DR. A.P.J ABDUL KALAM TECHNICAL UNIVERSITY, LUCKNOW

SYLLABUS & EVALUATION SCHEME

FOR

B. PHARMA

(Effective from the Session: 2017-18)

Scheme of Evaluation
Bachelor of Pharmacy (B. Pharm.)

Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial Pharmacy I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial Pharmacy I– Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**

Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

SEMESTER V

BP 501T. MEDICINAL CHEMISTRY-II (Theory)

45 Horus

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

H_1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H_2-antagonists: Cimetidine*, Famotidine, Ranitidine.

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

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleom ycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II **10 Hours**

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene,

Amiloride. Osmotic Diuretics: Mannitol

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

UNIT- III **10 Hours**

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

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

UNIT- IV **08 Hours**

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V **07 Hours**

Antidiabetic agents:

Insulin and its preparations

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

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics:

SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

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 by Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's Extra Pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry by A.I. Vogel.
11. Synthesis of Essential Drugs by Vardanyan and Hruby, Elsevier.
12. Medicinal and Pharmaceutical Chemistry by Singh and Kapoor.
13. Medicinal Chemistry- A Biochemical Approach by Nogrady
14. The Organic Chemistry of Drug Design and Drug Action by Silverman, Elsevier.

BP 502 T. Industrial Pharmacy I (Theory)

45 Hours

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

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

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

Course content:

3 hours/ week

UNIT-I **07 Hours**

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

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

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

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

UNIT-II **10 Hours**

Tablets:

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

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

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

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

UNIT-III **08 Hours**

Capsules:

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

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

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

UNIT-IV **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,
aseptic processing

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

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

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

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.

BP 506 P. Industrial Pharmacy I (Practical)

4 Hours/week

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

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B. Schwartz.
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman.
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman.
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition.
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS).
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman.
7. Pharmaceutics- The science of dosage form design by M. E. Aulton, Churchill Livingstone, Latest edition.
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005.
9. Drug stability- Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
10. Tutorial Pharmacy, by Cooper and Gunn, Petman Books Ltd., London.
11. The Theory and Practice of Industrial Pharmacy by Khar R. K., Vyas S.P., Ahmad F., Jain G. K., 4th Edition, CBS Publishers and Distributors.
12. Drug Delivery Systems by Juliano, R.L., Oxford University Press, Oxford.
13. Turco S. J., Sterile Dosage Form-Their Preparation and Clinical Application, LWW.

BP503.T. 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 **10 hours**

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 **10 hours**

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 **10 hours**

3. Autocoids and related drugs

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

UNIT-IV **08 hours**

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 **07 hours**

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

BP 507 P. 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 softwares and videos

Recommended Books (Latest Editions)

1. Rang and Dale's Pharmacology, Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Churchil Livingstone Elsevier
2. Basic and clinical pharmacology by Katzung B. G., Masters S. B., Trevor A. J., Tata McGraw-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. Applied Therapeutics, The Clinical use of Drugs by K., Bradley R.W. The Point Lippincott Williams & Wilkins.
5. Lippincott's Illustrated Reviews- Pharmacology by Mycek M.J, Gelnet S.B and Perper M.M..
6. Essentials of Medical Pharmacology by K.D.Tripathi. JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Principles of Pharmacology by Sharma H. L., Sharma K. K. Paras medical publisher
8. Modern Pharmacology with clinical Applications by Charles R.Craig& Robert.
9. Fundamentals of Experimental Pharmacology, Ghosh MN. Hilton & Company, Kolkata.
10. Handbook of experimental pharmacology by Kulkarni S.K. Vallabh Prakashan.
11. Text Book of Pharmacology, Barar F.S.K., Interprint.
12. Clinical Pharmacology, by Laurence, D.R. and Bannet P.N., Churchill Livingstone.
13. Modern Pharmacology by Craig C.R. and Stitzel, R.R., 4th Edition, Little Brown and Co.

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

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

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

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I **07 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: Lignans, Tea, Ruta
Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis
Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,
Tannins: Catechu, Pterocarpus
Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony
Glycosides: Senna, Aloes, Bitter Almond
Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III **06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

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

UNIT-IV **10 Hours**

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

UNIT V **0 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.

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
   a. Caffeine - from tea dust.
   b. Diosgenin from Dioscorea
   c. Atropine from Belladonna
   d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: **(**i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **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 penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

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

UNIT-III **10 Hours**

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

- **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV **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, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-
  2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V **07 Hours**

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

Recommended books: (Latest Edition)

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

SEMESTER VI

BP601T. 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, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

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

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, 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, Diloxanide, 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, Sulfamethoxaole*, 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, Tafts steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

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

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Horus/ week

I Preparation of drugs and intermediates

1 Sulphanilamide
2 7-Hydroxy, 4-methyl coumarin
3 Chlorobutanol
4 Triphenyl imidazole
5 Tolbutamide
6 Hexamine

II Assay of drugs

1 Isonicotinic acid hydrazide
2 Chloroquine
3 Metronidazole
4 Dapsone
5 Chlorpheniramine maleate
6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

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

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic Medicinal and Pharmaceutical Chemistry.
2. Foyes Principles of Medicinal Chemistry, Lippincott Williams and Wilkins.
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.
11. Synthesis of Essential Drugs by Vardanyan and Hruby, Elsevier.
12. Medicinal and Pharmaceutical Chemistry by Singh and Kapoor, Vallabh Prakashan.
13. Medicinal Chemistry: A Biochemical Approach by Nogrady, Oxford University Press.
14. An Introduction to Medicinal Chemistry by Patrick Oxford University Press.
15. Comprehensive Medicinal Chemistry by Hansch, Pergamon Press.
16. Practical Organic Chemistry by Mann and Saunders, Orient Longman Limited.
17. Vogel's Textbook of Practical Organic Chemistry, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.).

BP602 T. 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 poisonings and
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**

3. 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**

3. Chemotherapy

a. Antitubercular agents
b. Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08 hours**

3. Chemotherapy

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

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

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.

BP 608 P. 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 and Dale's Pharmacology, Churchil Livingstone Elsevier.
2. Basic and clinical pharmacology by Katzung B. G., Masters S. B., Trevor A. J., Tata McGraw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics.
4. Applied Therapeutics, The Clinical use of Drugs by Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W. The Point Lippincott Williams & Wilkins.
5. Lippincott's Illustrated Reviews- Pharmacology by Mycek M.J, Gelnet S.B and Perper M.M.
6. Essentials of Medical Pharmacology by K.D.Tripathi, Jaypee Brothers Medical Publishers (P) Ltd.
7. Principles of Pharmacology by Sharma H. L., Sharma K. K., Paras Medical Publisher.
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Fundamentals of Experimental Pharmacology by Ghosh, Hilton & Company.
10. Handbook of Experimental Pharmacology by Kulkarni S.K., Vallabh Prakashan.
11. Clinical Pharmacology by Laurene, D.R. & Bennet P.N., Churchill Livingstone.
12. Principles of Pharmacology by Paul, Chapman and Hall.
13. Concepts in Chronopharmacology by N.Udupa and P.D. Gupta.
14. Text Book of Pharmacology by Barar, Interprint.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

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

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

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I **11 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.

Indian Systems of Medicine

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

UNIT-II **7 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: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III **10 Hours**

Herbal Cosmetics

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

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

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

UNIT- IV **10 Hours**

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:
a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V **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.

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

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

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale.
4. Essential of Pharmacognosy by Dr.S.H.Ansari.
5. Pharmacognosy & Phytochemistry by V.D.Rangari.
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).
7. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
8. Pharmacognosy by Tyler V.E., Lynnr B. and Robbers J.E., 8th Edition, Lea & Febiger, Philadelphia.
9. Harborne J.B., Phytochemical Methods, Chapman & Hall International Edition.
10. Medicinal Plants of India, Vol. I & II, Indian Council of Medical Research.
11. Indian Materia Medica by Nadkarni A.K.Vol- 1&2, Popular Prakashan (P) Ltd.
12. A Selection of Prime Ayurvedic Plant Drugs by Sukh Dev, Anamaya Publisher.
13. Indian Herbal Pharmacopoeia, Vol. I & II, ICMR & RRL, Jammu.
14. Indian Ayurvedic Pharmacopoeia, Govt. of India.
15. The Wealth of India, Raw Materials (All volumes), Council of Scientific & Industrial Research.
16. Rastogi R. P. and Mehrotra B.N., Compendium of Indian Medicinal Plants I-IV, Publications & Information Directorate/Central Drug Research Institute.
17. Wallis T.E., Analytical Microscopy, J&A Churchill Ltd.
18. Practical Pharmacognosy by Kokate C.K., Vallabh Prakashan.
19. Pharmacognosy of Powdered Crude Drugs by Iyengar M.A., PharmaMed Press.
20. Anatomy of Powdered Crude Drugsby Iyengar, M.A. and Nayak S.C.K., PharmaMed Press.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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

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

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Course Content:

UNIT-I **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** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II **10 Hours**

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

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

UNIT- III **10 Hours**

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E ,t1/2,Vd,AUC,Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application.

UNIT- IV **08 Hours**

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

UNIT- V **07 Hours**

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

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition.
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura.
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick.
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland .
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 Robert F Notari Marcel Dekker Inn.
12. Remington's Pharmaceutical Sciences, Mack Publishing Company.
13. Drug Disposition & Pharmacokinetics by Curry, S. H., Pharma Book Syndicate.
14. Analytical Techniques for Biopharmaceuticals Development, by Robert, Rodriguezdiaz.
15. Clinical Pharmacokinetics, by Rowland M, and Tozer T.N. Lea and Febriger.
16. Fundamentals of Clinical Pharmacokinetics by Wagner J.G. Drugs Intelligence Publishers.
17. Pharmacokinetics for the Pharmaceutical Scientist by Wagner J.G. Technomic Publishing A.G.

BP 605 T. 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 production of:

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

d) Brief introduction to PCR

Unit III **10 Hours**

Types of immunity- humoral immunity, cellular immunity

a) Structure of Immunoglobulins

b) Structure and Function of MHC

c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.

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

e) Storage conditions and stability of official vaccines

f) Hybridoma technology- Production, Purification and Applications g)

Blood products and Plasma Substitutes.

Unit IV **08Hours**

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

Genetic organization of Eukaryotes and Prokaryotes

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

d) Introduction to Microbial biotransformation and applications.

e) Mutation: Types of mutation/mutants.

Unit V **07 Hours**

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

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

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

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

Recommended Books (Latest edition):

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

8. Prescott and Dunn's Industrial Microbiology, CBS Publishers and Distributors
9. Pharmaceutical Biotechnology by Vyas S.P. and Dixit V.K., CBS Publication.
10. Biotechnology by Kieslich K., Verleg Chernie.
11. Principles of Fermentation by Standury P.F.,Whitaker A. & Hall S.J., Aditya Book Private Limited.
12. Biotechnology- A Textbook of Industrial Microbiology by Crueger W. & Crueger A, Panima Publishing Corporation.

BP606T. PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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

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

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

Course content:

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

UNIT - II **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: Equipment 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 materials.

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

UNIT – IV **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 **07 Hours**

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

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series.
9. ICH guidelines, ISO 9000 and 14000 guidelines.
10. Pharmacopoeia of India, Ministry of Health, Govt. of India.
11. WHO-Quality Assurance of Pharmaceuticals, Vol. I & II, AITBS Publisher & Distributors.
12. Validation of API by Berry I.R. and Harpaz, D., 2nd Edition, CRC Press.
13. Analytical Profile of Drug Substance, by Florey K., (All volume), Academic Press, Elsevier.

Scheme of Evaluation (Choice Based Credit System)
Bachelor of Pharmacy (B. Pharm.)

SEVENTH SEMESTER

S. No.	Subject Code	Subject Name	L--T--P	T/P Marks (ESE)	Sessional	Total	Credit
Theory							
1.	*RPH-733/* *RPH-741*	Pharmaceutical Chemistry-VIII (Medicinal Chemistry-III)/ Pharmaceutics-XI Pharmaceutical Marketing & Management	3---0---0	70	30	100	3
2.	*RPH-734/* *RPH-740*	Pharmaceutics-IX (Biopharmaceutics & Pharmacokinetics)/ Pharmaceutics-X Pharmaceutical Biotechnology	3---0---0	70	30	100	3
3.	*RPH-735*	Pharmacology-III (Pharmacology & Pharmacovigilance)	3---0---0	70	30	100	3
4.	*RPH-736*	Pharmacognosy-IV	3---0---0	70	30	100	3
5.	*RPH-737*	Pharmaceutical Analysis-III (Pharmaceutical Analysis & Quality Assurance)	3---0---0	70	30	100	3
Practical/ Project							
6.	*RPH-734P/* *RPH-740P*	Pharmaceutics-IX (Biopharmaceutics & Pharmacokinetics) Practical/ Pharmaceutics-X (Pharmaceutical Biotechnology) Practical	0---0---4	50	50	100	2
7.	*RPH-735P*	Pharmacology-III (Pharmacology & Pharmacovigilance) Practical	0---0---4	50	50	100	2
8.	*RPH-736P*	Pharmacognosy-IV Practical	0---0---4	50	50	100	2
9.	*RPH-737P*	Pharmaceutical Analysis-III (Pharmaceutical Analysis & Quality Assurance) Practical	0---0---4	50	50	100	2
10.	*RPH-738P*	Hospital Training-II		50	50	100	1
TOTAL						**1000**	**24**

EIGHTH SEMESTER

S. No.	Subject Code	Subject Name	L--T--P	T/P Marks (ESE)	Sessional	Total	Credit
Theory							
1.	*RPH-839*	Pharmaceutical Chemistry-IX (Chemistry of Natural Products)	3---0---0	70	30	100	3
2.	*RPH-840/* *RPH-834*	Pharmaceutics-X Pharmaceutical Biotechnology/ Pharmaceutics-IX (Biopharmaceutics & Pharmacokinetics)	3---0---0	70	30	100	3
3.	*RPH-841/* *RPH-833*	Pharmaceutics-XI Pharmaceutical Marketing & Management/ Pharmaceutical Chemistry-VIII (Medicinal Chemistry-III)	3---0---0	70	30	100	3
4.	*RPH-842*	Pharmaceutics-XII (Food & Nutraceuticals)	3---0---0	70	30	100	3
5.	*RPH-843* *(A)* *(B)* *(C)* *(D)* *(E)*	Elective (Computational Methods in Drug Design Good Manufacturing Practices Clinical Pharmacy Standardization of Herbal Drugs Research Methodology)	3---0---0	70	30	100	3
Practical/ Project							
6.	*RPH-839P*	Pharmaceutical Chemistry-IX (Chemistry of Natural Products) Practical	0---0---4	50	50	100	2
7.	*RPH-840P/* *RPH-834P*	Pharmaceutics-X Pharmaceutical Biotechnology Practical/ Pharmaceutics-IX (Biopharmaceutics & Pharmacokinetics) Practical	0---0---4	50	50	100	2
8.	*RPH-842P*	Pharmaceutics-XII (Food & Neutraceuticals) Practical	0---0---4	50	50	100	2
9.	*RPH-843P* *(A)* *(B)* *(C)* *(D)* *(E)*	Elective Computational Methods in Drug Design Project Good Manufacturing Practices Project Clinical Pharmacy Project Standardization of Herbal Drugs roject Research Methodology Project	0---0---4	50	50	100	2
10.	*RPH-844P*	Report on Industrial/ Research Laboratory Visit		50	50	100	2
TOTAL						**1000**	**24**

SEVENTH SEMESTER

RPH-733/RPH-833

PHARMACEUTICAL CHEMISTRY-VIII (MEDICINAL CHEMISTRY-III)

Classification, mode of action, uses, recent advances and structure activity relationship of the following classes of drugs (Synthetic procedures of individually mentioned drugs only).

Unit I

Steroidal drugs: Introduction, classification, nomenclature, and stereochemistry of-

Androgens and anabolic steroids: Testosterone, Stanazolol. ***Estrogens and progestogens:*** Progesterone, Estradiol. ***Adrenocorticoids:*** Prednisolone, Dexamethasone.

Unit II

Chemotherapy of microbial infections:

Antibiotics: Penicillin, Semi-synthetic Penicillins (Ampicillin), Cephalosporins (Cefepime), Chloramphenicol, Tetracyclines (Doxycycline), Aminoglycosides, Macrolides.

Antifungals: Ketoconazole and Clotrimazole.

Antiseptics & disinfectants: Chlorhexidine.

Unit III

Chemotherapy of microbial infections:

Synthetic antibacterials: Sulphonamides (Sulphamethoxazole, Sulphadiazine, Sulphacetamide), Quinolones/Fluoroquinolones (Nalidixic acid, Ofloxacin).

Antimycobacterial agents: PAS, Ethambutol, Isoniazid, Dapsone.

Unit IV

Chemotherapy of parasitic infections:

Antimalarials: Chloroquine, Primaquine, Pyrimethamine.

Antiamoebics: Ornidazole, Diloxanide.

Anthelmintics: Albendazole.

Unit V

Cancer chemotherapy: Alkylating agents (Chlorambucil, Carmustine), Antimetabolites
(Methotrexate, 5-Fluorouracil), Anticancer antibiotics (Doxorubicin).

Antiviral/Anti-HIV agents: Amantadine, Acyclovir, Zidovudine, Saquinavir, Raltegravir.

BOOKS RECOMMENDED

1. Abraham D.J., Burger's Medicinal Chemistry and Drug Discovery, John Wiley and Sons Inc., New York.
2. Block J.H. and Beale J.M., Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams and Wilkins, Philadelphia.
3. Lemke T.L., Williams D.A., Roche V.F. and Zito S.W., Foyes Principles of Medicinal Chemistry, Lippincott Williams and Wilkins, Philadelphia.
4. Vardanyan R.S. and Hruby V.J., Synthesis of Essential Drugs, Elsevier, Philadelphia.
5. Singh H. and Kapoor V.K., Medicinal and Pharmaceutical Chemistry, Vallabh Prakashan, Delhi.
6. Nogrady T., Medicinal Chemistry: A Biochemical Approach, Oxford University Press, New York.
7. Patrick G.L., An Introduction to Medicinal Chemistry, Oxford University Press, New York.
8. Hansch C., Comprehensive Medicinal Chemistry, Pergamon Press, U.K.
9. Dharuman J., Chemistry of Synthetic Drugs, AITBS Publishers, New Delhi.
10. Mann F.G. and Saunders B.C., Practical Organic Chemistry, Orient Longman Limited, New York.
11. Furniss B.S., Hannaford A.J., Smith P.W.G. and Tatchell A. R., Vogel's Textbook of Practical Organic Chemistry, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi.

RPH-734/RPH834

PHARMACEUTICS-IX (BIOPHARMACEUTICS & PHARMACOKINETICS)

Unit I

Introduction to biopharmaceutics and pharmacokinetics and their role in formulation development. Mechanism of absorption, physicochemical and pharmaceutical factors influencing absorption, drug distribution, volume of distribution and distribution coefficient. Plasma protein binding and its significance.

Unit II

Significance of plasma drug concentration measurement.

Compartment models and non-compartment models: Definition and scope.

Pharmacokinetics of drug absorption: Zero order and first order absorption rate constant. Determination of absorption rate constant using Wagner-Nelson and Loo-Reigelman method.

Unit III

Compartment kinetics: One compartment and preliminary information of multicompartment models. Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intra venous (I.V.) bolus and I.V. infusion.

Unit IV

Dosage adjustment in patients with renal and hepatic disease. Clinical Pharmacokinetics: Definition and scope.

Unit V

Brief introduction to bioavailability and bioequivalence: Definition and significance.

Measurement of bioavailability.

Introduction to i*n-vivo in-vitro* correlation (IVIVC) and its significance. Review of regulatory requirements for conduction of bioequivalence studies.

RPH-734P/RPH834P

PHARMACEUTICS-IX (BIOPHARMACEUTICS & PHARMACOKINETICS) PRACTICAL

Suggested Practicals

1. *In-vitro* drug release study of the any powder, uncoated tablet, capsule, film-coated tablet, sustained release tablet and fast release (M.D, Dispersible etc.) tablet using various dissolution media.
2. To determine the % protein binding of some drugs.
3. To determine the effect of protein binding on drug bioavailability.
4. To calculate various Pharmacokinetic parameters from zero order drug release data, first order drug release data, blood data of *I.V.* bolus injection (one compartment model) and urinary excretion data of *I.V.* bolus. Injection using both methods (Rate of elimination & sigma minus method one compartment model).
5. To study *in-vitro* drug- drug interactions.
6. To study the passive diffusion of a drug using cellophane membrane.
7. To study the passive diffusion of a drug using egg membrane.
8. To determine the various Pharmacokinetic parameters from the given blood data of oral administration of dosage form.
9. Determination of bioavailability by urinary method.
10. Determination of bioequivalence by dissolution method.

BOOKS RECOMMENDED

1. Notari, R.E, Biopharmaceutics and Pharmacokinetics-An introduction, Marcel Dekker Inc. New York.
2. Rowland M, and Tozer T.N. Clinical Pharmacokinetics, Lea and Febriger, New York.
3. Wagner J.G. Fundamentals of Clinical Pharmacokinetics, Drugs Intelligence Publishers, Hamilton.
4. Wagner J.G. Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publishing A.G. Basel, Switzerland.
5. Gibaldi, M., Biopharmaceutics & Clinical Pharmacokinetics, Pharma Book Syndicate, Hyderabad.
6. Robert, Rodriguezdiaz, Analytical Techniques for Biopharmaceuticals Development.
7. Curry, S. H., Drug Disposition & Pharmacokinetics, Pharma Book Syndicate, Hyderabad.

RPH-735

PHARMACOLOGY-III (PHARMACOLOGY & PHARMACOVIGILANCE)

Unit I

Pharmacology of endocrine system: Hypothalamic and pituitary hormones, thyroid hormones and thyroid drugs. Parathormone, Calcitonin and Vitamin D, Insulin, oral hypoglycemic agents and Glucagon. Corticosteroids, androgens and anabolic steroids, Estrogens, Progesterone and oral contraceptives, drugs acting on the uterus.

Unit II

Chemotherapy: General principles of chemotherapy. Sulfonamides, Quinolones, Beta-lactam antibiotics, Chloramphenicol, Tetracyclines, Macrolides and Aminoglycosides.

Chemotherapy of parasitic infections: Tuberculosis, leprosy, malaria, fungal infections, viral diseases.

Unit III

Naturopathy: History, definitions, mechanism and its effect on various systems, hydrotherapy, mud therapy, chromotherapy, acupressure, aromatherapy and therapeutic massage.

Unit IV

Pharmacovigilance: Scope, definition and aims of pharmacovigilance and pharmacoepidemiology, therapeutic index- LD_{50} and ED_{50}, drug interactions.

Adverse drug reactions: Classification, mechanism, predisposing factors and causality assessment. Role of clinical pharmacist in reporting, evaluation, monitoring, prevention and management of ADR, drug induced diseases affecting different organ systems.

Fixed dose drug combinations (FDDCs): Rational and irrational combinations, FDDCs in Indian scenario.

Unit V

Epidemiological methods: ***Case control study:*** Selection of cases, selection of controls, matching, measurements of exposure, analysis, odds ratio, bias in case control study, advantages, disadvantages.

Cohort study: Concept, framework, combination of prospective and retrospective cohort study, relative risk, attributable risk, advantages, disadvantages.

RPH-735P

PHARMACOLOGY-III (PHARMACOLOGY & PHARMACOVIGILANCE) PRACTICAL

Suggested Practicals

1. To calculate the pA_2 value of Atropine and Chlorpheniramine.
2. Bioassay of Ach, Histamine and Oxytocin on suitable isolated preparations using matching assay, bracketing assay, interpolation, three point assay and four point assay.
3. Bioassay of histamine and acetylcholine using matching and interpolation method on rat and guinea pig.

The experiments should be conducted using software, wherever possible.

BOOKS RECOMMENDED:

1. Rang M.P., Dale MM, Riter JM, Pharmacology Churchill Livingstone, China.
2. Tripathi, K.D. Essentials of Medical Pharmacology, Jay Pee Publishers, New Delhi.
3. Satoskar & Bhandarkar: Pharmacology & Pharmacotheropeutics, Popular Prakashan Pvt. Ltd., Bombay.
4. Ghosh M.N. Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta.
5. Katzung, B.G. Basic & Clinical Pharmacology, Prentice Hall International, New Delhi.
6. Ronald D. Mann & Elizabeth B. Andrews, Pharmacovigilance, John Wiley & Sons, West Sussex, England.
7. Waller and Patrick, An Introduction to Pharmacovigilance, John Wiley & Sons, West Sussex, England.
8. Mohanta G.P., Elementary Pharmacovigilance, PharmaMed Press, Hyderabad.
9. Mohanta G.P., Manna P.K., Textbook of Pharmacovigilance: Concept and Practice, PharmaMed Press, Hyderabad.
10. Grover J.K., Experiments in Pharmacy & Pharmacology, CBS Publishers, New Delhi.
11. Kulkarni S.K., Hand Book of Experimental Pharmacology, Vallabh Prakashan, Delhi.
12. Barar F.S.K : Text Book of Pharmacology, Interprint, New Delhi.
13. Goodman & Gilman, The Pharmacological basis of Therapeutics, Eds: Hardman J.G., Limbird Le, Molinoss P.B., Ruddon R.W. & Gil A.G., Pergamon Press, U.K.
14. Laurene, D.R. & Bennet P.N.; Clinical Pharmacology, Churchill Livingstone, Harlow, England.
15. Paul L., Principles of Pharmacology, Chapman and Hall, New York.
16. Ravi Shanker K., Kiranmayi G.V.N., Pharmacology: A Companion Handbook with Illustrations, PharmaMed Press, Hyderabad.

17. Singh S. J., History and Philosophy of Naturopathy, Nature Cure Council of Medical Research, Lucknow.
18. Bakhru H. K., Complete Handbook of Nature Cure, Jaico Publishing House, New Delhi.
19. Pizzorno J. E., Murray M. T., The Encyclopedia of Natural Medicine, Simon & Schuster, New York, USA.
20. Sheffield Bioscience Programs, U.K. ISBN. 1-8747558-02-6.

RPH-736

PHARMACOGNOSY-III

Unit I

Systematic study of source, cultivation, collection, processing, commercial varieties, chemical constituents, substitutes/adulterants, uses, diagnostic macroscopic and microscopic features and specific chemical tests of following alkaloid containing drugs-

Pyridine-piperidine: Tobacco, Areca and Lobelia.

Tropane: Belladona, Hyoscyamus, Datura, Coca and Withania. **Quinoline and isoquinoline:** Cinchona, Ipecac and Opium. **Indole:** Ergot, Rauwolfia, Catharanthus and Nux-vomica.

Unit II

Imidazole: Pilocarpus.

Steroidal: Veratrum and Kurchi.

Alkaloidal amine: Ephedra and Colchicum.

Glycoalkaloid: Solanum. **Purines:** Coffee and Tea **Quinazoline:** Vasaka.

Unit III

Production and utilization of phytoconstituents: Calcium sennosides, Diosgenin, Solasodine, Podophyllotoxins, Tropane alkaloids, Isoquinoline alkaloids and Quinoline alkaloids.

Unit IV

Plant tissue culture: Historical development of plant tissue culture, type of culture, nutritional requirements, growth and maintenance, factors affecting plant tissue culture. Applications of plant tissue culture in pharmacy.

Unit V

Introduction to herbal fingerprinting using HPTLC technique. Introduction to herbal drug interactions.

Introduction to bioactive compounds enhancing bioavailability such as- Piperine, Vitamin K.

RPH736-P

PHAMACOGNOSY-IV PRACTICAL

Suggested Practicals

1. To study the morphology and microscopy of Datura and Withania.
2. To study the morphology and microscopy of Ipecac and Rauwolfia.
3. To study the morphology and microscopy of Catharanthus and Nux-vomica.
4. To study the morphology and microscopy of Ephedra and Kurchi.
5. To study the morphology and microscopy of Solanum and Vasaka.
6. a) Morphology of Areca, Colchicum.
   b) Transverse section of Catharanthus leaf and Kurchi bark.
7. To study the TLC profile of Catharanthus leaf.
8. To study the TLC profile of Withania root.
9. Chemical test of Tea, Tobacco, Datura and Withania.
10. Chemical test of Nux-vomica, Ephedra and Kurchi.
11. Preparation of different callus cultures using various parts of plants.
12. Study of micopropogation using callus culture.
13. Effect of various plant hormones on micropropogation.

BOOKS RECOMMENDED

1. Trease, G.E., and Evans, W.C., Pharmacognosy, Bailliere Tindall East Baorne, U.K.
2. Wallis. T.E. “Text Book of Pharmacognosy” J&A Churchill Ltd., London.
3. Kokate C.K., Gokhale A.S., Gokhale S.B., Cultivation of Medicinal Plants, Nirali Prakashan.
4. Tyler V.E., Lynnr B. and Robbers J.E., Pharmacognosy, 8th Edition, Lea & Febiger, Philadelphia.
5. Harborne J.B., Phytochemical Methods, Chapman & Hall International Edition, London.
6. Medicinal Plants of India, Vol. I & II, Indian Council of Medical Research, New Delhi.
7. Nadkarni A.K., Indian Materia Medica, Vol- 1&2, Popular Prakashan (P) Ltd., Bombay.
8. Sukh Dev, A Selection of Prime Ayurvedic Plant Drugs, Anamaya Publisher New Delhi.
9. Indian Herbal Pharmacopoeia, Vol. I & II, ICMR & RRL, Jammu.
10. Indian Ayurvedic Pharmacopoeia, Govt. of India.
11. The Wealth of India, Raw Materials (All volumes), Council of Scientific & Industrial Research, New Delhi.

12. Rastogi R. P. and Mehrotra B.N., Compendium of Indian Medicinal Plants I-IV, Publications & Information Directorate/Central Drug Research Institute, New Delhi.
13. Wallis T.E., Analytical Microscopy, J&A Churchill Ltd., London.
14. Kokate C.K., Practical Pharmacognosy, Vallabh Prakashan, New Delhi.
15. Iyengar M.A., Pharmacognosy of Powdered Crude Drugs, PharmaMed Press, Hyderabad.
16. Iyengar, M.A. and Nayak S.C.K., Anatomy of Powdered Crude Drugs, PharmaMed Press, Hyderabad.

RPH-737

PHARMACEUTICAL ANALYSIS-III
(PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE)

Unit I

Ultra violet and visible spectroscopy: Principle and origin of spectra, quantitative laws, chromophores and auxochromes, factors affecting absorption, instrumentation- single and double beam spectrophotometer, Woodward-Fieser rule, applications.

Infra-red spectroscopy: Principle, effect of hydrogen bonding and conjugation on absorption band, instrumentation, interpretation of IR spectra of simple compounds (Ethanol, Benzaldehyde). FTIR, applications of IR spectroscopy in pharmaceutical analysis.

Unit II

NMR spectroscopy: Principle of ^{1}H-NMR, chemical shift and factors affecting it, shielding and desheilding, spin-spin coupling and coupling constant, spin-spin splitting, instrumentation, NMR active compounds and study of ^{1}H-NMR spectra of- Ethanol, Benzaldehyde. Introduction to^{13}C-NMR.

Unit III

Mass spectrometry: Principle, fragmentation pattern in relation to molecular structure and functional groups including McLafferty rearrangement, ionization techniques (CI, FAB, ESI, MALDI), instrumentation, applications, mass spectra of some simple compounds (Ethanol, Benzaldehyde).

Unit IV

Miscellaneous techniques: Principle, instrumentation and applications of atomic absorption spectroscopy, fluorimetry and flame photometry.

Introduction to gel electrophoresis, scanning electron microscopy (SEM) and transmission electron microscopy (TEM).

Unit V

Quality Assurance: Basic concept of quality, difference between QC and QA, quality audit, types of quality audits, concept of TQM, ISO 9000 series. Elementary study of WHO guidelines. Different documents prepared by QA department (batch manufacturing record, master formula record, validation master plan). Basic concept of validation, types of validation, different validation parameters, protocols for process validation.

RPH-737P

PHARMACEUTICAL ANALYSIS-III
(PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE) PRACTICAL

1. Determination of λ_{max} of different compounds by UV-visible spectrophotometry.
2. Verification of Beer's law.
3. Determination of unknown concentration of some drugs by UV-visible spectrophotometry.
4. Simultaneous estimation of multi-component drugs by UV-visible spectrophotometry.
5. Determination of factors which affect λ_{max} by UV-visible spectrophotometry.
6. Interpretation of IR, Mass and NMR spectra.
7. Assay of official formulations containing single and more active ingredients using instrumental techniques.
8. Assay of pharmaceutical substances by flame spectrophotometry (NaCl, KCl oral sachet).
9. Separation of a protein mixture using gel electrophoresis.
10. Formation and maintenance of different documents/records formed by QA department.

BOOKS RECOMMENDED

1. Pharmacopoeia of India, Ministry of Health, Govt. of India.
2. Becket A. H. and Stenlake J. B., Practical Pharmaceutical Chemistry Vol. I and II, The Athlone Press of the University of London.
3. Chatten L. G., A text book of Pharmaceutical Chemistry, Vol. I & II, Marcel Dekker, New York.
4. Willard H.H.,Merrit L.L., Dean J.A.,Settle P.A., Instrumental Methods of analysis, Van Nostrand Renhold, New York.
5. Obonson J.W.R., Undergraduate Instrumental Analysis, Marcel Dekker Inc, New York, 1970.
6. Parikh V.H., Absorption Spectroscopy of Organic Molecules, Addison-Wesley Publishing Co., London.
7. Silverstein R.M.,and Webster F.X., Spectrometric Identification of Organic Compounds, John Wiley & Sons.
8. Skoog V., Principles of Instrumental Analysis, Holler-Neimen.
9. Kemp W., Organic spectroscopy, 3rd Edition, Palgrave, New York.
10. Kalsi P.S., Spectroscopy of Organic Compounds, New Age International Publishers, New Delhi.

11. Pavia D.L.,Lampman G.M., and Kriz G.S., Introduction to spectroscopy, 3rd Edition, Harcourt College Publishers, Philadelphia.
12. Florey K., Analytical Profile of Drug Substance (All volume), Academic Press, Elsevier.
13. WHO-Quality Assurance of Pharmaceuticals, Vol. I & II, AITBS Publisher & Distributors, Delhi.
14. Berry I.R. and Harpaz, D., Validation of API, 2ndEdition, CRC Press.

RPH-738P

HOSPITAL TRAINIGNG-II

Training of students at a hospital establishment for a minimum duration of 45 days. The hospital training shall include: First aid (wound dressing, artificial respiration etc.), different routes of injection, study of patient observation charts, prescriptions and dispensing, simple diagnostic reports etc.

May be performed at the end of the 6th semester.

EIGHTH SEMESTER

RPH-839

PHARMACEUTICAL CHEMISTYRY-IX (CHEMISTRY OF NATURAL PRODUCTS)

Unit I

General methods of isolation and separation of plant constituents, qualitative tests for the detection of plant constituents. Application of spectral techniques in the structure determination of natural products.

Biogenetic investigations and basic metabolic pathways (Alkaloids, Terpenes, Steroids). Brief introduction to biogenesis of secondary metabolites of pharmaceutical importance (Atropine, Quinine, Papaverine, Morphine and Reserpine).

Unit II

Extraction, isolation and structure elucidation of **alkaloids:** Tropanes (Atropine);
Phenanthrenes
(Morphine); Quinolines (Quinine); Isoquinolines (Papaverine); Indoles (Reserpine).

Unit III

Extraction, isolation and structure elucidation of-

Glycosides: Digoxin. **Flavonoids:** Quercetin. **Lignans:** Podophyllotoxin. **Purines**: Caffeine.

Unit IV

Extraction, isolation and structure elucidation of- **Terpenoids**: Camphor, Menthol, Citral.

Carotenoids: β- Carotene.

Vitamins: α -Tocopherol.

Quassinoids: Quassin.

Unit V

Natural allergens, photosensitizing agents and fungal toxins. Role of natural products in drug discovery and development.

Recent developments of natural products used as anticancer agents, antidiabetics, antimalarials and immunomodulators.

RPH-839P

PHARMACEUTICAL CHEMISTYRY-IX
(CHEMISTRY OF NATURAL PRODUCTS) PRACTICAL

Suggested Practicals

1. Isolation of Caffeine from tea leaves.
2. Isolation of Piperine from black pepper.
3. Isolation of Hesperidin from orange peel.
4. Isolation of Clove oil from clove.
5. Isolation of Caraway oil from caraway.
6. Isolation of Cumin oil from cumin.
7. To study the TLC profile of extracted oils.
8. To perform the column chromatography of any available herb.
9. To study the paper chromatographic profile of glycone portion separated from senna.
10. To isolate the active constituent of any available drug with the help of preparative TLC.
11. Quantitative determination of Ascorbic Acid present in amla.

BOOKS RECOMMENDED

1. Brain K.R. and Turner T.D., The Practical Evaluation of Phytopharmaceutical, Wright, Bristol.
2. Kokate C.K., "Practical Pharmacognosy" Vallabh Prakashan, New Delhi.
3. Stahl E., Thin Layer Chromatography: A Laboratory Hand Book, Springer International Edition, New York.
4. Harborne J.B., Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis, Springer (India) Pvt. Ltd., New Delhi.
5. Dewick P.M., Medicinal Natural Products: A Biosynthetic Approach, John Wiley and Sons Ltd., England.
6. Wagner H., Plant Drug Analysis, Springer, Berlin.
7. Cutler S.J. and Cutler H.G., Biologically Active Natural Products: Pharmaceuticals, CRC Press, London.

8. Manitto P., Biosynthesis of Natural Products, BSP Books Pvt. Ltd., Hyderabad.
9. Finar I.L.,Organic chemistry, Volume II: Stereochemistry and the Chemistry of Natural Products, Pearson Education, New Jersey.
10. Indian Herbal Pharmacopoeia, Indian Drug Manufacturers Association and Regional Research Laboratory, Jammu.
11. Agarwal O.P., Organic Chemistry, Natural Products, Krishna Prakashan Media (P) Ltd., Meerut.
12. Evans V.C., Trease and Evans Pharmacognosy, Harcourt Publishers Ltd., Sydney.
13. Wallis T. E., Textbook of Pharmacognosy, CBS Publishers and Distributors, New Delhi.
14. Kokate C.K., Practical Pharmacognosy, Vallabh Prakashan, Delhi.
15. Jarald E.E. and Jarald S.E., Textbook of Pharmacognosy and Phytochemistry, CBS Publishers and Distributors Pvt. Ltd., New Delhi.
16. Tyler V.E., “Pharmacognosy” Lea & Febiger, Philadelphia.
17. Deore S.L., Khadabadi S.S., Baviskar B.A., Pharmacognosy and Phytochemistry: A Comprehensive Approach, PharmaMed Press, Hyderabad.
18. Prasad M. R, Rao A.R., Advanced Medicinal Chemistry: A Laboratory Guide, PharmaMed Press, Hyderabad.

RPH-840/ RPH-740

PHARMACEUTICS-X (PHARMACEUTICAL BIOTECHNOLOGY)

Unit I

Immunology and immunological preparations: Principles, antigen and haptens, immune system, cellular and humoral immunity, immunological tolerance, antigen-antibody reactions and their applications, standardization and storage of vaccine.

Unit II

Recombinant DNA technology: A brief introduction to genetic engineering and techniques, production of r-DNA and their application, development of hybridoma for monoclonal antibodies and their application, protoplast fusion and biotechnological production of products such as Insulin and Somatotropin.

Unit III

Antibiotics: Screening of soil for organisms producing antibiotics. Fermentor: Basic design, control of different parameters and application. Isolation of mutants and factors affecting mutation.

Unit IV

Microbial transformation: Introduction, types of reactions mediated by microorganisms, selection of organisms, methodology of biotransformation, process improvements with special reference to steroids.

Unit V

Enzyme immobilization: Sources of enzymes, techniques of immobilization of enzymes and cell, advantages and limitation of immobilization, application of immobilization in pharmacy. Biotechnological production and pharmaceutical application of enzymes such as penicillinase, α-galactosidase, amylases and proteases.

RPH-840P/ RPH-740P

PHARMACEUTICS-X (PHARMACEUTICAL BIOTECHNOLOGY) PRACTICAL

Suggested Practicals

1. Estimation of protein in given sample.
2. Production of protoplast fused cells by chemical method.
3. Production of protoplast fused cells by mechanical method.
4. Estimation of immunological reaction (blood group etc.).
5. Assay of antibiotics.
6. Screening of soil for antibiotic producing microorganisms.
7. Immobilization of drug.
8. Immobilization of enzyme.
9. Immobilization of cell.
10. Protein estimation by gel electrophoresis.
11. Isolation of enzymes from natural sources.

BOOKS RECOMMENDED

1. Prescott and Dunn's Industrial Microbiology, CBS Publishers and Distributors, New Delhi.
2. Vyas S.P. and Dixit V.K., Pharmaceutical Biotechnology, CBS Publication, New Delhi.
3. Kieslich K. , Biotechnology, Verleg Chernie, Switzerland.
4. Standury P.F.,Whitaker A. & Hall S.J. ,Principles of Fermentation, Aditya Book Private Limited, New Delhi.
5. Crueger W. & Crueger A, Biotechnology- A Textbook of Industrial Microbiology, Panima Publishing Corporation, Delhi.

RPH-841/ RPH-741

PHARMACEUTICS-XI (PHARMACEUTICAL MARKETING & MANAGEMENT)

Unit I

Concepts of management: Definition, administrative management (planning, organizing, staffing, directing and controlling). Entrepreneurship development, introduction to operative management (personnel, materials, production, financial management).

Unit II

Principles of management: Coordination, communication, motivation, decision making, leadership, innovation and creativity.

Production management: A brief study of the different aspects of production management, methodology of activities: performance evaluation, review technique, maintenance management.

Unit III

Pharmaceutical marketing: Introduction to pharmaceutical marketing. Functions, buying, selling, transportation, storage and finance. Feedback information, channels of distribution, wholesale, retail, department store. Introduction to e-commerce (online shopping, online banking, pretail, marketing to prospective and established customers) and start up business.

Unit IV

Salesmanship: Principle of sales promotion, advertising, ethics of sales, merchandising, literature, detailing, recruitment, training, performance appraisal of sales force.

Unit V

Market research: Definition, steps and limitations of market research. Market segmentation and market targeting. Major concepts in demand measurement, estimating current demand. Geo-demo- graphic analysis. Estimating industry sales.

BOOKS RECOMMENDED

1. Beri, Marketing Research .Tata Mc Graw Hill Publishing Company Limited, New Delhi.
2. Chary S.N, Production and Operations Management. Tata Mc Graw Hill Publishing CompanyLimited, New Delhi.
3. Datta A.K., Materials Management. Prentice Hall of India Private Limited, New Delhi.
4. Massie L. Joseph, Essentials of Management. Prentice Hall of India Private Limited,

New Delhi.

5. Shreenivasan K.R., An Introduction to Industrial Management. Vikas Publishing House Private Limited, New Delhi.
6. Daver Rustam S., Salesmanship and Publicity. Vikas Publishing House Private Limited, New Delhi.
7. Mukopadhyay S., Pharmaceutical Selling, Sterling Publishers.
8. Koontz H, Weihrich H, Essentials of Management. Tata Mc Graw Hill Publishing Company Limited, New Delhi.
9. G Vidya Sagar, Pharmaceutical Industrial Management, Pharma Med Press, Hyderabad.
10. Micky C Smith, Principles of Pharmaceutical Marketing.CBS Publishers and Distributors, New Delhi.
11. Chaganti S.R., Pharmaceutical Marketing in India: Concept, strategy and cases. Pharma Med Press, Hyderabad.

RPH-842

PHARMACEUTICS-XII (FOOD & NEUTRACEUTICALS)

Unit I

Introduction to food technology.

Food Processing: Freezing, changes in food during refrigerated storage, progressive freezing, Ice crystal damage, effect of dehydration, microwave heating and drying methods on food products.

Unit II

Food packaging and preservation: Properties of packaging material used for food packaging, influence of packaging material on changes of food stuffs, brief description of packaging of frozen, dried products and thermally processed foods.

Brief description of food preservation and its methods.

Unit III

Neutraceuticals: Introduction, classification, categories and rational of use of neutraceuticals.

Brief description to dietary supplements, fortified foods, functional foods and phytoneutraceuticals.

Unit IV

Development and marketing of neutraceutical products: Supercritical fluid extraction technology-basics and application for extraction of neutraceuticals from various sources, Packaging, label claims. Regulatory aspects of neutraceutical products in India.

Unit V

Testing of neutraceuticals and food products: Testing of microbial load, nutritional value, heavy metals, calorific value and neutraceutical label claim test.

Brief introduction to Agmark, Bureau of Indian Standards (BIS) and Food Safety and Standards Authority of India (FSSAI).

RPH-842P

PHARMACEUTICS-XII (FOOD & NEUTRACEUTICALS) PRACTICALS

Suggested Practicals

1. Preparation of traditional health products e.g. Gulkand, Amla syrup
2. Formulation of health drinks.
3. Preparation and testing of some food products.
4. Testing of food packaging materials.
5. Preparation and testing of some neutraceuticals.

BOOKS RECOMMENDED

1. Potter, N. M., Food Science, CBS Publishers and Distributors, New Delhi.
2. Manay, S. and Shadaksharaswami, M., Foods: Facts and Principles, New Age Publishers, New Delhi.
3. Frazier W.C. and Westhoff, D.C., Food Microbiology, TMH, New Delhi.
4. Krammer, A. and Twigg B.A., Quality control for food industry, Third edition, AVI, West port.
5. Ranganna S., Handbook of Analysis and Quality control for Fruit and Vegetables Products, Tata McGraw Hill, New Delhi.
6. Girdharilal, Preservation of Food and Vegetables, ICAR, New Delhi.
7. Fellows P., Food Processing Technology: Principles and Practice, Ellis Horwood Ltd, Horwood.
8. Earle R. L., Unit Operations in Food Processing, Pergamon Press, New York.
9. Deore, S. L. Khadbadi S. S., and Baviskar B. A., Pharmacognosy and Phytochemistry: A Comprehensive Approach, PharmaMed Press, Hyderabad.
10. Robert E.C., Wildman, R., Taylor C. Wallace., Handbook of Nutraceuticals and Functional Foods, Second Edition. CRC Press, Boca Raton.

ELECTIVE

RPH-843(A)

COMPUTATIONAL METHODS IN DRUG DESIGN

Unit I

Introduction to drug design concept, rational approaches of drug design, role of computational chemistry in drug design. The concept of drug likeness and druggability.

Chemometrics: Introduction to multivariate analysis, linear (PCA, MLR, PLS) and non-linear methods, validation tools. Introduction to some statistical softwares (such as; SPSS, Graph Pad Prism etc.).

Unit II

Molecular Modeling: Introduction to the principles of molecular mechanics, quantum mechanics, molecular dynamics and their applications in drug design.

Unit III

Quantitative structure activity relationship (QSAR): Basic concepts of QSAR, molecular descriptors (2D and 3D parameters), biological parameters, tools and techniques, quantitative models, validation of models, introduction to 2D and 3D QSAR methodologies.

Unit IV

Virtual screening: Introduction to some molecule databases. Ligand based and structure based virtual screening. Similarity searching, various methods of similarity searching and their applications in virtual screening: QSAR modeling, pharmacophore modeling, shape based screening, fingerprint based screening etc.

Unit V

Structure based drug design: Protein Data Bank, molecular graphics, design of enzyme inhibitors, receptor based drug design, molecular docking and protein homology modeling. Introduction to bioinformatics and some drug design softwares (free and commercially available).

RPH-843(A)P

COMPUTATIONAL METHODS IN DRUG DESIGN PROJECT

Projects based on-

1. To perform the Hansch and Free-Wilson analysis for the given dataset.
2. To develop and validate a 3D-QSAR model on a given dataset.
3. To develop and validate a 3D-Pharmacophore model on a given dataset.
4. To create a 3D-QSAR based hypothesis for virtual screening on a small molecule dataset.
5. To create a shape-based pharmacophore query on a set of aligned molecules and perform a virtual screening on a small molecule dataset.
6. To perform the virtual screening on a small molecule dataset using different fingerprint methods.
7. To perform molecular docking simulation and study various non-covalent interaction in protein-ligand complex.
8. To perform a homology modeling for a given target using modeler.
9. To perform the structure based virtual screening on a small molecule dataset.
10. To perform the different machine learning methods on a given dataset.
11. To perform the drug-likeness (ADMET) for small molecules.

BOOKS RECOMMENDED

1. Patrick G.L., An Introduction to Medicinal Chemistry, Oxford University Press.
2. Perun T.J. and Propst C.L., Computer-aided Drug Design Methods and Applications, Saurabh Prakashan Pvt.Ltd., New Delhi.
3. Veerapandian P., Structure-based Drug Design, Sirohi Brothers Pvt. Ltd., Noida.
4. Burger A., A Guide to the Chemical Basis of Drug Design, A Wiley Interscience Publication (John Wiley & Sons), New York.
5. Wermuth C.G., The Practice of Medicinal Chemistry, Elsevier.
6. Purcell W.P., Bass G.E., Clayton J.M., Strategy of Drug Design: A Guide to Biological Activity, Pharmamed Press, Hyderabad.
7. Nogrady T., Medicinal Chemistry: A Biochemical Approach, Oxford University Press, NewYork.
8. Abraham D.J., Burger's Medicinal Chemistry and Drug Discovery, John Wiley and Sons Inc., New York.
9. Ananda Kumar T.D., Elementary Pharmacoinformatics, PharmaMed Press, Hyderabad.

RPH-843(B)

GOOD MANUFACTURING PRACTICES

Unit I

Introduction to good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP). Schedule M.

Standard operating procedure (SOP): Introduction, preparation, validation and revision.

Unit II

Documentation: Protocols, forms and maintenance of records in pharmaceutical industry, preparation of document for investigational new drug (IND), new drug application (NDA), abbreviated new drug application (ANDA) and export registration.

Unit III

Introduction to 21-Code of federal regulations. Current good manufacturing practices (c-GMP) guidelines according to United States Food and Drug Administration (USFDA), difference between GMP and c-GMP.

Unit IV

Pharmaceutical product recall: Recall classification, strategy for effective recall, FDA requested recall, firm initiated recall, recall status reports, termination of recall.

Introduction to finished product reprocessing and salvaging.

Unit V

Sampling: Introduction, WHO guidelines, sampling plans and techniques, operating characteristics curves, maintenance of sampling records of finished product and packaging material.

RPH-843(B)P

GOOD MANUFACTURING PRACTICES PROJECT

Projects based on-

1. Study the steps to generate SOP.
2. Generation and validation of SOP for Autoclave.
3. Generation and validation of SOP for Dissolution apparatus.
4. Generation and validation of SOP for Centrifuge.
5. Generation and validation of SOP for Balance (electronic and dispensing).
6. Generation and validation of SOP for Cleaning.
7. Generation and validation of SOP for Hot air oven.
8. Generation and validation of SOP for Disintegration apparatus.
9. Generation and validation of SOP for Friability apparatus.
10. Generation and validation of SOP for Incubator.
11. Generation of Master formula record.
12. Generation of Batch formula record.

BOOKS RECOMMENDED

1. Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, New York.
2. Garfield, Quality Assurance Principles for Analytical Laboratories, Published by Oxford University Press, USA.
3. Potdar M. A., Current Good Manufacturing Practices for Pharmaceuticals. PharmaMed Press, Hyderabad.
4. Loftus and Nash, Pharmaceutical Process Validation, Taylor & Francis, New York.
5. Florey, Analytical Profile of Drugs (All volumes), Academic Press, United States.
6. Indian Pharmacopoeia.
7. United States Pharmacopoeia.
8. British Pharmacopoeia.

RPH-843(C)

CLINICAL PHARMACY

Unit I

Introduction to clinical pharmacy: Definition, development and scope of clinical pharmacy. Variability in human response to drugs and influence of disease processes: Drug handling and prescribing in the elderly, infants and children. Drug usage in pregnancy and in breast-feeding women. Prescribing for patients with renal or hepatic disease. Pharmacogenetics: implications for altered or unusual drug handling. Pharmacoepidemiology.

Unit II

Data analysis and compiling: The patient's case history, communication skills including patient medication history interview, patient counseling. Pharmacoeconomics.

Medical writing: Regulatory and educational medical writing.

Literature review and meta-analysis: Process, methods and application, research, report and paper/ thesis writing.

Pharmacovigilance programme of India (PvPI) and Geneva (UPSALA).

Unit III

Daily activities of clinical pharmacists: Drug therapy monitoring (medication chart view, clinical review), therapeutic drug monitoring, ward round participation, drug utilization evaluation/ review (DUE)/ (DUR). Quality assurance of clinical pharmacy services.

Unit IV

Research design and conduct of clinical trials: Research support including planning and execution of clinical trials. Schedule Y, GLP, GCP and ICH Guidelines, trial master file and ethical requirements. Various phases of clinical trials. Categories of Phase IV studies. Bioavailability (BA) and bioequivalence (BE) studies and the estimation with the help of plasma-concentration profile curve. Statistical analysis plan (SAP) and its importance in clinical research.

Unit V

Data collection and biostatistical analysis: Statistical principles underlying clinical trials, data handling and role of biostatistician.

Sample size calculation, types of variables, Type I error and type II errors, application of parametric and non-parametric tests, confidence intervals, outliers. Data analysis with the help of bio-statistical software.

RPH-843(C)P

CLINICAL PHARMACY PROJECT

Projects based on-

Epidemiological survey and comparison of prescribed therapeutic agents/diagnostic reports on different diseases such as- Cardiovascular disorders, central nervous system disorders, gastro intestinal tract disorders, hormonal disorders, pathogenic diseases.

BOOKS RECOMMENDED

1. Scott L.T., Basic skills in interpreting laboratory data, American Society of Health System Pharmacists Inc., USA.
2. Rowland and Tozer, Clinical Pharmacokinetics, Williams and Wilkins Publication, Philadelphia, USA.
3. Shargel L., Biopharmaceutics and Applied Pharmacokinetics, Prentice Hall publication, New Delhi.
4. Parthasarthi G., Nyfort-Hansen K. and Nahata M.C., A Text book of Clinical Pharmacy Practice-Essential Concepts and Skills, Orient Longman, Chennai.
5. Colledge N.R., Walker B. R. and Stuart H., Ralston Davisson's Principles and Practice of Medicine, ELBS/Churchill Livingstone, Edinburgh, U.K.
6. Herfindal E.T. and Hirashman J.L., Clinical Pharmacy and Therapeutics Williams and Wilkins, Philadelphia, USA.
7. Wagner J.G., Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publishing A G Basel, Switzerland.
8. Katzung B., Masters S. and Trevor A., Basic and Clinical Pharmacology, McGraw Hill Professional, U.K.
9. Spilker B. and Schoenfelder J., Data Collection Forms in Clinical Trials, Raven Press, New York.
10. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London.
11. Stockley I.H., Drug interactions, Pharmaceutical Press, London.
12. Ravishankar K., Kiranmayi G.V.N., Clinical Pharmacy and Pharmacotherapeutics, PharmaMed Press, Hyderabad.

RPH-843(D)

STANDARDIZATION OF HERBAL DRUGS

Unit I

Commerce and quality control of natural medicinal plants products, organoleptic, microscopical, physical and chemical evaluation of crude drugs.

Unit II

Standardization of plant material as per WHO guidelines.

Unit III

Methods of extraction and modern techniques for the isolation, purification, separation estimation and characterization of active plant constituents.

Unit IV

Analysis of official formulations derived from crude drugs, including some ayurvedic preparations.

Unit V

General methods of screening of natural products for following biological activity:

a) Anti-inflammatory

b) Hypoglycaemic

c) Antifertility

e) Psychopharmacological.

RPH-843(D)P

STANDARDIZATION OF HERBAL DRUGS PROJECT

Projects based on-

1. Standardization of Ayurvedic liquid formulations on the basis of the following parameters- viscosity, pH, loss on drying, foaming index, chromatography.
2. Standardization of Ayurvedic powdered formulations on the basis of following parameters- extractable matter by using various solvents, ash value, stomatal and stomatal index, trichomes and their types, loss on drying, foaming index, fiber content, chromatography.
3. Stability studies of herbal products as per WHO guidelines.

BOOK RECOMMENDED

1. Trease, G.E., and Evans, W.C., Pharmacognosy, Bailliere Tindall East Baorne, U.K.
2. Tyler V.E., Lynnr B. and Robbers J.E., Pharmacognosy, 8th Edition, Lea & Febiger, Philadelphia.
3. Harborne J.B., Phytochemical Methods, Chapman & Hall International Edition, London.
4. Pharmacoepial Standards for Ayurvedic Formulations, CCRAS, Delhi.
5. Dhavan B.N. and Srimal R.C., The Use of Pharmacological Techniques for Evaluation of Natural Products. CDRI, Lucknow.
6. Brain K.R. and Turner T.D, The Practical Evaluation of Phytopharmaceuticals, Wright, Bristol.
7. Peach K. and Tracey MV, Modern Methods of Plant Analysis, Springer, Berlin.
17. Indian Herbal Pharmacopoeia, Vol. I & II, ICMR & RRL, Jammu.
8. Chaudhary. R.D., Herbal Drug Industry, Eastern Publisher, New Delhi.
9. Deore S.L., Khadabadi S.S., Baviskar B.A., Pharmacognosy and Phytochemistry: A Comprehensive Approach, PharmaMed Press, Hyderabad.
10. Nadkarni A.K., Indian Materia Medica, Vol- 1&2, Popular Prakashan (P) Ltd., Bombay.
11. Sukh Dev, A Selection of Prime Ayurvedic Plant Drugs, Anamaya Publisher New Delhi.
12. Indian Ayurvedic Pharmacopoeia, Govt. of India.
13. The Wealth of India, Raw Materials (All volumes), Council of Scientific & Industrial Research, New Delhi.
14. Mukherjee P.K., Quality Control of Herbal Drugs, Business Horizones Pharmaceutical Publisher, New Delhi.

RPH-843(E)

RESEARCH METHODOLOGY

Unit I

Fundamentals of research: Meaning and objective of research, types of research (basic, applied and patent oriented), defining research problem, research design including various methods, research process and steps involved.

Literature survey and documentation: Methods of literature survey, use of library, books, journals, e-journals, thesis, chemical abstracts and patent database, importance of documentation, documentation techniques, use of computer programs/packages (online resources such as- scientific search engines and online servers) in literature survey and documentation.

Unit II

Data collection and data analysis: Execution of the research, observation and collection of data, types of data (primary and secondary), methods of data collection, sample size, sampling procedure and methods. Data processing and analysis strategies. Research hypothesis (experimental and non-experimental), hypothesis testing (parametric and non-parametric tests), types of errors and their control, generalization and interpretation of results. Use of statistical softwares/ packages in data analysis (SPSS, Graph Pad Prism).

Unit III

Technical writing and reporting of research: Types of research report: Dissertation and thesis, research paper, review article, short communication, conference presentation, meeting report etc. Structure and organization of research reports: Title, abstract, key words, introduction, methodology, results, discussion, conclusion, acknowledgement, references, footnotes, tables and illustrations. Use of reference managing softwares (such as- MENDELEY, ENDNOTE). Impact factor, rating, indexing and citation of journals.

Detailed study of 'Instruction to Authors' of any ACS or ScienceDirect journal, a thorough understanding of steps involved in submitting articles electronically to any ACS or ScienceDirect journal (registration, new article submission, tracking process, submitting revised articles).

Unit IV

Research ethics, ethical consideration during animal experimentation including CPCSEA guidelines, impact of research on environment and society, commercialization of research, intellectual ownership, plagiarism and use of plagiarism detection softwares such as

TURNITIN, VIPER etc., responsibility and accountability of the researchers. Academia-Industry interface and research.

Project cost management: Cost analysis of the project, cost incurred on raw materials, procedure, instrumentation and biological testing.

Unit V

Funding agencies and research grants: Introduction to various research funding agencies such as-DST, DBT, AICTE, UGC, CSIR, ICMR, AAYUSH, and DRDO along with their functions in India. Writing a research project and procurement of research grant.

RPH-843(E)P

RESEARCH METHODOLOGY PROJECT

Projects based on-

1. Literature survey, data collection, formulation and testing of hypothesis, interpretation of results on a particular research project.
2. Use of statistical packages/ programs (such as SPSS, Graph Pad Prism) in data analysis.
3. Collection, compilation and execution of computational programs for research benefits.
4. Manuscript preparation, communication and follow-up of a research paper/review article.
5. Writing a research project for the procurement of research grant/travel grant from any funding agency.
6. Preparation and presentation of a research report (Oral and Poster presentations using Microsoft PowerPoint Package, Microsoft Publisher etc.).

BOOKS RECOMMENDED

1. Kothari C.R., Research Methodology Methods and Techniques, 2nd Edition, Wishwa Prakashan, New Delhi.
2. Lokesh K., Methodology of Educational research, 3rd revised Edition,Vikash Publishing House Pvt. Ltd., New Delhi.
3. Kumar R., Research Methodology, 2nd Edition, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
4. Rao G.N., Research Methodology and Qualitative Methods, B.S. Publications, Hyderabad.
5. Saunders M., Lewis P.and Thornhill A., Research Methods for Business Students,3rdEdition, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
6. Bolton S. and Bon C., Pharmaceutical Statistics: Practical and Clinical Applications, 4th edition, Marcel Dekker, New York.
7. Matad V., Anusuya D., Medicomarketing Writing, PharmaMed Press, Hyderabad.
8. Garg, B.L., Karadia, R., Agarwal, F. and Agarwal, U.K., 2002. An introduction to Research Methodology, RBSA Publishers.

RPH-844P

REPORT ON INDUSTRIAL/ RESEARCH LABORATORY VISIT

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

May be performed at the end of the 7th semester.