

**DEPARTMENT OF PHARMACEUTICAL SCIENCES  
UNIVERSITY OF KASHMIR  
SRINAGAR**

**COURSE NO: XXVI**

**PHARMACEUTICAL BIOTECHNOLOGY**

**Total hours: 25**

1. Brief Introduction to biotechnology with reference to Pharmaceutical sciences.
2. **Genetic Engineering:** Structure, function and properties of genetic material, Basic principles of genetic engineering, DNA recombination, Applications of genetic engineering in medicine.
3. **Enzyme and Cell Immobilization:** Methods for Immobilization, Applications.
4. **Plant biotechnology:** Natural plant products, their uses, plant cell culture for the production of useful chemicals, plant tissue culture, protoplast fusion, totipotency, direct gene transfer.
5. **Medical biotechnology:** Blood products, Immunoglobulins by hybridoma technology, Synthesis of monoclonal antibodies, biopolymers, derivative of biopolymers and their application in medicine.

**BOOKS RECOMMENDED:**

1. Molecular Biology and Biotechnology, Ed. By J.M.Walker and E.B.Gingold, Royal Society of Chemistry.
2. Biotechnology, Vol I, Ed. By R.J. Rohm and Verlag Chemie.
3. Biochemical Engineering by A.Iba, Humphry and Milles, University of Tokyo press.
4. Immobilized Enzymes, an introduction and application in Biotechnology by Michael Traven, Jhon Willey & Sons.
5. Immobilized Enzymes by Zaborsky(1973) CRS press, Degrandland, Ohio.
6. Essentials of Immunology by Roit, Blackwell Scientific publishing , London.

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**COURSE NO: XXVII**

**PHARMACEUTICAL MARKETING AND MANAGEMENT**

**No of lectures: 50**

- 1. Personnel Management And Industrial Relations:** Objectives and functions of personnel department, Employment and development of personnel industrial relations: Problems of labour management relations, Courses of industrial disputes, Remedies, Industrial dispute Act, Trade union , Grievance handling procedures, causes of grievances, needs for grievance procedure, grievance redressal machinery.
- 2. Motivation:** Objectives, Rules of motivation, Motivation steps, Types of motivation, Non-financial motivators, Theories of Motivation (McGregor's theory X and Y, Herzberg's time factor theory, McClelland's need for achievement theory, Vroom's Expectancy theory, Behavioural theory, Employee- Centered approach).
- 3. Communication:** Importance, Nature of communication, Oral Vs. written media of communication, Barriers to communication, communication failure, achieving effective communication.
- 4. Purchasing and Store keeping:** Objectives, Organisation and responsibilities of purchasing department, Methods of purchasing, Centralised and Decentralised purchasing. Types of store depot, Location and layout of a store, problems and development.
- 5. Materials Management:** Materials handling, Equipment, Inventory management, Economic ordering quantity, ABC analysis, Value analysis, Classification and codification of stores, Obsolete, Surplus and scrap management, Lead time, Inventory carrying costs, Safety stock, Solutions!© problems relating to EOQ.
- 6. Drug supply:** Planning and management, supply process and its pitfalls, planning for drug supply, planning models, steps to develop a formulary, predicting drug requirements, procurement cycle and its methods, designing training programmes to improve pharmaceutical logistics.
- 7. Pharmaceutical Marketing:** Goals, theories of selling process, company market test method, statistical demand analysis, types of sales organizations, salesmanship, qualifications of a salesman, channels of distribution, advertising, presentation and analysis of statistical data( charts, frequency distribution).
- 8. Establishment of a Pharmaceutical factory:** Choice of site, trends in location of a plant, plant facilities, layout of stores in an industry, layout of injectable unit or sterile area, tableting department and area requirement for each department.

**BOOKS RECOMMENDED:**

1. R.S. Davar, Personnel management and Industrial relations.
2. Mamoria, Personnel management.
3. D.R.Gupta and R.K Rajput, Purchasing and Store keeping.
4. Gopal Krishnan, M.Sundarsan, Materials Management.
5. Borbon, Managing Drug supply: Management sciences for health.
6. Philip Hotter, Principles of Marketing.

7. U.K. Srivastava, S.C.Sharma, Quantitative techniques for Managerial decision making.
8. Smith, Pharmaceutical Marketing.
9. SP-Aganil, Establishment of Pharmaceutical factory.

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**COURSE NO: XXVIII**

**PHARMACEUTICS-XI  
(Pharmaceutical Technology)  
Total No. of lectures: 50**

1. **Mixing:** Fluid mixing, Mechanism and types of flow, equipments solids mixing, mixing mechanism, equipment.
2. **Capsules: Hard gelatin capsules:** formulation of shell & contents, capsule production, filling operation and equipment employed. **Soft gelatin capsules:** Manufacture, processing and quality control.
3. **Microencapsulation:** Importance and Application, techniques, equipment employed.
4. **Tablets:** Production of tablets, additives and components for compression, forms of compressed tablets, evaluation. **Tablet coating:** Sugar coating, film coating, air suspension coating, film defects.
5. **Measurement of tablet punch forces:** Transmission of forces through a powder. Distribution of forces within the powder mass, Effect of pressure on relative volume, Adhesion and Cohesion of particle strength of granules and tablets. Factors affecting the strength of tablets.
6. **Pharmaceutical Aerosols:** Components, formulation, types of systems, manufacturing, operation of an aerosol package , quality control and testing, oral, inhalation, nasal and topical aerosols, future developments.
7. **Controlled Drug Delivery systems:** Introduction, terminology, Drug targeting, Design and fabrication of oral controlled release drug delivery system. Introduction to implantable and transdermal therapeutic system.
8. **Sustained action dosage form:** Drug replacement rate, unit drug dose, mechanisms, formulation and manufacture of sustained action dosage form.
9. **Packaging technology:** Types of containers; materials used, closures, unit dose packaging, strip packaging materials, packaging of solid, parenterals and Ophthalmic dosage forms.
10. **Good Manufacturing practices for Pharmaceuticals:** Status and applicability of regulation, current good manufacturing practices in manufacturing, processing, packaging & holding of drugs, production and process controls, ISO 9000 certification.

**PRACTICALS: Total hours: 100**

1. Preparation of tablets by the following techniques:-
  - a) Wet granulation ( Aqueous)
  - b) Wet granulation (Non-aqueous)
  - c) Dry granulation (Slugging)
2. Coating of tablets- sugar coating and film coating.
3. Strip packing of tablets.
4. Quality control of tablets.

5. Filling and sealing of hard capsules
6. Quality control of capsules
7. Preparation of sustained release dosage forms employing various techniques.
8. Preparation of an aerosol dosage form and its evaluation
9. Preparation of microcapsules by employing various techniques.
10. Any other experiments illustrative of the theory of syllabus.

**BOOKS RECOMMENDED:**

1. Lachman, 3rd edition, the theory and practice of Industrial Pharmacy.
2. Michael E. Aulton, *Pharmaceutics: The Science of Dosage form Design*.
3. Robinson and Lee, *Controlled Drug Delivery: Fundamentals and Applications*.
4. James Swarbrick, *Novel Drug Delivery Systems*, Vol. 14, View Chien.
5. Rhodes and Banker, *Modern Pharmaceutics*, Vol.40, 2<sup>nd</sup> ed.
6. Willing, Tuckerman and Hitchings, *Good Manufacturing practices for Pharmaceuticals*, 2<sup>nd</sup> edition
7. Remington's *Pharmaceutical sciences*.

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**COURSE NO: XXIX**

**PHARMACEUTICAL ANALYSIS- III**

**Total hours: 50**

1. **Chromatography:** Fundamental principles of Chromatography, adsorption, partition, column, paper, thin layer Chromatography, gas Chromatography, electrophoresis, high performance liquid Chromatography, instrumentation with particular reference to quantitative estimation of drugs and biopharmaceutical agents. Theory of Ion exchange, types of exchangers, Ion-exchange equilibrium, Ion-exchange separation, applications in Pharmaceutical analysis.
2. **Visible and ultraviolet absorption Spectrophotometer:** Principles of visual and UV absorption spectrophotometer, qualitative and quantitative analysis, instrumentation.
3. **Nuclear Magnetic Resonance Spectroscopy:** An introduction to the theory of NMR, Chemical shifts, Spin-spin coupling, NMR instrumentation and applications.
4. **Infrared Spectrophotometry:** Origin of Infrared spectra and regions, qualitative and quantitative analysis, instruments and applications.
5. **Mass Spectrometry:** Basic principles, instrumentation, the Mass spectra, determination of molecular formula, Molecular Ion peak, fragmentation, mass spectra of some simple molecules.
6. **Flame photometry:** Origin of spectra, Atomization and Ionization, instrumentation, background emission, qualitative and quantitative applications in Pharmaceutical analysis.
7. **Atomic absorption:** Theory of absorption of radiant energy by atoms, equipment, analytical applications.
8. **Emission spectroscopy:** Theory of emission spectra, equipment, qualitative and quantitative applications.
9. **Polarography:** Introduction, theoretical consideration, Organic polarography, dropping mercury electrode, basic principles of polarographic instruments, methods of analysis, experiments including amperometric titrations.

**PRACTICALS Total hours; 100**

1. Experiments based on thin layer and paper Chromatography.
2. Analysis of drugs by instrumental methods as included in Indian Pharmacopoeia.

**BOOKS RECOMMENDED:**

1. LG.Chatte, A textbook of Pharmaceutical chemistry, Vol I & II, Marcel Dekker, New York.
2. A.H.Beckett and J.B. Stenlake, Practical Pharmaceutical Chemistry, Vol I & II, Ale Athlone press of University of London.
3. H.H.Willard, L.L.Merritt and J.A Dean, Instrumental methods of Analysis, Van Nostrand Reinbold, New York.
4. J. Basset, R.C.Denney, G.H.Jeffery and J.Medthan, Vogel's textbook of Quantitative Inorganic Analysis including elementary Instrumental Analysis, The ELBS and Longman.
5. KAConnors, A textbook of Pharmaceutical Analysis, Wiley Interscience, New York.
6. Jenkins et. al. Quantitative Pharmaceutical Chemistry.

7. D.C. Garrat, The Quantitative analysis of Drugs, Chapman & Hall, London.
8. R.M.Silverstein, G.C. Bassler and J.C. Morrill, Spectroscopic identification of Organic compounds- Jhon Wiley & Sons, New York.
5. Jhon R. Dyer- Application of absorption spectroscopy of organic compounds.

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**COURSE NO: BPH XXX**

**MEDICINAL CHEMISTRY-III**

**Total hours :50**

**1. ANITICONVULSANTS**

Phenobarbitone, Phenytoin, Trimethadion, Paramethadion, Phensuxlmidate, Valproic acid, Primadone, Carbamazepine.

**2. ANTIHISTAMINICS**

Diphenhydramine, Lamotrigine, Dimethindene, Pyrilamine maleate, Triproleamine maleate, Pheniramine maleate, Promethazine, Cyclizine, Buclizine, Chlorpheniramine.

**3. ANTIPARKINSONISM DRUGS**

Bipridine, Trihexyphenidyl, Procyclidine, Thopropazine, Orphenadrine citrate, Levodopa, Amantidine.

**4. DIURETICS**

Chloroethacrylamide, Mercaptopurine, Chlorothiazide, Bendroflumethiazide, Polythiazide, Acetazolamide, Disulfamide, Chlorothalidone, Furosemide, Ethacrynic acid, Spirmolactone, Triamterene.

**5. NON-STEROIDAL ANTI-INFLAMMATORY AGENTS**

Indomethacin, Tolmetin, Ibuprofen, Diclofenac, Ketoprofen, Naproxen, Auranofin, aspirin, Phenylbutazone.

**6. EXPECTORANTS & ANTITUSSIVES**

Acetylcysteine, Bromohexine, Ammonium chloride, Guaniphesine, Eucalyptol, Benzonatate, Nacopine, Genopropoxyphene, Pholcodine.

**7. HYPOGLYCAEMIC AGENTS**

Insulin, Tolbutamide, Chlopropamide, Glibenclamide, Glipizide, Phentornine, Piglitazone.

**8. ANTIPYRETIC ANALGESICS**

Paracetamol, Acetanilide, salicylamide, Benorylate phenazone, Dipyrone, Mefenamic acid,

**9. URICOSURICS (Anti-gout Agents)**

Probenecid, Sulfapyridine, allopurinol, Colchicine, Prednisolone.

**10. MUSCLE RELAXANTS**

Chlorzoxazone, Pilocarpine, Crisoproder, Mephencsin, Dantrolene

**11. ADRENERGIC DRUGS:**

Adrenaline, Noradrenaline, Terbutaline, Amphetamine, Ephedrine, Isoprenaline,

**12. CHOLINERGICS**

Acetylcholine, Pilocarpine, Carbachol, Edrophonium, Physostigmine, anticholinesterases.

**13. ANTISPASMODICS**

Homatropine, Dipiperidine Hcl, Dicyclolomine, Orphenadrine citrate,

**14. PSYCHOACTIVE DRUGS**

Trifluoperazine, Haloperidol, Diazepam, Oxazepam, Alprazolam, Amitriptyline, Imipramine, Fluoxetine, Venlafaxine, Phenelzine, Tranylcypromine.

**PRACTICALS: Total hours: 100**

Synthesis of compounds of medicinal interest including synthesis involving two steps and synthesis of heterocyclic compounds.

**BOOKS RECOMMENDED:**

1. M.E.Wolf, Burger's Medicinal Chemistry, Jhon Wiley & Sons, New York.
2. R.F.Doerge, Wilson & Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott.
3. W.O Foye, Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia.
4. D.Lednicer and L.A Mitschier, The Organic Chemistry of Drug Synthesis Vol I,II &III, Jhon Wiley & Sons, New York.
5. Ashotosh Kar, Medicinal Chemistry, Wiley Eastern, Ltd., New Delhi.
6. I.L.Finar, Organic Chemistry Vol. II, The English Language Book society, London.

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**COURSE NO: XXXI**

**PHARMACOGNOSY- IV  
Total hours; 50**

1. Study of drugs containing glycosides: Nature, Occurrence, Chemistry and Biogenesis. **Anthraquinone glycosides:** Cascara, Aloe, *Rhubarb*, *Senna*. **Cardiac glycosides:** *Digitalis*, *Stropanthus*, Squill, *Thevetia*, **Bitter glycosides:** Quassia **Saponin glycosides:** *Dioscorea*, *Quillia*, **Flavonoid glycosides:** *Ruta graveolens*.
2. Study of drugs containing alkaloids: Nature, occurrence, Chemistry and Biosynthesis. **Pyridine-Piperidine alkaloids:** Nicotine, *Areca nut*. **Tropane alkaloids:** *Belladonna*, *Hyoscymus*, *Stramonium*, *Duboisia*. **Quinoline alkaloids:** *Cinchona* **Isoquinoline alkaloids:** *Opium*, *Ipecae*. **Indole alkaloids:** *Nuxvomica*, *Ergot*, *Rauwolfia*, *Catharanthus*. **Steroida! alkaloids:** *Kurchi*, *Solanum*. **Alkaloidal Amines:** *Ephedra*, *Colchicum*.
3. Botanical source, history, clinical uses, chemical constituents, authentication and standardization of traditional drugs such as *Tylophora indica*, *Tribulus terrestris*, *Allium sativum*, *Achyranthus aspera*, *Centella asiatica*, *Boerhaavia, diffusa*, *Phyllanthus embelica*, *Azadirachta indica*, *Ocimum sanctum*, *Commiphora mukul*, *Swertia chirata*, *Withania somnifera*.
4. Study og general aspects of plant tissue culture techniques and their contribution to phytopharmaceuticals. Plant growth regulators.
5. Processes of plant extraction and chromatographic techniques as applicable to Phtopharmaceuticals.
6. World wide trade, Commercial, potential and demand of crude drugs with reference to Phytochemical industry in India.

**PRACTICALS Total hours: 100**

1. Identification of drugs in 1,2 and 3 based on Morphological and sensory characters.
2. Microscopy of drugs underlined in 1 and 2 and chemical tests wherever applicable.
3. Extraction and preparation of T.L.C. profile of some volatile oil containing drugs.
4. Preparation of T.L.C. profile of alkaloidal extracts of *Datura*, *Nux-vomica*, *Rauwolfia* and *Cinchona*.
5. Extraction of Piperine from *Piper nigrum*, total alkaloids of *Datura*, *Diosgenin* from *Dioscorrea*, *Hesperidin* from Orange peels.
6. Project work.

**BOOKS RECOMMENDED**

1. Tyler & Brady, Textbook of Pharmacognosy.
2. Wealth of India, Raw materials, CSIR publications, New Delhi.

3. C.K.Attal and B.K.Kapoor, Cultivation and Utilization of Medicinal & Aromatic plants.
4. Trease and Evan's Pharmacognosy.
5. Essentials of Pharmacognosy by Prof. S.H.Ansari.s

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**COURSE NO: XXXII**

**PHARMACOLOGY- III  
Total hours:- SO**

**1. CHEMOTHERAPY**

- a. General principles of Chemotherapy
- b. Sulfonamides, Quinolones , aminoglycosides, tetracyclines, penicillines, cephalosporins and macrolide antibiotics
- c. Antiprotozoal drugs
- d. Antimalarials
- e. Antiamoebics
- f. Antifungal and antiviral drugs
- g. Anti-helmintics
- h. Chemotherapy of Tuberculosis and leprosy.
- i. Chemotherapy of cancer, Immunomodulators.

**2. PHARMACOLOGY OF ENDOCRINE SYSTEM**

- a. Pituitary hormones
- b. Thyroid, antithyroid drugs.
- c. Insulin, Oral hypoglycemics and glucagons.
- d. Adrenocortical steroids and their antagonists.
- e. Sex hormones, contraceptives and drugs used in fertility.
- f. Drugs regulating calcium homeostasis.

**3. BIOASSAYS**

- a. General principles and methods of Bioassays.
- b. Official methods of bioassay: Insulin, Heparin, Oxytocin, d-Tubocurarine, Vasopressin, Digitalis, ACTH, Glucagon, Gonadotrophin.

**4. EVALUATION OF NEW DRUGS**

- a. Acute, subacute and chronic toxicity tests.
- b. Teratogenicity & Carcinogenicity.
- c. Clinical trials.

**5. VITAMINS.**

**PRACTICALS: Total hours: 100**

Bioassay of following by using appropriate isolated tissue preparation:

- i. Acetylcholine,
- ii. Histamine.
- iii. Adrenaline.
- iv. Oxytocin.

**BOOKS RECOMMENDED (Theory):**

1. Modern Pharmacology by C.R.Craig and R.E. Stitzel.
2. Goodman and Gilman's, The Pharmacological basis of Therapeutics by Alfred Goodman Gilman, Theodore W.Rall, Alan Nies and Palmer Tylor.
3. Clinical Pharmacology by D.R Laurence and P.N Bennett
4. Essentials of Medical Pharmacology by K.D Tripathi
5. Pharmacology and Pharmacotherapeutics by R.S Satoskar and S.D Bhandarkar.
6. Essentials of Pharmacotherapeutics by F.S.K.Barar.
7. Pharmacology by H.P.Rang and M.M.Dale
8. Lewis's Pharmacology, revised by James Crossland
9. Pharmacopoeia of India
10. British Pharmacopoeia Practicals:
  11. Selected Topics in Experimental Pharmacology by U.K Sheth, N.K Dadkar, Usha G. Kamat.
  12. Pharmacological experiments on isolated preparations by Edinburgh University Pharmacology Staff, 1968.
  13. Evaluation of Drug activities: Pharmacometrics, Vol. I edited by D.R. Laurence and A.L. Bacharach.
  14. Textbook of in vitro Pharmacology by Ian Kitchen.
  15. Handbook of Experimental Pharmacology by s.K. Kulkarni
  16. Fundamentals of Experimental Pharmacology by M.N.Gosh.

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**COURSE NO: BPH XXXIII**

**BIOPHARMACEUTICS AND PHARMACOKINETICS**

**Total hours:50**

**A. BIOPHARMACEUTICS:**

1. Introduction to Biopharmaceutics, definition, historical development of the subject, Fundamental principles and concepts. Definitions and explanation of the various terms connected with the study of Biopharmaceutics like Bioavailability, Bioequivalence and inequivalence, Chemical equivalence, therapeutic equivalence etc.
2. **Drug Absorption:**  
Various mechanisms, physio-chemical factors affecting drug absorption, biological factors in drug absorption, dosage form considerations in gastrointestinal absorption.
3. **Drug disposition:**  
Distribution in blood, plasma-protein binding, cellular distribution, drug penetration to cell, drug excretion -renal, biliary, salivary and biotransformation.
4. **Bioavailability:**  
Concept of bioavailability and comparative bioavailability. Methods of estimation of bioavailability using blood level and urinary excretion data.

**B. PHARMACOKINETICS:**

1. Introduction to Pharmacokinetics, importance in bioavailability and clinical practice and concepts. Definition and explanation of terminologies used.
2. Absorption, distribution, metabolism and excretion of drugs. Biological half-life, apparent volume of distribution, Fluid compartments and circulatory system.
3. Compartments models:- Concepts and their importance in the study of Pharmacokinetics. One compartment open model. Determination of drug/metabolic levels on administration of single and multiple dose in plasma and urine after i.v injection. Oral administration and first order absorption. Percent absorbed time plot and absorption rates based on one compartment model.
4. Two compartments open model, Pharmacokinetics of single and multiple dose administration as applied to intravenous(rapid) and oral administration, intravenous transformation.

**PRACTICALS Total hours: 100**

1. Establishment of standard curve of a drug substance.
2. Disintegration and dissolution of pe-roral tablets.
3. Influence of vehicle on drug availability from topical dosage form in- vitro.
4. Release of drug from suppository base/ ointment base.
5. Evaluation of antacid products, by acid neutralizing capacity and Rosset-Rice test methods.

6. Comparative in-vitro release rate studies of marketed formulations.
7. Determination of bioavailability of marketed formulations by urinary excretion method.
8. Determination of bioavailability of marketed formulations by Plasma concentration method.
9. Drug release from capsules, effect of diluents etc.
10. Effect of protein binding by egg Albumin; dialysis method.
11. Determination of Pharmacokinetic parameters and determination and evaluation of bioavailability of drug administered by IV, IM and PO.
12. Practice numericals based on the portions covered under theory syllabus.

### **BOOKS RECOMMENDED**

1. Javed AH, Roop K.Khar and Alka Ahuja- a textbook of biopharmaceutics and Pharmacokinetics, Birla publishers, New Delhi.
2. J.G.Wager, Biopharmaceutics and relevant Pharmacokinetics, Drug intelligence publications, Mamilton, ILL
3. M.Gibaidi and D. Perrier, Pharmacokinetics, Marcel Dekker, New York.
4. J.G.Wagner, Fundamentals of clinical Pharmacokinetics, Drug intelligence publications.
5. R.E. Notray, Biopharmaceutics and Pharmacokinetics - An introduction.
6. M. Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics.
7. L, Shargel, B.C.Y.Andrew, Applied Biopharmaceutics and Pharmacokinetics.
8. J.Swarbrick, Biopharmaceutics.
9. Rowland, Malcolm and Tezer, Clinical Pharmacokinetics, Lea and Febiger, Philadelphia.
10. E.V Kelkin and J.R. Janders, Clinical pharmacy, Elsevier, North Holland Biomedical press, New York.
11. E.T. Horfindal and J.L. Hirschman, Clinical pharmacy and Therapeutics, The Williams and Wilkin Co. Baltimore.