispensing Pharmacy, PharmaMed Press, Hyderabad.
9. E.W. Martin, Dispensing of Medications (Formerly Husa's Pharmaceutical Dispensing)Mack Publishing Company, Eastern Pa.

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PHARMACEUTICAL CHEMISTRY-VI (BPH503)
(MEDICINAL CHEMISTRY- I)

UNIT - I

Basic Principles of MedicinalChemistry: Physico-chemical aspects (Optical, geometric and bioisosterism) of drug molecules and biological action; Drug receptor interaction including transduction mechanisms.
Brief concept on QSAR: Free Wilson model, Hansch analysis – its derivation and discussion on different parameters like electronic parameters, steric factor, and partition coefficient. Comparison between Free Wilson model and Hansch analysis, Molecular Connectivity Index.

UNIT - II

Drug metabolism: Phase I (biotransformation reactions), phase II (conjugation reactions), factors affecting drug metabolism.
Prodrug: Basic concept and its application.

UNIT - III

Classification, mode of action, uses and structure activity relationship of the following classes of drugs.
Drugs affecting adrenergic mechanism: Adrenergic receptors, biosynthesis of Catecholamines, chemical classification along with structures, S.A.R of adrenergic drugs, adrenergic agonists, adrenergic blockers.
Drugs affecting cholinergic mechanism: Introduction, SAR, cholinergic receptors, study of cholinergic agonists, indirectly acting cholinergic agonists, cholinergic blocking agents, and neuromuscular blocking agents.
Local Anesthetics': Introduction, chemical classification, ideal requirements, mode of action, SAR, structures of important local anaesthetics, metabolism and synthesis of benzocaine, procaine, lidocaine, tetracaine and cinchocaine.

UNIT - IV

Autacoids:
(i) Antihistamines: Diphenhydramine, Mepyramine, Chlorpheniramine, Promethazine, Chlorcyclizine, Cimetidine, Ranitidine.
(ii) Eicosanoids: Occurrences, Chemical nature, Medicinal applications
(iii) **Analgesic, Antipyretics, Anti-inflammatory (non-steroidal) agents:** Aspirin, Paracetamol, Ibuprofen, Phenylbutazone, Naproxan, Diclofenac sodium.

UNIT - V

Drugs affecting the Respiratory System: Anti-asthmatics, Expectorants and Anti-tussive Agents (Salbutamol, Terbutaline, Acetylcysteine, Bromhexine Hydrochloride, Guaifensin and Levopropoxyphene Napsylate).

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Practical

1. Separation and Qualitative analysis of Organic binary mixtures containing having salt, acidic, phenolic, amphoteric, basic and neutral nature (Solid + Solid (Solid), Solid + Solid (Eutectic)) with derivative preparations.

2. Monographs of selected official drugs including identification tests and tests for purity.

3. Synthesis of selected drugs and intermediates from the course content
   (i) Synthesis of Phenyl benzoate
   (ii) Synthesis of Methyl Pyrazolone
   (iii)Synthesis of Phenytoin
   (iv)Synthesis of Fluorescein
   (v)Synthesis of Benzimidazole

MEDICINAL CHEMISTRY – I

Reference Books:

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers - New York, Philadelphia.
2. William.O. Foye's, Principles of Medicinal Chemistry, B.I.Waverly Pvt. Ltd., New Delhi.
3. Burgers, Medicinal Chemistry, M.E.WeHy, Med.Chemistry M.E.
4. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
5. Pandeya N S "A Text book of Medicinal Chemistry" Vol. I and II , S.G. Publisher, 6, Dildayal Nagar, Varanasi -10
6. Indian Pharmacopoeia, 1996, 2007, 2010, The Controller of Publications, Civil Lines, Delhi - 54.
7. Kar, A., Medicinal Chemistry, Willey Eastern Ltd., New Delhi.
8. Vogel's Text book of Practical Organic Chemistry, ELBS/ Longman, London
9. Singh, H., Kapoor, V.K. Medicinal and Pharmaceutical Chemistry,Vallabh Prakashan New Delhi.

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PHARMACOGNOSY - III (BPH504)

Unit-I

Biosynthesis: Introduction to biogenesis

A. Employment of Radio-tracer techniques in Biogenetic studies.
B. A brief account of primary and secondary metabolite's production from carbon metabolism in plants.
C. Study of Calvin cycle, TCA cycle, Shikimic acid pathway, acetate hypothesis, isoprenoid pathway.
D. Biosynthesis of carbohydrates, lipids and volatile oils.

Unit-II

Extraction, Isolation and Chemistry of

A. Glycosides - Digitoxin, Diosgenin & Sarasapogenin
B. Lignans- Secoisolariciresinol diglycoside
C. Quassinoids- Bruceantin
D. Flavonoids- Rutin, Quercetin

Unit-III

Extraction, Isolation and Chemistry of Alkaloids

A. Atropine & related compounds
B. Quinine, reserpine, morphine, papaverine, ephedrine, ergot
C. Vinca Alkaloids.
D. Extraction, Isolation and Chemistry of Xanthine bases: Caffeine, theophylline and theobromine.

Unit-IV

Extraction: Theory of mass transfer, maceration, percolation, Soxhlet extraction and super critical fluid extraction.

Extraction, Isolation and Chemistry of Terpenoids: Camphor, Menthol, Citral, β- Carotene, α-Tocopherol, α-Pinene.

Unit-V

Study of Toxic Drugs: Allergens, hallucinogens, narcotics, mycotoxins, toxic mushrooms and Indian toxic plants.

A brief introduction to natural plant bitters and sweeteners.

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LIST OF PRACTICALS:

1. Identify Colchicum, Ipecac and Vinca leaves morphologically.
2. Identify Aconite, Hyoscyamus and Withania leaves morphologically.
3. Perform morphological, microscopic and chemical evaluation of Tobacco.
4. Perform morphological, microscopic and chemical evaluation of Withania.
5. Perform morphological, microscopic and chemical evaluation of Cinchona bark.
6. Perform morphological, microscopic and chemical evaluation of Rauwolfia root.
7. Perform morphological, microscopic and chemical evaluation of Nux vomica seeds.
8. Perform morphological, microscopic and chemical evaluation of Ephedra.
9. Perform morphological, microscopic and chemical evaluation of Kurchi bark.
10. Isolate Nicotine from tobacco.
11. Isolate Caffeine from tea leaves.
12. Isolate Quinine from cinchona.
13. Isolate alkaloids from nux vomica seeds.
14. Isolate starch from potatoes.
15. Perform morphological characterization like type of stomata and calculate the stomatal index, vein islets, vein termination numbers, microscopic and chemical evaluation of Datura leaves.
16. To identify and evaluate the given sample of Colchicum corm by morphological, microscopical and chemical evaluation)

BOOKS RECOMMENDED

1. Trease, G.E. and Evans, W.C., Pharmacognosy, Bailliere Tindall, Eastbourne, U.K.
2. Tayler, V.C., Brady, L.R. and Robers, J.E., Pharmacognosy, Lea and Febiger, Philadelphia.
3. Shah, C.S. and Quadry, J.S., A text book of Pharmacognosy, B.S. Shah Publishers, Ahmedabad.
4. Kokate, C.K., Purohit, A.P. and Gokhale, S.B., Pharmacognosy, Nirali Prakashan, Pune.
5. Indian Pharmacopoeia, Ministry of Health and Family Welfare, Govt. of India, New Delhi.
Wallis, T.E., Text Book of Pharmacognosy, Jand A Churchill Limited, London

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PHARMACOLOGY-II (BPH505)

Pathophysiology of CNS Disease & Pharmacology of drug used to treat them

UNIT-I

(i) Alcohol and alcoholism
(ii) Sedatives and hypnotics
(iii) Antianxiety agent & centrally acting muscle relaxants
(iv) Anticonvulsants
(v) CNS stimulants
(vi) Opoid Analgesic & antagonist
(vii) Local anesthetics & General anesthetics

UNIT-II

(A) Psychopharmacological agents
(i) Antipsychotics
(ii) Antidepressants
(iii) Antimaniacs
(iv) Hallucinogens
(B) Drugs used in neurodegenerative diseases
(i) Parkinson's Disease
(ii) Alzheimer's Disease

UNIT-III

Autocoids
(i) Histamine, bradykinin 5- HT and their antagonists.
(ii) Prostaglandins, leukotrienes and platelet activating factors.
Analgesic, Antipyretic, Anti-inflammatory and Anti-Gout Drugs:

UNIT-IV

Pharmacology of drugs acting on Respiratory System
(i) Drug therapy of asthma
(ii) Anti tussives, expectorant and mucolytic agent.

UNIT-V

Pharmacology of drugs acting on GIT
(i) Drugs used in ulcers
(ii) Drugs for treatment of diarrhoea and constipation.
(iii) Emetic and anti-emetics.

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PRACTICAL:

1. Bioassay for acetylcholine/histamine using isolated organ preparations (rat ileum/rat duodenum/rat colon/rat fundus/guinea pig ileum/guinea pig tracheal chain preparation/goat ileum)
   a) Matching bioassay or Bracketing bioassay
   b) Interpolation bioassay or graphical bioassay
2. Study the CNS depressants using cornea and pinna reflex test.
3. Study CNS stimulants by evaluation of locomotor activity (Actophotometer)
4. Study Central muscle relaxants using Rota rod apparatus
5. Study lenticular opacity produced by opioid analgesics in rodents.
6. Study anticonvulant effect of some drugs using maximum electroshock method and Chemical-induced convulsion method.
7. Study antianxiety effect of some drugs using elevated plus maze test or social interaction test or novelty suppressed feeding test in rodents.
8. Evaluate hypnotic activity of a drug by employing potentiation of thiopental induced sleeping time paradigm.
9. Study antipsychotic effect of some drugs using catalepsy test or inhibition of amphetamine stereotypy in rodents.
   Study intravenous anesthetics using righting reflex test.

BOOKS RECOMMENDED

1) Herfindal, E.T., Gourley, D.R., (eds.) (2000) Textbook of therapeutics Drug and disease management. 7th ed. Baltimore: Lippincott Williams and Wilkins

2) Hardmen, J.G., Limbird, L.E., Gilman A.,G., (eds.) (2001) Goodman and Gilman's The pharmacological basis of therapeutics. 10th ed. USA: The McGraw Hill Companies

3) Kumar, V., Abbas, A.K., Fausto, N., (eds.) (2004) Robbins and Cotran Pathologic basis of disease. 7th ed. Pennsylvania: Saunders

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Scheme of Examination

Six Semester- Bachelor of Pharmacy

S.No.	Subject Code	Subject Name	Periods per week			Credits	Maximum Marks (Theory Slot)		Maximum Marks (Practical Slot)		Total Marks
			L	T	P		End Sem. Exam.	Mid Sem.	End Sem. Practical & Viva	Practical mid sem+ Viva+Practical Record	
1	BPH601	Pharmaceutical Management	3	1	-	3+1=4	70	30	-	-	100
2	BPH602	Pharmaceutical Analysis II	3	1	2	4+2=6	70	30	60	40	200
3	BPH603	PHARMACEUTICAL CHEMISTRY – VII (Medicinal Chemistry-II)	3	1	2	4+2=6	70	30	60	40	200
4	BPH604	PHARMACOGNOSY – IV	3	1	2	4+2=6	70	30	60	40	200
5	BPH605	PHARMACOLOGY - III	3	1	2	4+2=6	70	30	60	40	200
6	BPH606	EDUCATIONAL STUDY TOUR	-	-	-	-	-	-		100	100
TOTAL			15	5	08	28	350	150	240	260	1000

Note: - One Credit Refers to one hour Teaching in Theory and two Hours in Practical
L: Lecture - T: Tutorial - P: Practical

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Pharmaceutical Management
(BPH 601)

Unit -I

Pharmaceutical Management :

Concepts on Management, Principles of Management, Administrative and Operative Management Enterpreneurship Development. Project formulation, evaluation and implementation. Status of pharmaceutical industries in India.

Pharmaceutical Factory Planning and layouts, preparation of flow diagrams, technical data sheets.

Unit -II

Pharmaceutical Economics:

Principles of economics with special reference to the laws of demands and supply, demand schedule, demand curves, general principles of insurance and inland and foreign trade, procedure of exporting and importing goods.

Unit-III

Pharmaceutical Production Management :

Different aspects of Production Management, Performance Evaluation Technique, flow-process, know how process and maintainence.

Material management: Basic principles of Material Management, Purchase, Store and Inventory control.

Unit-IV

Accountancy: Principles of accountancy, Journal entries and ledger posting, preparation of trial balance, cash book, bank reconciliation statement, rectification of errors, profits and loss account, balance sheet, purchase, keeping and pricing of stocks, treatment of cheques, bill of exchange, promissory notes and hundies, documentary bills.

Unit-v

Pharmaceutical Marketing:

Principles of sales promotion, advertising, and ethics of Sales, merchandising, Window display and literature detailing. Functions, wholesale, retail, and mail order business ,market research.

BOOKS RECOMMENDED:

1. Shukla, S. M., Advanced Accountancy, Mahershwari Sahitya Bhawan, Agra.
2. Gupta, R. L., Advanced Accountancy, Vol. I and II, Sultanchand & Company, New Delhi.
3. Koller, P., Marketing Management, Prentice Hall of India Limited.
4. Stanton, W. J., Fundamentals of Marketing Tata McGraw Hill Limited, New Delhi.
5. Buskir K. and Richard H., Principles of Marketing – The Management View, Hold Rinehard and Winston Incorporated, New York.
6. Sherlekar, S. R., Marketing Management, Himalaya Publishing House, New Delhi.
7. Mote,V. L., Paul, S. and Gupta, G. S., Managerial Economics Concepts and Cases, Tata McGraw Hill Limited, New Delhi.

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Pharmaceutical Analysis - II
(BPH 602)

UNIT-I

Chromatography: Paper Chromatography TLC, GLC, HPTLC and HPLC.

UNIT-II

Ultraviolet/Visible Molecular Absorption Spectroscopy Electromagnetic radiation – its properties and absorption by molecules, factors affecting absorption of radiation by molecules, Beer's Law and its deviations, instrumentation, sample handling techniques and pharmaceutical applications.

Atomic Absorption Spectroscopy,

UNIT-III

Infrared Spectrometry Theory of Absorption of Infrared Radiation by molecules, Infrared sources and Transducers, Instrumentation. Fourier Transform Infrared Spectroscopy, sample handling techniques and applications.

UNIT-IV

Nuclear Magnetic Resonance Spectroscopy Magnetic properties of nuclei, Origin of NMR spectrum, Environmental effects on NMR spectra, NMR spectrometers instrumentation and sample handling, applications of Proton NMR, Brief introduction to application of NMR to other nuclei.

UNIT-V

Molecular Mass Spectroscopy Origin of mass spectra, Ion sources, Mass Spectrometers – instrumentation and applications.

Flame Photometry. X- Ray Diffraction

1. **Practicals are related to theory section.**
2. **Analysis of drugs and raw materials using official pharmacopoeial methods based on modern instrumental techniques**

LIST OF PRACTICALS:

1. Determination of solvent cut off value of different solvents.
2. Study of effect of various solvents on spectral features of any drug.
3. Perform the quantitative spectrophotometric estimation of drug by single point method.
4. Perform the quantitative spectrophotometric estimation of drug by calibration curve method.
5. Perform the quantitative spectrophotometric estimation of drug by standard absorptivity method.
6. Simultaneous quantitative spectrophotometric estimation of two drugs

by simultaneous equation method.
7. Simultaneous quantitative spectrophotometric estimation of two drugs by dual wavelength method.
8. Simultaneous quantitative spectrophotometric estimation of two drugs by derivative spectroscopy.
9. To determine the tablet content of norfloxacin by hydrotrophy.
10. Interpretation of given IR spectra.
11. Quantitative estimation of alprazolam (Any drug) by RP-HPLC.
12. Simultaneous quantitative estimation of torsemide and spironolactone (Combination of two drugs) by RP-HPLC.
13. Acid and alkaline stress degradation study of any drug.
14. Photo and thermal stress degradation study of any drug.
15. Oxidative stress degradation study of any drug.

Books Recommended

1. R. M. Silverstein, G. C. Bassler and T. C. Morrihl, Spectrometric Identification of Organic Compounds, John Wiley, New York.
2. Jag Mohan, Organic Spectroscopy - Principles and Applications, Narosa.
3. D. Rendell, Fluorescence and Phosphorescence AOCL, Wiley.
4. D. A. Skoog, E. J. Holler and T. A. Nieman, Principles of Instrumental Analysis, Harcourt Asia Pte Ltd.
5. G. D. Christian, Analytical Chemistry, Wiley.
6. P. S. Kalsi, Spectroscopy of Organic Compounds, New Age Publicati

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PHARMACEUTICAL CHEMISTRY – VII
(MEDICINAL CH EMISTRY-II)
(BPH603)

UNIT- I

Classification and mode of action, uses, structure activity relationship including physicochemical, steric aspects and recent advances in research of the following categories of drugs:

Drug Acting on CNS

- General Anesthetics
- Hypnotics and Sedatives
- Antiseizure agents
- Opiod Analgesics
- Antiparkinsonian and Spasmolytic agents
- Hallucinogens, Stimulants, and related drugs of Abuse.
- Psychopharmacological Agents:,
- Anxiolytics.

UNIT -II

Drug Acting on GIT

- Laxative
- Antidiarrhoeal
- Anti spasmodic
- Antiulcers Drugs.

UNIT -III

Drug Acting on Hormonal System

- Insulin and oral Hypoglycemic agents
- Adrenocorticoids
- Sex Hormones: Male sex Hormones, Female sex Hormones.
- Thyroid and Antithyroid agents

UNIT -IV

Principles of Drug Design (Theoretical Aspects). Scientific Aspects of Drug Discovery, Preclinical Development, Mechanism based Approaches (Computer Aided Drug Design and Molecular Modeling)

UNIT - V

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Vitamins: Chemistry and Physiological function

BOOKS RECOMMENDED:

1. Foye, W.C., Principles of Medicinal Chemistry, Lea and Febiger, Philadelphia.
2. Wolff, M.E. Ed., Burger's Medicinal Chemistry, John Wiley and Sons, New York.
3. Hansch, C., Comprehensive Medicinal Chemistry, Pergamon Press, Oxford.
4. Delagado, J.N. and Remers, W.A.R, Wilson and Giswold's Text Book of Organic,Medicinal and Pharmaceutical Chemistry, J.Lippincott Co., Philadelphia.
5. Nogrady, T., Medicinal Chemistry-A Biochemical Approach, Oxford University Press, New York, Oxford.
6. Kar, A., Medicinal Chemistry, Willey Eastern Ltd., New Delhi.
7. Patrick, G., An Introduction to Medicinal Chemistry, Scientific Distributors, Mumbai.
8. Malone, Dyson and Purey, May's Chemistry of Synthetic Drugs.
9. Parimoo, P., Text Book of Medicinal Chemistry, CBS Publishers and Distributors, New Delhi.
10. Thomas, G., Introduction to Medicinal Chemistry, CBS Publishers and Distributors, New Delhi.

LIST OF PRACTICALS:

Organic spotting of binary mixtures of liquid + solid and liquid + liquid types along with identification of the type of mixture, micro-scale chemical separation, identification of the individual components, establishment of the identity of the separated components with the help of derivative preparation and TLC.

1. Synthesis and Characterization of Methylphenobarbital from Urea.
2. Synthesis and Characterization of Barbital from Urea.
3. Synthesis and Characterization of Nikethamide from Nicotinic acid.
4. Synthesis and Characterization of Pantaprazol.
5. Synthesis and Characterization of Diclofenamide.
6. Synthesis and Characterization of Phenobarbitone.
7. Synthesis and Characterization of Phenothiazine.
8. Synthesis and Characterization of Furosemide from 2,4 dichloro-benzoic acid.
9. Synthesis and Characterization of Levodopa from Vanillin.
10. Synthesis and Characterization of Sulfalene from p-aminobenzene sulphonyl chloride.
11. Synthesis and Characterization of Thioridazine.
12. Synthesis and Characterization of Chlorpromazine.
13. Synthesis and Characterization of Parbanic acid.
14. Estimation of Na^+, K^+, Ca^{++} ions using flame photometry.
15. To perform the QSAR Analysis by Free Wilson Approach.

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PHARMACOGNOSY-IV (BPH 604)

UNIT- I

Plant Tissue Culture
Historical development, nutritional requirements, growth and their maintenance, applications of plant tissue culture in Pharmacy and Pharmacognosy, and types of cultures related to cell suspension culture, callus culture, hairy root culture and protoplast culture

UNIT -II

Standardization & quality evaluation of herbal drugs: Identity, purity, assays. Macroscopic, Microscopic, Physicochemical, Phytochemical, Biological Evaluations of Herbal drugs.

UNIT- III

Introduction, classification and study of different chromatographic methods
TLC, Paper chromatography, Column chromatography, HPTLC, HPLC, GC, Ion exchange Chromatography, Size exclusion chromatography and their applications in evaluation of herbal drugs.

UNIT- IV

Marine pharmacognosy
An introduction of marine pharmacognosy and novel agents from marine sources like Cardiovascular active substances, cytotoxic, antimicrobial, antibiotic, anti-inflammatory, antispasmodic agents, marine toxin etc. Natural dyes, Immunomodulators and Adaptogents.

UNIT -V

Herbal formulation development and standardization

a) Preparation, GMP and stability testing of Herbal extracts andformulations
b) Role of Herbs in Cosmetics Hair care preparation - Henna, Amla, Hibiscus Skin Care preparation . Aloe vera, Turmeric, Sandal wood
c) Neutraceuticals, Cosmeceuticals, Phytosiomes.

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LIST OF PRACTICAL:

1. To perform chromatography of amino acids
2. To perform paper chromatography of sugars
3. To perform TLC of alkaloids
4. To perform TLC of extract of rauwolfi, datura
5. To perform TLC of volatile oils i.e. eucalyptus oil, menthe oil
6. To identify the presence of eugenol in clove oil by TLC
7. Determination of solvent extractive values (water/alcohol).
8. Determination of ash values.
9. Determination of volatile oils in crude drugs.
10. Determination of hemolytic activity.
11. Determination of foaming index and swelling index.
12. Determination of tannins.
13. Some experiments in plant tissue culture.
14. Phytochemical Evaluations of some crude drugs.

BOOKS RECOMMENDED:

1. Trease, G.E.and Evans, W.C., Pharmacognosy, Baillierc. Tindall, Eastbourne, U.K.
2. Tayler, V.E., Brady, L.R. and Robers, J.E., Pharmacognosy Lea and Febiger, Philadelphia
3. Kokate, C.K., Purohit, A.P. and Gokhale, S.B., Pharmacognosy Nirali Prakashan, Pune
4. C.R Atal and B.M. Kapoor, Cultivation & Utilization of Aromatic Plants, Council of Scientific
Industrial Research (CSIR) New Delhi

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Pharmacology-III
(BPH 605)

Unit - I

Pathophysiology of diseases of cardiovascular system and pharmacology of drugs used for their treatment

a) Cardiac Glycosides and CHF drugs
b) Antiarrythmic drugs
c) Antianginal drugs, Anti Ischemic Drugs
d) Antihypertensive drugs
e) Drug Affecting Renin-Angiotensin System

Unit - II

Pharmacology of drugs acting on hematopoietic system

a) Hematinics
b) Drugs affecting coagulation, bleeding and thrombosis
c) Plasma expanders
d) Hypolipidaemic drugs

Unit - III

Pharmacology of drugs acting on urinary system

a) Physiology of urine formation
b) Diuretic and Anti Diuretic

Unit -IV

Pathophysiology of diseases of endocrine system and pharmacology of drugs used for their treatment

a) Hypothalamic and pituitary hormones
b) Thyroid hormones and antithyroid drugs
c) Insulin, oral hypoglycemic agents and glucagons
d) Corticosteroids
e) Androgens and drugs for erectile dysfunction
f) Estrogens, progestins and contraceptives
g) Oxytocin and drugs acting on uterus
h) Drugs affecting calcium balance

Unit - IV

Vitamins and Mineral Pharmacological studies

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List of Practicals

1. Determine the strength of given sample (acetyl choline/ histamine) by three point bioassay method using isolated organ preparation (rat ileum/ rat duodenum/ rat colon/ rat fundus/ guinea pig ileum).
2. Determine the strength of given sample (acetyl choline/ histamine) by four point bioassay method using isolated organ preparation (rat ileum/ rat duodenum/ rat colon/ rat fundus/ guinea pig ileum).
3. Record the concentration response curve of oxytocin using rat uterus preparation.
4. Determine the sympatholytic activity of given drug sample using isolated guinea pig ileum preparation.
5. Compare the diuretic/saluretic activity of different drugs in rats.
6. Determine the effect of anticoagulants by subaqueous tail bleeding time method in rodents.
7. Study the effect of oral hypoglycemic agents in diabetic rodents.
8. Study the effect of thyroid hormones on the tensile strength of connective tissues in rats.
9. Study the effect of growth hormone on the weight gain in female rats.

BOOKS RECOMMENDED

1. Herfindal, E.T., Gourley, D.R., (eds.) (2000) Textbook of therapeutics Drug and disease management. 7th ed. Baltimore: Lippincott Williams and Wilkins
2. Hardmen, J.G., Limbird, L.E., Gilman A.,G., (eds.) (2001) Goodman and Gilman's The pharmacological basis of therapeutics. 10th ed. USA: The McGraw Hill Companies
3. Kumar, V., Abbas, A.K., Fausto, N., (eds.) (2004) Robbins and Cotran Pathologic basis of disease. 7th ed. Pennsylvania: Saunders
4. Barar, F.S.K., (2000) Essentials of therapeutics. New Delhi: S. Chand and Company (P) Ltd.
5. Satoskar, R.S., Bhandarkar, S.D., Rege, N.N., (2007) Pharmacology and Pharmacotherapeutics. 12th ed. Mumbai: Popular Prakashan
6. Seth, S.D., (ed.) (2005) Textbook of Pharmacology. 2nd ed. New Delhi. Elsevier
7. Tripathi, K.D. (1999) Essentials of medical pharmacology. 4th ed. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd.
8. Rang, H.P., et al. (eds.) (2003) Pharmacology. 5th ed. Philadelphia: Elsevier
9. Katzung, B.G., (2004) Basic and clinical pharmacology. 9th ed. USA: The McGraw Hill Companies.

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Scheme of Examination

Seventh Semester- Bachelor of Pharmacy

S.No.	Subject Code	Subject Name	Periods per week			Credits	Maximum Marks (Theory Slot)		Maximum Marks (Practical Slot)		Total Marks
			L	T	P		End Sem. Exam.	Mid Sem.	End Sem. Practical & Viva	Practical mid sem+ Viva+Practical Record	
1	BPH-701	Pharmaceutics –VIII (Pharm. Technology –I)	3	1	2	4+2=6	70	30	60	40	200
2	BPH-702	Pharmaceutics – IX (Bio pharmaceutics & Pharmacokinetic)	3	1	2	4+2=6	70	30	60	40	200
3	BPH-703	Pharm. Chem. VIII (Medicinal Chemistry–III)	3	1	-	4	70	30	-	-	100
4	BPH-704	Pharmaceutical Biotechnology	3	1	2	4+2=6	70	30	60	40	200
5	BPH-705	Pharmacology-IV (Clinical & Drug Interactions)	3	1	-	4	70	30	-	-	100
6	BPH-706	Project Work	-	-	2	2	-	-	50	-	50
Total			15	5	8	28	350	150	230	120	850

Note: - One Credit Refers to one hour Teaching in Theory and two Hours in Practical

L: Lecture - T: Tutorial - P: Practical

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Pharmaceutics- VIII (Pharmaceutical Technology –I)
(BPH701)

Formulation considerations, technology involved, equipment (machine) employed problems to be encountered, packaging evaluation and CMP (India, WHO & USFDA) requirements of the following dosage forms.

Unit-1

Solid Dosage Forms: Tablets, Tablet coatings and Capsules.

Semisolid Dosage Forms: ointments, Creams, Suppositories, Gels.

Unit-2

Liquid Dosage Forms: Liquid Orals, Dry Syrups.

Pharmaceutical Aerosol: Method of Preparation & Evaluation of Aerosol.

Unit-3

Sterile Dosage Forms: Parenteral (Small Volume Parenteral & Large Volume Parenteral) and ophthalmic Preparations, Evaluation of Sterile Dosage Forms.

Unit-4

Surgical products:

Definition, surgical cotton, surgical gauzes, bandages, adhesive tapes, absorbable and non-absorbable sutures, ligatures and catguts, Medical prosthetics and organ replacement materials.

Unit-5

Blood Products and Plasma Substitutes:

Collection, processing and storage of whole human blood, concentrated human RBC, dried human plasma, human normal immunoglobulin, plasma substitutes, ideal requirements, PVP, Dextran, etc. for control of blood pressure.

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Books Recommended

1. Rawlins, E.A., Text Book of Pharmaceutics, Bailliere Tindall.
2. Liberman, H.A., lachman, L. and Ker Inc. New York.
3. Pharmacopoeia Of India, Ministry of Health and family Welfare, Govt. of India, New Delhi.
4. Avis, K.E., Lachman, L.and Liberman, H.A., Pharmaceutical Dosage Forms-Parenteral Medication Vol.1-2, Marcel Decker Inc., New York.
5. Banker G.S. and Rhode C.T., Modern Pharmaceutics, Marcell Decker Inc., New York.
6. Bean, H.S., Beckett, A.H. and Carless, A.H., Advances in Pharmaceutical Sciences, Vol.1-4, Academic Press, London.

List of Practical

1. Prepare and evaluate Paracetamol Compressed Tablets.
2. Prepare and evaluate Effervescent Tablets of Aspirin.
3. Prepare and evaluate Dispersible tablets of Diclofenac Sodium.
4. Perform the Sugar Coating on the given sample of Tablets.
5. Perform the Film Coating on the given sample of Tablets.
6. Prepare and evaluate Antacid Suspension.
7. Prepare and evaluate B-Complex Syrup.
8. Prepare and evaluate Amoxicillin Dry Syrup.
9. Prepare and evaluate Castor Oil Emulsion.
10. Prepare and evaluate Diclofenac Sodium Suppositories.
11. Prepare and evaluate Vaporizing Ointment.
12. Prepare and evaluate Antiseptic Cream.
13. Prepare and evaluate Diclofenac Gel.
14. Prepare and evaluate Ciprofloxacin Eye Drop.
15. Prepare and evaluate Water for Injection.
16. Perform the Stability Studies of given sample of Paracetamol Tablets.

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Pharmaceutics -IX (Bio Pharmaceutics & Pharmacokinetics) (BPH702)

Unit-1

Introduction to bio pharmaceutics and pharmacokinetics development and their role in drug formulation.

Bio Pharmaceutics Definition, passage of drugs across biological barrier, Physiochemical, Biological and

Pharmaceutical factors influencing biopharmaceutical performance of drugs.

- **Gastrointestinal absorption of drugs:** Passage of drugs across biological membranes, nature of biological membranes, gastrointestinal absorption mechanisms.
- **Factors affecting drug absorption:** Physiological factors, dietary factors, physiochemical factors, pH partition hypothesis, dosage form factors.
- **Methods of studying gastrointestinal absorption:** In vitro and in vivo methods.
- **Drug disposition:** Distribution in blood, cellular distribution, plasma protein binding, tissue protein binding. Drug Excretion: Routes of drug excretion, renal excretion of drugs, factor affecting renal excretion, biliary and salivary excretion of drugs.
- **Drug Excretion:** Routes of drug excretion, renal excretion of drugs, factors affecting renal excretion, biliary and salivary excretion of drugs.
- **Drug biotransformation:** Pathways of drug metabolism, drug metabolizing enzymes, factors affecting drug metabolism and drug response, inhibition and stimulation of drug metabolism.

Unit-2

Pharmacokinetics

Absorption, distribution metabolism and excretion of drugs, fluid compartment and circulatory system, protein binding, significance of plasma drug concentration measurement.

Linear and Non Linear Pharmacokinetics

Reasons for non-linearity (saturation mechanism), Michaeles-menten equation, Definition and determination method of Vmax and Km.

Unit-3

Clinical Pharmacokinetics

Urinary excretions, computation of pharmacokinetic parameters from urine data, hepatic clearance, biliary excretion, excretion ratio, dosage regimen adjustment in patients with and without renal failure, pharmacokinetic drug interaction and their significance in combination therapy.

Unit-4

Compartment Models

Model selection criteria, alaika information criteria, one - compartment and two compartment models, Wagner-Nelson and loo Riegelman methods for estimation of absorption constants. Curve fittings, regression procedure and area under blood level curves.

Unit-5

Bioavailability and Bioequivalence

Bioavailability and Bio-equivalence, Federal requirements, Methods of determination of bioavailability using blood level and urinary excretion data, design and evaluations, bioavailability assessment.

Books recommended

1. Gibaldi, M.and Perrier d, Pharmacokinetics, 4th edn. Pharma mid press, Hydrabad
2. Notari, R.E., Biopharmaceutics and pharmacokinetics- An Introduction, marcel Decker, New York.
3. Jaiswal, Brahmankar Biopharmaquality and pharmacokinetics.
4. Leepeter I.D., Pharmacokinetic analysis
5. Niazi Textbook of Biopharmacokinetics and clinical pharmacokinetics.
6. Venkaateshwaru, Biopharmaceutics and pharmacokinetics, phared puss, Hydrabad.
7. Wagner- pharmacokinetics for the pharmastudies.
8. Dhachinamoorthi D: Biopharmaceutics and pharmacokinetics: A practical mannd
9. Shargel: pharmacokinetics & Biopharmacokinetics & Biopharmaceutics

List of Practical

1. Determine the percentage protein binding of the given drug.
2. Determine oral bioavailability of the given drug/formulation by urinary excretion method using animal model.
3. Perform bioequivalence study of two different brands of the marketed tablets of the given drug using animal model.
4. Determine the rate of in-vitro absorption of the given drug using everted intestinal sack.
5. Determine the effect of different pH condition on solubility of a weekly acidic or basic drug and study PH partition hypothesis.
6. Establish IVIVC for the given sample of drug.
7. Calculate elimination rate constant and elimination half-life of given excretion data by sigma minus method.
8. Calculate elimination rate constant and elimination half-life of the given drug data administered by I.v. bolus injection represented by one compartment model.
9. Calculate various pharmacokinetic parameters from the given data generated after single extra vascular administration of drug represented by one compartment model.
10. Calculate various pharmacokinetic parameters from the given data obtained by using two compartment open model.

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PHARMACEUTICAL CHEMISTRY-VIII

(MEDICINAL CHEMISTRY-III)

(BPH-703)

The synthesis of the selected drugs, mode of action, classification, uses, SAR of the following category of drugs:

Unit-I

Drugs Acting on Cardiovascular System:

- Cardiac Glycosides
- Anti-arrythmic Drugs
- Anti-anginal Drugs
- Anti-hypertensive Drugs
- Anti-hyperlipidimic Drugs

Unit-II

Drugs acting on Urinary System:

- Diuretics

Unit-III

Chemotherapeutic Agents-I

- Anti-metabolites (Including Sulpha durgs)
- Anti-tubercular
- Anthelmintics
- Anti-fungals
- β -lactum Antibiotics
- Aminoglycosides
- Protein synthesis inhibitors (Tetracyclins, Chloramphenicol, Macrolides)
- Miscellaneous Antibiotics (Bacitracin, Glycopeptides, Polymyxins)

Unit-IV

Chemotherapeutic Agents-II

- Anti-viral & Anti-HIV
- Anti-malarials
- Anti-protozoal
- Immuno- suppressive
- Anti-neoplastic

Unit-V

Drugs Affecting Uterine Motility

- Oxytocins (including prostaglandins and Ergot alkaloids).

Books Recommended:

1. Foye, W.C., Principles of Medicinal Chemisury, Lea and Febiger, Philadelphia.
2. Wolff, M.E. Ed., Burger's Medicinal Chemisury, John Wiley and Sons, New York.
3. Hansch, C., Comprehensive Medicinal Chemisury, Pergamon Press, Oxford
4. Delagado, J.N. and Remers, W.A.R, Wilson and Giswold's Text Book of Organic,Mediciant and Pharmaceutical Chemisury, J.Lippincott Co., Philadelphia.
5. Nogrady, T., Medicinal Chemisury-A Biochemical Approach, Oxford University Press, New York, Oxford.
6. Kar, A., Medicinal Chemistry, Willey Eastern Ltd., New Delhi.
7. Patrick, G., An Introduction to Medicinal Chemistry, Scientific Distributors, Mumbai.
8. Malone, Dyson and Purey, May's Chemistry of Synthetic Drugs.
9. Parimoo, P., Text Book of Medicinal Chemisury, CBS Publishers and Distributors, New Delhi.
10. Thomas, G., Introduction to medicinal Chemistry, CBS Publishers and Distributors, New Delhi.
11. Sten lake B.J. medicinal and pharm. Chemisury pharma mid press, Hyderabad.

BPH -704 : Pharmaceutical Biotechnology

UNIT-I

Historical Development:

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

Immunology and Immunological Preparations: Principles, Antigens and antibodies, Antigen-antibody reactions and their applications, Immune system.Cellular humoral immunity, Immunological tolerance, Hypersensitibity, Immunological and diagnostic preparations: Methods of their preparation, standardization and storage.

UNIT-II

Enzyme Immobilization – Techniques of Immobilization of enzymes, Kinetics and factors affecting enzymes kinetics, Enzymes based sensors, Study of enzymes such as Hyaluronidase, Penicillinase, StreptoKinase, Amylases etc. Immobilization of bacteria and plant cells, Applications of Immobilization.

UNIT-III

Genetic Recombination : Transformation, Conjugation, Transduction, Protoplast fusion, Gene cloning and their applications, Monoclonal antibodies and hybridoma technology, Recombinant DNA technology: Concepts, Methodology and Pharmaceutical applications. Study of drugs produced by biotechnology such as Activase, Humulin, Humatrope, Introne A, Monoclate, Orthoclone OKT3, Referon-A, Recombivax HB etc. Drug delivery systems in Gene therapy.

UNIT-IV

Microbiological Transformation – Introduction, Types of reactions mediated by microorganisms. Design of biouransformation processes, Selection of organism, Biotransformation processes and its improvements with special refrence to steroids.

UNIT-V

Industrial Biotechnology – Historical development, Fermenter and its design, Control of different parameters in fermentation process, Isolation of mutants, Use of mutagenic agents, Factors in influencing rate of mutation. Design of fermentation process, Fermentative, production of Alcohol, Acetic acid, Penicillin, Streptomycin, Riboflavin, Vitamin B12.

B.Pharm. Semester- VII. BPH 704 Pharmaceutical Biotechnology

List of Practicals

1. Detect the presence of the amylase enzyme in saliva.
2. Isolate the DNA from cauliflower.
3. Perform VDRL test for the given sample of blood.
4. Isolate the phospholipid from egg yolk.
5. Perform WIDAL test for the given sample of blood.
6. Perform DOT ELISA test of the given sample of blood.
7. Isolate the total RNA from yeast tablet.
8. Immobilize the given enzyme by adsorption method using calcium alginate beads.
9. Perform titre value of antibody in given blood sample.

BOOKS RECOMMENDED

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldsby 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., Whitaker A., and Hall J., S., Principles of fermentation technology, 2nd Edition, Aditya books Ltd., New Delhi

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PHARMACOLOGY –IV (Clinical & Drug Interactions)

(BPH-705)

UNIT- I

Classification and general consideration of antimicrobials drugs - Sulphonamides, quinolones B-lactum antibiotics Aminoglycosides Protein synthesis inhibitors (Tetracyclins,chloramphenicol,Macrolides)

UNIT -II

Classification and mechanism of action of Antitubercular drugs, antileprotic drugs,antiprotozoals, anthelmintics, antifungals Antiretroviral and antiviral drugs Miscellaneous antibiotics (Bacitracin, Glycopeptides, Polymyxins)

UNIT-III

Chemotherapy of cancer and immunosuppressive agents Basic concepts of Pharmacotherapy Individualization of drug therapy : Clinical pharmacokinetic and pharmacodynamics Drug use during pregnancy, Pediatrics and Geriatrics.

UNIT-IV

Classification and mechanism of action of drug acting on skin and mucus membrane.

UNIT-V

Miscellaneous drugs antiseptics,disinfectants,ectoparasiticides,chelating agents,vaccines and sera. Treatment of opioid, barbiturate, organophosphorous, and atropine poisoning Heavy metals and heavy metal antagonists

BOOK RECOMMENDED

1) Herfindal, E.T., Gourley, D.R., (eds.) (2000) Textbook of therapeutics Drug and disease management. 7 th ed.Baltimore : Lippincott Williams and Wilkins

2) Hardmen, J.G.Limbird, L.E. Gilman A., G., (eds.) (2001) Goodman and Gilman's The pharmacological basis of therapeutics. 10th ed. USA : The McGraw Hill Companies

3) Barar, F.S.K., (2000) Essential of therapeutics. New Delhi: S. Chand and Company (P) Ltd.

4) Satoskar, R.S. Bhandarkar, S.D., Rege, N.N., (2007) Pharmacology and Pharmacotherapeutics. 12th ed. Mumbai: Popular Prakashan

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5) Seth, S.D., (ed.) (2005) Textbook of Pharmacology. 2nd ed. New Delhi. Elsevier.

6) Tripathi, K.D. (1999) Essentials of Medical pharmacology. 4th ed. New Delhi : Jaypee Brothers Medical Publishers (P) Ltd.

7) Rang, H.P., et. (eds.) (2003) Pharmacology. 5th ed. Philadelphia Elsevier.

8) Katzung , B.G., (2004) Basic and clinical pharmacology. 9th ed. USA : The Mcgraw Hill Companies.

9) Dipiro, J.T., et al. (eds.) (1997) Pharmacotherapy. A pathophysiologic approach. 3rd ed. Stanford, Connecticut: Appleton and Longe.

10)Craig, C.R., Stitzel, R.E. (1999) Modern pharmacology with clinical applications. 5th ed. USA.

11) Guideliness for poison control. (1999) WHO, Geneva: AITBS Publisher, Delhi

12) Curry – Drug disposition and pharmacokinetics with a consideration of pharmacokinetics with a consideration of pharmacological and elinical relationships, 3rd edn., pharmumed pre

13) Kenakin Terry P: A pharmacological Primer – theory applications & methods, pharma med prre

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Scheme of Examination

Eighth Semester- Bachelor of Pharmacy

S.No.	Subject Code	Subject Name	Periods per week			Credits	Maximum Marks (Theory Slot)		Maximum Marks (Practical Slot)		Total Marks
			L	T	P		End Sem. Exam.	Mid Sem.	End Sem. Practical & Viva	Practical mid sem+ Viva+Practical Record	
1	BPH-801	Pharmaceutics – X(Pharmaceutical Technology -II)	3	1	2	4+2=6	70	30	60	40	200
2	BPH-802	Pharmaceutics –XI (Pharmaceutical Jurisprudence)	3	1	-	4	70	30	-	-	200
3	BPH-803	Pharmaceutical Analysis –III	3	1	2	4+2=6	70	30	50	40	200
4	BPH-804	Elective- I	3	1	-	4	70	30	-	-	100
5	BPH-805	Elective-II	3	1	-	4	70	30	-	-	100
6	BPH-806	Professional Training (4 Weeks)	-	-	4	4			100	-	100
Total			15	5	8	28	350	150	220	80	800

Note: - One Credit Refers to one hour Teaching in Theory and two Hours in Practical

L: Lecture - T: Tutorial - P: Practical

Elective –I

BPH-804 (A) – Packaging Technology

BPH -804 (B) – Drug Discovery and Development

BPH -804 (C) – Food and Nutraceutical Technology

Elective –II

BPH -805 (A) – Perfumes and colours

BPH -805 (B) – Clinical Research

BPH -805 (C) – Herbal Drug Technology

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w.e.f-2017-18

Pharmaceutics-X (Pharmaceutical Technology-II)

(BPH-801)

Unit-I

Granulation Technology

Production of granules on large scale by various techniques, evaluation of granules. Compression and consolidation of powdered solids. Heckel plots. Force displacement (F-D) Curves.

Unit-II

Microencapsulation Techniques

Coating of particles. Fluidized bed and air suspension coating. Phase separation co-acervation, multiorifice centrifugal, spray drying, spray congealing, polymerization complex emulsion techniques. Top bottom and tangential spray coating machines. Evaluation of microcapsules.

Unit-III

Sustained and Controlled Drug Delivery Systems

Concept of sustained release, designing of sustained release products, zero order and first order approximation concept. Matrix and reservoir based techniques. Product evaluation and testing.

Novel Drug Delivery Systems

Transdermal drug delivery systems. Osmotic drug delivery systems. Liposomes and implants.

Unit-IV

Packaging of Pharmaceutical Products

Objective of packaging, packaging components, types, functions, containers and closures, foil and blister packaging. Packaging equipment, legal and official requirements for containers and closures. Package testing.

Unit-V

Pilot Plant Scale-Up Techniques

General considerations, personnel requirements, space requirements, review of formula and raw materials. Processing equipments. Process evaluation. GMP considerations.

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Suggested Books:

1. Leon Lachman, Herbert A. Liebermann and Joseph L.Kanig., The Theory and Practice of Industrial Pharmacy.
2. Banker G.S. and Rhodes C.D., Modern Pharmaceutics.
3. Remington's Pharmaceutical Sciences.
4. Aulton M. E., The Science of Dosage Form Design.

LIST OF PRACTICAL'S

1. To perform comparison of the tablet by HPMC and PGs Binders.
2. To perform the punching of tablet by slugging process.
3. To prepare and evaluate the floating tablet of paracetamol.
4. To Perform and evaluate the fast deliver tablet of diclofenac sodium.
5. To prepare and evaluate diclofenac sodium emulgel formulation.
6. To study the effect of various suspending agents on CaCo3 suspension.
7. To perform the dissolution study of given tablet with curve fitting (zero & first order)
8. To prepare and microsphere by pan coating
9. To preparation and Characterization of Paracetamol Loaded Liposomes.
10. To prepare and submit waxes containing microsphere.
11. To perform phase separation coacervation used for microencapsulation (polymer-polymer interaction)
12. To prepare and submit Carbopol gel
13. To stability evaluation of various dosage forms and their expiration dating.
14. To formulation of oral S. R. Products & their evaluation by in-vitro dissolution profile
15. To evaluation of marketed parenteral suspension and emulsion for parameters like particle size, steri and rheological parameters.
16. To evaluation of given packaging material (Primary & tertiary packaging).
17. To preparation, filling, sealing, sterilization and evaluation of the injections.
18. To formulation and evaluation of transdermal patch of given drug.
19. To prepare and study of TDDS using different polymer.
20. To prepare and submit buccal patches.
21. To prepare & evaluate gastro retentive floating matrix tablet of atenolol.
22. To prepare and evaluate multiple emulsion .
23. To design and evaluation of mucoadhesive buccal film of paracetamol using aluminum foil and merc casting method.
24. To design and evaluation of diclofenac sodium ocusert.

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Pharmaceutics –XI (Pharmaceutical Jurisprudence)

(BPH-802)

Unit-I

An Introduction to Pharmaceutical Jurisprudence

Review of Indian regulatory legislations for drug and pharmaceutical industries, and Pharmaceutical education.

Unit-II

An Elaborated Study of the Following

A. Medicinal and Toilet Preparations (Excise Duties) Act 1955.
B. Pharmacy Act 1948.
C. Drugs and Cosmetics Acts 1940 and Rules 1945.
D. Narcotic Drugs and Psychotropic Substances Act 1985 and Rules.
E. Patent Act 1970.
F. Essential Commodities and Drug Price Control Order.

Unit-III

A Brief Study of the Following

A. Medical Termination of Pregnancy Act 1970 and Rules 1975.
B. AICTE Act 1987.
C. Prevention of Cruelty to Animal Act 1960.
D. Poison Act and rules.
E. MRTP Act.

Unit-IV

A Brief Study of the Following

A. Minimum Wages Act 1948.
B. State Shops and Establishment Act and Rules.
C. Factories Act 1948.
D. Insecticides Act 1968.
E. Drugs and Magic Remedies Act (Objectionable Advertisement Act 1954).

Unit-V

A Brief Study of the Following

A. Various prescription and non-prescription products.

B. Medical and surgical accessories.

C. Diagnostic aids and appliances marketed in India.

Suggested Books:

1. Jain N. K., A Textbook of Forensic Pharmacy.

2. Mittal, B.M., A Textbook of Forensic Pharmacy.

3. Malik V., Drug & Cosmetic Act.

4. The Gazette of India. The Drugs and Cosmetics act and rules.

5. The Gazette of India. The Patent act 1970 and its latest amendments.

PHARMACEUTICAL ANALYSIS-III

(BPH- 803)

Unit-I

Assay of Pharmaceutical Dosage Form

1. Analytical Method Development: Development of new analytical methods for bulk drugs and dosage forms using titrimetry, UV/visible spectrophotometry and HPLC.
2. Development of analytical methods for combination drug products, derivative spectrophotometric methods.
3. Development of stability indicating assay procedures. Drug analysis in biological fluids like blood plasma and urine.

Unit-II

Validation of Analytical Methods and Instruments

1. Validation of analytical methods: Parameters of validation. Pharmacopoeial requirements of analytical method validation.
2. Validation of analytical instruments: UV/visible spectrophotometer and HPLC as per Indian Pharmacopoeia.

Unit-III

ICH, GMP, cGMP and GLP in Pharmaceuticals

1. ICH guidelines for impurities in drug substances and drug products, Residual solvents.
2. Good Manufacturing Practices, c-GMP, Good Laboratory Practices.

Unit-IV

Quality Control in Pharmaceuticals

1. Quality control testing: Dosage form evaluation as per monograph with special reference to Indian Pharmacopoeia.

Unit-V

Assay of Active Pharmaceutical Ingredients and Water

1. Drug identification test, drug content and assay, content uniformity.
2. Sampling considerations.
3. Water analysis: Validation and qualification of water purification systems. Total organic carbon, pH, and conductivity test. Moisture content analysis in drug and dosage forms.

Suggested Books:

1. Indian Pharmacopoeia, 2007.
2. Current ICH guidelines.
3. Vogel's, Quantitative Inorganic Analysis.

LIST OF PRACTICAL'S

1. Quantitative estimation of at least ten formulations containing single drug or more than one drug, using instrumental techniques.
2. Estimation of Na+, K+, Ca++ ions using flame photometry.
3. IR of samples with different functional groups (-COOH, -COOR, _ CONHR; - NH2, -NHR, -OH, etc.).
4. Workshop to interpret the structure of simple organic compounds using UV, IR, NMR and MS.

Packaging Technology (Elective-I)

BPH-804 (A)

Unit-I

Packaging Material Science

Basic materials used in packaging, their properties, method of manufacturing and applications-Paper, Plastics, Glass, Metal, and Elastomers. Containers and closures: Introduction and applications of Glass containers, Plastic containers, Collapsible tubes, Plastic tubes, Aerosol containers, Closures, Liners, and Rubber stoppers.

Unit-II

Quality Control and Quality Assurance of Packaging Materials

Detection of defects in packaging materials, Quality testing of formed packs, Quality testing of containers and closures, testing of child resistance and temper evidence property of packaging materials. Quality control tests for containers and closures as per Indian Pharmacopoeia.

Unit-III

Tamper Resistant and Child Resistant Packages

Introduction, method of preparation, and applications of Blister and Strip packs, Film Wrappers, Bubble packs, Shrink seals, Sachet and Pouches, Tape seals, Breakable caps, Sealed tubes, Aerosol containers, etc. Introduction and applications of Form-Fill-Seal (FFS) technology.

Unit-IV

Legal and Regulatory Requirements

Requirements of labels and labeling as per Drug & Cosmetics act and rules. Product / patient information literatures. Regulatory aspects of storage, handling and distribution of packaging materials with special emphasis on Cgmp and cGLP requirements.

Unit-V

Packaging as a Marketing Tool

Market Considerations – Importance of Demography & Psychography, Retail Market (POP), Equity & Brand Name; Package Embellishment – Graphic Design Elements – Significance of Shape, Size,

Colour, Font, Texture, Lines, Balance & Unity, Symmetry & Harmony; Shelf Appeal Studies - Recall Questioning, Focus Group, Eye-Tracking, S-scope studies.

Suggested Books:

1. Drug and Cosmetic Act and Rules.
2. Dean, D.A.; Evans, E.R.; and Hall I.H., Pharmaceutical Packaging Technology.
3. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, The Theory and Practic of Industrial Pharma

Drug Discovery and Development (Elective –I)

BPH-804 (B)

Unit-I

Drug Discovery

Historical perspective, Drug discovery without a lead like penicillin and Lead discovery, Lead modification approaches, Identification of the active part; Pharmacophore, Functional group modification, Privileged structure and drug like molecules, Structure modification to increase potency and therapeutic index, Structure modification to increase Oral Bioavailability.

Unit-II

Drug Receptor Interactions

Theories of drug-receptor interactions, Membrane and Receptor- Structure, Functions and the mechanism of drug action (Receptor Response), Design of agonist and antagonists, Receptor theories, Models and their types.

Unit-III

Molecular Modeling Software

Introduction to molecular modeling software, brief information on academic freeware and commercial software and their applications in drug discovery.

Unit-IV

Computers Aided Drug Design

Basic concept of Computational chemistry like Quantum Mechanics, Molecular Mechanics, Force fields, Energy minimization, Conformational search, Molecular dynamics, SBDD(Structure Based Drug Design) LBDD (Ligand Based Drug Design), analog approach, pharmacophore mapping, Molecular-modeling and Virtual screening.

Unit-V

Quantitative Structure Activity Relationship

Free Wilson analysis, Hansch analysis, Physicochemical properties, Craig Plot, Application of Hansch analysis, Statistical methods in QSAR

Introduction to Bioinformatics and Structural Biology

Knowledge of various databases and bioinformatics tools available at these resources, the major content of the databases like Nucleic acid databases and Protein databases. Current advancements in bioinformatics, introduction to system biology, structural biology, structural bioinformatics. Applications of bioinformatics and system biology in drug discovery.

Suggested Books:

1. Comprehensive Medicinal Chemistry Vol-I (Hansch (1990) Pergamon pres.
2. Principle of Drug action-Goldstein.
3. Introduction to medicinal Chemistry, III Edn. Patrick (2001) Oxford
4. Organic Chemistry of Drug Design and Drug Action. R.B.Silverman (1993)Academic
5. Medicinal Chemistry Vol. I Burger.
6. Molecular Modeling, Principles and applications -Andrew Leach(Longman) 1998.
7. Statistical MethodS in Biology-Norman Bailey(1995) Cambridge.
8. Introduction to Bioinformatics by Aurther M lesk

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Food and Nutraceutical Technology (Elective –I)

BPH-804 (C)

UNIT-I

Functional Foods and Nutraceuticals

Sources and role of Tocotrienols, polyunsaturased fatty acids, sphingolipids, lecithin, choline, terpenoids. Vegetables, Cereals, milk and dairy products as Functional foods.

UNIT-II

Nutrition

Nutritive and Non-nutritive food components with potential health effects. Effect of processing on Nutrients. Soy proteins and soy isoflavones in human health; Functional foods from wheat and rice and their health effects. Role of Dietary fibers and nuts in disease prevention. General ideas about role of Probiotics and Prebiotics as nutraceuticals.

UNIT-III

Nutraceuticals

Properties, structure and functions of various Nutraceuticals: Glucosamine, Octacosanol, Lycopene, Carnitine, Melatonin and Ornithine alpha ketoglutarate. Use of proanthocyanidins, grape products, flaxseed oil as Nutraceuticals.

UNIT-IV

Food Processing and Preservation

(i) General principles and techniques of food processing and food preservation, shelf life of food and nutraceutical products. Food stability: methods to enhance stability- freezing, lyophilization, and air drying techniques.

(ii) Methods of food preservation, approved preservatives, Radiation and food preservation: Role of radiation in food preservation. Principles underlying destruction of micro-organisms by irradiation. Effect of irradiation on food constituents. Legal status of food irradiation.

(iii) Contamination and microbial spoilage of food products: Milk and milk products, eggs and poultry, fish, breads and cereals, meat, canned foods, vegetables and fruits. Food borne infections and intoxications.

UNIT-V

Regulatory Affairs

(a) Regulatory aspects of food and nutraceutical products. The prevention of Food Adulteration ct 1954, The Food Safety & Standards Act. 2006.

(b) Regulatory certifications: FPO regulations, Manufacturing guidelines, Manufacturing and Marketing licenses, AGMARK, Green Label certification, Organic food certifications.

Suggested Books:

1. Nutraceuticals by L. Rapport and B. Lockwood, Pharmaceutical Press.

2. Food packaging principals and practice. Gordon L. Robertson, Marcel and Dekker

3. Essentials of Food and Nutrition by Swaminathan M., Ganesh and Co, 1985

4. Dietary Supplements of Plant Origin, M. Maffei (Ed.), Taylor & Francis, 2003 Handbook of Nutraceuticals and Functional Foods Edited by Robert E.C. Wildman, Routledge Publishers.

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Perfumes and Colours (Elective –II)

BPH-805 (A)

UNIT-I

Perfumes

Historical background & present scenario of perfumery industry. Definition of odor, its classification. Definition of perfumes, attars, cologne, deodorants, aromatic waters. Chemical classification of perfumes obtained from plant and animal sources.

UNIT-II

Essential Oils

Introduction, study of various physical and chemical properties of essential oils. Study of various isolation methods of essential oils. Formulation of perfumes, formulation excipients, manufacturing methods of perfumes, deodorants, colognes, and aromatic waters. Regulatory considerations: Analysis & standardization of perfumes. Toxicological aspects of use of perfumes, safety study of perfumes on naked skin including various dermatological tests

UNIT-III

Colours

Definition of colour, lake, dye, pigment. Theory of color formation at molecules level including Hund's Rule of multiplicity volume band approach & molecular orbital approach to colour. Detailed classification of colour obtained from natural sources like plant & animal sources, colours obtained from mineral sources, synthesis colours, dyes & pigments. FDA classification of colours. Various physiochemical properties of dyes & colours.

UNIT-IV

Manufacturing of Colors

Manufacturing methods of colours, dyes, lakes, and pigments. Regulatory aspects of use of colours in drug and cosmetics as per schedule Q of Drug and Cosmetic Act. Analysis of colours using instrumental methods & chromatographic methods.

UNIT-V

Application of Perfumes

Applications of perfumes and colours in various cosmetics like skin, nail, and hair cosmetics, toiletries etc.

Suggested Books:

1. Sagarine, Cosmetic Science and Technology, Vol. 1-4.

2. Harry's Cosmetology.

3. The Chemistry and Manufacture & Cosmetics, Vol. IV - Mainson G. De. Nawarre.

4. Colour and Cosmetic colour material - New Cosmetic Science - Mitsui.

5. The Cosmetic Industry - edited by Norman Scientific & Regulatory foundation - F.Estrin.

Clinical Research (Elective –II)

BPH-805 (B)

UNIT-I

Introduction

Clinical pharmacy, duties and activities of a clinical pharmacist in hospital, monitoring of pharmacotherapy (patient chart review, medication counseling, clinical out put review), ward round participation, patient relevant history (dieses and medication), prescriptions,

drug prescribing guidelines, therapeutic drug monitoring.

UNIT-II

Patient data analysis

Introduction to common medical terminologies and abbreviation used in clinical pharmacy. Patient case history & case history formats, use of case history in evaluation of drug therapy.

UNIT-III

Clinical Laboratory Tests

Interpretation of laboratory tests used in evaluation of disease state. Tests for hormones, body organ function, blood, urine, microbial culture, etc.

UNIT-IV

Drug and Poison Information

Introduction to information resources and institutes, systemic approach in answering drug information queries, preparation of reports. Detection and assessment of adverse drug reactions and their documentation.

Clinical Pharmacokinetic

Individualization of drug therapy, introduction to clinical pharmacokinetics models, determination of drug clearance and volume of distribution, renal and

non-renal clearance, hepatic clearance.

UNIT-V

Clinical Trial

Designs of clinical trials, Good clinical practices (ICH & GCP guideline for safety and efficacy), Institutional Ethical Committee and its function. Various phases of clinical trials, introduction to monitoring and auditing of clinical trials. Basic concepts of biostatistics.

Clinical Research Organization

Organizational structure, present status and future prospects of clinical research organizations in India.

Suggested Books

1 Hefindal, E. T., Clinical Pharmacy & Therapeutics-. Williams & Wilkins.

2 Katzung, B., Basic and Clinical Pharmacology, Lange Medical Publication, California

3 Laurence D.R. and Bennet, P.N., Clinical Pharmacology, Churchill Livingstone

4 Walker, R. & Edwards, C., Clinical Pharmacy & Therapeutics, Churchill Livingston

5 DiPiro, J.T. et.al., Pharmacotherapy a pathophysiological approach, McGraw-Hill companies, Inc.

6 Green and Harris, Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall Publications.

Herbal Drug Technology (Elective –II)

BPH-805 (C)

UNIT-I

Introduction

Definition, source of herbal raw materials, identification, authentication, Collection and processing of herbal drugs. Seasonal & geographical variations, natural & artificial drying methods. Packaging & labeling of herbal drugs prior to extraction.

UNIT-II

Standardization Techniques

WHO guidelines for assessing quality of herbal medicine. Analysis of raw herbal extracts and their formulation using TLC, HPTLC, GC, HPLC, UV& IR techniques.

UNIT-III

Regulatory Requirements for Herbal Medicine Industries

Infrastructure, Quality control, safety and stability, import and export of herbal products. Analytical Pharmacognosy – drug adulteration and detection.

UNIT-IV

Plant Tissue Culture Techniques & its Application in Pharmacy

Introduction, techniques of initiation and maintenance of various types of cultures for industrial level production of phyto- constituents. Immobilized cell techniques & biotransformation studies including recent evelopments in production of biological active constituents in static, suspension and hairy root cultures. Brief account of plant based industries of India and world involved in R & D work on medicinal and aromatic plants and manufacturing herbal medicine.

UNIT-V

Herbal Formulations

Principles of Ayurveda, Ayurvedic dosage forms and their evaluation as per Ayurvedic pharmacopoeia. Formulation considerations of herbal infusion, decoction, lotion, washers, insect repellents, tincture, syrups, compresses, poultice, plasters, ointments, oils and salves, tablets and capsules.

Suggested Books:

1. Herbal Drug Technology by S.S. Agrawal & M. Paridhavi.

2. Modern Methods of Plant Analysis by Peach & Tracey

3. Biotechnology by S.S. Purohit.

4. Pharmacognosy by C.K. Kokate, A.P. Purohit and S.B. Gokhale

5. The Ayurvedic Pharmacopoeia of India

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Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Credit Based Semester System

Scheme

Master of Pharmacy - I Semester (Pharmacology)
(2 YDC, Session-2017-2018)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Credits Hours		Total Credits	Marks
			Theory			Practical						
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	L	P		
1	MPL 101T	Modern Pharmaceutical Analytical Techniques	75	15	10	--	--	--	4	--	4	100
2	MPL 102T	Advanced Pharmacology-I	75	15	10	--	--	--	4	--	4	100
3	MPL 103T	Pharmacological and Toxicological Screening Methods-I	75	15	10	--	--	--	4	--	4	100
4	MPL 104T	Cellular and Molecular Pharmacology	75	15	10	--	--	--	4	--	4	100
5	MPL 105P	Experimental Pharmacology - I	--	--	--	100	30	20	--	12	6	150
6	MPL 106P	Seminar /Assignment						100	--	7	4	100
Total			300	60	40	100	30	120	16	19	26	650

L : Lecture

P : Practical

(As Per PCI New-Delhi)

Registrar
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Sehore (M.P.)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope: This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments deals are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives: After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments.

THEORY 60 Hrs

1	UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy. Data Interpretation. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10 Hrs
3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography	10 Hrs
5	Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary	10 Hrs

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electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

6 Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs

Thermal Techniques: Principle, thermal transitions and instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5 th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2 nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3 rd Edition, John Wiley & Sons, 1982.

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ADVANCED PHARMACOLOGY - I (MPL 102T)

Scope: The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

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

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY 60 Hrs

1 General Pharmacology 12 Hrs

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

2 Neurotransmission 12 Hrs

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).

d. Non adrenergic non cholinergic transmission (NANC). Cotransmission

Systemic Pharmacology:

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

3 Central nervous system Pharmacology 12 Hrs

General and local anesthetics

Sedatives and hypnotics,

drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics.

4 Cardiovascular Pharmacology 12 Hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs

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5 Autocoid Pharmacology 12 Hrs

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

REFERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gilman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu. 6. Graham Smith. Oxford textbook of Clinical Pharmacology. 7. Avery Drug Treatment 8. Dipiro Pharmacology, Pathophysiological approach. 9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9 th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD. Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

S S S U T M S * SEHORE (M.P.) *

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PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I
(MPL 103T)

Scope: This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans.

THEORY — 60 Hrs

1 Laboratory Animals — 12 Hrs

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applications

Anaesthesia and euthanasia of experimental animals.

Maintenance and breeding of laboratory animals.

CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.

Bioassay-Principle, scope and limitations and methods

2 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. — 12 Hrs

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti- diarrheal and laxatives — 12 Hrs

4 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods. — 12 Hrs

5 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunomodulators, — 12 Hrs

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Immunosuppressants and immunostimulants.

General principles of Immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and L.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchil Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Gupta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.kulkarni, 3 rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2 nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

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Sri Satya Sai University
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CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Scope: The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

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

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology.

THEORY		60 Hrs
1	Cell biology Structure and functions of cell and its organelles Genome organization, Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing. Cell cycles and its regulation, Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.	12 Hrs
2	Cell signaling Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.	12 Hrs
3	Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting. Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12 Hrs
4	Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters	12 Hrs

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	Genetic variation in G protein coupled receptors **Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics** **Immunotherapeutics** **Types of immunotherapeutics, humanisation antibody therapy, immunotherapeutics in clinical practice**	
5	a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures: isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry. b. Biosimilars	12 Hrs

REFERENCES

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Ucinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson eLal
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

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PHARMACOLOGICAL PRACTICAL - I (MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC).

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cherll D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

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SRI SATYA SAI

University of Technology and Medical Sciences

(ESTABLISHED UNDER GOVT OF M.P. AND REGISTERED UNDER UGC 2(F) 1956)
Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Credit Based Semester System

Scheme

Master of Pharmacy - II Semester (Pharmacology)
(2 YDC, Session-2017-2018)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Credits Hours		Total Credits	Marks
			Theory			Practical						
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	L	P		
1	MPL 201T	Advanced Pharmacology II	75	15	10	--	--	--	4	--	4	100
2	MPL 202T	Pharmacological and Toxicological Screening Methods-II	75	15	10	--	--	--	4	--	4	100
3	MPL 203T	Principles of Drug Discovery	75	15	10	--	--	--	4	--	4	100
4	MPL 204T	Clinical Research and pharmacovigilance	75	15	10	--	--	--	4	--	4	100
5	MPL 205P	Experimental Pharmacology - II	--	--	--	100	30	20	--	12	6	150
6	MPL 206P	Seminar /Assignment						120	--	7	4	100
Total			300	60	40	100	30	120	16	19	26	650

L : Lecture P : Practical

(As Per PCI New-Delhi)

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ADVANCED PHARMACOLOGY - II

MPL 201T

Scope: The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

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

1. Explain the mechanism of drug actions at cellular and molecular level
2. Discuss the Pathophysiology and pharmacotherapy of certain diseases
3. Understand the adverse effects, contraindications and clinical uses of
4. drugs used in treatment of diseases

THEORY — 60 Hrs

1. Endocrine Pharmacology: — **12 hrs**

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation.

2. Chemotherapy: — **12 hrs**

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as β-lactams, aminoglycosides, quinolones, Macrolide antibiotics, Antifungal, antiviral, and anti-TB drugs.

3. Chemotherapy: — **12 hrs**

Drugs used in Protozoal Infections.

Drugs used in the treatment of Helminthiasis.

Chemotherapy of cancer.

Immunopharmacology.

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

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Immunosuppressants and Immunostimulants.

4. CIT Pharmacology **12 hrs**

Antiulcer drugs. Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bc

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.

5. Free radicals Pharmacology **12 hrs**

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, *Diabetes mellitus*.

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Corran Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology.
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr. Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

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PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

MPL 202T

Scope: This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

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

1. Explain the various types of toxicity studies.
2. Appreciate the importance of ethical and regulatory requirements for toxicity studies.
3. Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY **60 Hrs**

1. **Basic definition and types of toxicology:** **12 hrs**
   General, mechanistic, regulatory and descriptive.
   Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y
   OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development.
2. Acute, sub-acute and chronic- oral, dermal and inhalational studies **12 hrs**
   as per OECD guidelines.
   Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
   Test item characterization- importance and methods in regulatory toxicology studies.
3. Reproductive toxicology studies, Male reproductive toxicity studies, 12 hrs
   female reproductive studies (segment I and segment III), teratogenicity studies (segment II)
   Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies).
   In vivo carcinogenicity studies.
4. IND enabling studies (IND studies) - Definition of IND, importance of IND, **12 hrs**
   industry perspective, list of studies needed for IND submission.

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Safety pharmacology studies- origin, concepts and importance of safety pharmacology.
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies.

5. Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics 12 hrs
Importance and applications of toxicokinetic studies.
Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook. pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine. Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf).

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PRINCIPLES OF DRUG DISCOVERY

MPL 203T

Scope: The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

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

1. Explain the various stages of drug discovery.
2. Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
3. Explain various targets for drug discovery.
4. Explain various lead seeking method and lead optimization
5. Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY

60 Hrs

1. **An Overview of Modern Drug Discovery Process:** 12 hrs

Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

2. **Lead Identification-** 12 hrs

combinatorial chemistry & high throughput screening, *in silico* lead discovery techniques, Assay development for hit identification.

Protein structure.

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction.

3. **Rational Drug Design** 12 hrs

Traditional *vs* rational drug design, Methods followed in traditional drug design, High throughput screening. Concepts of Rational Drug Design, Rational Drug Design Methods:

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Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.

4. **Molecular docking:** 12 hrs

Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

5. **QSAR Statistical Methods:** 12 hrs

Regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.

2. Darryl León, Scott Markelln. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.

3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.

4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.

7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

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CLINICAL RESEARCH AND PHARMACOVIGILANCE

MPL 204T

Scope: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

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

1. Explain the regulatory requirements for conducting clinical trial
2. Demonstrate the types of clinical trial designs
3. Explain the responsibilities of key players involved in clinical trials
4. Execute safety monitoring, reporting and close-out activities
5. Explain the principles of Pharmacovigilance
6. Detect new adverse drug reactions and their assessment
7. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY — 60 Hrs

1. **Regulatory Perspectives of Clinical Trials:** — 12 hrs

   Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.

   Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR

   Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process.

2. **Clinical Trials:** Types and Design — 12 hrs

   Experimental Study- RCT and Non RCT,

   Observation Study: Cohort, Case Control, Cross sectional.

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Clinical Trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

3. **Clinical Trial Documentation-** **12 hrs**

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

4. **Basic aspects, terminologies and establishment of pharmacovigilance** **12 hrs**

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centers in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

5. **Methods, ADR reporting and tools used in Pharmacovigilance** **12 hrs**

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

6. **Pharmacoepidemiology, pharmacoeconomics, safety pharmacology** **12 hrs**

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REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research. New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research, Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

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PHARMACOLOGICAL PRACTICAL - II

MPL 205P

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by everted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

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REFERENCES

1. Fundamenals of experimenal Pharmacology-by M.N.Ghosh

2. Hand book of Experimenal Pharmacology-S.K.Kulakarni

3. Text book of in-vitro practical Pharmacology by Ian Kitchen

4. Bioassay Techniques for Drug Developmem by Atta-ur-Rahman, Iqbal choudhary and William Thomsen

5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

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Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Credit Based Semester System

Scheme

Master of Pharmacy - I Semester (Pharmaceutics)
(2 YDC, Session-2017-2018)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Credits Hours		Total Credits	Marks
			Theory			Practical						
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	L	P		
1	MPH 101T	Modern Pharmaceutical Analytical Techniques	75	15	10	--	--	--	4	--	4	100
2	MPH 102T	Drug Delivery System	75	15	10	--	--	--	4	--	4	100
3	MPH 103T	Modern Pharmaceutics	75	15	10	--	--	--	4	--	4	100
4	MPH 104T	Regulatory Affair	75	15	10	--	--	--	4	--	4	100
5	MPH 105P	Pharmaceutics Practical I	--	--	--	100	30	20	--	12	6	150
6	MPH 106P	Seminar /Assignment						100	--	7	4	100
Total			300	60	40	100	30	120	16	19	26	650

L : Lecture P : Practical

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MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Scope: This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives: After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments.

THEORY 60 Hrs

1 a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy. Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. — 11 Hrs

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. — 11 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy — 11 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors effecting resolution and applications of the following: — 10 Hrs

a) Paper chromatography

b) Thin Layer chromatography

c) Ion exchange chromatography

d) Column chromatography

e) Gas chromatography

f) High Performance Liquid chromatography

g) Affinity chromatography

5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: — 11 Hrs

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) iso electric focusing

b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's

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law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.

6 Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays. 05 Hrs

REFERENCES

1.Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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DRUG DELIVERY SYSTEMS (MPH 102T)

Scope: This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

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

The various approaches for development of novel drug delivery systems.

The criteria for selection of drugs and polymers for the development of delivering system

The formulation and evaluation of Novel drug delivery systems..

THEORY 60 Hrs

1	Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
2	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
3	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10 Hrs
4	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers	06 Hrs
5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L. Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wileyinterscience Publication, John Wiley and Sons, Inc. New York/ Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable.
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable.

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MODERN PHARMACEUTICS (MPH 103T)

Scope: Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage

THEORY 60 Hrs

1	a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	10 Hrs
2	Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation, Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
3	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10 Hrs
4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility	10 Hrs
5	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol. 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gilbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

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REGULATORY AFFAIRS (MPH 104T)

Scope: Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives: Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY 60 Hrs

1	a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development introduction , Hatch-Waxman act and amendments, CFR [CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	12 Hrs
2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures Informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.

4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.

5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.

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PHARMACEUTICS PRACTICALS - I (MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform in-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

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Bhopal-Indore Road, Opposite Pachama Oilfed Plant, Pachama, Sehore (M.P.) Pin-466001
Phone: 07562-223647, Fax: 07562-223644, website: www.sssutms.co.in, Email: info@sssutms.co.in

Credit Based Semester System

Scheme

Master of Pharmacy - II Semester (Pharmaceutics)
(2 YDC, Session-2017-2018)

S.No	Subject Code	Subject Name	Maximum Marks Allotted						Credits Hours		Total Credits	Marks
			Theory			Practical						
			End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	End Sem	Mid Sem Test (Two Tests average)	Continuous Mode	L	P		
1	MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	75	15	10	--	--	--	4	--	4	100
2	MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	75	15	10	--	--	--	4	--	4	100
3	MPH 203T	Computer Aided Drug Delivery System	75	15	10	--	--	--	4	--	4	100
4	MPH 204T	Cosmetic and Cosmeceuticals	75	15	10	--	--	--	4	--	4	100
5	MPH 205P	Pharmaceutics Practical II	--	--	--	100	30	20	--	12	6	150
6	MPH 206P	Seminar /Assignment						100	--	7	4	100
Total			300	60	40	100	30	120	16	19	26	650

L : Lecture

P : Practical

(As Per PCI New-Delhi)

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MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

MPH 201T

Scope: - This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

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

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS.
3. The formulation and evaluation of novel drug delivery systems.

THEORY — 60 Hrs

1. **Targeted Drug Delivery Systems:** — 12 hrs

   Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

2. **Targeting Methods:** — 12 hrs

   Introduction preparation and evaluation, Nano Particles & Liposomes: Types, preparation and evaluation

3. **Micro Capsules / Micro Spheres:** — 12 Hrs

   Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

4. **Pulmonary Drug Delivery Systems :** — 12 Hrs

   Aerosols, propellants, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

5. **Nucleic Acid Based Therapeutic Delivery System:** — 12 Hrs

   Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non-viral gene transfer). Liposomal gene delivery systems. Bio-distribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

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REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New-Delhi, First edition 1997 (reprint in 2001).

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ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
MPH 202T

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

Objectives: - Upon completion of this course it is expected that students will be able understand.

1. The basic concepts in bio-pharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY **60 Hrs**

1. Drug Absorption from the Gastrointestinal Tract: **12 Hrs**

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of *in vivo* data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

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2. **Biopharmaceutic considerations in drug product design and In vitro Drug Product Performance:** **12 Hrs**

Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, *In Vitro*: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

3. **Pharmacokinetics:** **12 Hrs**

Basic considerations, pharmacokinetic models, compartment modeling: one compartment model-IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis - Menten equation, estimation of k_m and v_m. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

4. **Drug Product Performance, *In Vivo*:** **12 Hrs**

Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

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5. **Application of Pharmacokinetics:** **12 hrs**

Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallabh Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel, Land YuABC, 2nedition, Connecticut Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
5. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970.
6. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995.
7. Dissolution, Bioavailability and Bioequivalence, Abdou, H.M, Mack Publishing Company, Pennsylvania 1989.
8. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
9. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski. 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
10. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
11. Basic Pharmacokinetics, 1st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing, 2009.
12. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

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COMPUTER AIDED DRUG DEVELOPMENT

MPH 203T

Scope: This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives: Upon completion of this course it is expected that students will be able to Understand.

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence (AI) and Robotics
8. Computational fluid dynamics(CFD)

THEORY **60 Hrs**

1. **a. Computers in Pharmaceutical Research and Development:** **12 hrs**

   A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling. Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling.

   b. Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q, guideline, Regulatory and industry views on Q,D, Scientifically based Q,D-examples of application.]

2. **Computational Modeling of Drug Disposition: Introduction,** Modeling

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Techniques: **12 hrs**

3. Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion. Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

4. **Computer-Aided Formulation Developments:** **12 Hrs**

Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis.

5. **a) Computer-aided biopharmaceutical characterization:** **12 Hrs**

Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Bio waiver considerations.

b) Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c) Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems.

6. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** **12 Hrs**

General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

REFERENCES

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COSMETICS AND COSMECEUTICALS

MPH 204T

This course is designed to impart knowledge and skills necessary forthefundamental need for cosmetic and cosmeceutical products.

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

a. Key ingredients used in cosmetics and cosmeceuticals.
b. Key building blocks for various formulations.
c. Current technologies in the market
d. Various key ingredients and basic science to develop cosmetics and cosmoceuticals
e. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY 60 Hrs

1. **Cosmetics-Regulatory:** 12 Hrs

Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics-Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

2. **Cosmetics -Biological aspects:** 12 Hrs

Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

3. **Formulation Building blocks:** 12 Hrs

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.

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Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4. **Design of Cosmeceutical products:** 12 Hrs

Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

5. **Herbal Cosmetics:** 12 Hrs

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology, 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P.P.Sharma,4th edition.
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

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PHARMACEUTICS PRACTICALS - II

MPH 205P

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation.
2. Preparation and evaluation of Alginate beads.
3. Formulation and evaluation of gelatin /albumin microspheres.
4. Formulation and evaluation of liposomes/niosomes.
5. Formulation and evaluation of spherules.
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands.
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug.
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnolin R software.
11. In vitro cell studies for permeability and metabolism.
12. DoE Using Design Expert® Software.
13. Formulation data analysis Using Design Expert® Software.
14. Quality-by-Design in Pharmaceutical Development.
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics.
16. Computational Modeling of Drug Disposition.
17. To develop Clinical Data Collection manual.
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams.
20. Development and evaluation of Shampoo and Toothpaste base.
21. To incorporate herbal and chemical actives to develop products.
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

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Bhopal-Indore Road, Opposite Pachama Oilfed Plant,Pachama,Sehore (M.P.) PIN-466001
Phone : 07562-223647,Fax : 07562-223644, website : www.ssutms.co.in, Email : info@ssutms.co.in

Scheme of Examination
Second Year – Master of Pharmacy (Pharmacology)

S. No.	Subject Code	Subject Name	Period per week (Hr)			Credits	Maximum Mark (Theory Slot)		Maximum Mark (Practical Slot)		Total Marks
			L	T	P		End Sem. Exam	Mid. Sem	Practical Record/ Assignment/Quiz /Presentation	End Sem. Practical/Viva	
1	MPCL-201	Dissertation (Synopsis/Viva-voice/ seminar/Presentation)	-	-	40	20	-	-	300	500	800
		Total			40	20	-	-	300	500	800

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Scheme of Examination
Second Year – Master of Pharmacy (Pharmaceutics)

S. No.	Subject Code	Subject Name	Period per week (Hr)			Credits	Maximum Mark (Theory Slot)		Maximum Mark (Practical Slot)		Total Marks
			L	T	P		End Sem. Exam	Mid. Sem	Practical Record/ Assignment/Quiz /Presentation	End Sem. Practical/Viva	
1	MPCS-202	Dissertation (Synopsis/Vivavoice/ seminar/Presentation)	-	-	40	20	-	-	300	500	800
		Total			40	20	-	-	300	500	800

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II B.PHARMACY FOR THE ACADEMIC YEAR 2017 ONWARDS

TITLE: COMMUNICATION SKILLS AND SOFT SKILLS **No.of Hours:30**

OBJECTIVE: To create awareness of communication skills and human refinement ideologies to a student in the right perspective.

The objective of the course is to impart the english language skills to communicate better and create awareness in soft skills to meet the corporate challenges.A handfull of theoretical and practical knowledge in all aspects of social etiquette,planning stategy and to speak and write confidently will add value to the budding pharmacist.

COURSE OUTCOMES: On complition of the course,student will be able to

1	Effectively communicate through verbal/oral communication and improve the listening skills.
2	Write precise briefs or reports and technical documents.
3	Actively participate in group discussion/meetings/interviews and prepare and deliver presentations.
4	Become more effective individual through goal/target,self motivation and practicing creative thinking.
5	Function effectively in multidisciplinary and heterogenous teams through the knowlegde of team work,interpersonal relationships and leadership quality.
6	Effectively apply active listening skills.

S.NO	CONTENTS	Prescribed hours
1	Value of english	3 hours
2	Importance of communications skills	2 hours
3	Qualities of a speakers/listeners	2 hours
4	How to speak without fear-Mock practice	10 hours
5	Importance of soft skills	3 hours
6	Qualities/ duties of a students	2 hours
7	Social etiquette	2 hours
8	Telephone etiquette	2 hours
9	Successful tips for exams	2 hours
10	Behavioural approch and attitude	2 hours

Name of faculty	DR BABINA BOHRA

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SRI SATYA SAI UNIVERSITY OF TECHNOLOGY & MEDICAL SCIENCES
DEPARTMENT OF PHARMACY

[Established Under Act. 06 of 2014 by Govt. of Madhya Pradesh]
Approved by Madhya Pradesh Private University Regulatory Commission

II/III B.PHARMACY -3rd SEMESTER

PROFESSIONAL ETHICS AND HUMAN VALUES

THEORY (30 HOURS)

Scope of the subject:

1. To bring awareness among pharmacy graduates on ethics and human values.
2. To understand and ethical theories and their application to work ethics.
3. To know various codes of ethics used by professional bodies.
4. To understand the concepts of corruption and its measures.
5. To learn about professional responsibilities as a pharmacist.

Outcomes of the subjects:

The students will able to:

a) Develop awareness on ethics and human values

b) Become morally and socially responsible.

c) Motivate others on moral values.

Course Outcomes;

1	To remember and recall the human values and professional ethics.
2	To outline the ethics norms,anticorruption measures and central vigilance bodies.
3	To apply moral concepts and reasoning in pharmacy.
4	To discover ethical issues in clinical pharmacy practice and manufacturing of pharmaceutical products.
5	To appraise professional societies and various pharmaceutical associations.
6	To adapt social pharmacy and code of pharmaceutical ethics.

Course content:

Topic	Duration (hrs)	References
Unit-I Human values: Morals, values and ethics-	04	R.S. Naagarazan Professional ethics and

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integrity –work ethics-service learning, civic virtue, respect for others, living peacefully-caring, sharping, honesty, courage, valuing time, co-operations, commitment, empathy, self-confidence, character and spirituality.		human values edition-I. New age international Pvt Ltd.,edition –I, chapter -1
Unit-II Introduction to professional ethics, cooption and its measures: Need of ethics in pharmacy , changing times ,RPSGB guidance,ethical norms, moral relativism, facts and values, ethical theory and concepts. Corruption in public life ,economic impact of corruption, payments that equate supply and demand; bribes as incentives payments,bribes to reduce costs,organized crime and corruption. Anti corruption measures-Anti corruption Bureau (ACB), Central Bureau of investigation(CBI), lokadalats, ombudsman, controller and auditor general (CAG) and right to information.	05	Joy wingfield and david Badcott, Pharmacy ethics and decision making, Pharmaceutical pres,Edition-I,Chapter-1.
Unit-III **Moral concepts and reasoning in Pharmacy:** Moral issues,rational inquires, moral automy,moral reasoning ad pharmacist,moral development theories,justice and human rights,trust and truthfulness and moral dilemmas	05	1. R.S. Naagarazan Professional ethics and human values edition-I. New age international Pvt Ltd.,edition –I, chapter -2 2. Joy wingfield and david Badcott, Pharmacy ethics and decision making, Pharmaceutical pres,Edition-I,Chapter-4
Unit-IV **Professionalism and industrial ethics:** Pharmacy and professionalism, ethical basis in professionalism and accountability,industrial ethics,pharmacist in different cluster with different ethical issues-clinical pharmacy practice,community pharmacy and manufacturing of pharmaceutical products.	05	1.Joy wingfield and david Badcott, Pharmacy ethics and decision making, Pharmaceutical pres,Edition-I,Chapter-4 2. R.S. Naagarazan Professional ethics and human values edition-I.

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		New age International Pvt Ltd.,edition –I, chapter -2
Unit-V **Professional societies and various pharmaceutical associations:-**Indian Pharmaceutical Association, Indian Pharmaceutical Congress Association, Indian Hospital Pharmacist Association, Indian Pharmacy Graduate Association,Association Of Pharmaceutical Teachers Of India,The All India Drug Control Officers Confederation,Indian Society For Technical Education,National Pharmaceutical Pricing Authority And Other Allied Professional Societies/Associations.	06	1.professional Pharmacy –M.L.Schroff 2. Harikishan singh: history of pharmacy in india and related aspects, Vol-I,II& III Pahramacopoeias and formularies,1st Edition,vallabh prakashan,2005
Social pharmacy and code of pharmaceutical ethics: The concept and context of social pharmacy principles of ethics,morality,ethical code, Pharmaceutical ethics in relation to job,trade,profession and medical profession. Pharmacist oath.	05	1. N.K. Jain,forensic pharmacy,eight edition,2014,484-492. 2. B.M.Mithal Atextbook of forensic pharmacy, vallabh prakashan,10th edition ,chapter-14

Futher reading:-

01. NK Jain, Health Education & Community Pharmacy. CBS Publ., New Delhi
02. R .M. Mehta Dispensing Pharmacy
03. Pharmacoethics: A problem based approach by G.Vidya Sagar
04. Gupta AK. Health Education and community pharmacy. CBS Publ., New Delhi

NAME OF COORDINATOR	DR HEMANT SHARMA

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