

University School of Pharmaceutical Sciences

Study scheme and Syllabus

Batch 2015 onwards

Programme : Pharmaceutical sciences

Level : Postgraduate

Course : M.Pharm.

Specialization : Pharmaceutics

Study Scheme for M.Pharm (Pharmaceutics)

Semester: 1st

S. No	Subject code	Subject Name	L	T	P	Credits
1	PS6101	Modern Pharmaceutical Analysis	4	0	0	4
2	PS6102	Core-I Novel Drug Delivery systems	4	0	0	4
3	PS6103	Drug Regulatory Affairs and Intellectual Property Rights	4	0	0	4
4	PS6104	Elective 1	4	0	0	4
5	PS6105	Pharmaceutics Lab-I	0	0	6	3
6	PS6106	Modern Analysis Lab	0	0	6	3
7	PS6107	Seminar-I	0	0	0	2
Total			16	0	12	24

Semester: 2nd

S. No	Subject code	Subject Name	L	T	P	Credits
1	PS6201	Core-II: Pharmaceutical Formulation & Development	4	0	0	4
2	PS6202	Core-III: Quality Control & Quality Assurance of Pharmaceuticals	4	0	0	4
3	PS6203	Research Methodology & Biostatistics	4	0	0	4
4	PS6204	Elective –II	4	0	0	4
5	PS6205	Pharmaceutics Lab-II	0	0	6	3
6	PS6206	Seminar-II	0	0	0	2
Total			16	0	6	21

Semester: 3rd

S. No	Subject code	Subject Name	L	T	P	Credits
1	PS7301	Seminar on Research envisaged for Dissertation	0	0	0	4
2	PS7302	Seminar on Recent Trends in Pharmaceutics	0	0	0	4
3		Research Work	0	0	30*	0*
Total			0	0	30	8

*Credits will be cumulated in the final semester evaluation

Semester: 4th

S. No	Subject code	Subject Name	L	T	P	Credits
1	PS7401	Seminar on Dissertation	0	0	0	4
2	PS7402	Research work	0	0	30	25*
3	PS7403	Viva Voce	0	0	0	5
Total			0	0	25	34

- Cumulative credit of 3rd and 4th semester

ELECTIVE I

- 1. Industrial Pharmacy and Pharmaceutical Validation**
- 2. Pharmacokinetics and Biopharmaceutics**
- 3. Clinical Trials**
- 4. Clinical Pharmacology**

ELECTIVE II

- 1. Bionanotechnology**
- 2. Cosmeticology**
- 3. Systemic Modern Pharmacology**
- 4. Safety Pharmacology**

DETAILED SYLLABUS OF PHARMACEUTICS

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6101	Modern Pharmaceutical Analysis	4	0	0	4

1. Spectroscopic methods:

Theory, Instrumentations, chemical applications and structural elucidation by UV, IR, ¹H NMR, ¹³C NMR including DEPT, Mass Spectrometry, ESR and Emission spectroscopy.

2. Separation techniques: Fundamental principles, theory, instrumentation and application of Gas-liquid chromatography, HPLC, Size Exclusion chromatography, GC-MS, LC-MS, UPLC, HPTLC, Ion Pair & Ion Exchange Chromatography

3. Thermal Analysis: Theory, Instrumentations and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC), Isothermal titration Calorimetry (ITC)

4. Powder X-ray Diffraction: Instrumentation and applications.

5. Electron Microscopy: Introduction to Scanning Electron Microscopy and Transmission Electron Microscopy.

Recommended Books

1. M. Orchin and H.H. Jaffe – Theory and application of ultra- violet spectroscopy. (John Wiley and Sons. N.Y).
2. Silverstein, Basseler, Morrill- Spectroscopic identification of organic compounds (John Wiley and Sons. N.Y).
3. Willard, Merritt, Dean – Instrumental methods of analysis (CBS Publishers and Distributors, Delhi).
4. C.N.R. Rao – Chemical Application of Infra-red spectroscopy. (Academic Press, N.Y.).
5. L.M. Jackmann and B.D. Sternhell – Application of NMR spectroscopy in organic chemistry (Pergamon Press, London.).
6. F.W. McLafferty- Interpretation of Mass Spectra.
7. P.D. Sethi – Quantitative Analysis of Drugs in Pharmaceutical formulations (VBS Publishers, Delhi).
8. IP/BP/USP- Latest edition
9. A.H. Beckett, J.B. Stenlake – Practical Pharmaceutical Chemistry, Part I and Part II (CBS Publishers Delhi)
10. J.R. Dyer – Application of Absorption Spectroscopy of Organic Compounds (Prentice Hall, London).

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6102	Core-I Novel Drug Delivery systems	4	0	0	4

1. Fundamentals of Controlled Release Drug Delivery:

Rationale of sustained/controlled drug delivery. Physicochemical and biological factors influencing design on the design of sustained and controlled release systems.

2. Oral controlled drug delivery systems:

Formulation, fabrication and evaluation of various oral systems based on dissolution, diffusion and dissolution, ion-exchange resins, pH-independent formulations, gastro retentive altered density formulations, colon targeted and pulsatile drug delivery.

3. Parenteral controlled release system:

Scope, terminology & techniques used, injectable controlled release, formulation of long acting contraceptive formulations; implantable drug delivery

4. Mucosal drug delivery models:

Mechanisms of transports of drugs through mucosal routes, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation.

5. Transdermal drug delivery system:

Permeation through skin including mechanism, permeation enhancers, in-vitro skin permeation, technologies for developing transdermal drug delivery system & evaluation parameters.

6. Vesicular Drug Delivery System:

Composition, preparation, characterisation, stability, clinical applications, production and scale up of different vesicular drug delivery system like liposomes, niosomes, microemulsion, emulsion, transferosome (any 5)

7. Nanoparticulate Drug Delivery System:

Nanoparticles: Polymeric Nanoparticles, solid lipid particles, hydrogel, peptide nanoparticles, nanocrystals & nanosuspensions and targeting strategies employing nanoparticles; Dendrimers: structure & properties, general methods of dendrimer synthesis, characterisation of dendrimer, application & commercial products.

8. Targeted drug delivery system:

Active & passive targeting, specific drug delivery to targeted organs like brain and lungs

9. Ocular Drug Delivery:

Issues and Challenges, Classification, factors affecting ocular drug availability, Processing Considerations.

10. Protein & peptide drug delivery system:

Different routes of delivery, practical considerations, importance of formulation considerations, toxicity, stability and regulatory perspectives

RECOMMENDED BOOKS

1. Remington's pharmaceutical sciences. 21 st Edition, Lippincott Williams and Wilkins- Vol. I & II
2. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Yie W. Chien. Vol- 50.
3. Controlled drug delivery system – Vicent H.L., Marcel Dekker Second Edition, Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol- 29.
4. Bentley's textbooks of pharmaceuticals – E.A. Rawlin

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5. Vesicular and Particulate Drug Delivery Systems, Edited by R.S.R Murty, Career Publications.
 6. Novel and controlled drug delivery systems – N.K. Jain
 7. Advances in Novel and Controlled Drug Delivery- N.K. Jain
 8. Chien, Y.W.: Novel Drug Delivery Systems, Marcel Dekker, New York and Basel

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6103	Drug Regulatory Affairs and intellectual property Rights	4	0	0	4

1. Drug Regulatory Affairs :

Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, Filing of INDA, NDA and ANDA for approval and registration.

2. Stability Testing :

Role of stability testing, stability test guidelines. Protocol of stability testing including testing under different climatic zones and conditions. Conduct of stability testing. determination of shelf life. Stability test equipment and recent developments in this area.

3. GMP of Pharmaceuticals:

Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports.

4. Quality by design

Introduction to QbD, USFDA's view of QbD, Elements of QbD, QbD tools, Design of experiments –Methods and applications. QTPP, CQA, CMA, CPP, QRM. Statistical design (Simplex and factorial design)

5. Intellectual property right (IPR) :

Introduction to IPR & Patents – Development of IP law in India, IPR regime, Introduction to IP laws in India, Role of IP in pharma industry growth.

Indian Patents Act 1970 and amendments, Procedure for patent application, Grant and opposition proceedings, Patent licensing, Patent infringement proceedings, IPAB – role and functions (IP Appellate Board),

6. Indian IP Case Studies: The Novartis Case, Lipitor case, Natco vs Bayer case of compulsory license, Patenting Traditional Knowledge (neem, Basmati, Haldi patent), Patenting of life forms (Diamond vs Chakravartty case)

American and European patent system: Requirements of patenting: utility, novelty, non-obviousness, patent specification & claims, Patent infringement and doctrine of equivalents, Federal circuit and patent system in Europe.

7. International treaties and conventions on IPR - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO, Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003

8. Introduction to Geographical indication / Trademark/ copyright: Filing procedures Patent search, Patent analysis & Patent drafting

9. Allied Patents Related Issues: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage

RECOMMENDED BOOKS

1. Pharmaceutical product development, edited by N.K. Jain, CBS publishers and distributors. New Delhi, and references there in.

2. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, 5th edition, revised and expanded by Sidney H. Willig, Marcel and Dekker.
3. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).]
4. CDER Publications and Guidance
5. EMEA Publications and Guidance
6. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
7. Orange Book, ICH guidelines, Indian Patents Act
8. Country specific Regulatory Guidelines (available from internet)
9. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
10. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6104	Elective I - Industrial Pharmacy & Pharmaceutical Validation	4	0	0	4

1. Preformulation:

- a) Introduction, Preformulation Testing Criteria, Regulatory Requirements, Testing Systems
- b) Dissociation, Partitioning and Solubility: Quantitative Structure–Activity Relationships, Partitioning, Measurement Strategies
- c) Release, Dissolution, and Permeation: Release, The Biopharmaceutics Classification Systems
- d) Solid-State Properties: Importance in pharmaceutical formulations of Crystals, solvates, Hydrates, Amorphous Forms, particle size, shape and density
- e) Chemical nature of drug: Scheme of Characterization, Impurities
- f) **Characterization of Biopharmaceutical Drugs:** Physio-Chemical Characterization Tests, Design of Preformulation Studies Methods in material characterization.
- g) **Excipients:** General considerations of excipients used in formulations and factors governing selection. Compatibility issues regarding excipients: drug-excipients and excipient-excipient, excipients-package interactions, Safety and regulatory issues of excipients
- h) Study of novel excipients: Superdisintegrants, directly compressible and spray dried diluents, film coating materials, solubilizing agents like surfactants, Cyclic Glucose Polymers, polymeric excipients for controlled release applications, Improved excipients functionality by co processing, Standardization of excipients
- i) **Polymers :** Polymer classification, physiochemical properties and polymer solutions. Biodegradable and Nonbiodegradable polymers. Application of polymers in controlled release of drugs, transport of small molecules in polymers, ionic polymers as drug carriers.

2. Industrial Processes:

- a) Granulation: Roller Compaction Technology, High-Shear Granulation, Low-Shear Granulation, Batch Fluid Bed Granulation, Extrusion/Spheronization as a Granulation Technique, Effervescent Granulation, Melt Granulation and Pelletization, Rapid Release Granulation, Continuous Granulation Technologies
- b) Lyophilization: LYOGUARD (New Concept for Bulk Freeze-Drying)
- c) Coating: Film-coating materials and their properties, Sterilization, Air handling: AHUs, Laminar Airflow Equipment, HEPA and VEPA filters, HVAC, Clean room classification.

3. Pharmaceutical Process Validation :

Basic concept, definition and regulatory basis of validation. Benefits of validation. Phases of equipment validation such as pre-purchase, post-purchase (IQ, OQ and PQ) and qualification of established /in-use equipment. Types of process validation related to prospective, retrospective and concurrent process validation. Re-validation of validation process and scale-up and post approval changes (SUPAC). Validation of tablets, liquids and sterile products. Validation of steam, dry heat, gaseous, radiation and filtration sterilization processes. Analytical Validation.

BOOKS RECOMMENDED

1. S H Yalkowsky (Ed), Techniques of Solubilization of Drugs, Marcel Decker Inc., Newyork USA
2. A Martin, Physical Pharmacy, 3rd Edition. B. I. Waverly Pvt. Ltd., New Delhi, India.
3. J.I. Wells, Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances, Ellis Horwood, Chiechester (UK).
4. R. Berry and R. A. Nash, Pharmaceutical Process Validation, Marcel Dekker, N.Y.
5. N. K. Jain (Editor), Pharmaceutical Product Development, Ist Edition, CBS Publisers and Distributer, New Delhi.
6. N. K. Jain (Editor), Controlled and novel drug delivery systems. Ist Edition, CBS Publisers and Distributer, New Delhi.
7. G.S Banker and C.T. Rhodes, Modern Pharmaceutics, second edition, Marcel Decker Inc., Newyork USA
8. S.P.Vyas and R.K.Khar, controlled drug delivery, concept and advances, first edition, vallabh prakashan , Delhi.

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6104	Elective I - Pharmacokinetics and Biopharmaceutics	4	0	0	4

1. Pharmacokinetics :

Basics of Pharmacokinetics, Significance of plasma drug level time profile

2. Compartment models

Pharmacokinetic models, basics of compartmental modeling including numeric applications (wherever possible) of:

- i. One compartment open body model (1-CBM), pharmacokinetics of single dose administration following intravenous (rapid), oral and intravenous transfusion administration, Wagner Nelson method and method of residuals (stripping) as applied to plasma concentration profiles following oral intake, Volume of distribution, Biological half-life and Clearance. Curve fitting (method of Residuals), regression procedures.
- ii. Multiple dose kinetics following intravenous (rapid) and oral administration, superposition principle, steady state kinetics.
- iii. Urinary excretion, merits and shortcomings, Sigma-minus plot, method of residuals as applied to cumulative and rate of excretion curves.
- iv. Two compartment open body model (2-CBM), pharmacokinetics of single dose administration as applied to intravenous (rapid) administration, method of residuals as applied to plasma concentration profiles following intravenous (rapid) administration.
- v. Pharmacokinetic basis of controlled drug delivery

3. Non-compartmental methods-Area under first moment curve (AUMC), drug clearance, apparent volume of distribution, mean residence time (MRT) and its significance.

4. Nonlinear Kinetics

Basics of Nonlinear Pharmacokinetics, Detection of nonlinearity (i.e., saturation mechanism) following i.v. intake, Michaelis Menten kinetics.

5. Biopharmaceutics :

Factors influencing drug absorption: Physicochemical, physiological and pharmaceutical

- (i) Physicochemical factors affecting biopharmaceutical performance of drugs, with special emphasis on pH-partition hypothesis, absorption of ionic drugs in light of unstirred water layer, dissolution rate, drug stability in gut, complexation, adsorption, etc.
- (ii) Physiological considerations affecting biopharmaceutical performance of drugs including membrane physiology, G.I. physiology, effect of food, gastric emptying and intestinal motility, etc.
- (iii) Bioavailability and equivalence concepts, significance, determination of bioavailability using blood level and urinary excretion data, protocol, Biowaivers in the light of BCS and IVIVC, federal requirements.
- (iv) Factors affecting drug distribution in body. Plasma protein binding and

implications, elements of Scatchard analysis for computation of binding parameters, factors influencing protein binding, effect of binding on drug pharmacokinetics.

6.Pharmacokinetics :

Introduction; pharmacokinetic relationships; duration of response; kinetics of pharmacological response; explanation of clinical response via pharmacokinetics; monitoring plasma concentrations of drugs during clinical use, Therapeutic drug monitoring (TDM), turnover concepts, individualization of dosage and dosage regimen, variability, Effect of genetics, age, weight, pharmacokinetics, disease and interacting drugs, use of creatinine clearance, problem solving.

Books Recommended:

1. W.A. Ritschel, Handbook of Basic Pharmacokinetics, Drug Intelligence, Hamilton, Latest Edition.
1. J.G. Wagner, Fundamentals of Chemical Pharmacokinetics, Drug Intelligence, Hamilton, Latest Edition.
2. A. Gennaro (ed.), Remington: The Science and Practice of Pharmacy, Mack Publishing Company, Pennsylvania, Latest Edition.
3. Shargel, L. and Yu, A., Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large, Norwalk, Latest Edition.
4. M. Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, Lea & Febiger, Latest Edition.
5. M. Gibaldi and D. Perrier, Pharmacokinetics, J. Swarbrick ed., Marcel Dekker, Latest Edition.

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6104	Elective I - Clinical trials	4	0	0	4

1. Introduction to clinical Trial: History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments.

Clinical Research Organizations in India and Schedule “Y” as per D&C Rules

2. Regularly affairs in clinical trials: IND, NDA, ANDA- Parts and contents, Safety monitoring boards, FDA in various countries including India

3. Issues in clinical trials:

Ethical and Legal issues: Principle, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report

4. Clinical trial design: Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls

5. Clinical trial protocol Development: Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial

6. Good Clinical Practice: Concept, importance, and GCP guidelines including ICH guidelines

7. Management of Clinical trials: Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient)

Monitoring of clinical trials: Organization Scheme, and governing body in the process of clinical trial monitoring Publications of clinical trials

8. Bioavailability, bioequivalence and Therapeutic Drug Monitoring: Concept, organization, advantages, special issues, applications, bioequivalence.

9. Data analysis issues in Clinical Trials: Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials

Recommended Books:

1. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier
2. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc GrawHill
3. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingstone, London
4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingstone, London
5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
6. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6104	Elective I - Clinical Pharmacology	4	0	0	4

1. Basic Principles of Clinical Pharmacology: History, Introduction to clinical Pharmacology, basic components and scope.

Clinical evaluation of new drugs: Organization, types of clinical research, phases of clinical research.

Therapeutic Drug Monitoring (TDM): Criterion for TDM, Clinical significance and its need on Patients associated with narrow therapeutic range of drugs.

Patient compliance, principles of pediatric and geriatric pharmacology, drug therapy in pregnant and lactating mothers.

Basic components of patient care and medication errors.

02. Pharmacotherapeutics, Management & Current Good Clinical Practice of following diseases:

Cardiovascular disorders: Hypertension, congestive heart failure, angina pectoris, myocardial infarction and ischemia, cardiac arrhythmia, atherosclerosis, hyperlipidemia, peripheral vascular disorders and coagulation disorders.

Gastrointestinal disorders: Peptic Ulcers, emesis, diarrhoea and constipation

Renal diseases: Acute and chronic renal failure, renal dialysis and transplantation, Drug doses in renal impairment.

Neurological Disorders: Pathophysiology and drug therapy of epilepsy, Parkinson's disease and Alzheimer's disease.

Psychiatric Disorders: Pathophysiology and drug therapy of anxiety, Schizophrenia, mood and sleep disorders.

Endocrine Disorders: Pathophysiology and drug therapy of diabetes mellitus, contraception, and infertility.

Metabolic and Sexual Disorders: Pathophysiology and drug therapy of obesity and erectile dysfunction

Respiratory diseases: Asthma, chronic obstructive pulmonary edema. Pulmonary embolism

Autoimmune and metabolic disorders: Rheumatoid arthritis, Osteoarthritis, gout and hyperuricemia, Diabetes mellitus (DM).

Hepatic disorders: Cirrhosis, hepatitis. Alcohol and drug induced complication associated with hepatic impairment.

Neoplastic disorders: General principles of cancer chemotherapy, and monoclonal antibodies.

Immunotherapy: Immunostimulant, Immunomodulators and Immunosuppressant.

Chemotherapy of Infectious Diseases: Mechanism of antibiotic resistance, antifungal and antiprotozoal, helminthiasis, tuberculosis, malaria, leprosy, AIDS, Dengue, Chickenquinea, and Swine flu

03. Drug interaction and rational for drug combinations: Various mechanisms of drug interaction, drug-food interaction and drug - drug interaction

04. Drug Toxicity and its prevention: Principles of toxicology, abnormal action of drugs such as tolerance, addiction, habituation, idiosyncrasy, allergy, hypersensitivity, antagonism, synergism, potentiation, tachyphylaxis. Adverse drug reactions and its monitoring.

05. Novel Target Sites for drug action: Physiological functions, pharmacological implications and therapeutic potential of the following target sites: Poly (ADP-ribose) polymerase (PARP), Caspases, Peroxisome proliferator activator receptors (PPAR)- α and γ , AMP activated protein kinases.

RECOMMENDED BOOKS:

1. Goodman and Gilman's. The Pharmacological Basic of Therapeutics, Mc Graw-Hill.
2. Harrison's Principle and Practice of Medicine, 18th Edition, Churchill, Livingston, London.
3. Roger and Walker. Clinical Pharmacy and Therapeutics, Churchill, Livingston, London.
4. Davidson's Principle of Internal Medicine, Mc Graw-Hill companies.
5. Speight TM and Holford NHG (ed). Avey's Drug Treatment: Principals and Practice of Clinical Pharmacology and Therapeutics. ADIS Press, Sydney, Australia.
6. Katzung BG. Basic and Clinical Pharmacology, Lange Medical Publisher, USA.
7. J.T. Dipiro, R.L. Talbert, , G.C. Yee, G.R. Matzke, B.G. Wells, L. Michael Posey (eds.), Pharmacotherapy : A Pathophysiologic Approach, 6th ed., The McGraw Hill Companies, Inc..
8. E.T. Herfindal and D.R Gourley, Text Book of Therapeutics: Drug and Disease Management, 7th ed., Lippincott Williams & Wilkins, USA.

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6105	Pharmaceutics Lab-I	0	0	6	3

List of Suggested Practicals

1. To prepare standard plots of given drug in buffer of pH 6.8 and 7.4
2. To carry out evaluation of marketed tablets of different brands
3. To carry out solubility studies of given poorly soluble drug sample in various solvents
4. To determine partition coefficient of given drug sample by shake flask method
5. To study the degradation pattern of aspirin into salicylic acid with respect to effect of temperature time and pH
6. To formulate and evaluate solid dispersion of given poorly soluble drug by using PEG 6000 in the ratio of 1:5 and 1:10 by hot melting method and solvent evaporation technique
7. To formulate and evaluate calcium alginate beads by using salt addition method
8. To formulate and evaluate mucoadhesive buccal patches of given drug
9. Formulation and evaluation of transdermal patch of given drug
10. To formulate and evaluate liposomes of given drug
11. To formulate liposomal gel by introducing prepared liposome in gelling agent.
12. To formulate and evaluate microspheres of given drug by salt addition method
13. To formulate and evaluate microsuspension of given insoluble drug
14. Formulation and Evaluation of microemulsion of given drug
15. To formulate and characterise basic multiple emulsion
16. To formulate and evaluate nanoparticles of given drug
17. Formulation and Evaluation of *In Situ* Gelling Drug Delivery system for the treatment of Ocular Diseases of given drug
18. Select any five drugs from different categories: Find out theoretically physicochemical and Biological properties of drug. Based on the information generated set the objectives regarding- Which dosage form will be more suitable for the drug, Technique to formulate the dosage form, Choice of excipients that can be used with explanation of role of each excipient used in formulation, Formulate dosage form and evaluate in comparison with marketed dosage form.
19. To determine the pharmacokinetic parameters by using given data of i/v bolus dose
20. To determine the pharmacokinetic parameters by using given data of oral dose

RECOMMENDED BOOKS

Same as Given in PS6102 and PS6104

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6106	Pharmaceutical Analysis Lab	0	0	6	3

1. Combination Drug Analysis (Any Five)

a. Vitamins b. Oral antidiabetics c. NSAIDs d. Antimicrobials e. Antihistamines f. Antihypertensive

2. Illustrations of theoretical principles using assay of drugs official in various pharmacopoeias (Any 10). This should cover titrimetric, spectrophotometric(including flamephotometric) methods, HPLC etc. The titrimetric methods should include argentometric, conductometric, and potentiometric end-point determination.

The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.

3. Interpretation of UV, IR, NMR and Mass spectra of some unknown intermediates and drugs. (Any two)

RECOMMENDED BOOKS

Same as Given in PS6101

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6201	Core-II Pharmaceutical Formulation & Development	4	0	0	4

1. Formulation and development of liquids

Phase behaviour of surfactants in binary and ternary systems. Factors affecting phase behaviour. Micellization, micelle structure, shape, size. Factors affecting CMC and micellar size thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of solubilisation in nonaqueous systems, interaction with polymers and oppositely charged species. Study of advances in liquid formulation including microemulsions, SEDDS, SMEDDS and multiple emulsions for oral and parenteral route

2. Formulation and development of semisolids: Semisolid formulation with special reference to penetration enhancers. Advances in semisolid formulations.

3. Formulation and development of tablets

Benefits, process design considerations; materials handling, processing step combination and elimination, tablet production equipment, layout and design of facilities, materials flow, quality assurance procedures including in-process quality control, construction, equipment and environmental considerations, materials management and inventory control. Advances in coating process, fluid-bed coating, particle coating.

4. Formulation and development of capsules

a. Hard gelatin capsules : Manufacturing process and material used in the shell Different materials used for automatic filling based on auger, vibratory and piston tamp fill (Dosing Disk and Dosator Machines) principles. General considerations in the design of hard gelatin capsule for formulations ,storage, packaging and stability consideration.

b. Soft gelatin capsules: General considerations of the development of soft gelatin capsules as a dosage form composition of shell, formulation strategies and carriers of the drug used and their manufacturing devices.

5. Parenterals

Manufacturing including various aspects of preparing SVP solutions, suspensions, powders/ freeze dried, powders for reconstitution,

6. Spheronization

Introduction, Extrusion-spheronization methods, formulation, process variable, equipments, evaluation of pellets.

7. Packaging developments : Regulatory perspective of selection and evaluation of Pharmaceutical packaging materials for conventional dosage forms, sterile formulations, aerosols and novel drug delivery Systems.

RECOMMENDED BOOKS:

1. Pharmaceutical dosage forms Lachman et al.,: Tablets, volume I,II,III
2. Pharmaceutical dosage forms Lachman et al. : Parenterals, volume I,II
3. Remington, Science and practice of Pharmacy, Vol.1, Lippincot williams and wilkins.
4. J.T. Carstensen, Drug Stability: Principles and Practices, Marcel Dekker, N.Y.

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5. N.K. Jain , Pharmaceutical product development. CBS publication and distributors, New Delhi.
 6. G.S. Banker and C.T.Rhodes, Modern Pharmaceutics, IInd edition , Marcel Dekker, INC, NewYork.
 7. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6202	Core-III Quality Control & Quality Assurance of Pharmaceuticals	4	0	0	4

1. Quality control and quality assurance technique: Basis concepts of Quality:- Developing quality culture.
2. Quality Assurance General Concepts: Definition of quality assurance concept and components of Q. A., Good Manufacturing Practices
3. Personnel, Premises and Equipments: Qualification, experience, training responsibilities and hygiene of personnel. Drainage system, Sewage, Sanitation, Lighting, maintenance of building and premises; Design, size, location, construction, cleaning and maintenance of equipments. Documents and formats related to personnel, premises and equipment.
4. Material Management: Purchasing, Raw material, packaging materials, Intermediate and Bulks products, Finished products, Rejected and recovered materials, recalled products, returned goods, Reagents and culture media, Waste materials, reference standards, Miscellaneous material. Documents and formats.
5. Manufacturing operations and control: Revised schedule M, sanitation of manufacturing premises, Mix –ups and cross contamination, processing of intermediates and Bulk product, Packaging operations, I.P.Q.C., Release of finished products process deviations, Drug product inspection, expiration dating, Document and formats.
6. Documents and Records: Specification, Master production and control record, Batch production and control record, Significance of SOPs and record, change control, Drug Master file, Documents and formats.
7. Quality control of Biological products: International Biological standards, safety testing of pharmaceutical Quality control of antibiotics.
8. Pharmaceutical Plant Audit: Department wise documents and audit questionnaire.
9. Sterile Pharmaceutical Products: GMP aspects related to sterile products- General guidelines, personnel, building and premises, equipment, sanitation, processing, sterilization, Quality control and validation, Documentation

Recommended Books:

1. Pharmaceutical Quality Assurance, MA Potdar, Nirali Prakashan, Pune
2. Validation of Pharmaceutical process, F. J. Carleton and J. Agalloco, Marcel Dekker Inc.
3. Pharmaceutical Process Validation, Second Ed., Ira R. Ferry & Robert Nash, Marcel Dekker Inc.
4. Good Manufacturing Practices for Pharmaceutical; A Plan for total Quality Control, 4 th Ed, Sidney willing.
5. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
6. Pharmaceutical Process Validation; By F. R., Berory and Robert A. Nash
7. Impurities Evaluation of Pharmaceutical; Satinder Ahiya Marcel Decker.
8. Quality Control of Packaging material in the Pharmaceutical Industry: Kenneth Harburn, Marcel Dekker.

9. Juran's Quality Control Handbook J.M. Juron.4th Ed. Good design practices for GMP Pharmaceutical facilities. Andrew A Signature, Marcel Dekker.

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6203	Research Methodology & Biostatistics	4	0	0	4

A. Research Methodology

1. Research:

Meaning and objective of research, types of research (basic, applied and patent oriented research), selecting a problem & preparing a research proposal for different types of research as mentioned above.

2. Literature survey and documentation:

Methods of Literature survey, Use of library, books, journals, e journals, thesis, chemical abstracts and patent data base, techniques of documentation, importance of documentation, uses of computer packages in documentation.

3. Technical writing:

Self study & Practice: Research report, paper, thesis writing [Title, abstract, key words, methodology, results, discussion, conclusion, acknowledgement, references, errata, foot notes], types of research paper [review article, research papers and short communications and meeting report], detailed study of 'Instruction to Authors' of IJPS journal, a thorough understanding of steps involved in submitting articles electronically to IJPS [registration, new article submission, tracking the process, submitting revised articles]. Impact factor, Rating, Indexing and citation etc.

4. Presentation:

Importance, types different skills, contained, format of model, introduction & ending, posture, gestures, eye contact, facial expressions, stage, fright, volume, pitch, speed, pause & language, visual aids & seating, questionnaire.

5. Project [cost] management:

Cost analysis of the project- cost incurred on raw materials, procedure, instrumentations & clinical trials.

6. Research organizations and procurement of research grants:

Introduction to various research organization (DST, DBT, AICTE, UGC, CSIR, DRDO, ICMR) along with their function in India, sources for procurement of research grants.

7. Ethics in Research:

Importance, privacy and confidentiality in Research, honesty and openness in Research, valid results, applicability, Plagiarism

B. Biostatistics

1. Basic Definitions and Concepts:

Variables and variation [continuous variables and discrete variables], sample and population [population parameters and sample statistics, random sampling], precision, accuracy and bias; significant figures. Mean, Median, Mode

2. Probability Distributions: Discrete and continuous random variables, probability distribution functions, expectation of random variables, mean, variance and moments of random variables, Binomial, Poisson, Normal, beta distribution functions, Chi-square distribution, F-distribution, Joint distributions, notion of covariance.

3. Sampling distribution, Point and interval estimations of mean, variance and proportion of single and multiple samples.

4. Hypothesis testing: Inferences concerning mean, variance and proportions, Chi-square test, goodness of fit.

5. Regression and Correlation: Linear regression and Correlation

6. ANOVA: One-way and two way ANOVA tests.

7. Parametric & Non Parametric tests: student t-test, chi-square test, f-test, Sign test, Rank sum test, Wilcoxon and Kruskal-Vallis test.

Recommended Books: -

1. Research In Education- John V. Best, John V. Kahn 10th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Thesis & Assignment – Jonathan Anderson
- 5 Writing a technical paper- Donald Menzel
6. Protection of industrial Property rights- P. Das & Gokul Das
7. Preparation for publication – King Edward Hospital Fund for London
8. Manual for evaluation of industrial projects-United Nations
9. Manual for the preparation of industrial feasibility studies
- 10 Pharmaceutical Statistics: Practical and Clinical Applications by Sanford Bolton and Charles Bon, fourth edition.
- 11 Research methodology: Methods and Techniques by C. R. Kothari, second edition
- 12 Research in Education by John W. Best and James V. Kahn, 11th edition
- 13 Instruction to Authors of journals.

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6204	Elective II- Bionanotechnology	4	0	0	4

1. Bionanotechnology: History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.

2. Nano-Drug Delivery: Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nanosize in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals, nanodrug delivery chip.

3. Safety Concern of Bionanotechnolicals

Inhalation, contact/dermal delivery, environmental impact, explosion hazards.

4. Plant and Animal Cell culture: Tissue culture media, primary cell culture, continuous cell culture, pharmaceutical applications of animal cell culture. Stem cell culture, cryopreservation/stem cell bank. Media and media composition (typical) for plant and cell cultures, names of commonly used animal cell lines, their tissue origin and typical applications.

5. Enzyme and Cell Immobilization:

Methods for Enzyme immobilization (adsorption, covalent binding, entrapment microencapsulation) with examples and applications. Introduction to biosensor and applications e.g. glucose oxidase, penicillinase.

6. Recombinant DNA Technology:

A. Steps involved in rDNA technology, enzymes involved in DNA technology with reference to restriction endonucleases and ligases, vector (plasmid, cosmid, YACs). Gene expression/ host (bacterial expression system, animal expression system, plant expression system).

B. Applications of rDNA technology for production of pharmaceutical products e.g. human Insulin, production of human growth hormone, interferon. Study of list of approved biotech derived products.

C. Hybridoma technology-Production and application of monoclonal antibodies.

7. Monoclonal Antibodies :

Production of monoclonal antibodies, diagnostic, therapeutic and analytical applications and their role in drug targeting.

8. Gene Therapy :

An introduction to genetic disorders, concepts and principles of gene, viral and non-viral gene delivery systems, safety and ethical considerations.

9. Environmental Biotechnology: Importance in pharmacy, biodegradation of plastic, pesticides and hydrocarbons, disposal of solid wastes, oil spills, cellulose etc. Bioremediation, biopesticides, biofertilizers, bioindicators.

Books Recommended:

1. Bainse William, Biotechnology from A to Z, Oxford University Press.
2. Carter S. J., Cooper and Gunn's Tutorial Pharmacy, CBS Publishers and Distributors, Delhi.
3. J. I. DeSouza, Killedar S. G., Biotechnology and Fermentation Process, Nirali Prakashan
4. Gennaro A. R., Remington - The Science and Practice of Pharmacy,, Lippincott Williams and Wilkins, New York.
5. Gupta P. K., Elements of Biotechnology, Rastogi Pub., Meerut.

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6. Higgins, Best D.J. and Jones J., Biotechnology: Principles and Applications, Blackwell Scientific Publications, Boston, MA.
 7. Kumar H. D., Textbook of Biotechnology, Affiliated East West Press, New Delhi.
 8. Pharmacopoeia of India, Govt. of India.

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6204	Elective II- Cosmeticology	4	0	0	4

1. Definition of cosmetics; historical background, classification of cosmetics and primary function
2. Structure of skin, hair, nails, tooth and skin appendages and interactions with cosmetics
3. Microbial contamination in cosmetics; Perfumes, colours and other raw material used in cosmetics- a brief review
4. Toxicology of cosmetics- irritation and sensitization reactions to cosmetics, tests to predict such reactions
5. Study of following Skin cosmetics with respect to raw materials, formulations, processing equipment and quality control: skin creams and lotions- cold creams, vanishing creams, bleach creams, acne creams, hand and body creams and lotions (barrier preparations), emollient creams, sunscreen products- sun tan and anti sunburn products, insect repellants, face powder, lipstick, rouge, face packs-cleansing preparations- moisturizers, bath oils
6. Study of following Hair care cosmetics with respect to raw materials, formulations, processing equipment and quality control: shampoos, women's hair dressings, men's hair dressings, hair tonics, hair conditioners, hair rinses, hair colorants, hair waving and straightening preparations, depilatories, shaving preparations and aids (after shave solution/ lotion/ cream), anti-lice preparations;
7. Study of following Nail products with respect to raw materials, formulations, processing equipment and quality control: pedicure and manicure preparations (nail polish, nail paint removers, cuticle removers, nail whiteners etc);
8. Study of following Dental care products with respect to raw materials, formulations, processing equipment and quality control: toothpaste, tooth powder, mouth washes and denture cleansers;
9. Study of following Eye makeup products with respect to raw materials, formulations, processing equipment and quality control: eye shadow, eye liner, mascara etc
10. Baby cosmetics;
11. Herbal cosmetics
12. Schedule S of Drug and Cosmetics Act in relation to cosmetic manufacture hygiene Pollution control-ecological concern.

Book Recommended

Sr.No	Title	Author/Editor	Edition	Publisher
1	Harry's Cosmeticology	Rieger	8 th , 2000	Leonard Hill Book & Intertext Publisher, London
2	Cosmetic Science(Vol 2)	M.M. Breuer	1978	Academic Press, London
3	Cosmetics:Formulation,Manufacturing & Quality Control	P.P. Sharma	1998	Vandana Publications, New Delhi
4	A Formulary Of Cosmetic Preparations	Michael & Irene Ash	1 st , 1977	George Godwin Ltd., London
5	Drugs & Cosmetics Act 1940	Vijay Malik	16 th 1997	Eastern Book Company

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6204	Elective II- Safety Pharmacology	4	0	0	4

1. Definition and scope of safety pharmacology and basic principles of toxicology.
2. Principals and study design of safety evaluation: Repeated dose studies (sub acute and chronic), Analysis of safety pharmacological data
3. Preclinical safety pharmacology: In vitro and in vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive and ocular toxicity, Safety testing for dermatological product
4. Clinical Safety pharmacology: Definition, data collection, reporting methods and assessment and analysis of adverse event (AE) monitoring during clinical trials
5. Clinical Evaluation: Clinical evaluation of antihypertensive agents, antianginal agents, antiepileptics, antidepressants, antipsychotics, antiparkinsonian agents, drugs used in Alzheimer's disease, antiulcer agents, and antidiabetics.
6. Pharmacovigilance: Definition, scope and aims of pharmacovigilance, Adverse drug reactions-Classification, mechanism, predisposing factors and causality assessment, Role of clinical pharmacist in reporting, evaluation, monitoring, prevention and management of ADRs.
7. Risk-benefit assessment: Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment
8. Regulatory requirements for the new drug safety assessment: Important guidelines such as ICH, OECD, USFDA, EMEA, Japan MHW

Recommended Books:

1. Sogliero-Gilbert, G., Drug safety assessment in clinical trials. Statistics, textbooks and monographs, New York: Dekker.
2. Marx, U. and V. Sandig, Drug testing in vitro : breakthroughs and trends in cell culture technology, Weinheim: Wiley-VCH.
3. Turner, J.R., New drug development : design, methodology, and analysis, Hoboken, N.J.: Wiley-Interscience.
4. Dmitrienko, A., C. Chuang-Stein, and R.B. D'Agostino, Pharmaceutical statistics using SAS : a practical guide, Cary, N.C.: SAS Institute.
5. Smith, C.G. and J. O'Donnell, The process of new drug discovery and Development., New York: Informa Healthcare.
6. Bénichou, C., Adverse drug reactions : a practical guide to diagnosis and management, Chichester, West Sussex, England; New York: Wiley.
7. Mann, R.D. and E.B. Andrews, Pharmacovigilance, Chichester, England ; Hoboken, NJ: John Wiley & Sons.
8. Cobert, B.L., Manual of drug safety and pharmacovigilance, Sudbury, Mass.: Jones and Bartlett Publishers.

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6204	Elective II- Systemic Modern Pharmacology	4	0	0	4

1. Basic Principles of Pharmacology: Mechanisms of drug action, membrane transporters and drug response, adverse drug reactions.
2. Pharmacology of the Autonomic Nervous System : Physiology of autonomic nervous system, Muscarinic receptor agonists and antagonists, Anticholinesterase agents, Agents acting at neuromuscular junction and autonomic ganglia, Adrenergic agonists and antagonists, 5-Hydroxytryptamine receptor agonists and antagonists
3. Pharmacology of Autacoids: Histamine, bradykinin, and their antagonists, Lipid derived autacoids: Eicosanoids and platelet activating factor,
4. Drugs Acting on the Central Nervous System: Neurotransmission in central nervous system, General anesthetics, Local anesthetics, Hypnotics and sedatives, Opioid analgesics, Pharmacology of ethanol, Drug addiction and drug abuse, Analgesic, Antipyretic, and Anti-inflammatory Agents
5. Drugs Affecting Renal and Cardiovascular Function : Diuretics, Vasopressin and other agents affecting the renal conservation of water, Renin, angiotensin, and their modulators, Calcium channel blockers
6. Pharmacology of Chemotherapeutic and Antimicrobial Agents : General considerations of antimicrobial therapy, Sulfonamides, trimethoprim, quinolones, other related agents, Penicillins, cephalosporins, and other beta-lactam antibiotics, Aminoglycosides, Protein synthesis inhibitors and miscellaneous antibacterial agents, Antifungal agents, Antiviral agents (Non-retroviral), Antineoplastic Agents,
7. Hormones and Their Antagonists: Pituitary hormones and their hypothalamic releasing factors, Thyroid and antithyroid drugs, Estrogens and progestins, Androgens, Adrenocortical steroids and their synthetic analogs, inhibitors of synthesis and actions of adrenocortical hormones, Agents affecting mineral ion homeostasis and bone turnover
8. Drugs Acting on the Blood and Blood-Forming Organs: Hematopoietic agents: Growth factors, minerals, and vitamins, Blood coagulation and anticoagulant, thrombolytic, and antiplatelet drugs,
9. Pharmacology of Dermatological Agents
10. Ocular Pharmacology
11. Immunosuppressants, Tolerogens, and Immunostimulants

Recommended Books

1. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 11th ed. Joel G.Hardman, Lee *E. Limbird, Alfred G. Gilman (eds.). International Edition, The McGraw Hill Companies, Inc.
2. H. P. Rang and M. M. Dale, "Pharmacology" 5th Ed. Churchill Livingstone.
3. B. G. Katzung, "Basic and Clinical Pharmacology" 9th Ed. McGraw-Hill Medical.
3. Ion channel and their modulators: calcium, potassium, sodium and chloride channels.
4. Apoptosis: basic functions, mechanisms and role of caspases. pharmacological and clinical implications
5. Adhesion therapy and cardiac and vascular remodelling.
6. Basic Concepts of Chronopharmacology and their implications to Drug Therapy.

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6205	Pharmaceutics Lab-II	0	0	6	3

Suggested Practicals Based on Core-II and Core-II offered in II semester

1. Comparative evaluation of different marketed products (tablets) of the same API
2. To compare the dissolution efficiency of a drug in plain and its solid dosage form.
3. To compare the dissolution profile of two marketed solid oral preparation by f1 and f2 factor.
4. Dissolution studies of drug in three different bio relevant dissolution media
5. To prepare and evaluate granules using HPMC in concentration
6. To formulate and evaluate sustained release tablet of given drug
7. To formulate and evaluate chewable tablets
8. To formulate and evaluate floating tablets
9. To formulate and evaluate mucoadhesive tablets
10. Stability study testing of tablet dosage forms (Any two products)
11. Evaluation of test sterility for commercial preparations including sterile water for injection and antibiotic injection.
12. Select any three poorly water soluble drugs. Plan a method for solubility enhancement of those drugs. Based on the method determine any three parameters like the effect of dielectric constant, stability constant, solubility parameter and effect of excipients on solubility and thermodynamic parameters of the drug.
13. Preparation of four different types of semisolid forms and evaluation of their performance using in vitro diffusion method
14. To formulate and evaluate Transdermal patch of given drug using permeation enhancers
15. To prepare liposome and determine drug entrapment efficiency and drug release
16. To prepare nanoparticles and carry out in vitro release studies.
17. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.

RECOMMENDED BOOKS

As given in PS6201 and PS6202